

Second
Edition

Textbook of **Forensic Pharmacy**

Pharmaceutical Jurisprudence



**Bhaskar Chaurasia
Rajiv Kumar Chaurasia**



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Second Edition

Textbook of

Forensic Pharmacy

Pharmaceutical Jurisprudence

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to



Late Dr. B D Chaurasia

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Preface to the Second Edition

The *Textbook of Forensic Pharmacy* is a valuable resource for pharmacy students, covering Acts, Rules, Bills, Orders, and Statutes. It offers professional assistance, ethical stability, and legal protection for the profession. Designed for diploma, undergraduate and postgraduate programs, it comprehensively explains theory, objectives, and offenses under the Act. This book is beneficial for students and teachers.

Following multiple reprints, this second edition of our book features new chapters on pharmaceutical ethics, legislation, and the profession, including the NPPA, the DPCO Act 2013, the RTI Act 2005, Drugs and Cosmetics Act schedules (P, T, U, F, M), and updated events, making it accessible to all pharmacy and applied science students.

The second edition of Forensic Pharmacy is structured to cover the major and latest syllabi in 27 chapters, covering all topics proposed by PCI.

Chapters 1 to 4 detail The Pharmacy Act 1948, PCI, State Pharmacy Council, education regulations, The Drugs and Cosmetics Act, 1940 and Rules, 1945, their administration, import, manufacture, and sale, label design, The Medicinal and Toilet Preparations (Excise Duties) Act, 1955 and Rules, 1956, and The Narcotic Drugs and Psychotropic Substances Act, 1985 and Rules. These chapters cover the import, manufacture, sale, export, and transshipment of drugs and cosmetics, as well as the cultivation, production, and export of opium poppy and poppy straw. They also cover the import, export, and transshipment of narcotic drugs and psychotropic substances.

Chapters 5 and 6 detail the Essential Commodities Act, 1955, its control, production, supply, distribution, pricing, confiscation, New Drug Policy, objectives of Pharmaceutical Policy-2002, and price control span.

Chapters 7 to 9 detail the Drugs and Magic Remedies Act, 1954, which prohibits the advertisement of certain classes, the Poisons Act, 1919, which deals with the import and sale of poisonous substances, and the MTP Act, 1971, which permits pregnancy termination.

Chapters 10 to 12 detail the Prevention of Cruelty to Animals Act, 1960, Animal Welfare Board of India, experiments on animals, CPCSEA, IAEC, breeding, stocking, Shops and Establishments Act, 1954 working hours, service conditions, wages, leave, inspections, Insecticides Act, 1968 and Rules, 1971, Central Insecticides Board, Registration Committee, Central Insecticide Laboratory, and registration of insecticides.

Chapters 13 to 15 detail the AICTE Act, 1987, its objectives, powers, and functions, Factories Act, 1948, approval, licensing, and registration of factories, site appraisal committees, worker health and safety, holidays, working hours, wages, Minimum Wages Act, 1948, minimum wage rates, and hour of work.

Chapter 16 covers intellectual property rights (IPR), patents, the 1970 Patents Act, exclusive marketing rights, patentee rights, international forensic pharmacy arrangements, pharmaceutical product patent protection, copyright, trademarks, the Madrid Agreement, Madrid Protocol, and the Designs Act, 1911, as well as the procedure for obtaining a patent and registration of designs.

Chapters 17 to 19 detail the Consumer Protection Act, 1986, complaint nature, Standards of Weights and Measures Act, 1976, Code of Pharmaceutical Ethics, objectives, and pharmacist's oath.

Chapter 20 delves into Medical and Health Accessories, while Chapter 23 delves into the available prescription and non-prescription drugs, diagnostic aids, and medical appliances in the market.

Chapters 21 and 23 cover Prescription and Non-prescription Drugs and Diagnostic Aids, new drug approval, clinical trials, federal regulations, IND application, drug documents, export registration, pharmacy, practice areas, the future of pharmacy, pharmaceutical education, India's profession, career options, pharmacist demand, and international demand. They also discuss the future of pharmacy, pharmaceutical education, and career options for pharmacists.

Chapters 24 and 25 outline the scope, objectives, and functions of Pharmaceutical Legislation, including the Drugs Enquiry Committee, The National Pharmaceutical Pricing Authority (NPPA), Price Monitoring and Resource Unit (PMRU), introduction to the DPCO Act, 2013, price calculation, retail price of formulations, and price of formulations in NLEM.

Chapters 26 and 27 detail the Right to Information Act of 2005, including filing procedures, appeals, penalties, compensation, transparency, and accountability in government, as well as the Drugs and Cosmetics Act, 1940, Schedules (P, T, U, F, M).

The authors express their gratitude to various teachers and colleagues who contributed to the first edition of their work. They are particularly grateful to Dr Uma Shankar Nagayach, Dr Surendra Mohan Tiwari, Dr Suman Jain, Dr Ashutosh Kar, Dr Manoj Sharma, Dr Vikash Sharma, Dr Sudhir Bharadwaj, Dr Pratap Singh Jadon, Dr Ankur Agrwal, Dr Vinay Jain, Eng Jitendra Chaurasia, Dr Aakanksha Chaurasia, and Dr Bhagat Singh Jaiswal for their invaluable contributions.

We express our gratitude to Mr Satish Kumar Jain, Mr YN Arjuna, and their team from CBS Publishers & Distributors Pvt Ltd for their outstanding efforts in the second edition.

We express gratitude to our family members and, ultimately, to God.

**Bhaskar Chaurasia
Rajiv Kumar Chaurasia**

Preface to the First Edition

Pharmacy profession has made tremendous growth during the last 50 years and hence pharmaceutical education has also been promoted at the highest levels of standards. The present book on the subject of forensic pharmacy is compiled and edited to cover the syllabi of diploma, undergraduate and postgraduate courses in pharmacy. This book provides a systematic and comprehensive coverage of the theory as well as the illustration of application thereof. Every chapter covers the definitions, objectives, and offences under the Act. This book will be useful to both the students as well as the teachers.

The systematic structure of the book is assigned to cover the major syllabi of forensic pharmacy in 25 chapters and includes all topics of syllabus proposed by AICTE.

Chapters 1 to 5 describe pharmaceutical legislation, Drugs Enquiry Committee (DEC), pharmaceutical industries in India, the Pharmacy Act, 1948, PCI, Education Regulation, State pharmacy councils, joint State councils, inter-State agreements, the Drugs and Cosmetics Act, 1940 and Rules, 1945, Schedules under the D and C Act and Rules, administration of the D and C Act and Rules, import, manufacture and sale of drugs and cosmetics, design of labels, the Medicinal and Toilet Preparations (Excise Duties) Act, 1955, and Rules, 1956, manufacture of medicinal and toilet preparations in bond and outside bond, warehousing of alcoholic preparations, export of alcoholic preparations, inter-State transport of alcoholic preparations, the Narcotic Drugs and Psychotropic Substances Act, 1985, prohibition, control and regulation of the narcotic drugs and psychotropic substances, opium poppy cultivation and production of opium and poppy straw, manufacture, sale and export of opium, manufacture of manufactured drugs, import, export and transshipment of narcotic drugs and psychotropic substances.

Chapters 6 to 8 describe the Essential Commodities Act, 1955, control, production, supply, distribution of essential commodities, pricing of essential commodities, confiscation of essential commodity, the Drug Price Control Order (DPCO) of 1995, sale prices of bulk drugs, calculation of retail price of formulation, New Drug Policy, objectives of Pharmaceutical Policy-2002, and span of price control.

Chapters 9 to 11 describe the Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954, prohibited advertisement, classes of advertisement exempted under the Drugs and Magic Remedies Act, the Poisons Act, 1919, poisonous substances, import possession and sale of poison, the MTP Act, 1971, termination of pregnancy, approved for termination of pregnancy.

Chapters 12 to 14 explain the Prevention of Cruelty to Animals Act, 1960, treating animals cruelly, animal welfare board of India, experiments on animals, CPCSEA, IAEC, performing animals, breeding and stocking of animals, the Shops and Establishments Act, registration of the shop or establishment, working hours, service conditions, wages, leave, inspection of establishments, the Insecticides Act, 1968 and Rules, 1971, the Central Insecticides Board, Registration Committee, Central Insecticide Laboratory, registration of insecticides, import, manufacture and sale of certain insecticides.

Chapter 15 to 17 describes AICTE Act, 1987, objectives of the AICTE Act, power and functions of AICTE, the Factories Act, 1948, approval, licensing and registration of factories, constitution of site appraisal committees, health and safety of the workers, holidays and working hours, wages, the Minimum Wages Act, 1948, fixing minimum rates of wages, fixing hour of work.

Chapter 18 describes intellectual property rights, patents, Patents Act, 1970, inventions not patentable, procedure for obtaining patent, exclusive marketing rights, rights of patentees, international

arrangement, patent protection for pharmaceutical products, copyright, coverage provided by copyright, rights under copyright, infringement of copyright, trademarks, Madrid Agreement, Madrid Protocol, the Designs Act, 1911, registration of design.

Chapters 19 to 21 describe the Consumer Protection Act, 1986, nature of complaint, the Standards of Weights and Measures Act, 1976, Code of Pharmaceutical Ethics, its objectives, and Pharmacist's Oath.

Chapter 22 describes the medical and health accessories, and Chapter 23 explains prescription drugs and non-prescription drugs, diagnostics aids, and medical appliances available in the market.

Chapters 24 and 25 describe new drug approval, clinical trials, code of federal regulations, investigational new drug (IND) application, drug documents, abbreviated new drug application, export registration, export registration procedure, documents prepared for export registration, pharmacy, types of pharmacy practice areas, the future of pharmacy, pharmaceutical education, regulation of pharmacy education, profession and practice in India, career options of pharmacist, demand of pharmacists, international demand of pharmacists.

We wish to acknowledge our great indebtedness to our teachers and colleagues who have contributed towards the first edition in one way or other. However, our most sincere thanks are due to Dr Uma Shankar Nagayach (former Principal, Degree College, Mahoba), Dr Surendra Mohan Tiwari (former Reader, GR Medical College, Gwalior), Dr (Mrs) Suman Jain (Principal, Shri Ram College of Pharmacy, Banmore), Dr Ashutosh Kar (Director, Shri RNS College of Pharmacy, Gormi), Dr Manoj Sharma (Principal, Shri RNS College of Pharmacy, Gormi).

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We are also highly thankful to Mr Satish K Jain, Mr Vinod K Jain and Mr YN Arjuna and their team (CBS Publishers & Distributors Pvt Ltd) for their dynamic efforts for this publication.

We are also thankful to our family members, and finally we are thankful to God.

**Bhaskar Chaurasia
Rajiv Kumar Chaurasia**

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The Pharmacy Act, 1948

INTRODUCTION

In India there was no restriction to practice the profession of pharmacy. One could practise this profession as any other profession. Persons, having no knowledge and having no education in pharmacy or pharmaceutical chemistry or pharmacology, were engaged in this profession. Hundreds of cases were brought to the notice of the government wherein the compounding, mixing or dispensing of medicines was being done by persons who were not adequately educated in this line. The system was causing great harm to the health of people by wrong compounding, mixing or dispensing. It was found necessary to enact a law for the regulation of the profession and practice of pharmacy. To achieve this goal the Pharmacy Bill, 1947 was introduced in the legislature which was later referred to the select committee. The recommendations of the selection committee were incorporated in the bill. The Pharmacy Bill, 1947, having been passed by the legislature received its assent on 4th March, 1948. This act may be called the Pharmacy Act, 1948. It extends to the whole of India except the State of Jammu and Kashmir.

Salient Features

This act was enacted for the regulation of the profession and practice of pharmacy. The Pharmacy Act has been divided into 5 Chapters

and 46 Sections. The salient features are as follows:

1. The Pharmacy Council of India consists of a team for a period of 5 years.
The inter university board has members of different departments like pharmacy, pharmacology, pharmaceutical chemistry, etc. 6 members are nominated by the Central Government and one member from the Medical Council of India. Director General of Health Services, Drug Controller, Director of Central Drug Laboratory, and Chief Chemist (central revenues) are also members.
2. Central Council with approval of Central Govt. regulates education, period of study, practical training, equipments, facilities, and standard of examination.
3. The act approves formation of State Pharmacy Councils.
4. Registration of pharmacists is done with their name, age, sex, residential address, and qualification.

Any person more than 18 years holding degree or diploma in pharmacy or other field engaged in corresponding of drugs in hospital, dispensary or 10th class having 5 years of dispensary experience, can be registered. Special provision are given for displaced person who has been carrying on profession of pharmacy before March 1948 and Indian carrying pharmacy outside the India but satisfy the conditions of registration.

5. Removal of name after recommendation of executive committee of central or state body for infamous conduct, suppression or misrepresentation of fact.
6. Any person who is found guilty for violation of law can be punished with a fine of Rupees Five hundred-one thousand or 6 months imprisonment or both.

At present there are so many approved institutes imparting Diploma in Pharmacy (D. pharm) and Degree of Pharmacy (B. Pharm) and Master Degree of Pharmacy (M. pharm).

Aims and Objectives of the Pharmacy Act, 1948

It is desirable that, as in most other countries, only persons who have attained a minimum standard of professional education should be permitted to practice the profession of pharmacy. It is accordingly proposed to establish a Central Council of Pharmacy, which will prescribe the minimum standards of education and approve courses of study and examinations for pharmacists, and Provincial Pharmacy Councils, which will be responsible for the maintenance of provincial registers of qualified pharmacists. It is further proposed to empower provincial governments to prohibit the dispensing of medicine on the prescription of a medical practitioner otherwise than by, or under the direct and personal supervision of, a registered pharmacist.

Aims

- The Pharmacy Act of 1948, which was later revised in 1959, 1976 and 1984, aims at regulating the profession of pharmacy in India.
- Since pharmacists deal with sale and even prescription of medicine, it is necessary to ensure that they have adequate knowledge of drugs and treatments.
- It should be noted that consuming a wrong medicine cannot only result in irreversible damage to the body, in grave cases it may result in loss of life as well.

Objectives

The Pharmacy Act has been passed:

- To regulate the profession of pharmacy. Whereas it is expedient to make better provision for the regulation of the profession and practice of pharmacy and for that purpose to constitute Pharmacy Councils.
- To provide uniform education and training for the prospective pharmacist.
- To maintain control over the person entering the profession of pharmacy, by providing for their registration in every state.

DEFINITIONS

- a. **“Agreement”** means an agreement entered into under section 20 (Inter-State Agreements).
- b. **“Approved”** means approved by the Central Council under section 12 (approved courses of study and examinations) or section 14 (qualifications granted outside the territories to which this act extends).
- c. **“Central Council”** means the Pharmacy Council of India constituted under Section 3 (constitution and composition of Central Council).
- d. **“Central Register”** means the register of pharmacists maintained by the Central Council under section 15 A (the Central Register).
- e. **“Executive Committee”** means the executive committee of the Central Council or of the State Council, as the context may require.
- f. **“Indian University”** means a university within the meaning of section 3 (constitution and composition of Central Council) of the University Grants Commission Act, 1956, and includes such other institutions, being institutions established by or under a central act, as the Central Government may, by notification in the official gazette, specify in this behalf.

g. "Medical Practitioner" means a person:

- i. Holding a qualification granted by an authority specified or notified under section 3 (constitution and composition of Central Council) of the Indian Medical Degrees Act, 1916, or specified in the schedules to the Indian Medical Council Act, 1956.
 - ii. Registered or eligible for registration in a medical register of a state meant for the registration of persons practising the modern scientific system of medicine.
 - iii. Registered in a medical register of a state, who, although not falling within is declared by a general or special order made by the State Government in this behalf as a person practising the modern scientific system of medicine for the purposes of this act.
 - iv. Registered or eligible for registration in the register of dentists for a state under the Dentists Act, 1948.
 - v. Who is engaged in the practise of veterinary medicine and who possesses qualifications approved by the State Government.
- h. "Register"** means a register of pharmacists prepared and maintained under the act.
- i. "Registered Pharmacist"** means a person whose name for the time being is entered in the register of the state in which he for the time being is residing or carrying on his profession or business of pharmacy.
- j. "State Council"** means a State Council of Pharmacy constituted under section 19 (constitution and composition of State Councils), and includes a joint State Council of Pharmacy constituted in accordance with an agreement under Section 20 (Inter-State Agreements).
- k. "University Grant Commission"** means the University Grants Commission established under section 4 (incorporation of Central Council.) of the University Grants Commission Act, 1956.

THE PHARMACY COUNCIL OF INDIA

The Pharmacy Council of India (PCI), also known as Central Council, was constituted under section 3 of The Pharmacy Act, 1948. The pharmacy education and profession in India up to graduate level is regulated by the pharmacy council of India, a statutory body governed by the provisions of The Pharmacy Act, 1948 passed by the Indian Parliament.

The Pharmacy Act 1948 was enacted on 4 March 1948 with the following preamble—"An Act to regulate the profession of pharmacy. Whereas it is expedient to make better provision for the regulation of the profession and practice of pharmacy and for that purpose to constitute pharmacy councils". The PCI was constituted on 9 August 1949 under section 3 of the pharmacy act. PCI is reconstituted every five years.

Objectives of the PCI

- Regulation of the pharmacy education in the country for the purpose of registration as a pharmacist under the Pharmacy Act.
- Regulation of profession and practice of pharmacy.

Functions and Duties

- To prescribe minimum standard of education required for qualifying as a pharmacist (under Section 10 {education regulations} of the pharmacy act).
- Framing of Education Regulations prescribing the conditions to be fulfilled by the institutions seeking approval of the PCI for imparting education in pharmacy (under Section 10).
- To ensure uniform implementation of the educational standards throughout the country (under Section 10).
- Inspection of pharmacy institutions seeking approval under The Pharmacy Act to verify availability of the prescribed norms (under Section 16 {inspection} of the Pharmacy Act).
- To approve the course of study and examination for pharmacists, i.e. approval of the

academic training institutions providing pharmacy courses (under Section 12 {approved courses of study and examinations} of the Pharmacy Act).

- To withdraw approval, if the approved course of study or an approved examination does not continue to be in conformity (under Section 13).

A. CONSTITUTION

- I. **Constitution and composition of Central Council:** The Central Government shall, as soon as may be, constitute a Central Council consisting of the following elected, nominated and ex-officio members, namely.

Elected Members

1. 6 members, among whom there shall be at least one teacher of each of the subjects, pharmaceutical chemistry, pharmacology and pharmacognosy elected by the University Grants Commission from among the teaching staff of an Indian university or a college affiliated thereto which grants a degree or diploma in pharmacy.
2. One member elected from amongst themselves by the members of the Medical Council of India.
3. One member to represent each state elected from amongst themselves by the members of each State Council, who shall be a registered pharmacist.

Nominated Members

4. 6 members, of whom at least 4 shall be persons possessing a degree or diploma in, and practising pharmacy or pharmaceutical chemistry, nominated by the Central Government.
5. One member to represent each State nominated by the State Government, who shall be a registered pharmacist.
6. One member to represent each Union Territory, nominated by the Union

Territory Council, being eligible for registration under Section 31 (provisions related to the qualifications for entry on first register) of the act.

7. A representative of the University Grants Commission and a representative of the all India council for technical education.

Ex-officio Members

8. The Director General, Health Services, ex-officio member is unable to attend any meeting, a person authorized by him in writing can do so.
9. The Drugs Controller, India, ex-officio member is unable to attend any meeting, a person authorised by him in writing can do so.
10. The Director of the Central Drugs Laboratory, ex-officio member.
- II. **Incorporation of Central Council:** The council constituted under section 3 shall be a body corporate by the name of the Pharmacy Council of India, having perpetual succession and a common seal, with power to acquire and hold property both movable and immovable, and shall by the said name sue and be sued.
- III. **President and Vice-President of Central Council:** The President and Vice-President of the Central Council shall be elected by the members of the said council from among themselves. The President or Vice-President shall hold office as such for a term not exceeding five years and not extending beyond the expiry of his term as member of the Central Council, but subject to his being a member of the central council, he shall be eligible for re-election.
- IV. **Mode of elections:** Elections under this chapter shall be conducted in the prescribed manner, and where any dispute arises regarding any such election it shall be referred to the Central Government whose decision shall be final.

B. TERM OF OFFICE, VACANCIES, REMUNERATION AND ALLOWANCES

- I. *Term of office and casual vacancies:* Subject to the provisions of this section, a nominated or elected member shall hold office for a term of 5 years from the date of his nomination or election or until his successor has been duly nominated or elected, whichever is longer. A nominated or elected member may at any time resign his membership by writing under his hand addressed to the President, and the seat of such member shall thereupon become vacant. A nominated or elected member shall be deemed to have vacated his seat if he is absent without excuse, sufficient in the opinion of the Central Council, from three consecutive meetings of the Central Council or if he ceases to be a member of the teaching staff, Medical Council of India or a registered pharmacist, as the case may be. A casual vacancy in the Central Council shall be filled by fresh nomination or election, as the case may be, and the person nominated or elected to fill the vacancy shall hold office only for the remainder of the term for which the member whose place he takes was nominated or elected. No act done by the Central Council shall be called in question on the ground merely of the existence of any vacancy in, or any defect in the constitution of the Central Council. Members of the Central Council shall be eligible for re-nomination or re-election.
- II. *Staff remuneration and allowances:* The Central Council shall appoint a registrar who shall act as the secretary to that council and if need, as its treasurer too. The Central Council shall appoint such other officers and servants to enable the council to carry out its functions under this act. The Central Council may require and take security from the registrar or any other officer or servant, for the due performance of his duties as that council

may consider necessary. The Central Council empowered to fix, the remuneration and allowances to be paid to the President, Vice-President, and other members of that council and the pay and allowances and other conditions of service of officers and servants of that council, with the previous sanction of the Central Government.

C. COMMITTEES

- I. *The Executive Committees:* The Central Council shall, as soon as may be, constitute an executive committee consisting of the President (who shall be chairman of the executive committee) and Vice-President, ex-officio, and 5 other members elected by the Central Council from amongst its members. A member of the executive committee shall hold office as such until the expiry of his term of office as member of the central council, but, subject to his being a member of the Central Council, he shall be eligible for re-election. In addition to the powers and duties conferred and imposed upon it by this act the executive committee shall exercise and discharge such powers and duties as may be prescribed.
- II. *Other Committees:* The Central Council may constitute from among its members other committees for such general or special purposes as that council may deem necessary and for such periods not exceeding five years as it may specify, and may co-opt for a like period persons, who are not members of the Central Council, as members of such committees. The remuneration and allowances to be paid to the members of such committees shall be fixed by the Central Council with the previous sanction of the Central Government. The business before such committees shall be conducted in accordance with such regulations as may be made under this act.

D. FUNCTIONS OF PCI

- I. ***Education regulations (Section 10):*** The Education regulations are approved by the Central Government.
 1. The Central Council may, subject to the approval of the Central Government, make regulations, to be called the Education Regulations, prescribing the minimum standard of Education Required for qualification as a pharmacist.
 2. In particular and without prejudice to the generality of the foregoing power, the Education Regulations 1991 may prescribes:
 - a. The nature and period of study and of practical training (not less than 500 hours over a period of not less than 3 months provided that not less than 250 hours are devoted to actual dispensing of prescriptions in a recognized hospital or dispensary or pharmacy/chemist and druggist or licensed drug manufacturing unit) to be undertaken before admission to an examination.
 - b. The equipment and facilities to be provided for students undergoing approved courses of study.
 - c. The subjects of examination and the standards therein to be attained.
 - d. Any other conditions of admission to examinations.
 3. Copies of the draft of the education regulations and of all subsequent, amendments thereof shall be furnished by the Central Council to all State Governments, and the Central Council shall before submitting the education regulations or any amendment thereof, as the case may be, to the Central Government for approval take into consideration the comments of any State Government received within three months from the furnishing of the copies as aforesaid.
 4. The education regulations shall be published in the official gazette and in

such other manner as the Central Council may direct.

5. The Executive Committee from time to time shall report to the Central Council on the efficacy of the education regulations and may recommend to the Central Council such amendments thereof as it may think fit.

Amendments in education regulations: The present education regulations is framed by PCI with the approval of Central Government.

Amendments to these regulations are first circulated to the State Governments for their comments. If the comments are received with in 3 months, then they may be taken in consideration by the Central Council and then amendments are send to central government for its approval. After approval by Central Government it is published in the official gazette. Executive Committee shall report to the council from time to time about the efficacy of regulations and may recommend amendments in the present regulation.

- II. ***Application of education regulations to States:*** At any time after the constitution of the State Council under this act and after consultation with the State Council, the State Government may, by notification in the official gazette, declare that the education regulations shall take effect in the state. Provided that where no such declaration has been made, the education regulations shall take effect in the state on the expiry of 3 years from the date of the constitution of the state council.

- III. ***Approved courses of study and examination:*** Any authority or institution in a state which conducts a course of study for pharmacists may apply to the Central Council for approval of the course, and the Central Council, if satisfied, after such enquiry as it thinks fit to make, that the said course of study is in conformity with the Education Regulations, shall declare the said course of study to be an approved course of study for the purpose

of admission to an approved examination for pharmacists.

Any authority or institution in a state which holds an examination in pharmacy may apply to the Central Council for approval of the examination, and the Central Council if satisfied, after such enquiry as it thinks fit to make, that the said examination is in conformity with the education regulations, shall declare the said examination to be an approved examination for the purpose of qualifying for registration as a pharmacist under this act.

Every authority in the state which conducts an approved course of study or holds an approved examination shall furnish such information as the Central Council may, from time to time, require as to the courses of study and training and examination to be undergone, as to the ages at which such courses of study and examination are required to be undergone and generally as to the requisites for such courses of study and examination.

IV. Inspection: The Executive Committee may appoint such number of inspectors.

Power of inspector: An inspector may:

- a. Inspect any institution which provides an approved course of study.
- b. Attend at any approved examination.
- c. Inspect any institution whose authorities have applied for the approval of its course of study or examination and attend, as it may deem requisite for the purposes of this act at any examination of such institution.

An inspector attending at any examination shall not interfere with the conduct of the examination, but he shall report to the executive committee on the sufficiency of every examination he attends and on any other matter in regard to which the executive committee may ask him to report. The executive committee shall forward a copy of every such report to the authority or institution concerned, and shall also forward a copy together with any comments there on which the said authority or institution

may have made, to the Central Government and to the Government of the State in which the authority or institution is situated.

V. Withdrawal of approval: Where the executive committee reports to the Central Council that an approved course of study or an approved examination does not continue to be in conformity with the education regulations, the Central Council shall give notice to the authority concerned of its intention to take into consideration the question of withdrawing the declaration of approval accorded to the course of study or examination. As the case may be, and the said authority shall within 3 months from the receipt of such notice forward to the Central Council through the State Government such representation in the matter as it may wish to make. After considering any representation which may be received from the authority concerned and any observations there on which the State Government may think fit to make, the council may declare that the course of study or the examination shall be deemed to be approved only when completed or passed, as the case may be, before a specified date.

VI. Approval of other qualifications: The Central Council may approve any qualification granted by an authority outside India to be an approved qualification for the purpose of qualifying for registration under this act if a sufficient guarantee of the requisite skill and knowledge is afforded. It may also declare at anytime that such qualification shall be deemed additional, to be approved only when granted before or after a specified date. Provided that the state or country in which a qualification is granted permits citizens of India to enter and practice the profession of pharmacy. Thus foreign qualifications are approved on a reciprocal basis.

Approval of courses of study and examinations, withdrawal of approval and approval of foreign qualifications are declared by making a

resolution at a meeting of the Central Council and are effective as soon as they are published in the official gazette.

VII. *Mode of declarations:* All declarations shall be made by resolution passed at a meeting of the Central Council, and shall come into effect as soon as they are published in the official gazette.

VIII. *The central register of pharmacist:* According to the provisions of the Pharmacy (Amendment) Act, 1976, the Central Council shall cause to be maintained in the prescribed manner a register of pharmacists to be known as the Central Register, which shall contain the names of all persons for the time being entered in the register for a state. Each State Council shall supply to the Central Council five copies of the register for the state as soon as may be after the 1st day of April of each year, and the registrar, of each State Council, shall inform the Central Council, without delay, all additions to, and other Amendments in, the register for the State made from time to time. It shall be the duty of the registrar of the Central Council to keep the central register in accordance with the orders made by the Central Council, and from time to time to revise the central register and publish it in the gazette of India. The central register shall be deemed to be public document within the meaning of the Indian Evidence Act, 1872 and may be proved by the production of a copy of the register as published in the gazette of India.

IX. *Registration in the central register:* The registrar of the Central Council shall, on receipt of the report of registration of a person in the register for a State, enter his name in the central register.

X. *Information to be furnished:* The Central Council shall furnish copies of its minutes and minutes of the Executive Committee and annual report of its activities to the Central Government. The Central Government may publish in such manner as it

may think fit any report, furnished to it under the provision related to the Inspection.

XI. *Accounts and audit:* The Central Council shall maintain proper accounts and other relevant records and prepare an annual statement of accounts, in accordance with such general directions as may be issued and in such form as may be specified by the Central Government in consultation with the Comptroller and Auditor-General of India. The accounts of the Central Council shall be audited annually by the Comptroller and Auditor-General of India or any person authorized by him in this behalf and any expenditure incurred by him or any person so authorized in connection with such audit shall be payable by the Central Council to the Comptroller and Auditor-General of India. The Comptroller and Auditor-General of India and any person authorized by him in connection with the audit of the accounts of the Central Council shall have the same rights and privileges and authority in connection with such audit as the Comptroller and Auditor-General of India has in connection with the audit of government accounts, and in particular, shall have the right to demand the production of books of accounts, connected vouchers and other documents and papers. The accounts of the Central Council as certified by the Comptroller and Auditor-General of India or any person authorized by him in this behalf together with the audit report thereon shall be forwarded annually to the Central Council which shall forward the same with its comments to the Central Government.

XII. *Power to make regulations:* The Central Council may, with the approval of the Central Government make regulations consistent with this act to carry out the purposes of this act.

STATE PHARMACY COUNCILS

State Pharmacy Council is a statutory body constituted by the State Government under the provisions of the Pharmacy Act of 1948.

Objective: The main objective of the State Pharmacy Council is to regulate the profession of pharmacy in the State.

Function: The prime function of the State Pharmacy Council is to grant registration to the eligible pharmacists possessing requisite qualification as per the Pharmacy Act and to enforce the necessary provisions of the Pharmacy Act, 1948. In addition to task of registration, they are also responsible for the maintenance of the register of pharmacists of the whole State and also exercise such other controls over the practicing pharmacists, as be necessary.

A. CONSTITUTION

I. **Constitution and composition of State Councils:** under the act the State Government shall constitute a State Council (under Section 19) consisting of the following members, namely:

Elected and Nominated Members

1. 6 members, elected from amongst themselves by registered pharmacists of the state.
2. 5 members, of whom at least 3 shall be persons possessing a prescribed degree or diploma in pharmacy or pharmaceutical chemistry or registered pharmacists, nominated by the State Government.
3. One member elected from amongst themselves by the members of each Medical Council or the Council of Medical Registration of the State.

Ex-officio Members

4. The Chief Administrative Medical Officer of the State ex-officio or if he is unable to attend any meeting, a person authorized by him in writing to do so.
5. The officer-in-charge of Drugs Control Organization of the State under the

Drugs and Cosmetics Act, 1940, ex-officio or if he is unable to attend any meeting, a person authorized by him in writing to do so.

6. The Government Analyst under the Drugs and Cosmetics Act, 1940, ex-officio.

II. Inter-State Agreements (Section 20):

1. When two or more State Government enter into an agreement may decide:
 - a. For the constitution of a Joint State Council for all the participating states.
 - b. That the State Council of one state shall serve the needs of the other participating states, such agreement is called Interstate Agreement.
2. Under this act such an agreement may:
 - a. Provide for the apportionment between the participating state of the expenditure in connection with the State Council or Joint State Council.
 - b. Determine which of the participating State Governments shall exercise the several functions of the State Government under this act, and the references in this act to the State Government shall be construed accordingly.
 - c. Provide for consultation between the participating State Governments either generally or with reference to particular matters arising under this act.
 - d. Make such incidental and ancillary provisions, not inconsistent with this act, as may be deemed necessary or expedient for giving effect to the agreement.
3. An agreement under this section shall be published in the official gazettes of the participating states.

III. Constitution/composition of Joint State Councils (Section 21):

Joint State Council: Two or more states may agree to form a Joint State Pharmacy Council

for definite or indefinite period of time. By this agreement, the State Pharmacy Council of one state is to serve the needs of other state or states. A Joint State Council consists of the following members:

Elected and Nominated Members

1. Not less than 3 and not more than 5 members elected amongst themselves by the registered pharmacists of each of the participating states.
2. One member elected from amongst themselves by the members of each Medical Council or the Council of Medical Registration of each participating state.
3. Not less than 3 but not more than 4 members nominated by each participating State Government.

Ex-officio Members

4. The Chief Administrative Medical Officer of each participating state or his authorised person.
5. The officer in-charge of Drugs Control Organization of each Participating State or his authorised person.
6. The Government Analyst of each participating state under Drug and Cosmetic Act, 1940.

Functions of Joint State Council: The State Pharmacy Council of one State is to serve the needs of the other State or States. The council has to prepare annual accounts statement and the amount of expenditure is to be shared by all the states. According to registration of pharmacist and maintenance of the register every year after 1st April, the State Council shall supply 5 copies of the register to PCI with updated amendments.

IV. Incorporation of State Councils: Every State Council shall be a body corporate by such name as may be notified by the State Government in the official gazette or, in the case of a Joint State Council, as may be

determined in the agreement, having perpetual succession and a common seal, with power to acquire or hold property both movable and immovable and shall by the said name sue and be sued.

V. President and Vice-President of State Council: The President and Vice-President of the State Council are elected by the members from amongst themselves. Provided that for 5 years from the first constitution of the State Council the President shall be a person nominated by the State Government who shall hold office at the pleasure of the State Government and where he is not already a member, shall be a member of the State Council. The President or Vice-President shall hold office as such for a term not exceeding 5 years and not extending beyond the expiry of his term as a member of the State Council, but subject to his being a member of the State Council, he shall be eligible for re-election.

VI. Mode of Elections: Elections under this act shall be conducted in the prescribed manner, and where any dispute arises regarding any such election, it shall be referred to the State Government whose decision shall be final.

B. TERM OF OFFICE, VACANCIES, REMUNERATION AND ALLOWANCES

I. Term of office and casual vacancies: Under this act, a nominated or elected member, other than nominated president, shall hold office for a term of 5 years from the date of his nomination or election or until his successor has been duly nominated or elected, whichever is longer. A nominated or elected member may at any time resign his membership by writing under his hand addressed to the President, and the seat of such member shall thereupon become vacant. A nominated or elected member shall be deemed to have vacated his seat

if he is absent without excuse sufficient in the opinion of the State Council from three consecutive meetings of the State Council, or if he is elected, if he ceases to be a registered pharmacist or causes to be a member of the Medical Council or Council of Medical Registration of the State, as the case may be. A casual vacancy in the State Council shall be filled by fresh nomination or election, as the case may be, and the person nominated or elected to fill the vacancy shall hold office only for the remainder of the term for which the member whose place he takes was nominated or elected. No act done by the State Council shall be called in question on the ground merely of the existence of any vacancy in, or any defect in the constitution of, the State Council. Members of the State Council shall be eligible for re-nomination or re-election.

- II. ***Staff, remuneration and allowances:*** With the previous sanction of the State Government the State Council may appoint a Registrar who shall also act as secretary and also a treasurer of the State Council. The State Council may also appoint such other officers and servants to carry out its functions. Fix the salaries and allowances and other conditions of service of the secretary and other officers and servants of the State Council and also fix the rates of allowances payable to members of the State Council.

C. INSPECTION

- I. ***Inspection by State Councils:*** A State Council may, appoint inspectors having the prescribed qualifications.

Power of Inspector: An inspector may:

- a. Inspect any premises where drugs are compounded or dispensed and submit a written report to the registrar.
- b. Enquire whether a person who is engaged in compounding or dispensing of drugs is a registered pharmacist.

- c. Investigate any complaint made in writing in respect of any contravention of this act and report to the registrar.
- d. Institute prosecution under the order of the executive committee of the State Council.
- e. Exercise such other powers as may be necessary.

Any person wilfully obstructing an inspector in the exercise of his powers under this act or any rules made there under shall be punishable with imprisonment up to 6 months, or with fine not exceeding 1,000 rupees, or with both. Every inspector shall be deemed to be a public servant under section 21 of the Indian Penal Code 1860.

- II. ***Information to be furnished:*** The State Council shall furnish such reports, copies of its minutes and of the minutes of the executive committee, and abstracts of its accounts to the State Government as the State Government may from time to time require and copies thereof shall be sent to the Central Council. The State Government may publish, in such manner as it may think fit, any report, and copy, abstract or other information furnished to it under this section.

D. COMMITTEE

The executive committee of State Councils:

1. The State Council shall constitute an executive committee consisting of the President (who shall be Chairman of the Executive Committee) and Vice-President, ex-officio and such number of other members elected by the State Council from amongst them as may be prescribed.
2. A member of the executive committee shall hold office as such until the expiry of his term of office as member of the state council, but, subject to his being a member of the State Council, he shall be eligible for re-election.
3. In addition to the powers and duties conferred and imposed upon it by this act, the executive committee shall exercise and

discharge such powers and duties as may be prescribed.

E. FUNCTIONS OF STATE PHARMACY COUNCIL

Registration of pharmacists: The Pharmacy Act provides for the registration of pharmacists to regulate the entry of persons in this profession. It ensures that only those persons having requisite qualifications training and experience relating to the compounding dispensing and handling, storage, etc. of the drugs are allowed to enter the practice of pharmacy. Name of registered pharmacists are entered in the registers maintained by the State Councils and the Central Council.

I. Preparation and maintenance of register:

In every State, the State Government shall cause to be prepared a register of pharmacists for the state. The State Council shall maintain the register in accordance with the provisions of this act.

The register shall include the following particulars, namely:

- a. The full name and residential address of the registered person.
- b. The date of his first admission to the register.
- c. His qualifications for registration.
- d. His professional address, and if he is employed by any person, the name of that person.
- e. Such further particulars as may be prescribed.

II. Preparation of first register: For the purpose of preparing the first register, the State Government shall constitute a registration tribunal consisting of three persons and shall also appoint a registrar who shall act as secretary of the registration tribunal. The State Government shall appoint a date on or before which applications for registration, which shall be accompanied by the prescribed fee, shall be made to the registration tribunal. The registration tribunal shall examine every application received on or before the

appointed date, and if it is satisfied that the applicant is qualified for registration under section 31, shall direct the entry of the name of the applicant on the register. The first register so prepared shall thereafter be published in such manner as the State Government may direct, and any person aggrieved by a decision of the registration tribunal expressed or implied in the register as so published may, within 60 days from the date of such publication, appeal to an authority appointed by the State Government in this behalf by notification in the official gazette. The registrar shall amend the register in accordance with the decisions of the authority appointed and shall thereupon issue to every person whose name is entered in the register a Certificate of Registration in the prescribed form. Upon the constitution of the State Council, the register shall be given into its custody, and the State Government may direct that all or any specified part of the application fees for registration in the first register shall be paid to the credit of the State Council.

III. Qualifications for entry on first register: (section 31) A person who has attained the age of 18 years shall be entitled on payment of the prescribed fee, be entitled to have his name entered in the first register if he resides, or carries the business or profession of pharmacy, in the state and if he:

- a. Holds a degree or diploma in pharmacy or pharmaceutical chemistry or a chemist and druggist diploma of an Indian University or a State Government, as the case may be, or a prescribed qualification granted by an authority outside India.
- b. Holds a degree of an Indian University other than a degree in pharmacy or pharmaceutical chemistry and has been engaged in the compounding of drugs in a hospital or dispensary or other place in which drugs are regularly dispensed on prescriptions of medical practitioners for a total period of not less than 3 years.

- c. Has passed an examination recognised as adequate by the State Government for compounders or dispensers.
- d. Has been engaged in the compounding of drugs in a hospital or dispensary or other place in which drugs are regularly dispensed on prescriptions of medical practitioners for a total period of not less than five years prior to the date notified by the State Government for receipt of applications for entry of names on the first register to the registration tribunal.

IV. Qualifications for subsequent registration (Section 32): After the date appointed by the State Government for receiving the applications for registration by the registrational tribunal and before the education regulations have taken effect in the state, a person who has attained the age of 18 years shall be entitled to have his name entered in the register on payment of the prescribed fee, if he resides or carries the business or profession of pharmacy in the state and if he:

- a. Satisfies the conditions prescribed with the prior approval of the Central Council, or where no conditions have been prescribed, the conditions entitling a person to have his name entered on the first register, and has passed a matriculation or an equivalent examination.
- b. Is a registered pharmacist in another state.
- c. Possesses a qualification granted by an authority outside India, but approved by the Central Council and has passed a matriculation or an equivalent.

After the education regulations have taken effect in the state, a person shall on payment of the prescribed fee be entitled to have his name entered on the register if he has:

- a. Attained the age of 18 years.
- b. Resides, or carries the business or profession of pharmacy, in the state.
- c. Passed an approved examination or possesses a qualification approved by the Central Council.

- d. Is a registered pharmacist in another State.

V. Special provisions for registration of certain persons: The Pharmacy (Amendment) Act of 1959 made special provisions for the registration.

- 1. Notwithstanding anything contained in the provision related to the qualifications for subsequent registration. A State Council may also permit to be entered on the register:
 - a. The names of displaced persons who have been carrying on the business or profession of pharmacy as their principal means of livelihood from a date prior to the 4th day of March, 1948, and who satisfy the conditions for registration in the first register of the state.
 - b. The names of citizens of India who have been carrying on the business or profession of pharmacy in any country outside India and who satisfy the conditions for registrations in the first register of the state.
 - c. The names of persons who is resided in an area which has subsequently become a territory of India and who satisfy the conditions for registration in the first register of the state.
 - d. The names of persons who carry on the business or profession of pharmacy in the state, and:
 - i. Would have satisfied the conditions for registration, on the date appointed, had they applied for registration on or before that date; or
 - ii. Have been engaged in the compounding of drugs in a hospital or dispensary or other place in which drugs are regularly dispensed on prescriptions of medical practitioners as defined in this act for a total period of not less then 5 years prior to the date appointed.

- e. The names of persons who were qualified to be entered in the register for a state as it existed immediately before the 1st day of November, 1956, but who, by reason of the area in which they reside or carried on their business or profession of pharmacy have become part of a state as formed on that date, are not qualified to be entered having in the register for the latter state only by reason of their not having passed either a matriculation examination or an examination prescribed as being equivalent to a matriculation examination or an approved examination or do not possess qualification obtained from outside India and recognized by the Central Council.
- f. The names of persons:
 - i. Who were included in the register for a State as it existed immediately before the 1st day of November, 1956.
 - ii. Who, by reason of the area in which they resided or carried on their business or profession of pharmacy having become part of a state as formed on that date, reside or carry on such business or profession in the latter state.
- g. The names of persons who reside or carry on their business of profession or pharmacy in an area in which this chapter takes effect after the commencement of The Pharmacy (Amendment) Act, 1959, and who satisfy the conditions for registration in the first register of the state.
- 2. Any person who desires his name to be entered in the register shall make an application in that behalf to the State Council, and such application shall be accompanied by the prescribed fee.
- 3. The provisions of this section shall remain in operation for a period of 2 years

from the commencement of The Pharmacy (Amendment) Act, 1959.

VI. *Special provisions for registration of displaced persons, repatriates and other persons:*

- 1. The Pharmacy (Amendment) Act, 1976 provide for the registration of the following categories of person for a period of 2 years from the commencement of this Amendment Act:
 - a. Person who possess degree or diploma in pharmacy or pharmaceutical chemistry or chemists and druggists diploma of an Indian University or State Government, or have passed an examination recognized adequate for compounders and dispensers by the State Government and who were eligible for registration between the closing of the first register and the date when the education regulations came into effect.
 - b. The names of persons approved as "qualified persons" before 31st December, 1969 for compounding or dispensing of medicines under The Drugs and Cosmetics Act, 1940 and the Rules made thereunder.
 - c. The names of "displaced person" from Bangladesh who left that country after 14th April, 1957 but before 25th March 1971, and "repatriates" from Burma, Sri Lanka, Uganda or any other country who left or were displaced from such countries after 14th April 1957 who were carrying on business or profession of pharmacy as their principal means of livelihood in any country outside India for a total period of not less than 5 years from a date prior to the date of application for registration.
- 2. The last provisions have been misused and a large number of unqualified persons are reported to have been registered in some states.

VII. Scrutiny of applications for registration: After the date appointed, applications for registration shall be addressed to the registrar of the State Council and shall be accompanied by the prescribed fee. If upon such application the registrar is of opinion that the applicant is entitled to have his name entered in the register under the provisions of this act for the time being applicable, he shall enter the name of the applicant in the register. Any persons, whose application for registration is rejected by the registrar, may within three months from the date of such rejection appeal to the State Council, and the decision of the State Council thereon shall be final. Upon entry in the register of a name under section, the registrar shall issue a certificate of registration in the prescribed form.

No person whose name has been removed from the register of any state shall be entitled to have his name entered in the register except with the approval of State Council. Any person, whose application for registration has been rejected by the registrar, may within 90 days from the date of such rejection, appeal to the state council whose decision shall be final. Registration is valid up to 31st December of the year of registration.

VIII. Renewal fees: The State Government may direct that for the retention of a name on the register after the 31st day of December of the year following the year in which the name is first entered on the register, there shall be paid annually to the State Council such renewal fee as may be prescribed, and where such direction has been made, such renewal fee shall be due to be paid before the first day of April of the year to which it relates. When a renewal fee is not paid by the due date, the registrar shall remove the name of the defaulter from the register. On payment of the renewal fee, the registrar shall issue a receipt therefore and such receipt shall be a proof of renewal of registration.

IX. Entry of additional qualifications: A registered pharmacist shall on payment of the prescribed fee be entitled to have entered in the register any further degrees or diplomas in pharmacy or pharmaceutical chemistry which he may obtain.

X. Removal of name from register:

1. The executive committee may order that the name of a registered pharmacist shall be removed from the register, where it is satisfied, after giving him a reasonable opportunity of being heard and after such further inquiry, on the following grounds:
 - i. If his name has been entered into the register by error or on account of misrepresentation or suppression of a material fact, or
 - ii. If that he has been convicted of any offence or has been guilty of any infamous conduct in any professional respect which in the opinion of the executive committee, renders him unfit to be kept in the register.
 - iii. If that a person employed by him for the purposes of his business of pharmacy or employed to work under him in connection with any business of pharmacy has been convicted of any such offence or has been guilty of any such infamous conduct as would, if such person were a registered pharmacist, render him liable to have his name removed from the register under clause (ii). Provided that no such order shall be made under clause (iii) unless the executive committee is satisfied:
 - a. That the offence or infamous conduct was instigated or connived at by the registered pharmacist.
 - b. That the registered pharmacist at any time during the period or twelve months immediately preceding the date on which the offence

- or infamous conduct took place has committed a similar offence or been guilty of similar infamous conduct.
- c. That any person employed by the registered pharmacist for the purposes of his business of pharmacy or employed to work under him in connection with any business of pharmacy has at any time during the period of twelve months immediately preceding the date on which the offence or infamous conduct took place, committed a similar offence or been guilty of similar infamous conduct, and that the registered pharmacist had, or reasonably ought to have had, knowledge of such previous offence or infamous conduct.
 - d. That where the offence or infamous conduct continued over a period, the registered pharmacist had, or reasonably ought to have had, knowledge of the continuing offence or infamous conduct.
 - e. That where the offence is an offence under the Drugs and Cosmetics Act, 1940, the registered pharmacist has not used due diligence in enforcing compliance with the provisions of that act in his place of business and by persons employed by him or by persons under his control.
2. An order may direct that the person whose name is ordered to be removed from the register shall be ineligible for registration in the state under this act either permanently or for such period as may be specified.
 3. An order shall be subject to confirmation by the State Council and shall not take effect until the expiry of three month from the date of such confirmation.
4. A person aggrieved by an order which has been confirmed by the State Council may, within thirty days from the communication to him of such confirmation, appeal to the State Government, and the order of the State Government upon such appeal shall be final.
5. A person whose name has been removed from the register under this section shall forthwith surrender his certificate or registration to the registrar, and the name so removed shall be published in the official gazette.
- XI. ***Restoration to register:*** The State Council may at any time for reasons appearing to it sufficient order that upon payment of the prescribed fee the name of a person removed from the register shall be restored thereto. Provided that where an appeal against such removal has been rejected by the State Government, an order under this section shall not take effect until it has been confirmed by the State Government.
- XII. ***Bar of other jurisdiction:*** No order refusing to enter a name on the register or removing a name from the register shall be called in question in any court.
- XIII. ***Issue of duplicate certificate of registration:*** Where it is shown to the satisfaction of the registrar that a certificate of registration has been lost or destroyed, the registrar may, on payment of the prescribed fee, issue a duplicate certificate in the prescribed form.
- XIV. ***Printing of register and evidentiary value of entries therein:*** As soon as may be after the 1st day of April subsequent to the commencement of The Pharmacy (Amendment) Act, 1959, the registrar shall cause to be printed copies of the register as it stood on the said date. The registrar shall thereafter cause to be printed as soon as may be after the 1st day of April in each year copies of the annual supplement to the register referred to in above sub-section, showing all additions to and other amendments in, the said register. The register shall be brought up-to-date 3 months before

ordinary elections to the State Council are held and copies of this register shall be printed. The same copies referred to in above sub-section shall be made available to persons applying therefor on payment of the prescribed charge and shall be evidence that on the date referred to in the register or annual supplement, the persons whose name are entered therein were registered pharmacists.

MISCELLANEOUS

A. Offences and Penalties

I. Penalty for falsely claiming to be registered: If any person whose name is not for the time being entered into the register of the state falsely pretends that it is so entered or uses in connection with his name or title any words or letters reasonably calculated to suggest that his name is so entered, he shall be punishable on first conviction with fine which may extend to 500 rupees and on any subsequent conviction with imprisonment extending to 6 months or with fine not exceeding 1,000 rupees or with both.

The use of the description "Pharmacist", "Chemist", "Druggist", "Pharmaceutist", "Dispenser", "Dispensing Chemist", or any combination of such words or of any such word with any other word shall be deemed to be reasonably calculated to suggest that the person using such description is a person whose name is for the time being entered in the register of the State. The onus of proving that the name of a person is for the time being entered in the register of a State shall be on him who asserts it.

Cognizance of an offence punishable under this section shall not be taken except upon complaint made by order of the State Government or any officer authorized in this behalf by the State Government or by order of the executive committee of the State Council.

II. Dispensing by unregistered persons: On or after such date as the State Government

may by notification in the official gazette appoint in this behalf, no person other than a registered pharmacist shall compound, prepare, mix, or dispense any medicine on the prescription of a medical practitioner. Provided that this shall not apply to dispensing by a medical practitioner of medicine for his own patients, or with the general or special sanction of the State Government, for the patients of another medical practitioner.

Whoever contravenes the provisions of above sub-section shall be punishable with imprisonment for a term which may extend to 6 months, or with fine not exceeding 1,000 rupees or with both. Cognizance of an offence punishable under this section shall not be taken except upon complaint made by order of the State Government or any officer authorized in this behalf by the State Government or by order of the executive committee of the State Council.

Provided further that where no such date is appointed by the Government of a State, these provisions shall take effect in that State on the expiry of a period of 8 years from the commencement of The Pharmacy (Amendment) Act, 1976 (1st September 1984).

III. Failure to surrender certificate of registration: If any person whose name has been removed from the register fails without sufficient cause forthwith to surrender his certificate of registration he shall be punishable with fine which may extend to 50 rupees. Cognizance of an offence punishable under this section shall not be taken except upon complaint made by an order of the executive committee.

IV. Payment of part of fees to Central Council: The State Council before the end of June in each year shall pay the central council a sum equivalent to one-fourth of the total fees realized by the State Council under this Act during the period of 12 months ending on the 31st day of March of that year.

B. Enquiry

Appointment of commission of enquiry: Whenever it appears to the Central Government that the Central Council is not complying with any of the provisions of this act, the Central Government may appoint a commission of enquiry consisting of three persons, two of whom shall be appointed by the Central Government one being the judge of a high court, and one by the council and refer to it the matters on which the enquiry is to be made.

The commission shall proceed to enquire in such manner as it may deem fit and report to the Central Government on the matters referred to it together with such remedies, if any, as the commission may like to recommend. The Central Government may accept the report or remit the same to the commission for modification or reconsideration. After the report is finally accepted, the Central Government may order the Central Council to adopt the remedies so recommended within such time as may be specified in the order and if the council fails to comply within the time so specified, the Central Government may pass such order or take such action as may be necessary to give effect to the recommendations of the commission. Whenever it appears to the State Government that the state council is not complying with any of the provisions of the act, the State Government may likewise appoint a similar commission of enquiry and pass such order or take such action.

C. Rules

Power to make rules:

1. The State Government may, by notification in the official gazette, make rules to carry out the purposes of this act.
2. In particular and without prejudice to the generality of the foregoing power such rules may provide for:
 - a. The management of the property of the State Council and the maintenance and audit of its accounts.

- b. The manner in which elections shall be conducted.
- c. The summoning and holding of meetings of the State Council, the times and places at which such meetings shall be held, the conduct of business thereat and the number of members necessary to form a quorum.
- d. The powers and duties of the President and Vice-President of the State Council.
- e. The constitution and function of the executive committee, the summoning and holding of meetings thereof, the times and places at which such meetings shall be held, and number of members necessary to constitute a quorum.
- f. The qualifications, the term of office and the powers and duties of the registrar and other officers and servants of the State Council including the amount and nature of the security to be given by the treasurer.
- g. The qualifications, powers and duties of an inspector.
- h. The particulars to be stated and the proof of qualifications to be given in application for registration under this act.
- i. The conditions for registration under the provision related to the qualifications for subsequent registration.
- j. Fees payable under this act and the charge for supplying copies of the register.
- k. The form of certificates of registration.
- l. The maintenance of a register.
- m. The conduct of pharmacists and their duties in relation to medical practitioners the public and the profession of pharmacy.
- 3. Every rule made by the State Government under this section shall be laid, as soon as may be after it is made, before the State Legislature.

The Drugs and Cosmetics Act, 1940 and Rules, 1945

INTRODUCTION

The development and strength of any country is a parameter and indication of the health and vigour of its people. The health of the people depends among other things: an adequate nutrition, better hygienic conditions and proper facilities for the care and cure of the disease. Drugs are important social instruments for the prevention and cure of diseases and ailments. All countries in the world have enforced effective laws and rules which ensure the availability of proper and standard drugs to the public without difficulty.

The Indian legislature passed the Drugs and Cosmetics Act, 1940 with the object to regulate the import, manufacture and distribution and sale of drugs. It is applicable on Allopathic, Homeopathic, Unani and Siddha Drugs as well on contraceptives, mosquito repellents, creams, lotions, cosmetics and devices used for internal and external use for diagnosis.

Under the Drugs and Cosmetics Act, 1940, the regulation of manufacture, sale and distribution of drugs is primarily the concern of the state authorities while the central authorities are responsible for approval of new drugs, clinical trials in the country, laying down standards for drugs, control over the quality of imported drugs, coordination of the activities of drug control organization and providing expert advice with a view of bringing about uniformity in the enforcement of Drug and Cosmetic Act.

Objectives

- The Drugs and Cosmetics Act, 1940 provides the central legislation, which regulates import, manufacture and distribution or sale of drugs and cosmetics in the country.
- The main objective of the act is to ensure that the drugs available to the people are safe and efficacious and the cosmetics marketed are safe for use.
- The D and C Act regulate the import of drugs into India so that no substandard or spurious drugs get imported in India.
- This act regulates the manufacture of drugs so that no substandard or spurious drugs get manufactured in the country.
- This act provides the regulation of sale and distribution of drugs and cosmetics whereby only qualified and trained persons can undertake their handling, compounding and distribution.
- This act also provides the regulation of manufacture, sale and distribution of Ayurveda, Siddha, Unani and Homeopathic Drugs.
- This act enables to have regular inspection of license premises by drug inspectors.
- This act enables to have control over the standards over the drugs and cosmetics by taking samples and by getting them tested and analysed in the Drug Control Laboratories of State and Centre.

- To provide special provisions to regulate the preparations, standardizations and storage of biological and other special products.
- To prescribe the manner of labelling and packaging of various classes of drugs and cosmetics.

This act also provides for constitution of two "Boards" namely the Drugs Technical Advisory Board and Ayurvedic and Unani Drugs Technical Advisory Board to advise the Central and State Governments on technical matters and to carry out the other functions assigned to it by this act. It also provides the establishment of two Drugs Consultative Committees, one for the Allopathic and other for the Ayurvedic, Siddha and Unani Drugs to advise the various governments and boards on matters tending to secure uniformity throughout the country in the administration of the act.

There are two Schedules to the drug and cosmetic act and more than thirty Schedules to the rules.

Brief History

The Drugs Act was enacted in 1940. The drugs rules were promulgated in December 1945 and the enforcement started in 1947. The Act as enacted in 1940 has since been amended several times. It is now titled as Drugs and Cosmetics Act and Rules.

The Central Drug Standard Control Organization

- The Central Drugs Standard Control Organization (CDSCO) headed by the Drugs Controller General India (DCGI) discharges the functions allocated to Central Government.
- The CDSCO is attached to the office of the director general of health services in the ministry of health and family welfare.

Drugs Controller General India: The DCGI (Drugs Controller General India) is a statutory

authority under the act and has port offices, zonal offices with drug inspectors and drug testing laboratories functioning under him.

Functions of the Central Government: The main functions of the Central Government are:

- a. Approval of new drugs introduced in the country.
- b. Permission to conduct clinical trials.
- c. Registration and control on the quality of imported drugs.
- d. Laying down regulatory measures and amendment of acts and rules.
- e. Laying down standards for drugs, cosmetics, diagnostics and devices and updating IP.
- f. Approval of licenses as central license approving authority for manufacture of large volume parenterals and vaccines and operation of blood banks and also of such other drugs as may be notified by govt. from time to time.
- g. Coordinating the activities of the states and advising them on matters related to uniform administration of the act and rules in the country.

Salient Features of the Drug and Cosmetic Act, 1940 and Rules, 1945

- The Drug and Cosmetic Act, 1940 has been divided into 5 chapters. The Drug and Cosmetic Rules, 1945 has been divided into 19 parts, each part dealing with a particular subject.
- The qualification, constitution, powers and functions of the administrative agencies of the act and rules to advise the government on technical matters for the efficient administration to import, manufacture and sale of drugs and cosmetics.
- License should be issued by licensing authority to import, manufacture, sale and distribution of all standard drugs and cosmetics. The act enables to control over the manufacture of drugs.
- The act enables to regulate the sale and distribution of drugs, which prevent hand-

- ling of drugs by unqualified and untrained persons.
- The act and rules enable to regulate the manufacture of drugs for examination, test or analysis and import or manufacture of new drug for clinical trials and marketing.
- The act enables to prescribe the manner of labeling and packaging of the various classes of drugs and cosmetics.
- The act and rules provide for the establishment of Ayurvedic, Siddha and Unani DTAB, Consultative Committee, Government Analysts, Licensing Authority, Inspectors for the efficient administration of Ayurvedic, Siddha and Unani Drugs to advise the governments on technical matters arising out of the administration of the act. License should be granted by licensing authority to manufacture for sale of all standards Ayurvedic, Siddha and Unani Drugs. Manner of labelling, packing and limit of alcohol in Ayurvedic (Including Siddha) or Unani Drugs. Punishment with imprisonment for the offences related to manufacture for sale of Ayurvedic, Siddha or Unani Drug.
- The act and rules enable to regulate the import, manufacture for sale, labelling and packaging of Homoeopathic medicines.
- The act enables to provide special provisions to regulate the preparation, standardization and storage of biological and other special products.
- Licensing authority should be granted, the licence to the approval of institutions for carrying out tests on drugs, cosmetics and raw materials used in their manufacture on behalf of licensees for manufacture for sale of drugs/cosmetics under the D and C Rules.

DEFINITIONS

- a. “**Ayurvedic, Siddha or Unani Drug**” includes all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of

disease or disorder in human beings or animals, and manufactured exclusively in accordance with the formulae described in the authoritative books of Ayurvedic, Siddha and Unani (Tibb) systems of medicine, specified in the first schedule.

- aa. “**The Board**” means:
 - i. In relation to Ayurvedic, Siddha or Unani Drug, the Ayurvedic, Siddha or Unani Drugs Technical Advisory Board constituted under section 33 C (Ayurvedic, Siddha and Unani Drugs Technical Advisory Board).
 - ii. In relation to any other drug or cosmetic, the Drugs Technical Advisory Board constituted under section 5 (The Drugs Technical Advisory Board).
- aaa. “**Cosmetic**” means any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic.
- b. “**Drug**” includes:
 - i. All medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes.
 - ii. Such substances other than food intended to affect the structure or any function of human body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the official gazette.

- iii. All substances intended for use as components of a drug including empty gelatin capsules.
- iv. Such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the official gazette, after consultation with the board.
- c. **"Government Analyst"** means:
 - i. In relation to Ayurvedic, Siddha or Unani Drug, a government analyst appointed by Central Government or a State Government under section 33 F (Government Analysts).
 - ii. In relation to any other drug or cosmetic, a government analyst appointed by the Central Government or a State Government under section 20 (Government Analysts).
- d. **"Inspector"** means:
 - i. In relation to Ayurvedic, Siddha or Unani Drug, an inspector appointed by the Central Government or State Government under section 33 G (Inspectors).
 - ii. In relation to any other drug or cosmetic, an Inspector appointed by the Central Government or a State Government under Section 21.
- e. **"Manufacture"** in relation to any drug or cosmetic includes any process or part of a process for making, altering, ornamenting, finishing, packing, labelling, breaking up or otherwise treating or adopting any drug or cosmetic with a view to its sale or distribution but does not include the compounding or dispensing of any drug, or the packing of any drug or cosmetic, in the ordinary course of retail business and "to manufacture" shall be construed accordingly.
- f. **"To Import"**, with its grammatical variations and cognate expressions means to bring into India.
- g. **"Patent or Proprietary Medicine"** means:
 - i. In relation to Ayurvedic, Siddha or Unani-Tibb Systems of medicine all formulations containing only such ingredients mentioned in the formulae described in the authoritative books of Ayurveda, Siddha or Unani-Tibb Systems of medicine specified in the first schedule, but does not include a medicine which is administered by parenteral route and also a formulation included in the authoritative books.
 - ii. In relation to any other systems of medicine, a drug which is a remedy or.
 - iii. Prescription presented in a form ready for internal or external administration of human beings or animals and which is not included in the edition of Indian Pharmacopoeia for the time being or any other Pharmacopoeia authorized in this behalf by Central Government after consultation with the Drugs Technical Advisory Board Constituted under section 5 (The Drugs Technical Advisory Board).
- h. **Homoeopathic Medicines** include any drug which is recorded in homoeopathic proving or therapeutic efficacy of which has been established through long clinical experience as recorded in authoritative homoeopathic literature of India and abroad and which is prepared according to the techniques of homoeopathic pharmacy and covers combination of ingredients of such homoeopathic medicines but does not include a medicine which is administered by parenteral route.
- i. **"Central License Approving Authority"** means the Drugs Controller, India, appointed by the Central Government.
- j. **"Director"** means the Director of the Central Drugs Laboratory.
- k. **"Laboratory"** means the Central Drugs Laboratory.
- l. **"Registered Homeopathic Medical Practitioner"** means a person who is registered

- in the central register or state register of homeopathy.
- m. "Registered Medical Practitioner" means a person:
- Holding a qualification granted by an authority specified or notified under Section 3 of the Indian Medical Degrees Act, 1916, or specified in the schedules to the Indian Medical Council Act, 1956.
 - Registered or eligible for registration in a medical register of a statement for the registration of persons practicing the modern scientific system of medicine excluding the homoeopathic system of medicine.
 - Registered in a medical register, other than a register for the registration of homoeopathic practitioner, of a state, who although not falling within sub-clause (i) or sub-clause (ii) declared by a general or special order made by the State Government in this behalf as a person practicing the modern scientific system of medicine for the purposes of this act.
 - Registered or eligible for registration in the register of dentists for a state under the Dentists Act, 1948.
 - Who is engaged in the practice of veterinary medicine and who possesses qualification approved by the State Government.
- n. 'Retail Sale' means a sale whether to a hospital, or dispensary, or a medical, educational or research institute or to any other person other than a sale by way of wholesale dealing.
- o. 'Sale by way of wholesale dealing' means sale to a person for the purpose of selling again and includes sale to a hospital, dispensary, medical, educational or research institution.
- p. 'Poisonous substance' means a substance specified in Schedule E.

ADMINISTRATION OF THE ACT AND RULES

For the efficient administration of drug and cosmetics act and the rules, following agencies have been provide:

Advisory

- The Drugs Technical Advisory Board.
- The Drugs Consultative Committee.

Analytical

- The Central Drugs Laboratory
- Drug Control Laboratories in State
- Government Analyst

Executive

- Licensing Authorities
- Controlling Authorities
- Drug Inspectors
- Customs Collectors

THE DRUGS TECHNICAL ADVISORY BOARD

A. The Drugs Technical Advisory Board (DTAB)

Constitution and composition: DTAB is constituted by Central Government under section 5 of the act.

- The Central Government shall constitute a board (to be called the Drugs Technical Advisory Board) to advise the Central

SCHEDULES

Schedules of the Drugs and Cosmetics Act, 1940.	
First Schedule of the Act	List of authoritative books of Ayurvedic, Siddha and Unani-Tibb Systems of medicines.
Second Schedule of the Act	Standards to be complied with imported drugs manufactured for sale, stocked or exhibited for sale or distributed.

Schedules to the Rules, 1945.

Schedule A	Specimens of the prescribed forms for making application for licenses, issue and renewal of licenses, for sending memorandum, etc.
Schedule B	Rates of fee for test or analysis by the CDL or state drug laboratories, e.g. pyrogen test – INR 500/- bioassay of antibiotic – INR 400/- etc.
Schedule C and C ₁	List of biological products and other special products whose import, manufacture, sale and distribution are governed by special provision.
Schedule C	List of biological and special products like ophthalmic preparations, parenteral preparations and sterile disposable devices, whose import, manufacture, sale and distribution are governed by special provisions.
Schedule C ₁	List of other special products, liver special products like digitalis, adrenaline, liver extract preparations and vitamins, antibiotics, hormones preparations other than injections, whose import, manufacture, sale and distribution are governed by special provisions.
Schedule D	List of drugs that are exempted from certain provisions that are applicable to the import of drugs.
Schedule D ₁	Registration of the manufacturer or his authorized agent for import of drugs and to use further in manufacturing.
Schedule D ₂	Registration of bulk drugs/formulations/special products for its import in India.
Schedule E	(Omitted in June 1982) list of exemption to certain allopathic poisonous substances.
Schedule E ₁	List of poisonous substances under Ayurvedic, Siddha and Unani System. Drugs of plant origin Drugs of animal origin Drugs of mineral origin
Schedule F and F ₁	Special provisions applicable to the production, testing, storage, packing and labelling of biological and other special products. Schedule F: Equipment, supply, GMP/SOP, sterile air classification, master formula, quality assurance for blood banks, blood donation. Schedule F1: Special provisions applicable to vaccines, antiseras and diagnostic antigens in respects of production, testing, storing labelling and packing. Standards for surgical dressing. Standards for umbilical tapes.
Schedule F ₂	Details of the standards—Ophthalmic preparations
Schedule F ₃	List of substances that are required to be used under medical supervision and which are labelled to be accordingly, e.g. aminopterin, ethosuximide, pheniramine, etc.
Schedule G	
Schedule H	List of substances that should be sold by retail only on the prescription of a registered medical practitioner (list of prescription drugs), e.g. diclofenac, ciprofloxacin, inj. ranitidine, etc.
Schedule I	(Omitted in June 1982) Particulars regarding calculation of proportions of poisons.
Schedule J	Diseases or ailments which a drug may not purport or cure or make claims to prevent or cure, e.g. AIDS, angina pectoris.
Schedule K	List of drugs that are exempted from certain provisions relating to the manufacture of the drugs.

Contd.

Schedules to the Rules, 1945.	
Schedule L	(Omitted in June 1982) List of certain prescription drugs.
Schedule M	GMP and requirements of factory premises, plants and equipments.
Schedule M ₁	For manufacture of homoeopathic drugs.
Schedule M ₂	For manufacture of cosmetics.
Schedule M ₃	For manufacture of medical devices.
Schedule N	List of minimum equipments (apparatus) and books which a pharmacy should possess.
Schedule O	Classification and standards for disinfectant fluids.
Schedule P	Life periods and storage conditions for certain drugs.
Schedule P ₁	Pack sizes of drugs for marketing.
Schedule Q	List of coal tar dyes, coloring agents and pigments permitted to be used to be used in cosmetics and soaps.
Schedule R	Sampling, testing and standards for condom and mechanical contraceptives.
Schedule R ₁	Standards for medical devices.
Schedule S	Standards for cosmetics.
Schedule T	GMP for Ayurvedic, Siddha and Unani Medicines.
Schedule U	Particulars to be shown in manufacturing, raw materials and analytical records of drugs.
Schedule U ₁	Particulars to be shown in manufacturing, raw materials and analytical records of drugs.
Schedule V	Standards for Patent and Proprietary Medicines.
Schedule W	(Omitted in Feb 2000) list of drugs which shall be marketed under generic names.
Schedule X	List of drugs whose import, manufacture and sale, labelling and packaging are governed by special provisions.
Schedule Y	Requirements and guidelines for permission to import and / or manufacture of new drugs for sale or to undertake clinical trials.

Government and the State Governments on technical matters arising out of the administration of this act and to carry out the other functions assigned to it by this act. All rules related to the import, manufacture, sale and distribution of drugs and cosmetics under the act are required to be framed and modified in consultation with the board. However, if required, the Central Government may also make rules without consulting the board but has to consult the board within six months and consider may suggestion by it.

2. The board shall consist of 18 members, of whom 8 are *ex-officio*, 5 nominated and 5, elected members, as follows:

Ex-officio Members

- i. The Director General of Health Services, who shall be the chairman.
- ii. The Drugs Controller, India.
- iii. The Director of the Central Drugs Laboratory, Calcutta.
- iv. The Director of the Central Research Institute, Kasauli.
- v. The Director of the Indian Veterinary Research Institute, Izatnagar.
- vi. The President of the Medical Council of India.
- vii. The President of the Pharmacy Council of India.
- viii. The Director of the Central Drug Research institute, Lucknow.

Elected and Nominated Members

- ix. One person, to be **elected** by the Executive Committee of the Pharmacy Council of India, from among teachers in pharmacy or pharmaceutical chemistry or pharmacognosy on the staff of an Indian university or a college affiliated thereto.
- x. One person, to be **elected** by the Executive Committee of the Medical Council of India, from among teachers in medicine or therapeutics on the staff of an Indian University or a college affiliated thereto.
- xi. One pharmacologist to be **elected** by the governing body of the Indian Council of Medical Research.
- xii. One person to be **elected** by the Central Council of the Indian medical Association.
- xiii. One person to be **elected** by the council of the Indian Pharmaceutical Association.
- xiv. Two persons to be **nominated** by the Central Government from among persons who are in-charge of drugs control in the states.
- xv. One person to be **nominated** by the Central Government from the pharmaceutical industry.
- xvi. Two persons holding the appointment of **Government Analyst** under this act, to be **nominated** by the Central Government.
- 3. The nominated and elected members of the Board shall hold office for three years, but shall be eligible for re-nomination and re-election.
- 4. The Board may, subject to the previous approval of the Central Government, make bye-laws fixing a quorum and regulating its own procedure and the conduct of all business to be transacted by it.
- 5. The Board may constitute sub-committees and may appoint to such sub-committees for such periods, not exceeding three years,

as it may decide, or temporarily for the consideration of particular matters, persons who are not members of the Board.

- 6. The functions of the board may be exercised notwithstanding any vacancy thereon.
- 7. The Central Government shall appoint a person to be secretary of the board and shall provide the board with such clerical and other staff as the Central Government considers necessary.

B. Functions of DTAB

- To advise the Central and State Government on the technical matters arising out of the administration of the act.
- To carry out such other functions as may be intrusted to it by the Central Government.
- To appoint sub-committees for consideration of particular matters as and when needed.

THE DRUGS CONSULTATIVE COMMITTEE

A. The Drugs Consultative Committee (DCC): The Central Government may constitute an advisory committee to be called "the Drugs Consultative Committee". The Drugs Consultative Committee (DCC) is constituted under section 7 of the act.

B. Constitution of DCC:

- i. The Drugs Consultative Committee shall consist of two representatives of the Central Government to be nominated by Central Government.
- ii. One representative of each State Government to be nominated by the State Government.

C. Power of DCC: The drugs consultative committee shall meet when required to do so by the Central Government and shall have power to regulate its own procedure.

D. Functions of DCC:

- i. To advise the Central Government, the State Governments and the Drugs Technical Advisory Board on any matter

tending to secure uniformity throughout India in the administration of this act.

- ii. To carry out such other functions as may be entrusted to it by the Central Government.

Note: Nothing discussed above in respect of the drugs technical advisory board and the drugs consultative committee applies to Ayurvedic, Siddha and Unani Drugs.

THE CENTRAL DRUGS LABORATORY

A. The Central Drugs Laboratory (CDL): CDL established by Central Government under Section 6.

1. The Central Government shall establish a Central Drugs Laboratory under the control of a Director to be appointed by the Central Government, to carry out the functions entrusted to it by this act.

If the Central Government so prescribes, the functions of the Central Drugs Laboratory in respect of any drug or cosmetic or class of cosmetics shall be carried out at the Central Research Institute, Kasauli, or at any other prescribed laboratory and the functions of the Director of the Central Drugs Laboratory in respect of such drug or cosmetic or class of cosmetics shall be exercised by the Director of that institute or of that other laboratory, as the case may be.

2. The Central Government may, after consultation with the board, make rules prescribing:
 - i. The functions of the Central Drugs Laboratory.
 - ii. The procedure for the submission of the said laboratory of samples of or cosmetics for analysis or test, the forms of the laboratory's reports thereon and the fees payable in respect of such reports.
 - iii. Such other matters as may be necessary or expedient to enable the said laboratory to carry out its functions.

B. Functions of CDL:

1. It shall be the function of the laboratory:
 - i. To analyse or test such samples of drugs as may be sent to it by custom officers under the law related to the sea customs, or test such samples submitted by Government Analyst under this act.
 - ii. To carry out such other duties as may be entrusted to it by the Central Government or, with the permission of the Central Government, by a State Government after consultation with the Drugs Technical Advisory Board.
2. The Central Research Institute, Kasauli for carrying out the assigned functions in respect of:
 1. Sera.
 2. Solution of serum proteins intended for injection.
 3. Vaccines.
 4. Toxins.
 5. Antigens.
 6. Anti-toxins.
 7. Sterilized surgical ligature and sterilized surgical suture.
 8. Bacteriophages.

Provided that the functions of The Director in respect of oral Polio Vaccine shall be exercised by the Deputy Director and head of the Polio Vaccine Testing Laboratory in case of Central Research Institute, Kasauli only.
- 2A. The functions of the laboratory in respect of oral polio vaccine shall be carried out by the following institutes:
 - a. Pasteur Institute of India, Coonoor.
 - b. Enterovirus Research Centre (Indian Council of Medical Research), Haffkin Institute Compound, Parel, Bombay-400012.
 - c. The National Institute of Biologicals, Noida.
3. The Indian Veterinary Research Institute, Izatnagar or Mukteshwar in respect of:
 1. Anti-sera for veterinary use.
 2. Vaccines for veterinary use.

3. Toxoids for veterinary use.
4. Diagnostic antigens for veterinary use.
4. The Central Indian Pharmacopoeia Laboratory, Ghaziabad, in respect of condoms.
5. The Laboratory of the Serologist and Chemical Examiner to the Government of India, Calcutta in respect of VDRL antigen.
6. The Central Drug Testing Laboratory, Thane, Maharashtra in respect of intrauterine devices and falope rings.
7. The functions of the laboratory in respect of human blood and human blood products including components, to test for freedom of HIV antibodies, shall be carried out by the following institutes, hospitals namely:
 - a. National Institutes of Communicable Disease, Department of Microbiology, Delhi.
 - b. National Institute of Virology, Pune.
 - c. Centre of Advanced Research in Virology, Christian Medical College, Vellore.
8. The Homoeopathy Pharmacopoeia Laboratory, Ghaziabad in respect of homoeopathic medicines and the function of the Director in respect of the homeopathic medicine.
9. The National Institute of Biologicals, Noida in respect of blood grouping reagent and diagnostic kits for human immunodeficiency virus, hepatitis B surface antigen and hepatitis C virus.

Dispatch of samples for test or analysis to CDL:

Samples for test or analysis under, shall be sent by registered post in a sealed packet, enclosed together with a memorandum in Form 1, in an outer cover addressed to the director. The packet as well as the outer cover shall be marked with a distinguishing number. A copy of the memorandum in Form 1 and a specimen impression of the seal used to seal the packet shall be sent separately by registered post to the director.

Recording of condition of seals: On receipt of the packet, it shall be opened by an officer authorized in writing in that behalf by the director who shall record the condition of the seal on the packet.

Report of result of test or analysis: After test or analysis the result of the test or analysis, together with full protocols of the tests applied, shall be supplied forthwith to the sender in Form 2.

Fees: The fees for test and analysis shall be those specified in schedule B.

Signature of certificates: Certificates issued under these rules by the laboratory shall be signed by the Director or by an officer authorized by the Central Government by notification in the official gazette to sign such certificates.

DRUGS CONTROL LABORATORIES IN THE STATE

Each state of India shall establish one or more testing laboratories to analyse and test the samples of drugs and cosmetics manufactured and/or sold within their state. Samples are drawn by the drugs inspectors during their inspection and sent for testing. Drugs Control Laboratories may also undertake analysis and testing of drugs and cosmetics on behalf of private persons or concerns that do not have such facilities to do so, on payment of prescribed fees and shall furnish the report of analysis in the prescribed form.

GOVERNMENT ANALYSTS

A. Government Analysts: Government Analysts appointed by Central or State Government under section 20 of the act.

1. The State Government may, by notification in the official gazette, appoint such persons, having the prescribed qualifications, to be government analysts for such areas in the state and in respect of such drugs or classes of drug or such cosmetics or classes of cosmetics as may be specified in the notification.
2. The Central Government may also appoint such persons as it thinks fit, having the prescribed qualifications, to be government analysts in respect of such drugs or classes of drugs or such cosmetics or classes of cosmetics as may be specified in the notification.

3. Notwithstanding anything contained in above sub-sections neither the Central Government nor the State Government shall appoint as a government analyst any official not serving under it without the previous consent of the government under which he is serving.
4. No person who has any financial interest in the import, manufacture or sale of drugs or cosmetics shall be appointed to be a government analyst under this act.

B. Qualifications of Government Analyst: A person appointed as a Government Analyst under the act shall be:

- a. A person who is a graduate in medicine or science or pharmacy or pharmaceutical chemistry of a university established in India by law or has an equivalent qualification recognized by the Central Government for such purpose and has had not less than five years' post-graduate experience in the testing of drugs in a laboratory under control of:
 - i. A Government Analyst appointed under the act.
 - ii. The head of an institution or testing laboratory approved for the purpose by the appointing authority, or has completed training on testing of drugs, including items stated in Schedule C, in Central Drugs Laboratory.
- b. A person who possesses a postgraduate degree in medicine or science or pharmacy or pharmaceutical chemistry of a University established in India by law or has an equivalent qualification recognized by the Central Government for such purpose or possesses the Associateship diploma of the institution of chemists (India) obtained by passing the said examination with "Analysis of drugs and pharmaceuticals" as one of the subjects and has had after obtaining the said postgraduate degree or diploma not less than three years' experience in the testing of drugs in a laboratory under the control of:

- i. A Government Analyst appointed under the act.
- ii. The head of an institution or testing laboratory approved for the purpose by the appointing authority or has completed training on testing of drugs, including items stated in Schedule C, in Central Drugs Laboratory.

Provided that:

- i. For purpose of examination of items in Schedule C, the persons appointed and having degree in medicine, physiology, pharmacology, microbiology, pharmacy should have experience or training in testing of said items in an institution or laboratory approved by the appointing authority for a period of not less than six months and the person appointed but not having degree in the above subjects should have experience or training in testing of said Schedule C drugs for a period of not less than three years in an institution or laboratory approved by the appointing authority or have completed two years training on testing of drugs including items stated in Schedule C in Central Drugs Laboratory.
- ii. For a period of four years from the date on which this part of the act takes effect in the states, persons whose training and experience are regarded by the appointing authority as affording, subject to such further training, if any, as may be considered necessary, a reasonable guarantee of adequate knowledge and competence, may be appointed as Government Analysts. The persons so appointed may, if the appointing authority so desires, continue in service after the expiry of the said period of four years.
- iii. No person who is engaged directly or indirectly in any trade or business connected with the manufacture of drugs shall be appointed as a government analyst for any area.

Provided further that for the purpose of examination of anti-sera, toxoid and vaccines

and diagnostic antigens for veterinary use, the person appointed shall be a person who is a graduate in veterinary science, or general science, or medicine or pharmacy and has had not less than five years' experience in the standardization of biological products or person holding a postgraduate degree in veterinary science, or general science, or medicine or pharmacy or pharmaceutical chemistry with an experience of not less than three years in the standardization of biological products. Provided also that persons, already appointed as Government Analysts may continue to remain in service, if the appointing authority so desires, notwithstanding the fact that they do not fulfil the qualifications.

C. Duties of Government Analysts:

1. The Government Analyst shall cause to be analysed or tested such samples or drugs and cosmetics as may be sent to him by inspectors or other persons under this act and shall furnish reports of the results of test or analysis.
2. A Government Analyst shall from time to time forward to the government reports giving the result of analytical work and research with a view to their publication at the discretion of government.

D. Procedure:

- I. **Procedure followed by Government Analyst on receipt of sample:** On receipt of a package from an Inspector containing a sample for test or analysis, the Government Analyst shall compare the seals on the packet or on portion of sample or container with the specimen impression received separately and shall note the condition of the seals on the packet or on portion of sample or container. After the test or analysis has been completed, he shall forthwith supply to the inspector a report in triplicate in Form 13 of the result of the test or analysis, together with full protocols of the tests or analysis applied:

It shall be deemed to be full and sufficient compliance with the requirement of the rule in

respect of the supply of "protocols of the tests or analysis applied", if:

1. For Pharmacopoeial drug, where the tests or methods of analysis prescribed in the official Pharmacopoeia are followed, references to the specific tests or analysis in the Pharmacopoeias are given in the report.
2. For Patent or Proprietary Medicines for which the tests and methods prescribed in any of the official pharmacopoeias are applicable and are followed, references to the specific tests or analysis in the pharmacopoeias are given in the report.
3. For Patent or Proprietary Medicines containing pharmacopoeial drugs for which the official tests or analysis or methods of assays are modified and applied, a description of the actual tests or, as the case may be, analysis or methods of assays so applied is mentioned in the report.
4. For Patent or Proprietary medicines for which no pharmacopoeial tests or methods of analysis are available or can be applied but for which tests or methods of analysis given in standard books or journals are followed, a description of such tests or methods of analysis applied together with the reference to the relevant books or journals from which the tests or methods of analysis have been adopted, is given in the report.
5. For those drugs for which methods of test are not available and have been evolved by the Government Analyst, a description of tests applied is given in the report.

II. Reports of Government Analysts:

1. The Government Analyst to whom a sample of any drug or cosmetic has been submitted for test or analysis shall deliver to the inspector submitting it a signed report in triplicate in the prescribed form.

2. The inspector on receipt thereof shall deliver one copy of the report to the person from whom the sample was taken and another copy to the person, if any, whose name, address and other particulars have been disclosed, and shall retain the third copy for use in any prosecution in respect of the sample.
 3. Any document purporting to be a report signed by a Government Analyst shall be evidence to the facts stated therein, and such evidence shall be conclusive unless the person from whom the sample was taken or the person whose name, address and other particulars have been disclosed has, within 28 days of the receipt of a copy of the report, notified in writing the inspector or the court before which any proceedings in respect of the sample are pending that he intends to adduce evidence in controversion of the report.
 4. Unless the sample has already been tested or analysed in the Central Drugs Laboratory, where a person has notified his intention of adducing evidence in controversion of a Government Analyst's report, the court may, of its own motion or in its discretion at the request either of the complainant or the accused, cause the sample of the drug or cosmetic produced before the magistrate to be sent for test or analysis to the said laboratory, which shall make the test or analysis and report in writing signed by, or under the authority of, the Director of the Central Drugs Laboratory the result thereof, and such report shall be conclusive evidence of the facts stated therein.
 5. The cost of a test or analysis made by the Central Drugs Laboratory shall be paid by complainant or accused as the court shall direct.
- III. Report of result of test or analysis:** An application from a purchaser for test or

analysis of a drug under section 26 of the act shall be made in Form 14-A and the report of test or analysis of the drug made on such application shall be supplied to the applicant in Form 14-B.

- IV. Fees:** The fees to be paid by a person submitting to the Government Analyst under section 26 of the act for test or analysis of a drug purchased by him shall be those specified in Schedule B.

LICENSING AUTHORITY

A. Licensing Authority: Any application for the grant or renewal of a license for import, manufacturing, sale, etc. of any drug or cosmetic is to be made to the licensing authority appointed by the Central and State Governments. The qualification of Licensing Authority has been recently prescribed under the new Rule 50A by D and C (9th Amendment) Rules, 1989.

B. Qualification of a Licensing Authority: No person shall be qualified to be a licensing authority under the act unless:

- i. He is a graduate in pharmacy or pharmaceutical chemistry or in medicine with specialization in clinical pharmacology or microbiology from a university established in India by law.
- ii. He has experience in the manufacture or testing of drugs or enforcement of the provisions of the act for a minimum period of five years.

Provided that the requirements as to the academic qualification shall not apply to those inspectors and the Government Analysts who were holding those positions on the 12th day of April, 1989.

C. Power and functions: The Licensing Authority may with the approval of the Central Government by an order in writing delegate the power to sign licenses and registration certificate and such other powers as may be specified in the order to any other person under his control.

D. Procedure of Licensing Authority or Central License Approving Authority: If the licensing authority after such further enquiry, if any, as he may consider necessary, is satisfied that the requirements of the rules under the act have been complied with and that the conditions of the license and the rules under the act will be observed, he shall issue a license under this part. If the licensing authority is not so satisfied, he shall reject the application and shall inform the applicant the reasons for such rejection and of the conditions which must be satisfied before a license can be granted and shall supply the applicant with a copy of the inspection report.

CONTROLLING AUTHORITY

A. Controlling Authority:

1. All inspectors appointed by the Central Government shall be under the control of an officer appointed in his behalf by the Central Government.
2. All inspectors appointed by the State Government shall be under the control of an officer appointed in his behalf by the State Government.
3. For the purposes of these rules an officer appointed by the Central Government, or as the case may be, an officer appointed by the State Government, shall be a controlling authority.

The qualification of controlling authority has been recently prescribed under the new rule 50 A by Drugs and Cosmetics (9th Amendment) Rules, 1989.

B. Qualification of a Controlling Authority: No person shall be qualified to be a controlling authority under the act unless:

- i. He is a graduate in pharmacy or pharmaceutical chemistry or in medicine with specialization in clinical pharmacology or microbiology from a university established in India by law.
- ii. He has experience in the manufacture or testing of drugs or enforcement of the

provisions of the act for a minimum period of five years. Provided that the requirements as to the academic qualifications shall not apply to those inspectors and the Government Analysts, who were holding those positions on the 12th day of April, 1989.

C. Power: The power of a person or an organized assemblage of persons to manage, direct, superintend, restrict, regulate, govern, and administer.

DRUGS INSPECTORS

A. Drugs Inspectors: Drugs Inspectors appointed by Central or State Government under Section 21 of the Act.

1. The Central Government or a State Government may, by notification in the official gazette, appoint such person, having the prescribed qualification, to be Inspectors for such areas as may be assigned to them by the Central Government or State Government, as the case may be.
2. The powers which may be exercised by an Inspector and the duties which may be performed by him, the drugs or classes of drugs or cosmetics or classes of cosmetics in relation to which and the conditions, limitations or restrictions subject to which, such powers and duties may be exercised or performed shall be such as may be prescribed.
3. No person who has any financial interest in the import, manufacture or sale of drugs or cosmetics shall be appointed to be an Inspector under this section.
4. Every Inspector shall be deemed to be public servant within the meaning of Section 21 of the Indian Penal Code, 1860, and shall be officially subordinate to such authority having the prescribed qualification as the government appointing him may specify in this behalf.

B. Qualifications: A person who is appointed as an inspector under the act shall be a person who

has a degree in pharmacy or pharmaceutical sciences or medicine with specialization in clinical pharmacology or microbiology from a university established in India by law.

However, only those inspectors shall be authorised to inspect the manufacture of the substances mentioned in Schedule C:

- i. Who have not less than 18 months experience in the manufacture of atleast one of the substances specified in Schedule C.
- ii. Who have not less than 18 months experience in testing of atleast one of the substances in Schedule C in a laboratory approved for this purpose by the licensing authority.
- iii. Who have gained experiences of not less than three years in the inspection of firms manufacturing any of the substances specified in Schedule C during the tenure of their services as drugs inspector shall be authorised to inspect the manufacture of the substances mentioned in Schedule C.

Provided further that the requirement as to the academic qualification shall not apply to the persons appointed as inspectors on or before the 18th day of October, 1993.

C. Powers of Inspectors:

1. Subject to the provisions of procedure of inspectors and of any rules made by the Central Government in this behalf, within the local limits of the area for which an inspector is appointed:
 - a. An inspector may, inspect:
 - i. Any premises wherein any drug or cosmetic is being manufactured and the means employed for standardizing and testing the drug or cosmetic.
 - ii. Any premises wherein any drug or cosmetic is being sold, or stocked or exhibited or offered for sale, or distributed.
 - b. An inspector may, take samples of any drug or cosmetic:
 - i. Which is being manufactured or being sold or is stocked or exhibited or offered for sale, or is being distributed.
 - ii. Taking samples from any person who is in the course of conveying, delivering or preparing to deliver such drug or cosmetic to a purchaser or a consignee.
- c. At all reasonable times, with necessary assistance:
- i. An inspector may, search any person, who, he has reason to believe, has secreted about his person, any drug or cosmetic in respect of which an offence under this part of the act has been, or is being, committed.
 - ii. An inspector may, enter and search any place in which he has reason to believe an offence under this act has been, or is being committed.
 - iii. An inspector may, stop and search any vehicle, vessel, or other conveyance which, he has reason to believe, is being used for carrying any drug or cosmetic in respect of which an offence under this act has been, or is being, committed, and order in writing the person in possession of the drug or cosmetic in respect of which the offence has been, or is being, committed, not to dispose of any stock of such drug or cosmetic for a specified period not exceeding twenty days, or unless the alleged offence is such that the defect may be removed by the possessor of the drug or cosmetic, seize the stock of such drug or cosmetic and any substance or article by means of which the offence has been, or is being committed or which may be employed for the commission of such offence.
 - cc. An inspector may, examine any record, register, document or any other material object found with any person, or in any place mentioned above seize the same if he has reason to believe that it may furnish evidence of the commission of an offence.

- cca. An inspector may require any person to produce any record, register, or other document relating to the manufacture for sale or for distribution, stocking, exhibition for sale, offer for sale or distribution of any drug or cosmetic in respect of which he has reason to believe that an offence under this act has been, or is being, committed.
2. The provisions of the code of criminal procedure, shall, so far as may be, apply to any search or seizure under this part of the act as they apply to any search or seizure made under the authority of a warrant issued under section 94 of the said code.
 - 2A. Every record, register or other document seized or produced shall be returned to the person, from whom they were seized or who produce the same, within a period of twenty days of the date of such seizure or production, as the case may be, after copies thereof or extracts there from certified by that person, in such manner as may be prescribed, have been taken.
 3. If any person willfully obstructs an Inspector in the exercise of the powers conferred upon him by or under this act or refuses to produce any record, register or other document when so required, he shall be punishable with imprisonment which may extend to three years, or with fine, or with both.
- D. Procedure of Inspectors:**
1. Where an Inspector takes any sample of a drug or cosmetic under the act, he shall tender the fair price and may require a written acknowledgement for the same.
 2. Where the price tendered is refused, or where the inspector seizes the stock of any drug or cosmetic, he shall tender a receipt therefore in the prescribed form.
 3. Where an inspector takes a sample of a drug or cosmetic for the purpose of test or analysis, he shall intimate such purpose in writing in the prescribed form to the person from whom he takes it and, in the presence of such person unless he willfully absents himself, shall divide the sample into four portions and effectively seal and suitably mark the same and permit such person to add his own seal and mark to all or any of the portions so sealed and marked.
 4. The inspector shall restore one portion of a sample so divided or one container, as the case may be, to the person from whom he takes it, and shall retain the remainder and dispose of the same as follows:
 - i. One portion or container he shall forthwith send to the Government Analyst for test or analysis.
 - ii. The second he shall produce to the Court before which proceedings, if any, are instituted in respect of the drug or cosmetic.
 - iii. The third, where taken, he shall send to the person, if any, whose name, address and other particulars have been disclosed.
 5. Where an inspector takes any action under the provision related to his powers:
 - i. He shall use all dispatch in ascertaining whether or not the drug or cosmetic contravenes any of the provisions related to the prohibition of manufacture and sale of certain drugs and cosmetics under this act and, if it is ascertained that the drug or cosmetic does not so contravene, forthwith revoke the order passed under the said clause or, as the case may be take, such action as may be necessary for the return of the stock seized.
 - ii. If he seizes the stock of the drug or cosmetic, he shall as soon as may be, inform a Judicial Magistrate and take his orders as to the custody thereof.
 - iii. Without prejudice to the institution of any prosecution, if the alleged contravention be such that the defect may be remedied by the possessor of the drug or cosmetic, he shall, on being satisfied that the defect has been so remedied,

- forthwith revoke his order under the said clause.
6. Where an inspector seizes any record, register, document or any other material object under clause power of inspectors according to this act, he shall, as soon as may be, inform a Judicial Magistrate and take his orders as to the custody thereof.

Forms of receipts for seized drug, cosmetic, record register, document or any other material object: A receipt by an inspector for the stock of any drug or cosmetic or for any record, register, document or any other material object seized by him according to the provision of his power under this act shall be in Form 16.

Manner of certifying copies of seized documents: The drugs inspector shall return the documents, seized by him under this act or produced before him according to the provision of his power under this act, within a period of 20 days of the date of such seizure or production, to the person from whom they have seized or, as the case may be, the person who produced them, after copies thereof extracts there from have been singed by the concerned drug Inspector and the person from whom they have seized, or as the case may be, who produced such records.

Form of intimation of purpose of taking samples: When an inspector takes a sample of a drug for the purpose of test or analysis, he shall intimate such purpose in writing in Form 17 to the person from whom he takes it.

Form or receipt for samples of drugs where fair price tendered is refused: Where the fair price, for the samples of drugs taken for the purpose of test or analysis, tendered under section 23 has been refused, the inspector shall tender a receipt therefor to the person from whom the said samples have been taken as specified in Form 17-A.

Procedure for dispatch of sample to Government Analyst: The portion of sample or the container sent by an Inspector to the Government Analyst for test or analysis under the act shall be sent by registered post or by hand in a

sealed packet, enclosed together with a memorandum in Form 18, in an outer cover addressed to the Government Analyst. A copy of the memorandum and a specimen impression of the seal used to seal the packet shall be sent to the Government Analyst separately by registered post or by hand.

Procedure for disposal of confiscated drugs:

The court shall refer the confiscated drugs to the Inspector concerned for report as to whether they are of standard quality or contravene the provisions of the act or the rules in any respect. If the inspector, on the basis of Government Analyst's report finds the confiscated drugs to be not of standard quality or to contravene any of the provisions of the act or the rules made thereunder, he shall report to the court accordingly. The court shall thereupon order the destruction of the drugs. The destruction shall take place under the supervision of the Inspector in the presence of such authority, if any, as may be specified by the court. If the inspector finds that the confiscated drugs are of standard quality and do not contravene the provisions of the act or the rules made thereunder, he shall report to the court accordingly. The court may then order the inspector to give the stocks of confiscated drugs to hospital or dispensary maintained or supported by the government or by the charitable institution.

E. Duties of Inspectors:

I. **Duties of Inspectors of premises licensed for sale:** Subject to the instructions of the controlling authority, it shall be duty of an Inspector authorized to inspect premises licensed for the sale of drugs:

1. To inspect not less than once a year, all establishments licensed for the sale of drugs within the area assigned to him.
2. To satisfy himself that the conditions of the licenses are being observed.
3. To procure and send for test or analysis, if necessary, imported packages which he has reason to suspect contain drugs being sold or stocked or exhibited for

- sale in contravention of the provisions of the act or rules thereunder.
4. To investigate any complaint in writing which may be made to him.
 5. To institute prosecutions in respect of breaches of the act and rules thereunder.
 6. To maintain a record of all inspections made and action taken by him in the performance of his duties, including the taking of samples and the seizure of stocks and to submit copies of such record to the controlling authority.
 7. To make such enquiries and inspections as may be necessary to detect the sale of drugs in contravention to the act.
 8. When so authorized by the State Government, to detain imported packages which he has reason to suspect contain drugs, the import of which is prohibited.
- II. *Inspection of manufacture of drugs:*** Duties of Inspectors specially authorized to inspect the manufacture of drugs or cosmetics.
- Subject to the instructions of the controlling authority it shall be the duty of an inspector authorized to inspect the manufacture of drugs:
1. To inspect not less than once a year, all premises licensed for manufacture of drugs or cosmetics within the area allotted to him to satisfy himself that the conditions of the license and provisions of the act and rules thereunder are being observed.
 2. In the case of establishments licensed to manufacture products specified in Schedule C and C₁ to inspect the plant and the process of manufacture, the means employed for standardizing and testing the drugs or cosmetics, the methods and place of storage, the technical qualifications of the staff employed and all details of location, construction and administration of the establishment likely to affect the potency or purity of the product.
 3. To send forthwith the controlling authority after each inspection a detailed report indicating the conditions of the license and provisions of the act and rules thereunder which are being observed and the conditions and provisions, if any, which are not being observed.
 4. To take samples of the drugs or cosmetics manufactured on the premises and send them for test or analysis in accordance with these rules.
 5. To institute prosecutions in respect of breaches of the act and rules thereunder.

IMPORT OF DRUGS AND COSMETICS

The term “import” is derived from the conceptual meaning as to bring in the goods and services into the port of a country. The buyer of such goods and services is referred to an “importer” who is based in the country of import whereas the overseas based seller is referred to as an “exporter”. Thus an import is any good (e.g. a commodity) or service brought in from one country to another country in a legitimate fashion, typically for use in trade. It is a good that is brought in from another country for sale. Import goods or services are provided to domestic consumers by foreign producers. An import in the receiving country is an export to the sending country.

Import and registration: According to new rules, import license will be required for all types of drugs instead of existing import license requirements for Schedule C and C₁ and Schedule X drugs only. Import license in Form 10 would be granted after completing the registration of overseas manufacturers and their specific drugs to be imported. The import license for specific drugs will be valid for 3 years from the date on which these are granted. The import license fee has been kept ₹ 1000/- for a single drug and at the rate of ₹ 100/- for additional drug. The fee of import licenses for test and analysis of a drug has been kept ₹ 100/- for a single drug and at the rate of ₹ 50/- for each additional drug. The exemption from import licenses for the import of bulk drugs by the formulations for actual use under Schedule D

has been deleted. A provision has been made that only drugs with minimum 60% of retained shelf-life shall be allowed to be imported in the country. A separate provision has been made to enable the govt. hospitals to import small quantities of essential new drugs for the treatment of their own patients. The fee for such import licenses has been kept ₹ 100/- for a single drug and the rate of ₹ 50/- for each additional drug.

QUALITY OF DRUGS

As per drugs and cosmetics act quality of drugs are given as follows:

Standards of Quality (Section 8)

1. "Standard quality" means:
 - a. In relation to a drug, that the drug complies with the standard set out in the second schedule.
 - b. In relation to a cosmetic, that the cosmetic complies with such standard as may be prescribed.
2. The Central Government, after consultation with the board and after giving by notification in the official gazette not less than 3 months notice of its intention so to do, may by a like notification add to or otherwise amend the second schedule, for the purpose of this part of the act, and thereupon the second schedule shall be deemed to be amended accordingly.

Misbranded Drugs (Section 9)

A drug is termed as misbranded:

- a. If it is so coloured, coated, powdered or polished that damage is concealed or if it is made to appear of better or greater therapeutic value than it really is.
- b. If it is not labelled in the prescribed manner.
- c. If its label or container or anything accompanying the drug bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular.

Misbranding should, as well, be as such can not be detected by a lay purchaser with the ordinary diligence. A phonetic similarly in two trade mark like cocogem and kotogem is not sufficient. There should be reasonable probability of deception.

Adulterated Drugs (Section 9A)

A drug is termed as adulterated:

- a. If it consists, in whole or in part, of any filthy, putrid or decomposed substance.
- b. If it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health.
- c. If its container is composed in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.
- d. If it bears or contains, for purposes of colouring only, a colour other than one which is prescribed.
- e. If it contains any harmful or toxic substance which may render it injurious to health.
- f. If any substance has been mixed therewith so as to reduce its quality or strength.

Spurious Drugs (Section 9B)

A drug is termed as spurious:

- a. If it is imported under a name which belongs to another drug.
- b. If it is an imitation of, or a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug.
- c. If the label or the container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist.

- d. If it has been substituted wholly or in part by another drug or substance.
- e. If it purports to be the product of a manufacturer of whom it is not truly a product.

- Classes of drugs which can be imported without any license.

Misbranded Cosmetics (Section 9C)

A cosmetic shall be deemed to be misbranded:

- a. If it contains a colour which is not prescribed.
- b. If it is not labelled in a prescribed manner.
- c. If the label or container or anything accompanying the cosmetic bears any statement which is false or misleading in any particular.

Spurious Cosmetics (Section 9D)

A drug shall be deemed to be spurious:

- a. If it is imported under the name which belongs to another cosmetic.
- b. If it is an imitation of, or is a substitute for, another cosmetic or resembles another cosmetic in a manner likely to deceive or bears upon it or upon its label or container the name of another cosmetic, unless it is plainly or conspicuously marked so as to reveal its true character and its lack of identity with such other cosmetic.
- c. If the label or the container bears the name of an individual or company purporting to be the manufacturer of the cosmetic, which individual or company is fictitious or does not exist.
- d. If it purports to be the product of a manufacturer of whom it is not truly a product.

A. Drugs Whose Import is Prohibited

Prohibition of import of certain drugs or cosmetics: Prohibition of import of certain drugs or cosmetics under Section 10 of the act. from such date as may be fixed by the Central Government by notification in the official gazette in this behalf, no person shall import:

1. Any drug or cosmetic which is not of standard quality.
2. Any misbranded drug or misbranded or spurious cosmetic.
3. Any adulterated or spurious drug.
4. Any drug or cosmetic for the import of which a license is prescribed, otherwise than under, and in accordance with, such license.
5. Any Patent or Proprietary Medicine, unless there is displayed in the prescribed manner on the label or container thereof the true formula or list of active ingredients contained in it, together with the quantities thereof.
6. Any drug which by means of any statement, design or device accompanying it or by any other means, purports or claims to cure or mitigate any such disease or ailment, or to have any such other effect, as may be prescribed.
7. Any cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended.
8. Any drug or cosmetic the import of which is prohibited by rule made under this act.

Nothing in this section shall apply to the import, subject to prescribed conditions, of small quantities of any drug for the purpose of examination, test or analysis or for personal use.

The Central Government may, after consultation with the board (DTAB), by notification in the official gazette, permit, subject to any conditions specified in the notification, the import of any drug or class of drugs not being of standard quality.

IMPORT OF DRUGS

For the purposes of import, which is deemed to be the process of bringing a material from a place outside India to a place in India. The details of import of drugs can be discussed below:

- Classes of drugs whose import is prohibited.
- Classes of drugs which may be imported under license or permit.

B. Import of Drugs Under License

The following classes of drugs may be imported under the license or permission granted by the licensing authority:

- Import of Schedule C, C₁ and X drugs
 - Drugs specified in Schedule C and C₁ excluding those specified in Schedule X.
 - Drugs specified in Schedule X.
- Import of small quantities of drugs
 - Import of drugs for examination, test or analysis.
 - Import of drugs for personal use.
 - Import of new drug by a government hospital or autonomous medical institution.
 - Import of any new drug.

An application for import license should be made to proper authority in the prescribed form. A license remains valid up to 31st December of the year in which it is granted, unless earlier suspended or cancelled. Any person who is not satisfied by a suspension or cancellation order passed by the licensing authority may appeal in the high court.

A separate license is necessary in respect of drugs from each manufacture. A separate import license is required in respect of drugs manufactured at each premises when a single manufacture abroad has more than one factory situated at different places.

Licenses for import of drugs manufactured by one manufacturer: A single application may be made and a single license may be issued, in respect of the import of more than one drug or class of drugs manufactured by the same manufacturer. The drugs or classes of drugs are manufactured at one factory or more than one factory functioning conjointly as a single manufacturing unit. If a single manufacturer has two or more factories situated in different places, manufacturing the same or different drugs a separate license shall be required in respect of the drugs manufactured by each such factory (Table 2.1).

Conditions of import license: An import license shall be subject to the following conditions:

1. The manufacturer shall at all times observe the undertaking given by him or on his behalf in Form 9.
2. The licensee shall allow any inspector authorized by the licensing authority in that behalf to enter with or without notice any premises where the imported substance is stocked, to inspect the means, if any, employed for testing the substance and to take samples.
3. The licensee shall on request furnish to the licensing authority from every batch of each substance or from such batch or batches as the licensing authority may from time to time specify a sample of such amount as the licensing authority may consider adequate for any examination required to be made, and the licensee shall, if so required, furnish full protocols of the tests, if any, which have been applied.
4. If the licensing authority so directs the licensee shall not sell or offer for sale any batch in respect of which a sample is or protocols are furnished under the last preceding subrule until a certificate authorizing the sale of the batch has been issued to him by or on behalf of the licensing authority.
5. The licensee shall, on being informed by the licensing authority that any part of any batch of the substance has been found by the licensing authority not to conform with the standards of strength, quality and purity prescribed under this act, or the rules thereunder and on being directed so to do withdraw the remainder of that batch from sale and, so far as may in the particular circumstances of the case be practicable, recall the issues already made from that batch.
6. The licensee shall maintain a record of all sales by him of substances for the import of which a license is required, showing particulars of the substance and of the person to whom sold and such further particulars, if any, as the licensing authority may specify and such record shall be open to the

Table 2.1: Form no. for the grant of various import license

Form 8	Application for license to import drugs (excluding those specified in Schedule X) to the Drugs and Cosmetics Rules, 1945.
Form 8-A	Application for license to import drugs specified in schedule X to the Drugs and Cosmetics Rules, 1945.
Form 9	Form of undertaking to accompany an application for an import license.
Form 10	License to import drugs (excluding those specified in Schedule X) to the Drugs and Cosmetic Rules, 1945.
Form 10-A	License to import drugs specified in Schedule X to the Drugs and Cosmetic Rules, 1945.
Form 11	License to import drugs for the purpose of examination, test or analysis.
Form 11-A	License to import drugs by a government hospital or autonomous medical institution for the treatment of patients.
Form 12	Application for license to import drugs for purpose of examination, test or analysis.
Form 12-A	Application for the issue of a permit to import small quantities of drugs for personal use.
Form 12-AA	Application for license to import small quantities of new drugs by a government hospital or autonomous medical institution for the treatment of patients.
Form 12-B	Permit for the import of small quantities of drugs for personal use.
Form 40	Application for issue of registration certificate for import of drugs into India under the Drugs and Cosmetics Rules, 1945.
Form 41	Registration certificate to be issued for import of drugs into India under Drugs and Cosmetics Rules, 1945.

inspection of any inspector authorised in that behalf by the licensing authority.

In respect of the sale or distribution of drugs specified in Schedule X, the licensee shall maintain separate record or register showing the following particulars, namely:

- i. Name of the drug.
- ii. Batch number.
- iii. Name and address of the manufacturer.
- iv. Date of transaction.
- v. Opening stock on the business day.
- vi. Quantity of drug received, if any, and the source from which received.
- vii. Name of the purchaser, his address and license number.
- viii. Balance quantity of drug at the end of the business day.
- ix. Signature of the person under whose supervision the drugs have been supplied.
7. The licensee shall comply with such further requirements, if any, applicable to the

holders of import licenses, as may be specified in any rules, subsequently made under this part of the act of the act and of which the licensing authority has given to him not less than four months' notice.

I. Import of Schedules C, C₁ and X Drugs

- Drugs specified in Schedules C and C₁ excluding those specified in Schedule X.
- Drugs specified in Schedule X.

An import license is required for the import of any biological or other special products specified in Schedules C, C₁ excluding X, and specified in Schedule X.

In addition to the general conditions for the import license one special condition for import of Schedules C and C₁ drugs is that the licensing authority must be satisfied that the premises where the imported substances will be stocked by the importer are equipped with proper accommodation for preserving the properties of the imported drug. The license of Schedules C

and C₁ drugs must comply with the undertaking given in Form 9.

Form and manner of application for import license: An application for an import license shall be made to the licensing authority for drugs excluding those specified in schedule X in Form 8, and for drugs specified in schedule X in Form 8-A, by manufacturer having a valid wholesale license for sale or distribution of drugs under these rules, and shall be accompanied by a license fee of 100 rupees for a single drug and an additional fee at the rate of one thousand rupees for each additional drug and by an undertaking in Form 9 duly signed by or on behalf of the manufacturer. In the case of any subsequent application made by the same importer for import license for drugs manufactured by the same manufacturer, the fee to accompany each such application shall be 100 rupees for each drug. A fee of 250 rupees shall be paid for a duplicate copy of the license issued under this rule, if the original is defaced, damaged or lost.

Import licenses: An import license in Form 10 shall be required for the import of drugs, excluding those specified in Schedule X, and an import license in Form 10-A shall be required for the import of drugs specified in Schedule X. The licensing authority may with the approval of the Central Government by an order in writing delegate the power to sign licenses and registration certificate and such other powers as may be specified in the order to any other person under his control.

Condition to be satisfied before a license in Form 10 or Form 10-A is granted:

1. A license in Form 10 or in Form 10-A shall be granted by the licensing authority having regard to the premises, where the imported substances will be stocked, are equipped with proper storage accommodation for preserving the properties of the drugs to which the license applies and the occupation, trade or business ordinarily carried out by the applicant.

The licensing authority may refuse to grant a license in Form 10-A in respect of any applicant where he is satisfied:

- a. That the applicant has not complied with the provisions of the act or these rules or
- b. That by reasons of:
 - i. His conviction under the act or these rules or the Narcotic Drugs and Psychotropic Substances Act, 1985 or the Rules made there under.
 - ii. Previous suspension or cancellation of the license granted to him.
He is not a fit person to whom license shall be granted.
2. Any person who is aggrieved by the order passed by the licensing authority under this rule may, within thirty days of the receipt of the order, appeal to the Central Government and the Central Government may after such enquiry into the matter as it considers necessary and after giving the appellant an opportunity for making a representation in the matter, make such orders in relation thereto as it thinks fit.

Duration of import license: A license unless, it is sooner suspended or cancelled, shall be valid for a period of 3 years from the date of its issue. If application for a fresh license is made 3 months before the expiry of the existing license, the current license shall be deemed to continue in force until orders are passed on the application.

Suspension and cancellation of import license: If the manufacturer or licensee fails to comply with any of the conditions of an import license, the licensing authority may after giving the manufacturer or licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefore, suspend or cancel it for such period as it thinks fit, either wholly or in respect of some of the substances to which it relates.

IMPORT OF SMALL QUANTITIES OF DRUGS

- Import of drugs for examination, test or analysis.
- Import of drugs for personal use.
- Import of drugs by a government hospital or autonomous medical institution for the treatment of patient.

II. Import of Drugs for Examination, Test or Analysis

Small quantities of drugs, the import of which is otherwise prohibited may be imported for the purpose of examination, test or analysis. A license is necessary for the import of small quantities of drugs for analytical purposes. For which application has to be made to the licensing authority duly signed by the head of the institution where the drugs are to be analysed or tested. An application for a license for examination, test or analysis shall be made in Form 12 and the license shall be granted in Form 11.

The issue of the license is subject to the following conditions:

1. Drug can be imported only under a license in Form 11.
2. The licensee shall use the substances imported under the license exclusively for purposes of examination, test or analysis and shall carry on such examination, test or analysis in the place specified in the license, or in such other places as the licensing authority may from time to time authorize.
3. The licensee shall allow any inspector authorized by the licensing authority in this behalf to enter, with or without prior notice, the premises where the substances are kept, and to inspect the premises and investigate the manner in which the substance are being used and to take samples thereof.
4. The licensee shall keep a record of and shall report to the licensing authority, the substances imported under the license, together with the quantities imported, the date of importation and the name of the manufacturer.

5. The licensee shall comply with such further requirements, if any applicable to the holders of licenses for examination, test or analysis as may be specified in any rules subsequently made under the provision related to import of drugs and cosmetics of this act and of which the licensing authority has given to him not less than one month's notice.

Application for license for examination, test or analysis: An application for a license for examination, test or analysis shall be made in Form 12 and shall be made or countersigned by the head of the institution in which, or by a proprietor or director or the company or firm by which the examination, test or analysis will be conducted. Every application in Form 12 shall be accompanied by a fee of 100 rupees for a single drug and an additional fee of 50 rupees or each additional drug. The fees shall be paid through a challan in the Bank of Baroda, Kasturba Gandhi Marg, New Delhi-110001 or any other branch or branches of Bank of Baroda, or any other bank, as notified, from time to time, by the Central Government, to be credited under the head of account 0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines.

Cancellation of license for examination, test or analysis: A license for examination, test or analysis may be cancelled by the licensing authority for breach of any of the conditions subject to which the license was issued. A licensee whose license has been cancelled may appeal to the Central Government within 3 months of the date of the order.

III. Import of Drugs for Personal Use

Small quantities of drugs, the import of which is otherwise prohibited, can be imported for personal use subject to the following conditions:

- i. The drugs shall form part of a passenger's bona fide baggage and shall be the property of, and be intended for the exclusive personal use of the passenger.
- ii. The drugs shall be declared to the customs authorities if they so direct.
- iii. The quantity of any single drug imported shall not exceed one hundred average doses.

The licensing authority may in an exceptional case, in any individual case sanction the import of a large quantity.

Any drug, imported for personal use but not forming part of bona fide personal baggage, may be allowed to be imported subject to the following conditions, namely:

- i. The licensing authority, on an application made to it in Form 12-A is satisfied that the drug is for bona fide personal use.
- ii. The quantity to be imported is reasonable in the opinion of the licensing authority and is covered by prescription from a registered medical practitioner.
- iii. The licensing authority grants a permit in respect of the said drug in Form 12-B.

IV. Import of New Drug by a Government Hospital or Autonomous Medical Institution

Import of drugs by a government hospital or autonomous medical institution for the treatment of patient.

Small quantities of new drug, the import of which is otherwise prohibited under this Act, may be imported for treatment of patients suffering from life-threatening diseases or diseases causing serious permanent disability or such disease requiring therapies for unmet medical needs, by a medical officer of a government hospital or an autonomous medical institution providing tertiary care, duly certified by the medical superintendent of the government hospital, or head of the autonomous medical institution, subject to the following conditions, namely:

1. No new drug shall be imported for the said purpose except under a license in Form 11-A, and the said drug has been approved for marketing in the country of origin.
2. The license shall use the substances or drugs imported under the license exclusively for the purpose of treatment of patients suffering from life threatening diseases, or diseases causing serious permanent dis-

bility, or such diseases requiring therapies for unmet medical needs, under the supervision of its own medical officers at the place, specified in the license or at such other places, as the licensing authority, may from time to time authorize.

3. The licensee shall allow an inspector authorised by the licensing authority in this behalf to enter, with or without prior notice, the premises where the substances or drugs are stocked, and to inspect the premises and relevant records and investigate the manner in which the substances or drugs are being used and to take, if necessary, samples thereof.
4. The licensee shall keep a record of and shall submit the said report half yearly to the licensing authority, the substances or drugs imported under the license, together with the quantities imported and issued to the patients, the date of importation, the name of the manufacturer, the name and address of the patient for whom the drug is prescribed and the name of disease.
5. The licensee shall comply with such other requirements, if any, applicable to the holders of import licenses for import of new drugs for treatment of patients by government hospitals, as may be specified from time to time in any rule subsequently made under this act and of which the licensing authority has given to him not less than one month's notice.
6. The drug shall be stocked under proper storage conditions and shall be dispensed under the supervision of a registered pharmacist.
7. The quantity of any single drug so imported shall not exceed 100 average dosages per patient.

Provided that the licensing authority may, in exceptional circumstances, sanction the import of drug a large quantity.

Application for license to import small quantities of new drugs by a government hospital

or autonomous medical institution for the treatment of patients: An application for an import license for small quantities of a new drug for the purpose of treatment of patients suffering from life threatening diseases, or diseases causing serious permanent disability, or such diseases requiring therapies for unmet medical needs, shall be made in Form 12-AA, by a medical officer of the government hospital or autonomous medical institution, which shall be certified by the medical superintendent of the government hospital or head of the autonomous medical institution, as the case may be.

License: An import license to import drugs by a government hospital or autonomous medical institution for the treatment of patients shall be made in Form 11-A.

Cancellation of license for import of small quantities of new drugs: A license for import of small quantities of a new drug, for the purpose of the treatment of patients suffering from life threatening diseases, or diseases causing serious permanent disability, or such diseases requiring therapies for unmet medical needs, by a government hospital or an autonomous medical institution may be cancelled by the licensing authority for breach of any of the conditions subject to which the license was issued or for contravention of any of the provisions of the act and rules made thereunder. A licensee whose license has been cancelled may appeal to the Central Government within 3 months from the date of the receipt of the order, and the Central Government may after such enquiry into the matter, as it considers necessary and after giving the appellant an opportunity for representing his views, may pass such orders in relation thereto, as it thinks fit.

V. Import of New Drugs

Drugs whose composition is not recognized as safe or used by experts and not been used widely for any appreciable period of time and regarded as new drugs. Permission for the import of these

may be obtained after giving the detailed of the standards of quality, purity and strength, etc. should be supplied to the licencing authority as provided in Schedule Y.

C. Import of Drugs Without License or Permission

Drugs, excepting those discussed above, may be imported without any permit or license. However, before such drugs are imported into the country, their importers or manufacturers should submit a declaration to the customs collector that they comply with all the provisions of Chapter III (provisions related to the import of drugs and cosmetics) of this act and rules made under the same.

PROCEDURE FOR THE IMPORT OF DRUGS

No drug can be imported unless it is packed and labeled in conformity with the prescribed rules. All consignments of drugs to be imported should be accompanied by an invoice or other statement showing the make and address of manufacturer and the names and quantities of the drugs. Before importing drugs for which a license is not required, a declaration signed by the manufacturer on behalf of the importer that the drugs comply with the provisions of the act and rules, should be supplied to the custom collector.

1. If the customs collector has reason to doubt whether any drugs comply with the provisions related to the import of the drugs and rules thereunder he may, and if requested by an officer appointed for this purpose by the Central Government shall, take samples of any drugs in the consignment and forward them to the Director of the laboratory appointed for this purpose by the Central Government and may detain the drugs in the consignment of which samples have been taken until the report of the Director of the said laboratory or any other officer empowered by him on this behalf,

subject to the approval of the Central Government, on such samples is received. Provided that if the importer gives an undertaking in writing not to dispose of the drugs without the consent of the customs collector and to return the consignment or such portion thereof as may be required, the customs collector shall make over the consignment to the importer.

2. If an importer who has given an undertaking under the proviso to sub-rule (1) is required by the customs collector to return the consignment or any portion thereof he shall return the consignment or portion thereof within 10 days of receipt of the notice.
3. If the Director of the laboratory appointed for the purpose by the Central Government or any other officer empowered by him on this behalf, subject to the approval of the Central Government, reports to the customs collector that the samples of any drug in a consignment are not of standard quality, or that the drug contravenes in any other respect the provisions of import of drugs and cosmetics of the act or the rules thereunder and that the contravention is such that it cannot be remedied by the importer, the customs collector shall communicate the report forthwith to the importer who shall, within two months of his receiving the communication either export all the drugs of that description in the consignment, to the country in which they were manufactured or forfeit them to the Central Government which shall cause them to be destroyed. Provided that the importer within 15 days of receipt of the report may make a representation against the report to the customs collector, and the customs collector shall forward the representation with a further sample to the licensing authority, who after obtaining, if necessary, the report of the Director of the Central Drugs Laboratory, shall pass orders thereon which shall be final.
4. If the Director of the laboratory appointed for the purpose by the Central Government or any other officer empowered by him on this behalf, subject to the approval of the Central Government reports to the customs collector that the samples of any drug contravene in any respect the provisions of import of drugs and cosmetics of the act or the rules thereunder and that the contravention is such that it can be remedied by the importer, the customs collector shall communicate the report forthwith to the importer and permit him to import the drug, on his giving an undertaking in writing not to dispose of the drug without the permission of the officer authorized in this behalf by the Central Government.

OTHER PROVISIONS REGARDING IMPORT OF DRUGS

- I. *Standards for certain imported drugs:* No drug shall be imported unless it complies with the standard of strength, quality and purity, if any, and the test prescribed in the rules shall be applicable for determining whether any such imported drug complies with the said standard. The drugs intended for veterinary use, the standards of strength, quality and purity, if any, shall be those that are specified in Schedule F₁ and the test prescribed in that Schedule shall be applicable for determining whether any such imported drug complies with the said standards and where no standards are specified in Schedule F₁ for any veterinary drug, the standards for such drug shall be those specified in the current edition, for the time being in force, of the British Pharmacopoeia Veterinary. The licensing authority shall not allow the import of any drug having less than sixty percent residual shelf-life period as on the date of import. Provided that in exceptional cases the licensing authority may, for

reasons to be recorded in writing, may allow, the import of any drug having lesser shelf-life period, but before the date of expiry as declared on the container of the drug.

- II. Place through which drugs may be imported into India:** No drug shall be imported into India except through one of the following places, namely: (under Section 43A).

1. **Freozeppore cantonment and Amritsar railway stations:** In respect of drugs imported by rail across the frontier with Pakistan.
2. **Ranaghat, Bongaon and Mohiassan railways stations:** In respect of drugs imported by rail across the frontier with Bangladesh.
3. **Raxaul:** In respect of drugs imported by road and railway lines connecting raxaul in India and Birganj in Nepal.
4. **Chennai, Kolkata, Mumbai and Cochin, Nhava Sheva and Kandla:** In respect of drugs imported by sea into India.
5. **Chennai, Kolkata, Mumbai, Delhi, Ahemdabad and Hyderabad:** In respect of drugs imported by air into India.

Consignments of drugs in transit through India to foreign countries and which are not intended to be sold or distributed in India are exempted from the provisions regulating the import of drugs. However, if the consignments are covered by import licenses granted by countries of destination, the importer has to produce such licenses at the time of import.

- III. Power of Central Government to prohibit import of drugs and cosmetics in public interest (Section 10A):** If the Central Government is satisfied that the use of any drug or cosmetic is likely to involve any risk to human beings or animals or that any drug does not have the therapeutic value claimed for it or contains ingredients and

in such quantity for which there is no therapeutic justification and that in the public interest it is necessary or expedient so to do then, that government may, by notification in the official gazette, prohibit the import of such drug or cosmetic.

- IV. Application of law relating to sea customs and powers of customs officers (Section 11):** The law for the time being in force relating to sea customs and to goods, the import of which is prohibited by Section 18 of the Sea Customs Act, 1878 shall, subject to the provisions of section 13 of this act, apply in respect of drugs and cosmetics the import of which is prohibited under this act, and officers of customs and officers empowered under that act to perform the duties imposed thereby on a customs collector and other officers of customs, shall have the same powers in respect of such drugs and cosmetics as they have for the time being in respect of such goods as aforesaid. The customs collector or any other officer of the government authorized by the Central Government in this behalf, may detain any imported package which he suspects to contain any drug or cosmetic the import of which is prohibited under this act and shall forthwith report such detention to the drugs controller, India, and, if necessary, forward the package or sample of any suspected drug or cosmetic found therein to the Central Drugs Laboratory for analysis.

- V. Prohibition of import after expiry of potency:** No biological or other special product specified in Schedule C or C₁ shall be imported after the date shown on the label, wrapper or container of the drug as the date up to which the drug may be expected to retain a potency not less than, or not to acquire a toxicity greater than, that required, or as the case may be, permitted by the prescribed test.

VI. Prohibition of import of certain drugs: No drug, the manufacture, sale or distribution of which is prohibited in the country of origin, shall be imported under the same name or under any other name except for the purpose of examination, test or analysis.

OFFENCES AND PENALTIES RELATED TO THE IMPORT OF DRUGS

1. Whoever himself or by any other person on his behalf imports:
 - a. Any drug deemed to be adulterated or deemed to be a spurious drug or any spurious cosmetic or any cosmetic of the nature shall be punishable with imprisonment for a term which may extend to 3 years and a fine which extend to 5,000 rupees.

Subsequent offence: Whoever having been convicted of an offence—is again convicted (subsequent conviction) of an offence under that clause, shall be punishable with imprisonment for a term which may extend to 5 years or fine 10,000 rupees, or both.

- b. Any drug or cosmetic other than a drug or cosmetic referred to in clause (a) the import of which is prohibited shall be punishable with imprisonment for a term which may extend to 6 months, or with fine which extend to 5,000 rupees or both.

Subsequent offence: Punishment with imprisonment for a term which may extend to one year, or with fine which may extend to 10,000 rupees, or both.

- c. Any drug or cosmetic in contravention of the provision of any notification issued, shall be punishable with imprisonment for a term which may extend to 3 years, or with fine which extend to 5,000 rupees, or both.

Subsequent offence: Punishment with imprisonment for a term which may extend 5 years or fine up to 10,000 rupees, or both.

MISCELLANEOUS PROVISIONS RELATED TO THE IMPORT OF DRUGS

- I. **Drugs exempted from import provisions:** The drugs specified in Schedule D are exempted from the provisions related to import of drugs.
- II. **Confiscation:** Where any offence punishable has been committed, the consignment of the drugs or cosmetics in respect of which the offence has been committed shall be liable to confiscation.
- III. **Consignments:** Drugs, consignments of which are in transit through India to foreign countries and which shall not be sold or distributed in India shall be exempted from the requirements of provision related to the import of the drugs of the Drugs and Cosmetics Act, 1940 and the rules made thereunder. Provided that if the government of the countries to which the drugs are consigned regulate their import by the grant of import licenses, the importer shall at the time of import into India, produce such import licenses.

MANUFACTURE OF DRUGS AND COSMETICS

“Manufacturing” means the production, preparation, propagation, conversion or processing of a drug or device, either directly or indirectly, by large volume extraction from substances of natural origin, or independently by means of chemical or biological synthesis, and includes any packaging or repackaging of a substance or labelling or relabelling of its container, and the promotion and marketing of such drugs and devices. “Manufacturing” also includes the preparation and promotion of commercially available products from bulk compounds for resale by pharmacists to anyone other than a patient via a prescription, practitioners, or other persons.

“Manufacture” in relation to any drug, includes any process or part of a process for

making, altering, finishing, packing, labelling, breaking or otherwise treating or adapting any drug with a view its sale and distribution, but does not include the compounding or dispensing of any drug or the packing of any drug in the ordinary course of retail business, and "to manufacture" shall be construed accordingly. "Manufacturer" means any person who manufactures a drug.

Following license are granted for the manufacturing of drugs under the D and C Act and rules thereunder:

- Drugs other than those specified in Schedules C and C₁ and X.
- Drugs specified in schedule X not specified in Schedules C and C₁.
- Drugs specified in Schedule C, C₁ Excluding those specified in Schedule X.
- Drugs specified in Schedules C, C₁ and X.
- Manufacture of large volume parenterals sera and vaccines specified in Schedules C and C₁ Excluding those specified in Schedule X.
- Drugs for the purpose of examination, test or analysis.
- Loan license.
 - Drugs other than those specified in Schedules C and C₁.
 - Drugs specified in Schedules C and C₁.
- Repacking license.
 - Drugs other than those specified in Schedules C and C₁ Excluding those specified in Schedule X.
- License to manufacture of whole human blood and components for sale or distribution.
 - License to operate a blood bank for collection, storage and processing of whole human blood and/or its components for sale or distribution.
 - License to manufacture and store blood products for sale or distribution.
- Any new drugs

If drugs are manufactured on more than one set of premises, separate licenses are required in respect of each such set of premises.

There are two types of conditions which are required to be satisfied for all manufacturing license, conditions which are required to be satisfied before a license is granted (conditions precedent) and conditions which are required to be satisfied after the grant of license (conditions subsequent).

MANUFACTURE APPLICATIONS, LICENSES, FEES AND PENALTY (TABLE 27.2)

Duplicate copy of the license: A fee of Rs. 1,000 shall be paid for the duplicate copy of the license issued, if the original is defected, damaged or lost.

PROHIBITION OF MANUFACTURE AND SALE

Prohibition of manufacture and sale of certain drugs and cosmetics: From such date as may be fixed by the State Government by notification in the official gazette in this behalf, no person shall himself or by any other person on his behalf:

1. Manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale:
 - i. Any drug which is not of a standard quality, or is misbranded, adulterated or spurious.
 - ii. Any cosmetic which is not of a standard quality or is misbranded or spurious.
 - iii. Any Patent or Proprietary Medicine, unless there is displayed in the prescribed manner on the label or container thereof the true formula or list of active ingredients contained in it together with the quantities thereof.
 - iv. Any drug which by means of any statement, design or device accompanying it or by any other means, purport or claims to prevent, cure or mitigate any such disease or ailment, or to have any such other effect as may be prescribed;

Table 2.2: Manufacture applications, license, fees and penalty

S.No.	Category of drugs	Application form no.	License form no.	Fees for grant/renewal	Fee + penalty after expiry but within six months	Fee for addl. item for more than 10 item for each category
1.	Drugs other than those specified in schedules C and C ₁ and excluding those specified in X	24-B up to 10 items for each category	25-B	Lic. fees of ₹ 500 + Insp. Fee of ₹ 200 for every inspection or for renewal of license.	₹ 500 + ₹ 250 p.m. or part thereof in addition to an inspection fee of ₹ 200	₹ 100 for each addl. item.
	i. Repacking of drugs	24-F up to 10 items for each category	25-F	Lic. Fee of ₹ 6000 + Insp. Fee of ₹ 1500 for every inspection or for renewal of license.	₹ 6000 + ₹ 1000 p.m. or part thereof in addition to insp. Fee of ₹ 1000.	₹ 300 per item
	ii. Drugs specified in Schedule 'X'	24 up to 10 items for each category	25	Lic. Fee of ₹ 6000 + Insp. Fee of ₹ 1500 for every inspection or for renewal of license.	₹ 6000 + ₹ 1000 p.m. or part thereof in addition to insp. Fee of ₹ 1500.	₹ 300 per item
	iii. Any other drugs (drugs other than those specified in Schedules C and C ₁)	24-A up to 10 items for each category	25-A	Lic. Fee of ₹ 6000 + Insp. Fee of ₹ 1500 for every inspection or for renewal of license.	₹ 6000 + ₹ 1000 p.m. or part thereof in addition to insp. Fee of ₹ 1500.	₹ 300 per item
	iv. Loan license (drugs other than those specified in Schedules C and C ₁)	27 up to 10 items for each category	25-A	Lic. Fee of ₹ 6000 + Insp. Fee of ₹ 1500 for every inspection or for renewal of license.	₹ 6000 + ₹ 1000 p.m. or part thereof in addition to insp. Fee of ₹ 1500.	₹ 300 per item
2.	Drugs specified in Schedules C and C ₁ excluding those specified in Sch. X					
	i. Own unit	27-A up to 10 items for each category	28-A	Lic. Fee of ₹ 6000 + Insp. Fee of ₹ 1500 for every inspection or for renewal of license.	₹ 6000 + ₹ 1000 p.m. or part thereof in addition to insp. Fee of ₹ 1500.	₹ 300 per item
	ii. Loan license drugs specified in Schedules C and C ₁	27-B up to 10 items for each category	28-B	Lic. Fee of ₹ 6000 + Insp. Fee of ₹ 1500 for every inspection or for renewal of license.	₹ 6000 + ₹ 1000 p.m. or part thereof in addition to insp. Fee of ₹ 1500.	₹ 300 per item
	iii. Drugs specified in Schedules C and C ₁ and X	27-D up to 10 items for each category	28-D	Lic. Fee of ₹ 6000 + Insp. Fee of ₹ 1500 for every inspection or for renewal of license.	₹ 6000 + ₹ 1000 p.m. or part thereof in addition to insp. Fee of ₹ 1500.	₹ 300 per item
	v. Whole human blood and components	27-C	28-C	Lic. Fee of ₹ 6000 + Insp. Fee of ₹ 1500 for every inspection or for renewal of license.	₹ 6000 + ₹ 1000 p.m. or part thereof in addition to insp. Fee of ₹ 1500.	₹ 250
3.	Mfg. of drugs for purpose of examination, test/analysis	30	29			

- v. Any cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended.
- vi. Any drug or cosmetic in contravention of any of the provisions of this chapter or any rule made thereunder.
- 2. Sell, or stock or exhibit or offer for sale, or distribute any drug or cosmetic which has been imported or manufactured in contravention of any of the provisions of this act or any rule made thereunder.
- 3. Manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale, or distribute any drug or cosmetic, except under, and in accordance with the conditions of, a license issued for such purpose under this act.

Nothing in this section shall apply to the manufacture, subject to prescribed condition of small quantities of any drug for the purpose of examination, test or analysis.

The Central Government may, after consultation with the board, by notification in the official gazette, permit, subject to any conditions specified in the notification, the manufacture for sale, or for distribution, sale, stocking or exhibiting or offering for sale or distribution of any drug or class of drugs not being of standard quality.

MANUFACTURE

Manufacture for sale or distribution of drugs.

Grant or renewal of licenses by the Central License Approving Authority:

1. Notwithstanding anything contained in this part, on and from the commencement of the Drugs and Cosmetics (9th Amendment) Rules 1992, a license for the manufacture for sale or distribution of drugs as specified from time to time by the Central Government by notification in the official gazette, for the purpose of this rule, shall be granted or renewed, as the case maybe,

by the central license approving authority (appointed by the Central Government) provided that the application for the grant or renewal of such license shall be made to the licensing authority.

2. On receipt of the application for grant or renewal of a license, the licensing authority shall:
 - i. Verify the statement made in the application form.
 - ii. Cause the manufacturing and testing establishment to be inspected in accordance with the provisions of Rule 79.
 - iii. In case the application is for the renewal of license, call for the informations of the past performance of the licensee.
3. If the licensing authority is satisfied that the applicant is in a position to fulfill the requirements laid down as in these rules, he shall prepare a report to that effect and forward it along with the application and the license (in triplicate) to be granted and renewed, duly completed to the central license approving authority.
4. If on receipt of the application and the report of the licensing authority referred to in subrule (3) and after taking such measures including inspection of the premises by the inspector, appointed by the Central Government under the act, with or without an expert in the concerned field if deemed necessary, the central license approving authority, is satisfied that the applicant is in a position to fulfill the requirements laid down in these rules, he may grant or renew the license, as the case may be.

If the central license approving authority is of the opinion that the applicant is not in a position to fulfill the requirements laid down in these rules, he may, notwithstanding the report of the licensing authority, by order, for reasons to be recorded in writing, reject the application for grant or renewal of license as the case may be.

Manufacture on more than one set of premises: If drugs are manufactured on more than one set of premises a separate application shall be made and a separate license shall be issued in respect of each such set of premises.

1. MANUFACTURE OF DRUGS OTHER THAN THOSE SPECIFIED IN SCHEDULES C, C₁ AND X AND MANUFACTURE OF DRUGS SPECIFIED IN SCHEDULE X AND NOT SPECIFIED IN SCHEDULES C AND C₁

Application for the grant or renewal of license for the manufacture of drugs other than those specified in Schedules C, C₁ and X should be made to the licensing authority in Form 24 and for the manufacture of drugs specified in Schedule X but not specified in Schedules C and C₁ in Form 24-F. The respective license shall be issued in Form 25 and 25-F.

Conditions for the grant or renewal of a license: Before a license in Form 25 or Form 25-F is granted or renewed, the following conditions shall be complied with by the applicant:

1. The manufacture shall be conducted under the active direction and personal supervision of competent technical staff consisting at least of one person who is a whole-time employee and who is:
 - a. A graduate in pharmacy or pharmaceutical chemistry of a university established in India by law or have an equivalent qualification recognized and notified by the Central Government for such purpose of this rule and has had at least 18 months practical experience after the graduation in the manufacture of drugs. This period of experience may, however, be reduced by 6 months if the person has undergone training in manufacture of drugs for a period of 6 months during his university course.
 - b. A graduate in science of a university established in India by law or have an

equivalent qualification recognized and notified by the Central Government for such purpose of his degree has studied chemistry as a principal subject and has had at least 3 years practical experience in the manufacture of drugs after his graduation.

- c. A graduate in chemical engineering or chemical technology or medicine of a university established in India by law or have an equivalent qualification recognized and notified by the Central Government for such purpose with general training and practical experience, extending over a period of not less than 3 years in the manufacture of drugs, after his graduation.
- d. Holding any foreign qualification the quality and content of training of which are comparable with those prescribed in clause (a) clause (b) or clause (c) and is permitted to work as competent technical staff under this rule by the Central Government.

For drugs other than those specified in Schedules C, C₁ and X and meant for veterinary use, the whole-time employee under whose supervision the manufacture is conducted shall be graduate in veterinary science or pharmacy or general science or medicine of a university recognized by the Central Government and who has had at least 3 years practical experience in the manufacture of drugs excluding graduate in pharmacy who shall have at least 18 months practical experience in the manufacture of drugs.

The knowledge of pharmaceutical chemistry or pharmacy is not essential for the manufacture of disinfectant fluids, insecticides, liquid paraffin, medicinal gases, non chemical contraceptives, plaster of paris and surgical dressings. The licensing authority may permit the manufacture of these substances under the active direction and personal supervision of the

competent technical staff, who, although not having any of the above qualifications but having adequate experience in the manufacture of such substance.

2. The factory premises shall comply with the conditions prescribed in Schedule M.
3. The applicant shall provide adequate space, plant and equipment for the manufacturing operations, the space, plant and equipment recommended for various operations are given in Schedule M.
4. The applicant shall provide and maintain adequate staff, premises and laboratory equipment for carrying out tests of the strength, quality and purity of the substances at a testing unit, which shall be separate from the manufacturing unit and the head of the testing unit, shall be independent of the head of the manufacturing unit.

The manufacturing units, which, before the commencement of the Drugs and Cosmetics (amendment) Rules, 1977, were making arrangements with institutions approved by the licensing authority for such tests to be carried out on their behalf may continue such arrangements up to the 30th June, 1977.

For tests requiring sophisticated instrumentation techniques or biological or microbiological methods other than sterility the licensing authority may permit such tests to be conducted by institutions approved by it under Part XV-A (approval of institutions for carrying out tests on drugs, cosmetics and raw materials used in their manufacture on behalf of licensees for manufacture for sale of drugs/cosmetics) of these rules for this purpose.

- 4A. The head of the testing unit referred to in condition (4) shall possess a degree in medicine or science or pharmacy or pharmaceutical chemistry of a university recognized for this purpose and shall have experience in the testing of drugs, which in the opinion of the licensing authority is considered adequate.

5. The applicant shall make adequate arrangements for the storage of drugs manufactured by him.
6. The applicant shall, while applying for a license to manufacture patent or proprietary medicines, furnish to the licensing authority evidence and data justifying that the Patent or Proprietary Medicines:
 - i. Contain the constituent ingredients in therapeutic/prophylactic quantities as determined in relation to the claims or conditions for which the medicines are recommended for use or claimed to be useful.
 - ii. Are safe for use in the context of the vehicles, excipients, additives and pharmaceutical aids used in the formulation and under the conditions in which the formulation for administration and use are recommended.
 - iii. Are stable under the conditions of storage recommended.
 - iv. Contain such ingredients and in such quantities for which there is therapeutic justification.
 - v. Have the approval, in writing, in favour of the applicant to manufacture drugs formulations falling under the purview of new drug, from the licensing authority.
7. The licensee shall comply with the requirements of good manufacturing practices as laid down in Schedule M.

Duration of license: A license in Form 25 or 25 remains valid for a period of 5 years on and from the date on which it was issued unless suspended or cancelled earlier. If the application for the renewal of a license is made before its expiry, or if the application is made within 6 months of its expiry after payment of additional fee, the license shall continue to be in force until orders are passed on the application and the license shall be deemed to have expired if the application for its renewal is not made within 6 months of its expiry.

Conditions of license: A license in Form 25 and Form 25-F shall be subject to the conditions stated therein and to the following further conditions, namely:

- a. The licensee shall provide and maintain staff, premises and the equipment and plant for proper manufacture and storage of substances.
- b. The licensee shall comply with the provisions of the act and of these rules and with such further requirements, if any, as may be specified. Provided that where such further requirements are specified in the rules, these would come into force, 4 months after publication in the official gazette.
- c. The licensee shall either in his own laboratory or in any other approved laboratory tests each batch or lot of the raw material used by him for the manufacture of his products and also each batch of the final product and shall maintain records or registers showing the particulars in respect of such tests as specified in Schedule U. The records or registers shall be retained for a period of 5 years from the date of manufacture.
- d. The licensee shall keep records of the details of manufacture as per particulars given in Schedule U of each batch of the drugs manufactured by him and such records shall be retained for a period of 5 years.
- e. The licensee shall allow an Inspector appointed under the act, to enter, with or without prior notice, any premises and to inspect the plant and the process of manufacture and the means employed in standardizing and testing the drugs.
- f. The licensee shall allow an inspector appointed under the act to inspect all registers and records maintained under these rules and to take samples of the manufactured drugs and shall supply to such inspector such information as he may require for the purpose of ascertaining whether the provisions of the act and the rules thereunder have been observed.
- g. The licensee shall, from time to time, report to the licensing authority any changes in the expect staff responsible for the manufacture or testing of the drugs and any material alterations in the premises or plant used for the purpose which have been made since the date of the last inspection made on behalf of the licensing authority.
- h. The licensee shall, on request, furnish to the licensing authority, the controlling authority or to such authorities as the licensing authority or the controlling authority may direct from every batch, or batches of drugs as the licensing authority or the controlling authority may from time to time specify, a sample of such quantity as may be considered adequate by such authority for any examination and, if so required, also furnish full protocols of tests which have been applied.
- i. If the licensing authority or the controlling authority so directs and if requested by the licensee who had also furnished prima facie reason for such directions, the licensee shall not sell or offer for sale any batch in respect of which a sample is or protocols are furnished under clause (h) until a certificate authorizing the sale of the batch has been issued to him by or on behalf of the licensing authority or the controlling authority.
- j. The licensee shall on being informed by the licensing authority or the controlling authority that any part of any batch of the drug has been found by the licensing authority or the controlling authority not to conform with the standards of strength, quality or purity specified in these rules and on being directed so to do, withdraw the remainder of the batch from sale, and, so far as may in the particular circumstances of the case be practicable, recall all issues already from that batch.

- k. The licensee shall maintain an inspection Book in Form 35 to enable an inspector to record his impressions and the defects noticed.
- l. The licensee shall maintain reference samples from each batch of the drugs manufactured by him in a quantity which is at least twice the quantity of the drug required to conduct all the tests performed on the batch. In case of drugs bearing an expiry date on the label, the reference samples shall be maintained for a period of three months beyond the date of expiry or potency. In case of drugs where no date of expiry or potency is specified on the label, the reference samples shall be maintained for a period of three years from the date of manufacture.
- m. The licensee, who has been granted a license in Form 25-F, shall forward to the licensing authority of the concerned States of manufacture and supply of the drug a statement of the sales effected to manufacturers, wholesalers, retailers, hospitals, dispensaries and nursing-homes and registered medical practitioners every three months. He shall also maintain accounts of all transactions giving details as indicated below in a register bound and serially page numbered and such records shall be retained for a period of 5 years or one year after the expiry of potency, whichever is later:

A. Accounts of the Drugs Specified in Schedule X Used for the Manufacture

1. Date of issue.
2. Name of the drug.
3. Opening balance of stock on the production day.
4. Quantity received, if any, and source from where received.
5. Quantity used in manufacture.
6. Balance quantity on hand at the end of the production day.
7. Signature of the person in-charge.

B. Accounts of Production

1. Date of manufacture.
2. Name of the drug.
3. Batch number.
4. Quantity of raw material used in manufacture.
5. Anticipated yield.
6. Actual yield.
7. Wastage.
8. Quantity of the manufactured goods transferred.

C. Accounts of the Manufactured Drugs

1. Date of manufacture.
2. Name of the drug.
3. Batch number.
4. Opening balance.
5. Quantity manufactured.
6. Quantity sold.
7. Name of the purchaser and his address.
8. Balance quantity at the end of the day.
9. Signature of the person in-charge.
- n. The licensee shall store drugs specified in Schedule X in bulk form and when any of such drug is required for manufacture in a place other than its place of storage it shall be kept in a separate place under the direct custody of a responsible person.
- o. The licensee shall comply with the requirements of 'Good Manufacturing Practices' as laid down in Schedule M.

II. MANUFACTURE OF DRUGS SPECIFIED IN SCHEDULES C AND C₁ EXCLUDING THOSE SPECIFIED IN SCHEDULE X, AND

MANUFACTURE OF DRUGS SPECIFIED IN SCHEDULES C, C₁ AND X, AND

MANUFACTURE OF LARGE VOLUME PARENTERALS/SERA AND VACCINES SPECIFIED IN SCHEDULES C AND C₁ EXCLUDING THOSE SPECIFIED IN SCHEDULE X

Application for the license to manufacture drugs specified in Schedules C, C₁ excluding those

specified in Schedule X should be made to the licensing authority in Form 27 and for drugs specified in Schedules C, C₁ and X in Form 27-B. Application to manufacture for sale or for distribution of large volume parenterals, sera and vaccines (specified in Part X-B) shall be issued in Form 27-D. The respective license shall be issued in Forms 28 and 28-B and Form 28-D.

The Conditions for the Grant or Renewal of Such Licenses

Before a license in Form 28 or Form 28-B or Form 28-D is granted or renewed, the following conditions shall be complied with by the applicant:

1. The manufacture will be conducted under the active direction and personal supervision of competent technical staff consisting at least of one person who is a whole time employee and who is:
 - a. A graduate in pharmacy or pharmaceutical chemistry of a university established in India by law or has an equivalent qualification recognized and notified by the Central Government for such purpose of this rule and has had at least 18 months' practical experience after the graduation in the manufacture of drugs to which this license applies this period of experience may however be reduced by 6 months if the person has undergone training in manufacture of drugs to which the license applies for a period of 6 months during his university course.
 - b. A graduate in science of a university established in India by law or has an equivalent qualification recognized and notified by the Central Government for such purpose of his degree has studied chemistry or microbiology as a principal subject and has had at least 3 years practical experience in the manufacture

of drugs to which this license applies after his graduation.

- c. A graduate in medicine of a university established in India by law or has an equivalent qualification recognized and notified by the Central Government for such purpose with at least 3 years experience in the manufacture and pharmacological testing of biological products after his graduation.
- d. A graduate in chemical engineering of a university recognized by the Central Government with at least three years' practical experience in the manufacture of drugs to which this license applies after his graduation.
- e. Holding any foreign qualification the quality and content of training of which are comparable with those prescribed in clause (a) clause (b) clause (c) or clause (d) and is permitted to work as competent technical staff under this rule by the Central Government.

For the drugs specified in Schedules C and C₁ meant for veterinary use, the whole time employee under whose supervision the manufacture is conducted may be a graduate in veterinary science or general science or medicine or pharmacy of a university, recognized by the Central Government and who has had at least 3 years experience in the manufacture of biological products.

Provided also that for the medical devices specified in Schedule C, the whole time employee under whose supervision the manufacture is conducted may be a graduate in science with physics or chemistry or microbiology as one of the subjects, or graduate in pharmacy, or degree/diploma holder in mechanical or chemical or plastic engineering of a university recognized by the Central Government for such purposes.

2. The factory premises shall comply with the conditions prescribed in Schedule M

and Schedule M₃ in respect of medical devices.

3. The applicant shall provide adequate space, plant and equipment for any or all the manufacturing operations; the space, plant and equipment recommended for various operations are given in Schedule M and Schedule M₃.
4. The applicant shall provide and maintain adequate staff, premises and laboratory equipment for carrying out such tests of the strength, quality and purity of the substances as may be required to be carried out by him under the provisions of Part X (special provisions relating to biological and other special products) of these rules including proper housing for animals used for the purposes of such tests, the testing unit being separate from the manufacturing unit and the head of the testing unit being independent of the head of the manufacturing unit.

The manufacturing units which before the commencement of the Drugs and Cosmetics (amendment) Rules, 1977, were making arrangements with institutions approved by the licensing authority for such tests to be carried out on their behalf may continue such arrangements up to the 30th June, 1977.

For tests requiring sophisticated instrumentation techniques or biological or microbiological methods other than sterility the licensing authority may permit such tests to be conducted by institutions approved by it under Part XV-A of these rules for this purpose.

- 4A. The head of the testing unit referred to in condition (4) shall possess a degree in medicine or science or pharmacy or pharmaceutical chemistry of a university recognized for this purpose and shall have experience in the testing of drugs, which in the opinion of the licensing authority is considered adequate.

5. The applicant shall make adequate arrangements for the storage of drugs manufactured by him.
6. The applicant shall furnish to the Licensing Authority, if required to do so, data on the stability of drugs which are likely to deteriorate for fixing the date of expiry which shall be printed on the labels of such drugs on the basis of the data so furnished.
7. The applicant shall, while applying for license to manufacture patent or proprietary medicines, furnish to the licensing authority evidence and data justifying that the patent or proprietary medicines:
 - i. Contain the constituent ingredients in therapeutic/prophylactic quantities as determined in relation to the claims or conditions for which the medicines are recommended for use or claimed to be useful.
 - ii. Are safe for use in the context of the vehicles, excipients, additives and pharmaceutical aids used in the formulations and under the conditions in which the formulations for administration and use are recommended.
 - iii. Are stable under the conditions or storage recommended.
 - iv. Contain such ingredients and in such quantities for which there is therapeutic justification.
 - v. Have the approval in writing in favour of the applicant to manufacture drug formulations falling under the range of new drug, from the licensing authority.
8. The licensee shall comply with the requirements of "Good Manufacturing Practices" as laid down in Schedule M.

Duration of license: An original license in Form 28, Form 28-B and Form 28-D or renewed license in Forms 26, 26-F, and Form 26-H or a renewed license in Form 26, unless sooner suspended or cancelled shall be valid for a

period of 5 years on and from the date on which it is granted or renewed. If the application for the renewal of a license is made before its expiry, or if the application is made within 6 months of its expiry after payment of additional fee, the license shall continue to be in force until orders are passed on the application and the license shall be deemed to have expired if the application for its renewal is not made within 6 months of its expiry.

Conditions of Licenses

A license in Form 28, Form 28-B or Form 28-D shall be subject to the special conditions, if any, set out in Schedule F or Schedule F₁, as the case may be, which relate to the substance in respect of which the license is granted and to the following general conditions:

- a. i. The licensee shall provide and maintain an adequate staff and adequate premises and plant for the proper manufacture and storage of the substances in respect of which the license is issued.
ii. Without prejudice to the generality of the foregoing requirement, every holder of a license who for any purpose engaged in the culture or manipulation of pathogenic spore-bearing microorganisms shall provide to the satisfaction of the licensing authority separate laboratories and utensils and apparatus required for the culture or manipulation of such microorganisms, the laboratories, utensils and apparatus so provided not being used for the manufacture of any other substance.
- b. The licensee shall provide and maintain staff, premises and equipment.
- c. The licensee shall maintain records of manufacture as per particulars given in Schedule U.
ii. The licensee shall either in his own laboratory or in any laboratory approved by the licensing authority test each batch or lot of the raw material used by him for the manufacture of his product and also each batch of the final product and shall maintain records or registers showing the particulars in respect of such tests as specified in Schedule U. The records or registers shall be retained in the case of a substance for which a potency date is fixed for a period of two years from the expiry of such date, and in the case of other substances for a period of 5 years from the date of manufacture.
- d. The licensee shall allow an inspector appointed under the act to enter, with or without prior notice, any premises where the manufacture is carried on and to inspect the premises, and in the case of substances specified in Schedules C and C₁, to inspect the plant and the process of manufacture and the means employed for standardizing and testing the substance.
- e. The licensee shall allow an inspector appointed under the act, to inspect all registers and records maintained under these rules and to take samples of the manufactured product and shall supply to such Inspector such information as he may require for the purpose of ascertaining whether the provisions of the act and rules thereunder have been observed.
- f. The licensee shall from time to time report to the licensing authority any changes in the expert staff responsible for the manufacture or testing of the substance and any material alterations in the premises or plant used for that purpose which have been made since the date of the last inspection made on behalf of the licensing authority before the issue of the license.
- g. The licensee shall on request furnish to the licensing authority, controlling authority or to such authorities as the licensing authority or the controlling authority may direct, from every batch of drug as the licensing authority or the controlling

- authority may from time to time specify, a sample of such quantity as may be considered adequate by such authority for any examination and, if so required, also furnish, full protocols of the tests which have been applied.
- h. If the licensing authority or the controlling authority so directs, the licensee shall not sell or offer for sale any batch in respect of which a sample is, or protocols are furnished under the last preceding subparagraph until a certificate authorizing the sale of the batch has been issued to him by or on behalf of the licensing authority or the controlling authority.
 - i. The licensee shall on being informed by the licensing authority or the controlling authority that any part of any batch of the substance has been found by the licensing authority or the controlling authority not to conform with the standards of strength, quality or purity specified in these rules and on being directed so to do, withdraw the remainder of that batch from sale and so far as may in the particular circumstances of the case be practicable recall all issues already made from that batch.
 - j. No drug manufactured under the license shall be sold unless the precautions necessary for preserving its properties have been observed throughout the period after manufacture.
 - k. The licensee shall comply with the provisions of the act and of these rules and with such further requirements, if any, as may be specified in any rules subsequently made under Chapter IV of the Act, provided that where such further requirements are specified in the rules, these would come into force four months after publication in the official gazette.
 - l. The licensee shall maintain an inspection book in Form 35 to enable an inspector to record his impression and defects noticed.
 - m. The licensee shall maintain reference samples from each batch of the drugs manufactured by him in a quantity which is at least twice the quantity of the drug required to conduct all the tests performed on the batch. In case of drugs bearing an expiry date on the label, the reference samples shall be maintained for a period of three months beyond the date of expiry of potency. In case of drugs where no date of expiry is specified on the label the reference samples shall be maintained for a period of three years from the date of manufacture.
 - n. The licensee, who has been granted a license in Form 28-B shall forward to the licensing authority of the concerned states of manufacture and supply of the drug a statement of the sales effected to manufacturers, wholesalers, retailers, hospitals, dispensaries and nursing homes and registered medical practitioners every three months. He should also maintain accounts of all transactions giving details as indicated below in a register bound and serially page numbered and such records shall be retained for a period of five years or one year after the expiry of potency, whichever is later:
- A. Accounts of the Drugs Specified in Schedule X used for the Manufacture*
1. Date of issue.
 2. Name of the drug.
 3. Opening balance of stock on the production day.
 4. Quantity received, if any, and source from where received.
 5. Quantity used in manufacture.
 6. Balance quantity on hand at the end of the production day.
 7. Signature of the person in-charge.

B. Accounts of Production

1. Date of manufacture.
2. Name of the drug.
3. Batch number.
4. Quantity of raw material used in manufacture.
5. Anticipated yield.
6. Actual yield.
7. Wastage.
8. Quantity of the manufactured goods transferred.

C. Accounts of the Manufactured Drugs

1. Date of manufacture.
2. Name of the drug.
3. Batch number.
4. Opening balance.
5. Quantity manufactured.
6. Quantity sold.
7. Name of the purchaser and his address.
8. Balance quantity at the end of the day.
- o. The licensee shall store drugs specified in Schedule X in bulk from and when any of such drug is required for manufacture in a place other than its place of storage it shall be kept in a separate place under the direct custody of a responsible person.
- p. The licensee shall comply with the requirements of 'Good Manufacturing Practices' as laid down in Schedule M.

III. MANUFACTURE FOR EXAMINATION, TEST OR ANALYSIS

Manufacture of drugs for the purpose of examination, test or analysis: A license is required to the manufacture of any drug in small quantity for the purpose of examination, test or analysis. If a person proposing to manufacture does not hold a license to manufacture drugs specified in Schedules C and C₁ or to manufacture drugs other than those specified in Schedules C, C₁ and X, he shall obtain a license in Form 29 before commencing such manufacture. In case of drugs not specified as safe

for use, a license in Form 29 can be granted only on producing a no objection certificate (NOC) from the licencing authority appointed by the Central Government, application should be made by or countersigned by the head of institution or director of the firm or company which proposes to undertake manufacture. The license remains valid for periods of one year at a time.

The provisions related to the prohibition of manufacture and sale of certain drugs and cosmetics under the act shall not apply to the manufacture of any drug in small quantities for the purpose of examination, test or analysis if the conditions prescribed in this part are fulfilled.

Any drug manufactured for the purpose of examination, test or analysis shall be kept in containers bearing labels indicating the purpose for which it has been manufactured. If any drug manufactured for the purpose of examination, test or analysis is supplied by the manufacturer to any other person, the container shall bear a label on which shall be stated the name and address of the manufacturer, the accepted scientific name of the substance if known, or if not known a reference which will enable the substance to be identified and the purpose for which it has been manufactured.

Application for a license: An application for a license in Form 29 shall be made to the Licensing Authority appointed by the State Government for the purpose of this part (hereafter in this part referred to as the licensing authority) in Form 30 and shall be made by or countersigned by the head of the institution in which, or a director of the firm or company by which, the substance will be manufactured. Every application in Form 29 shall be accompanied by a fee of rupees 250.

Conditions of License

A license in Form 29 shall be subject to the following conditions:

- a. The licensee shall use the drugs manufactured under the license exclusively for purpose of examination, test or analysis, and shall carry on the manufacture and examination, test or analysis at the place specified in the license.
- b. The licensee shall allow any inspector appointed under the act to enter, with or without notice, the premises where the drugs are manufactured and to satisfy himself that only examination, test or analysis work is being conducted.
- c. The licensee shall keep a record of the quantity of drugs manufactured for examination, test or analysis and of any person or persons to whom the drugs have been supplied.
- d. The licensee shall comply with such further requirements, if any, applicable to the holders of licenses in Form 29 as may be specified in any Rules subsequently made under the Act and of which the licensing authority has given him not less than one month's notice.
- e. The licensee shall maintain an inspection book to enable an inspector to record his impressions and defects noticed.

Duration of license: A license in Form 29 shall, unless sooner cancelled, be in force for a period of one year from the date of issue, and may thereafter be renewed for periods of one year at a time.

Cancellation of licenses: The licensing authority may after giving the licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the persons therefore, cancel a license issued under this part, either wholly or in respect of some of the substances to which it relates, if in his opinion, the licensee has failed to comply any of the conditions of the license or with any provisions of the act or rules thereunder. A licensee whose license has been suspended or cancelled may appeal to the State

Government within three months of the date of the order.

IV. LOAN LICENSE TO MANUFACTURE OF DRUGS

A loan license means a license which a licensing authority may issue to an applicant who does not have his own arrangements for manufacture but who intends to avail himself of the manufacturing facilities owned by a licensee in Form 25.

For the purpose of issuing loan licenses to manufacture for sale or for distribution of drugs are divided into following categories:

- Drugs other than those specified in Schedules C and C₁ the license shall be issued in Form 25-A.
- Drugs specified in Schedules C and C₁ the license shall be issued in Form 28-A.

A. DRUGS OTHER THAN THOSE SPECIFIED IN SCHEDULES C AND C₁

Application for the grant or renewal of loan licenses: There are provisions in the act for the grant of license for the manufacture of drugs to applicant who do not have their own arrangements for the manufacture of drugs, who wish to avail of the facilities existing with another person licensed to manufacture drugs. Loan licenses are issued for the manufacture, for sale or distribution of drugs other than those specified in Schedules C, C₁ and X. Application for grant or renewal of such loan license shall be made in Form 24-A and the license shall be issued in Form 25-A.

B. DRUGS SPECIFIED IN SCHEDULES C AND C₁

Applications for the grant or renewal of loan licenses for the manufacture for sale or for distribution of drugs specified in Schedules C and C₁ excluding those specified in Part X-B (requirements for the collection, storage, processing and distribution of whole human blood, human blood components by blood banks and manufacture of blood products) and

Schedule X shall be made in Form 27-A to the licensing authority and shall be made upto ten items for each category of drugs categorized in Schedule M and Schedule M-III and shall be accompanied by a fee of rupees six thousand and an inspection fee of rupees 1500 for every inspection or for the purpose of renewal of licenses. License shall be issued in Form 28-A.

Conditions for the grant of renewal of loan license in Form 25-A or Form 28-A: A loan license to manufacture for sale or for distribution or drugs other than those specified in Schedules C, C₁ and X shall be issued in Form 25-A. A loan license to manufacture for sale or for distribution drugs specified in Schedules C and C₁ excluding the drugs, specified in Schedule X shall be issued in Form 28-A.

Before a license is granted or renewed, the applicant shall, while applying for a license to manufacture patent or proprietary medicines, furnish to the licensing authority evidence and date justifying that the patent or proprietary medicines:

1. Contain the constituent ingredients in therapeutic/prophylactic quantities as determined in relation to the claims or conditions for which the medicines are recommended for use or claimed to be useful.
2. Are safe for use in the context of the vehicles, recipients, additives and pharmaceutical aids used in the formulations and under conditions in which the formulations for administration and use are recommended.
3. Are stable under the conditions of storage recommended.
4. Contain such ingredients and in such quantities for which there is therapeutic justification.

Conditions of License in Form 25-A or Form 28-A

- a. The license in Form-25-A or Form 28-A, shall be deemed to be cancelled or suspended, if

the license owned by the licensee in Form-25 or Form-28, whose manufacturing facilities have been availed of by the licensee, is cancelled or suspended, as the case may be, under these Rules.

- b. The licensee shall comply with the provisions of the act and of these rules and with such further requirements if any, as may be specified in any rules subsequently made under Chapter IV of the act provided that where such further requirements are specified in the rules, these would come into force 4 months after publication in the official gazette.
- c. The licensee shall test each batch or lot of the raw material used by him for the manufacture of his products and also each batch of the final product and shall maintain records or registers showing the particulars in respect of such tests as specified in Schedule U.

The records or registers shall be retained for a period of five years from the date of manufacture. The licensee shall allow an Inspector to inspect all registers and records maintained under these rules and shall supply to the Inspector such information as he may require for the purpose of ascertaining whether the provisions of the act and these Rules have been observed.

- d. The licensee shall either:
 - i. Provide and maintain, to the satisfaction of the licensing authority adequate staff and adequate laboratory facilities for carrying out test of the strength, quality and purity of the substances manufactured by him.
 - ii. Make arrangements with some institution approved by the licensing authority under Part XV-A (approval of institutions for carrying out tests on drugs, cosmetics and raw materials used in their manufacture on behalf of licensees for manufacture for sale of drugs/cosmetics)

of these Rules for such tests to be regularly carried out on his behalf by the institution.

- e. The licensee shall maintain reference samples from each batch of the drugs manufactured by him in a quantity which is atleast twice the quantity of the drug required to conduct all the tests performed on the batch. In case of drugs bearing an expiry date on the label the reference samples shall be maintained for a period of three months beyond the date of expiry of potency. In case of drugs where no date of expiry of potency is specified on the label, the reference samples shall be maintained for a period of three years from the date of manufacture.
- f. The licensee shall maintain an inspection book in Form 35 to enable an inspector to record his impressions and the defects noticed.

V. REPACKING LICENSES

The term 'repacking' means the process of breaking up any drug from a bulk container into small package and the labelling of each such package with a view to its sale and distribution, but does not include the compounding or dispensing or the packing of any drug in the ordinary course of the retail business.

As stated earlier a license is required for the repacking of drugs other than those specified in Schedules C and C₁. License for repacking of the drugs can be had on application to the licencing authority just like other manufacturing license.

Application for grant or renewal of license to manufacture for sale or for distribution of drugs, other than those specified in Schedules C and C₁ excluding those specified in Schedule X shall be made to the licensing authority appointed by the State Government for the purpose of this part and shall be made in Form 24-B for repacking of drugs for sale or distribution. License shall be granted in Form 25-B.

Conditions for the grant or renewal of a license in Form 25-B.

Before a license in Form 25-B is granted or renewed the following conditions shall be complied with by the applicant:

- 1. The repacking operation shall be carried out under hygienic conditions and under the supervision of a competent person.
- 2. The factory premises shall comply with the conditions prescribed in Schedule M.
- 3. The applicant shall have adequate arrangements in his own premises for carrying out tests for the strength, quality and purity of the drugs at a testing unit which shall be separate from the repacking unit.

The repacking units, which before the commencement of the Drugs and Cosmetics (2nd amendment) Rules, 1977, were making arrangements with institutions approved by the licensing authority for such tests to be carried out on their behalf, may continue such arrangements upto the 31st July, 1977.

Provided that for tests requiring sophisticated instrumentation techniques or biological or microbiological methods the licensing authority may permit such test to be conducted by institutions approved by it under Part XV-A of these rules for this purpose.

A person who satisfies the following minimum qualifications shall be deemed to be a "competent person" for the purposes of Rules 71-A or 74-A of these rules, namely:

- a. A person who holds the diploma in pharmacy approved by the Pharmacy Council of India under the Pharmacy Act, 1948 or a person who is registered under the said act.
- b. A person who has passed the intermediate examination with chemistry as one of the principal subjects or an examination equivalent to it or an examination recognized by the licensing authority as equivalent to it.
- c. A person who has passed the matriculation examination or an examination recognized by the licensing authority as equivalent to

it and has had not less than four years practical experience in the manufacture, dispensing or repacking of drugs.

Conditions of License

A license in Form 25-B shall be subject to the conditions stated therein and to the following conditions:

- a. The repacking of drugs shall at all times be conducted under the personal supervision of at least one person who is approved as a competent person by the licensing authority.
- b. The licensee shall either provide and maintain adequate arrangements in his own premises for carrying out tests of the strength, quality and purity of the drugs repacked or make arrangements with some institution approved by the licensing authority under Part XV-A of these rules for such tests to be regularly carried out on his behalf by the institution.
- c. The licensee shall make adequate arrangements for the storage of drugs.
- d. The licensee shall comply with the provisions of the act and of these rules and with such further requirements, if any, as may be specified in any rules subsequently made under Chapter IV of the act.

Provided that where such further requirements are specified in the rules, these would come into force four months after publication in the official gazette.

- e. The licensee shall allow any inspector appointed under the act to enter with or without notice, any premises where the packing of drugs in respect of which the license is issued is carried on, to inspect the premises and to take samples of repacked drugs.
- f. The licensee shall, either in his own laboratory or, in any other laboratory approved by the licensing authority, test each batch or lot of raw material used by him for

repacking and also each batch of the product thus repacked and shall maintain records or registers showing the particulars in respect of such tests as specified in Schedule U. The records or registers shall be retained for a period of five years from the date of repacking. The licensee shall allow the Inspector to inspect all registers and records maintained under these rules and shall supply to the Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and these Rules have been observed.

- g. The licensee shall maintain an inspection book, in Form 35, to enable an inspector to record his impressions and the defects noticed.
- h. The licensee shall maintain reference samples from each batch of the drugs manufactured by him in a quantity which is at least twice the quantity of the drug required to conduct all the tests performed on the batch. In case of drugs bearing an expiry date on the label, the reference sample shall be maintained for a period of three months beyond the date of expiry of potency. In case of drugs where no date of expiry of potency is specified on the label, the reference samples shall be maintained for a period of 3 years from the date of manufacture.

VI. MANUFACTURE OF WHOLE HUMAN BLOOD AND COMPONENTS FOR SALE OR DISTRIBUTION

In this part:

"Blood" means and includes whole human blood, drawn from a donor and mixed with an anticoagulant.

"Blood component" means a drug prepared, obtained, derived or separated from a unit of blood drawn from a donor.

"Blood products" means a drug manufactured or obtained from pooled plasma of blood by fractionation, drawn from donors.

"Blood bank" means a place or organization or unit or institution or other arrangements made by such organization, unit or institution for carrying out all or any of the operations, for collections, apheresis, storage, processing and distribution of blood drawn from donors and/or for preparation, storage and distribution of blood components.

Application for grant/renewal of license for the operation of a blood bank for processing of whole blood and/or preparation of blood components shall be made in Form 27-C and application for grant/renewal of license to manufacture blood products for sale or distribution shall be made in Form 27-E. The respective license shall be issued in Form 28-C or Form 28-E.

License fees of ₹ 6,000 and an inspection fees of ₹ 1,500 for every inspection thereof or for the purpose of renewal of license shall be paid.

If the applicant applies for renewal of license after the expiry but within 6 months of such expiry the fee payable for the renewal of the licensee shall be rupees 6,000 and inspection fees of rupees one thousand and five hundred plus an additional fees at the rate of rupees one thousand per month or a part thereof in addition to the inspection fee.

A fee of ₹ 1,000 shall be paid for a duplicate copy of license issued under this rule, if the original is defaced, damaged or lost. Application by licensee to manufacture additional drugs listed in the application shall be accompanied by a fee of rupees 300 for each drug listed in the application.

On receipt of the application for the grant or renewal of such license, the Licensing Authority shall:

- i. Verify the statements made in the application form.
- ii. Inspect the manufacturing and testing establishment in accordance with the provisions of Rules 122-I.

- ii. In case the application is for renewal of license, information of past performance of the licensee shall be verified.

If the licensing authority is satisfied that the applicant is in position to fulfill the requirements laid down in the rules, he shall prepare a report to that effect and forward it along with the application and the license (in triplicate) to be granted or renewed, duly completed to the central license approving authority.

If the licensing authority is of the opinion that the applicant is not in a position to fulfill the requirements laid down in these rules, he may, by order, for reason to be recorded in writing, refuse to grant or renew the license, as the case may be.

Conditions for the grant or renewal of such license: Form of license for the operation of a blood bank/processing of whole human blood for components and manufacture of blood products and the conditions for the grant or renewal of such license. A license for the operation of a blood bank or for processing whole human blood for components and manufacture of blood products shall be issued in Form 28-C or Form 28-E or Form 26-G or Form 26-I.

Before a license in Form 28-C or Form 28-E or Form 26-G or Form 26-I is granted or renewed the following conditions shall be complied with by the applicant:

1. The operation of the blood bank and/or processing of whole human blood for components/manufacture of blood product shall be carried out under the active direction and personal supervision of competent technical staff consisting of at least one person who is whole time employee and who is a medical officer and possessing:
 - a. Postgraduate Degree in Medicine-M.D. (pathology/transfusion medicines).
 - b. Degree in Medicine (M.B.B.S.) with Diploma in Pathology or transfusion

medicine having adequate knowledge in blood group serology, blood group methodology and medical principles involved in the procurement of blood and/or preparation of its components.

- c. Degree in Medicine (M.B.B.S.) having experience in blood bank for one year during regular service and also has adequate knowledge and experience in blood group serology, blood group methodology and medical principles involved in the procurement of blood and/or preparation of its components.

The Degree or Diploma being from a University recognized by the Central Government explanation for the purpose of this condition, the experience in blood bank for one year shall not apply in the case of persons who are approved by licensing authority and/or central license approving authority prior to the commencement of the Drugs and Cosmetics (amendment) Rules, 1999.

2. The applicant shall provide adequate space, plant and equipment for any or all the operations of blood collection or blood processing. The space, plant and equipment required for various operation is given in schedule 'F', Part XII-B and or XII-C.
3. The applicant shall provide and maintain adequate technical staff as specified in schedule 'F', Part XII-B and/or XII-C.
4. The applicant shall provide adequate arrangements for storage of whole human blood, human blood components and blood products.
5. The applicant shall furnish to the licensing authority, if required to do so, data on the stability of whole human blood, its components or blood products which are likely to deteriorate, for fixing the date of expiry which shall be printed on the labels of such products on the basis of the data so furnished.

Duration of license: An original license in Form 28-C or Form 28-E or a renewed license in Form 28-G or Form 28-I unless sooner suspended or cancelled shall be valid for a period of five years from the date on which the year in which it is granted or renewed.

Conditions of License

"A license in Form 28-C, Form 28-E shall be subject to the special conditions set out in Schedule F, Part XII-B and Part XII-C, as the case may be, which relate to the substance in respect of which the license is granted or renewed and to the following general conditions, namely":

- 1a. The licensee shall provide and maintain adequate staff, plant and premises for the proper operation of a blood bank for processing whole human blood, its components and/or manufacture of blood products.
- b. The licensee shall maintain staff, premises and equipments as specified in Rule 122-G. The licensee shall maintain necessary records and registers as specified in Schedule F, Part XII-B and Part XII-C.
- c. The licensee shall test in his own laboratory whole human blood, its components and blood products and maintain records and registers in respect of such tests as specified in Schedule F, Part XII-B and Part XII-C. The records and registers shall be maintained for a period of 5 years from the date of manufacture.
- d. The licensee shall maintain/preserve reference sample and supply to the inspector the reference sample of the whole human blood collected by him in adequate quantity to conduct all the prescribed tests.
2. The licensee shall allow an inspector appointed under the act to enter, with or without prior notice, any premises where the activities of the blood bank are being carried out, for the processing of whole human blood and/or blood products, to

inspect the premises and plant and the process of manufacture and the means employed for standardizing and testing the substance.

3. The licensee shall allow an Inspector appointed under the act to inspect all registers and records maintained under these rules and to take samples of the manufactured product and shall supply to Inspector such information as he may require for the purpose of ascertaining whether the provisions of the act and rules thereunder have been observed.
4. The licensee shall from time to time report to the licensing authority any changes in the expert staff responsible for the operation of a blood bank/processing of whole human blood for components and/or manufacture of blood products and any material alterations in the premises or plant used for that purpose which have been made since the date of last inspection made on behalf of the Licensing Authority before the grant of the license.
5. The licensee shall on request furnish to the licensing authority, or central license approving authority or to such authority as the licensing authority, or the central license approving authority may direct, from any batch unit of drugs as the licensing authority or the central license approving may from time to time specify, sample of such quantity as may be considered adequate by such authority for any examination and, if so required, also furnish full protocols of the test which have been applied.
6. If the licensing authority or the central license approving authority so directs, the licensee shall not sell or offer for sale any batch/unit in respect of which a sample is, or protocols are furnished under the last preceding sub-paragraph until a certificate authorizing the sales of batch/unit has been issued to him by or on behalf of the licensing authority or the central license approving authority.
7. The licensee shall on being informed by the licensing authority or the controlling authority that any part of any batch/unit of the substance has been found by the licensing authority or the central license approving authority not to conform with the standards of strength, quality or purity specified in these rules and on being directed to do so, withdraw, from sales and so far as may in the particular circumstances of the case be practicable recall all issues already made from that batch unit.
8. No drug manufactured under the license shall be sold unless the precautions necessary for preserving its properties have been observed throughout the period after manufacture. Further no batch/unit manufactured under this license shall be supplied/distributed to any person without prescription of registered medical practitioner.
9. The licensee shall comply with the provisions of the act and of these rules and with such further requirements, if any, as may be specified in any rules subsequently made under Chapter IV of the act, provided that where such further requirements are specified in the rules, these would come in force four months after publication in the official gazette.
10. The licensee shall maintain an inspection book in Form 35 to enable an inspector to record his impressions and defects noticed.
11. The licensee shall destroy the stocks of batch/unit which does not comply with standard tests in such a way that it would not spread any disease/infection by way of proper disinfection method.
12. All bio-medical waste shall be treated, disposed off or destroyed as per the

provisions of the Bio-medical Wastes (Management and Handling) Rules, 1996.

The licensee shall neither collect blood from any professional donor or paid donor nor shall he prepare blood components and/or manufacture blood products from the blood drawn from such a donor.

VII. MANUFACTURE OF NEW DRUGS

The application for any new drugs including their fixed dose combinations should be accompanied by data as specified in Schedule Z.

SOME OTHER PROVISIONS RELATED TO THE MANUFACTURE OF DRUGS

A. Cancellation and suspension of licenses:

1. The central license approving authority may, after giving the licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefore, cancel a license issued under this part, or suspend it for such period as he thinks fit either wholly or in respect of any of the drugs to which it relates or direct the licensee to stop manufacture, sale or distribution of the said drugs and an Inspector, if in his opinion, the licensee has failed to comply with any of the conditions of the licensee or with any provisions of the act or rules made thereunder.
2. The licensing authority may, for such licenses granted or renewed by him, after giving the licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reason therefor, cancel a license issued under this Part or suspend it for such period as he thinks fit, either wholly or in respect of some of the substances to which it relates, or direct the licensee to stop manufacture, sale or distribution of the said drugs and an Inspector if, in his opinion, the licensee has failed to comply with any of the conditions

of the license or with any provision of the act or rules thereunder.

3. A licensee whose license has been suspended or cancelled by the central license approving authority or licensing authority under sub-rule (1) or sub-rule (2) as the case maybe, may within ninety days of the receipt of a copy of the order by him prefer an appeal to the Central Government or the State Government, as the case may be, and the Central Government or the State Government may after giving the licensee an opportunity of being heard, confirm, reverse or modify such order.

B. *Power of Central Government to prohibit manufacture of drug and cosmetic in public interest:* Without prejudice to any other provision contained in this chapter, if the central government is satisfied, that the use of any drug or cosmetic is likely to involve any risk to human beings or animals or that any drug does not have the therapeutic value claimed or purported to be claimed for it or contains ingredients and in such quantity for which there is no therapeutic justification and that in the public interest it is necessary or expedient so to do, then, that government may, by notification in the official gazette, prohibit the manufacture, sale or distribution of such drug or cosmetic.

C. *Prohibition for the manufacture for sale of cyclamates and preparations containing cyclamates:* No person shall manufacture for sale cyclamates and preparations containing cyclamates.

D. *Disclosure of the name of the manufacturer:* Every person, not being the manufacturer of a drug or cosmetic or his agent for the distribution thereof, shall, if so required, disclose to the inspector the name, address and other particulars of the person from whom he acquired the drug or cosmetic.

E. *Persons bound to disclose place where drugs or cosmetics are manufactured or kept:* Every person for the time being in-charge of any

premises whereon any drug or cosmetic is being manufactured or is kept for sale or distribution shall, on being required by an inspector so to do, be legally bound to disclose to the inspector the place where the drug or cosmetic is being manufactured or is kept, as the case may be.

F. Maintenance of records and furnishing of information: Every person holding a license under this act shall keep and maintain such records, registers and other documents as may be prescribed and shall furnish to any officer or authority exercising any power or discharging any function under this act such

information as is required by such officer or authority for carrying out the purposes of this act.

G. Confiscation of drugs, implements, machinery: Where any person has been convicted for contravening any of the provisions of Chapter IV (provisions related to the manufacture, sale and distribution of drugs and cosmetics) of the act or any rule made thereunder, the stock of the drug in respect of which the contravention has been made shall be liable to confiscation. Where any person has been convicted for the manufacture of any drug deemed to be misbranded, or adulterated drug,

Sale Applications, Licenses, Fees and Penalty

S.No.	Category	Type sale	Application form	License form	Fees for grant/renewal	Fee + penalty after expiry but within six months
1.	Drugs other than those specified in Schedules C and C ₁ and X	Wholesale	19	20-B	₹ 1500	₹ 1500 + ₹ 500 p.m. or part thereof
		Retail sale	19	20	₹ 1500	₹ 1500 + ₹ 500 p.m. or part thereof
		Restricted (gen. store)	19-A	20-A	₹ 500	₹ 500 + ₹ 250 p.m. or part thereof
2.	Drugs specified in Schedules C and C ₁ but excluding those specified in Schedule 'X'	Wholesale	19	21-B	₹ 1500	₹ 1500 + ₹ 500 p.m. or part thereof
		Retail sale	19	21	₹ 1500	₹ 1500 + ₹ 500 p.m. or part thereof
		Restricted (gen. store)	19-A	21-A	₹ 500	₹ 500 + ₹ 250 p.m. or part thereof
3.	Drugs specified in Schedule 'X'	Wholesale	19-C	20-G	₹ 500	₹ 500 + ₹ 250 p.m. or part thereof
		Retail sale	19-C	20-F	₹ 500	₹ 500 + ₹ 250 p.m. or part thereof
4.	Sale of drugs from motor vehicles					
	1. Drugs other than those specified in Schedules C and C ₁	Wholesale	19-AA	20-BB	₹ 500	₹ 500 + ₹ 250 p.m. or part thereof
	2. Drugs specified in Schedules C and C ₁	Wholesale	19-AA	21-BB	₹ 500	₹ 500 + ₹ 250 p.m. or part thereof

Fees for duplicate copy of org. Lic.:—₹ 150

or for manufacture for sale, or stocking or exhibiting for sale or distribution of any drug without a valid license, any implements or machinery used in such manufacture, sale or distribution and any receptacle, packages, or coverings in which such drug is contained and the animals, vehicles, vessels or other conveyances used in carrying such drug shall also be liable to confiscation.

SALE OF DRUGS

Sale of drug is a technical job, which requires persons with specialized training. A sale is the pinnacle activity involved in the selling products or services in return for money or other compensation. It is an act of completion of a commercial activity.

"Sale" or "Sell" includes barter and exchange and also includes offering or attempting to sell or causing or allowing to be sold or exposing for sale or receiving or sending or delivering for sale or having in possession for sale or having in possession any drug knowing that the same is likely to be sold or offered or exposed for sale, and refers only to sale for human consumption or use.

The seller, the provider of the goods or services that completes a sale in response to an acquisition or to an appropriation or to a request.

"Dealer" means a person carrying on the business of purchase or sale of drugs, whether as a wholesaler or retailer and whether or not in conjunction with any other business and includes his agent.

"Distributor" means a distributor of drugs or his agent or a stockiest appointed by a manufacturer or an importer for stocking his drugs for sale to a dealer.

"Retailer" means a dealer carrying on the retail business of sale of drugs to customer.

"Wholesaler" means a dealer or his agent or a stockiest appointed by a manufacturer or an importer for the sale of his drugs to a retailer, hospital, dispensary, medical, educational or

research institution purchasing bulk quantities of drugs.

Sale of drugs can be by way of

- **Wholesale** from the stockiest to the shopkeeper.
- **Retail sale** from the shopkeepers to the patient.

After the enforcement of D and C Act, 1940, the sale of drugs has become a restricted practice and only those persons who have been granted license by the licencing authorities of the state can engage themselves in the wholesale, retail compounding or dispensing of drugs.

For the purpose of issuing sale license, the drugs have been divided into the following categories:

- Drugs other than those specified in Schedules C and C₁ and X.
- Drugs specified in Schedules C and C₁ Excluding those specified in Schedule X.
- Drugs specified in Schedule X.

The license are granted for retail or wholesale with respect to all the above categories. A license for the sale of drugs remains valid up to 31st December of the year in which the license is granted or renewed.

Applications for the Grant of a License

Applications for the grant or renewal of a license to sell, stock, exhibit or offer for sale or distribute drugs:

1. The State Government shall appoint licensing authorities for the purpose of sale of drugs other than homoeopathic medicines for such areas as may be specified.
2. Applications for the grant or renewal of a license to sell, stock, exhibit or offer for sale or distribute drugs, other than those included in Schedule X, shall be made in Form 19 accompanied by a fee of ₹ 1,500 or Form 19-A accompanied by a fee of ₹ 500, as the case may be, or in the case of drugs included in Schedule X shall be made in

Form 19-C accompanied by a fee of 500 rupees, to the licensing authority.

In the case of an itinerant vendor or an applicant who desires to establish a shop in a village or town having population of 5,000 or less, the application in Form 19-A shall be accompanied by a fee of ₹ 10.

3. A fee of 150 rupees shall be paid for a duplicate copy of a license to sell, stock, exhibit or offer for sale or distribute drugs, other than those included in Schedule X, or for a license to sell, stock, exhibit or offer for sale or distribute drugs, included in Schedule X, if the original is defaced, damaged or lost.

In the case of itinerant vendor or an applicant who desires to established a shop in a village or town having a population of 5,000 or less, the fee for a duplicate copy of a license if the original is defaced, damaged or lost, shall be ₹ 2.

4. Application for renewal of a license to sell, stock, exhibit or offer for sale or distribute drugs, after its expiry but within 6 months of such expiry shall be accompanied by a fee of ₹ 1,500 plus an additional fee at the rate of 500 rupees per month or part thereof in Form 19, ₹ 500 plus an additional fee at the rate of ₹ 250 per month or part thereof in Form 19-A and ₹ 500 plus an additional fee at the rate of ₹ 250 per month or part thereof in Form 19-C.

In the case of an itinerant vendor or an applicant desiring to open a shop in a village or town having a population of 5,000 or less the application for such renewal shall be accompanied by a fee of ₹ 10, plus an additional fee at the rate of ₹ 8 per month or part thereof.

RETAIL SALE

"Retail Sale" means a sale to a purchaser for the purpose of consumption or use and not for resale.

The premises that are licensed for the retail sale of drugs are:

- Drugs stores (which do not have a qualified person).
 - Chemists and druggists (which have a qualified person).
 - Pharmacy, pharmacist, dispensing chemist.
- For retail sale two types of license are granted:
- General license
 - Restricted license

General license is granted to persons who have premises for the business and who engage the services of a 'qualified persons' to supervise the sale of drugs and do the compounding and dispensing.

LICENSES FOR RETAIL SALE

A. General License

For the purpose of issuing General Licenses for retail sale the drugs are divided into following categories:

- Drugs other than those specified in Schedules C and C₁ and X, license shall be issued in Form 20.
- Drugs specified in Schedules C and C₁ but excluding those specified in Schedule 'X', license shall be issued in Form 21.
- Drugs specified in Schedule 'X', license shall be issued in Form 20-F.

I. Drugs Other than those Specified in Schedules C and C₁ and X

General license to sell, stock or exhibit or offer for sale, or distribute drugs by retail other than those specified in Schedules C, C₁ and X.

II. Drugs Specified in Schedules C and C₁, but Excluding those Specified in Schedule 'X'

License to sell, stock or exhibit or offer for sale, distribute by retail drugs specified in Schedules C and C₁ excluding those specified in Schedule X.

III. Drugs Specified in Schedule 'X'

License to sell, stock or exhibit for sale or distribute by retail drugs specified in Schedule X.

Conditions for the Grant of General License to Retail Sale

Conditions to be satisfied before a license in Form-20, Form 20-F or 21 are granted:

1. A General license to sell, stock, exhibit or offer for sale or distribute drugs shall not be granted or renewed to any person unless the authority empowered to grant the license is satisfied that the premise in respect of which the license is to be granted or renewed are adequate, equipped with proper storage accommodation for preserving the properties of the drugs to which the license applies and are in-charge of a person competent in the opinion of the licensing authority to supervise and control the sale, distribution and preservation of drugs.

In the case of a pharmacy a license in Form-20 or 21 shall not be granted or renewed unless the licensing authority is satisfied that the requirements prescribed for a pharmacy in Schedule N have been complied with.

The license in Form 20-F shall be granted or renewed only to a pharmacy and in areas where a pharmacy is not operating, such license may be granted or renewed to a chemist and druggist.

2. In granting a license the authority empowered to grant it shall have regard to the average number of licenses granted during the period of 3 years immediately preceding, and to the occupation, trade or business ordinarily carried on by such applicant during the period of 3 years.

The licensing authority may refuse to grant or renew a license to any applicant or licensee in respect of whom it is satisfied that by reason of his conviction of an offence under the act or these rules, or the previous cancellation or suspension of any license granted thereunder,

he is not a fit person to whom a license should be granted under this rule. Every such order shall be communicated to the licensee as soon as possible.

The licensing authority shall satisfy himself that the premises in respect of which a license is to be granted are in respect of an application for the grant of a license in Form-20 or Form-21 or both, the licensing authority shall satisfy itself that the premises are of an area of not less than 10 square meters.

The provisions of the preceding proviso shall not apply to the premises for which licenses have been issued by the licensing authority before the commencement of the Drugs and Cosmetic (1st Amendment) Rules, 1997.

3. Any person who is aggrieved by the order passed by the licensing authority may, within 30 days from the date of receipt of such order, appeal to the State Government and the State Government may, after such enquiry into the matter as it considers necessary and after giving the appellant an opportunity for representing his views in the matter, make such an order in relation thereto as it thinks fit.

Conditions of the General License to Retail Sale in Form 20 or Form-21 or Form 20-F

- a. This license shall be displayed in a prominent place in a part of the premises open to the public.
- b. The licensee shall report to the licensing authority any change in the qualified staff incharge within one month of such change.
- c. No drug shall be stocked or sold unless such drug has been purchased under cash/credit memo from a duly licensed dealer or a duly licensed manufacturer.
- d. The licensee shall inform the licensing authority in writing in the event of any change in the constitution of the firm operating under the license. Where any change in the constitution of the firm takes

place, the current license shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless in the meantime, a fresh license has been taken from the licensing authority in the name of the firm with the changed constitution.

- e. The license in Form 20 for drugs other than those specified in Schedules C and C₁ and X shall comply with the provisions of the Drugs and Cosmetics Act, 1940 and the rules thereunder for the time being in force.
- f. ***License in Form 21 for drugs specified in Schedules C and C₁ but excluding those specified in Schedule 'X':*** If the licensee wants to sell, stock or exhibit for sale or distribute, during the currency of the license, additional categories of drugs listed in Schedules C and C₁ excluding those specified in Schedule X but not included in this license, he should apply to the licensing authority for the necessary permission. This license will be deemed to extend to the categories of drugs in respect of which such permission is given. This permission shall be endorsed on the license by the licensing authority.

B. Restricted Licenses

A restricted license are granted to persons who deal in sale of drugs, do not require the service of a qualified person.

For the purpose of issuing Restricted Licenses for retail sale the drugs are divided into following categories:

- Drugs other than those specified in Schedules C, C₁ and X.
- Drugs specified in Schedules C, C₁ and excluding X.

Form of License

- Restricted license to sell, stock or exhibit or offer for sale, or distribute drugs by retail other than those specified in Schedules C, C₁ and X for dealers who do not engage the

services of a qualified person should be granted in Form 20-A.

- License to sell, stock or exhibit or offer for sale distribute by retail drugs specified in Schedules C, C₁ and excluding X for dealers who do not engage the services of a qualified person should be granted in Form 21-A.
- No license is granted in this category for drugs specified in Schedule X.

Restricted Licenses shall be Issued in Forms 20-A and 21-A

- a. Restricted licenses shall be issued subject to the discretion of the licensing authority, to dealers or persons in respect of drugs whose sale does not require the supervision of a qualified person.
- b. Licenses to itinerant vendors shall be issued only in exceptional circumstances for bona fide traveling agents of firms dealing in drugs or for a vendor who purchases drugs from a licensed dealer for distribution in sparsely populated rural areas where other channels of distribution of drugs are not available.
- c. The licensing authority may issue a license in Form 21-A to a traveling agent of a firm but to no other class of itinerant vendors for the specific purpose of distribution to medical practitioners or dealers, samples of biological and other special products specified in Schedule C.

Provided that traveling agents of licensed manufacturers, agents, of such manufacturers and importers of drugs shall be exempted from taking out license for the free distribution of samples of medicines among members of the medical profession, hospitals, dispensaries and the medical institution or research institutions.

Conditions for the Grant of Restricted Licenses to Retail Sale

Conditions to be satisfied before a license in Form 20-A or Form 21-A is granted:

1. A restricted license shall not be granted to any person, unless the authority empowered to grant the license is satisfied that the premises in respect of which the license is to be granted are adequate and equipped with proper storage accommodation for preserving the properties of drugs to which the license applies. Provided that this condition shall not apply in the case of license granted itinerant vendors.
2. In granting a license the authority empowered to grant it shall have regard to:
 - i. The number of licenses granted in the locality during one year immediately preceding.
 - ii. The occupation, trade or business carried on by such applicant or licensee in respect of whom it is satisfied that by reason of his conviction of an offence under the act or these rules or the previous cancellation or suspension of any license granted thereunder, he is not a fit person to whom a license should be granted under this rule.
3. Any person who is aggrieved by the order passed by the licensing authority in sub-rule (1) may, within 30 days from the date of the receipt of such order appeal to the State Government and the State Government may, after such enquiry into the matter as it considers necessary and after giving the appellant an opportunity for representing his views in the matter make such order in relation thereto as it thinks fit.

Conditions of Restricted License to Retail Sale in Form 20-A or Form 21-A

- a. This license shall be displayed in a prominent and conspicuous place in a part of the premises open to public or shall be kept on the process of the vendor who shall produce it on demand by an Inspector or an officer authorised by the State Government in this behalf.

- b. The licensee shall comply with the provisions of the Drugs and Cosmetics Act, 1940 and the rules thereunder for the time being in force.
- c. The licensee shall deal only in such drugs as can be sold without the supervision of a "qualified person" as defined under the Drugs and Cosmetics Rules, 1945.
- d. No drug shall be sold unless such drug is purchased under cash or credit memo from duly licensed manufacturer.
- e. The licensee shall inform the licensing authority in writing in the event of any change in the constitution of the firm operating under the license. Where any change in the constitution of the firm takes place, the current license shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh license has been taken from the licensing authority in the name of the firm with the changed constitution.

WHOLESALE OF DRUGS

Wholesale means the selling of goods in relatively large quantities and usually at lower prices than at retail, esp. such selling to retailers for resale to consumers.

Wholesale of drugs means sale of drugs to the hospitals, dispensaries, medical, educational and research institutions and to the person who purchases it for selling again.

For the purpose of issuing sale license by wholesale the drugs are divided into following categories:

- Drugs other than those specified in Schedules C and C₁ and X in Form 20-B.
- Drugs specified in Schedules C and C₁ but excluding those specified in Schedule 'X' in Form 21-B.
- Drugs specified in Schedule 'X' in Form 20-G. Sale of drugs from Motor Vehicles.

- Drugs other than those specified in Schedules C and C₁ in Form 20-BB.
- Drugs specified in Schedules C and C₁ in Form 21-BB.

Conditions for a License to Sale Drugs by Wholesale

Conditions to be satisfied before a license in Forms 20-B, 20-G, or 21-B is granted:

1. A license to sell, stock, exhibit or offer for sale or distribute drugs shall not be granted or renewed to any person unless the authority empowered to grant the license is satisfied that the premise in respect of which the license is to be granted or renewed are well-equipped with proper storage accommodation for preserving the properties of the drugs to which the license applies and are in-charge of a person competent in the opinion of the licensing authority to supervise and control the sale, distribution and preservation of drugs.
2. In granting a license the authority empowered to grant it shall have regard to the average number of licenses granted during the period of 3 years immediately preceding, and to the occupation, trade or business ordinarily carried on by such applicant during the period aforesaid.

The licensing authority may refuse to grant or renew a license to any applicant or licensee in respect of whom it is satisfied that by reason of his conviction of an offence under the act or these Rules, or the previous cancellation or suspension of any license granted thereunder, he is not a fit person to whom a license should be granted under this rule. Every such order shall be communicated to the licensee as soon as possible.

3. In respect of an application for the grant of a license in Form 20-B or Form 21-B or both, the licensing authority shall satisfy himself that the premises in respect of which a wholesale license is to be granted are:

- i. Of an area of not less than ten square meters.
- ii. In the charge of a competent person, who:
 - a. Is a registered pharmacist.
 - b. Has passed the matriculation examination or its equivalent examination from a recognised board with four years of experience in dealing with sale of drugs.
 - c. Holds a degree of a recognised University with one year's experience in dealing with drugs.
4. Any person who is aggrieved by the order passed by the licensing authority may, within 30 days from the date of receipt of such order, appeal to the State Government and the State Government may, after such enquiry into the matter as it considers necessary and after giving the appellant an opportunity for representing his views in the matter, make such an order in relation thereto as it thinks fit.

CATEGORIES OF LICENSES FOR SALE OF DRUGS BY WHOLESALE

A. Drugs other than Specified in Schedules C, C₁ and X

License to sell, stock or exhibit or offer for sale, or distribute by wholesale, drugs other than specified in Schedules C, C₁ and X.

Conditions of License

The license is issued in Form 20-B is subjected to the following conditions:

1. This license shall be displayed in a prominent place in part of the premises open to the public.
2. The licensee shall comply with the provisions of the Drugs and Cosmetics Act, 1940 and the rules thereunder for the time being in force.
3. i. No drug shall be sold unless such drug is purchased under a cash or credit memo

from a duly licensed dealer or a duly licensed manufacturer.

ii. No sale of any drug shall be made to a person not holding the requisite license to sell, stock or exhibit for sale or distribute the drug.

Provided that this condition shall not apply to the sale of any drug to:

- a. An officer or authority purchasing on behalf of Government.
- b. A hospital, medical, educational or research institution or a registered medical practitioner for the purpose of supply to his patients.
- c. A manufacturer of beverages, confectional biscuits and other nonmedicinal products, where such drugs are required for processing these products.

4. The licensee shall inform the licensing authority in writing in the event of any change in the constitution of the firm operating under the license. Where any change in the constitution of the firm taken place, the current license shall be deemed to be valid for a maximum period of three months from the date on which the changes takes place unless, in the meantime, a fresh license has been taken from the licensing authority in the name of the firm with the changed constitution.

B. Drugs Specified in Schedules C and C₁ but Excluding those Specified in Schedule 'X'

License to sell, stock or exhibitor offer for sale or distribute by **wholesale** drugs specified in Schedules C and C₁ excluding those specified in Schedule X.

Conditions of License

The license is issued in Form 21-B is subjected to the following conditions:

1. This license shall be displayed in a prominent place in a part of the premises open to the public.

2. If the licensee wants to sell, stock or exhibit for sale or distribute during the currency of the license additional categories of drugs listed in Schedules C and C₁ excluding those specified in Schedule X but not included in this license. He should apply to the licensing authority for the necessary permission. This license will be deemed to extend to the categories of drugs in respect of which such permission is given. This permission shall be endorsed on the license by the licensing authority.

3. i. No drug shall be sold unless such drug is purchased under a cash or credit memo from a duly licensed dealer or a duly licensed manufacturer.
- ii. No sale of any drug shall be made for purposes of resale to a person not holding the requisite license to sell, stock or exhibit for sale or distribute the drug.

Provided that this condition shall not apply to the sale of any drug to:

- a. An officer or authority purchasing on behalf of Government.
- b. A hospital, medical, educational or research institute or a registered medical practitioner for the purpose of supply to his patients.
- c. A manufacturer of hydrogenated vegetable oils, beverages, confectionary and other nonmedicinal products, where such drugs are required for processing these products.

C. Drugs Specified in Schedule 'X'

License to sell, stock or exhibit or offer for sale, or distribute by wholesale drugs specified in Schedule X.

Conditions of the License

The license is issued in Form 20-G is subjected to the following conditions:

1. This license shall be displayed in a prominent place in a part of the premises open to the public.

2. The licensee shall comply with the provisions of the Drugs and Cosmetics Act, 1940 and the Rules made thereunder.
3. No drug shall be stocked or sold unless such drug has been purchased under a cash or credit memo from a duly licensed dealer or a duly licensed manufacturer.
4. The licensee shall forward to the licensing authority copies of the invoices of sales made to the retail dealers.
5. No sale of any drug by wholesale shall be made to a person not possessing the requisite license to sell, stock or exhibit for sale or distribute drugs specified in Schedule X.
Provided that this condition shall not apply to the sale of any drug to:
 - a. An officer or authority purchasing on behalf of government.
 - b. A hospital, medical, educational or research institution, nursing home, registered medical practitioner for the purpose of supply to its/his patients or manufacturer holding a license in Form 25-E or 28-B to manufacture the Drugs containing drug included in Schedule X.
6. The licensee shall inform the licensing authority in writing in the event of any change in the constitution of the firm operating under the license, where any change in the constitution of the firm takes place, the current license shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless in the meantime, a fresh license has been taken from the licensing authority in the name of the firm with the changed constitution.

SALE OF DRUGS FROM MOTOR VEHICLES

Application for the grant or renewal of a license to sell by wholesale or to distribute from a motor vehicle shall be made to the licensing authority in Form 19-AA and shall be accompanied by a

fee of Rs. 500. If the applicant applies for the renewal of a license after its expiry but within 6 months of such expiry, the fee payable for renewal of such license shall be ₹ 500 plus an additional fee at the rate of ₹ 250 per month or part thereof. A fee of ₹ 150 shall be paid for a duplicate copy of a license issued under this rule, if the original is defaced, damaged or lost.

A license shall be issued for sale by wholesale or for distribution from a motor vehicle of drugs other than those specified in Schedule C and Schedule C₁ in Form 20-BB and of drugs specified in Schedule C and Schedule C₁ in Form 21-BB. Provided that such a license shall not be required in a case where a public carrier or a hired vehicle is used for transportation or distribution of drug.

Categories of licenses for sale of drugs from motor vehicles under the D and C Act and Rules:

A. Drugs other than those Specified in Schedules C and C₁

License to sell, stock or exhibit or offer for sale by wholesale, or distribute drugs other than those specified in Schedule C and Schedule C₁, shall be granted in Form 20-BB to the Drugs and Cosmetics Rules, 1945 from a motor vehicle.

B. Drugs Specified in Schedules C and C₁

License to sell by wholesale or to distribute drugs specified in Schedule C and Schedule C₁, shall be granted in Form 21-BB to the Drugs and Cosmetics Rules, 1945 from a motor vehicle.

Conditions of License in Form 20-BB or Form 21-BB

The license is issued in Form 20-BB or Form 21-BB is subjected to the following conditions:

1. A license in Form 20-BB or Form 21-BB shall be displayed in prominent place on the vehicle.
2. i. No drugs shall be sold by wholesale or distributed unless such drug is purchased

- under a cash or credit memo from a duly licensed dealer or a duly licensed manufacturer.
- ii. No sale by wholesale or distribution of any drug shall be made to a person not holding the requisite license to sell, stock, or exhibit for sale or distribute the drug. Provided that this condition shall not apply to the sale of any drug to:
- An officer or authority purchasing on behalf of the government.
 - A hospital, medical, educational or research institution or a registered medical practitioner for the purpose of supply to his patients.
 - A manufacturer of beverages, confectionary, biscuits and other non-medical products where such drugs are required for processing these products.
3. The licensee shall inform the licensing authority in writing in the event of change in the constitution of the firm operating under the license. Where any change in the constitution of the firm takes place, the current license shall deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh license has been taken from the licensing authority in the name of the firm with the changed constitution.
4. The licensee shall inform the licensing authority in writing in the event of any change in ownership of the vehicle specified in this license within 7 days of such change.
5. The license in Form 20-BB shall comply with the provisions of the Drugs and Cosmetics Act, 1940 and the rules made thereunder for the time being in force.
6. In Form 21-BB, no drugs to which the license applies shall be sold by the licensing authority from time to time in the official gazette has been observed throughout the period during which it has been in the possession of the licensee.
7. In Form 21-BB, if the licensee wants to sell by wholesale or distribute during the currency of the license, additional categories of drugs listed in Schedules C and C₁ not included in this license, he shall apply to the licensing authority for necessary permission. This license shall be deemed to extend to the categories of drugs in respect of which such permission is given. This shall be endorsed on the license by the licensing authority.

OTHER PROVISIONS RELATED TO THE SALE OF DRUGS

A. Power of Licensing Authority: A licensing authority may with the approval of the State Government by an order in writing delegate the power to sign licenses and such other powers as may be specified in the order to any other person under his control.

B. Sale at more than one place: If drugs are sold or stocked for sale at more than one place, separate application shall be made, and a separate license shall be issued, in respect of each such place. Provided that this shall not apply to itinerant vendors who have no specified place of business and who will be licensed to conduct business in a particular area within the jurisdiction of the licensing authority.

C. Duration of license: An original license or a renewed license to sell drugs, unless sooner suspended or cancelled, shall be valid for a period of 5 years on and from the date on which it is granted or renewed.

If the application for renewal of license in force is made before its expiry or if the application is made within 6 months of its expiry, after payment of additional fee, the license shall continue to be in force until orders are passed on the application. The license shall be deemed to have expired if application for its renewal is not made within six months after its expiry.

D. Cancellation and suspension of licenses:

1. The licensing authority may, after giving the licensee an opportunity to show cause why such an order should not be passed by an order in writing stating the reasons therefor, cancel a license issued under this part or suspend it for such period as he thinks fit, either wholly or in respect of some of the substances to which it relates, if in his opinion, the licensee has failed to comply with any of the conditions of the license or with any provisions of the act or rules thereunder.

Provided that, where such failure or contravention is the consequence of an act or omission on the part of an agent or employee, the license shall not be cancelled or suspended if the licensee proves to the satisfaction of the licensing authority:

- a. That the Act or omission was not instigated or connived at by him or, if the licensee is a firm or company by a partner of the firm or a director of the company.
 - b. That he or his agent or employee had not been guilty of any similar act or omission within twelve months before the date on which the act or omission in question took place, or where his agent or employee had been guilty of any such act or omission the licensee had not or could not reasonably have had, knowledge of that previous act or omission.
 - c. If the Act or omission was a continuing act or omission, he had not or could not reasonable have had knowledge of that previous act or omission.
 - d. That he had used due diligence to ensure that the conditions of the license or the provisions of the act or the rules thereunder were observed.
2. A licensee whose license has been suspended or cancelled may, within 3 months of the date of order under sub-rule (1), prefer an appeal against that order to the State Government, which shall decide the same.

E. Procedure for disposal of drugs in the event of cancellation of license:

1. In case a licensee, whose license has been cancelled, desires to dispose of drugs he has in his possession in the premises in respect of which the license has been cancelled, he shall apply in writing to the licensing authority for this purpose, giving the following particulars, namely:
 - a. The name and address of the person to whom the drugs are proposed to be sold or supplied together with the number of the license for sale or manufacture as the case may be held by him.
 - b. The names of drugs together with their quantities, batch numbers, the names and addresses of their manufacturers and the dates of their expiry, if any, proposed to be sold to the person mentioned in clause (a).
2. The licensing authority may, after examination of the particulars referred to in sub-rule (1) and, if necessary, after inspection by an Inspector of the premises where the drugs are stocked, grant the necessary permission for their disposal.

**OFFENCES AND PENALTIES FOR MANUFACTURES,
SALES OF DRUGS AND COSMETICS****I. Penalty for Manufacture and Sale of Drugs**

Whoever, himself or by any other person on his behalf, manufactures for sale or for distribution, or sells, or stocks or exhibits or offers for sale or distributes:

- a. Any drug deemed to be adulterated or spurious or which when used by any person for or in the diagnosis, treatment, mitigation, or prevention of any disease or disorder is likely to cause his death or is likely to cause such harm on his body as would amount to grievous hurt within the meaning of Section 320 of the Indian Penal

Code, solely on account of such drug being adulterated or spurious or not of standard quality, as the case may be, shall be punishable with imprisonment for a term which shall not be less than 5 years but which may extend to a term of life and with fine which shall not be less than 10,000 rupees.

b. ***Any drug:***

- i. Deemed to be adulterated, but not containing any toxic or harmful substance which may render it injurious to health.
- ii. Without a valid license shall be punishable with imprisonment for a term which shall not be less than 1 year but which may extend to 3 years and with fine which shall not be less than ₹ 5,000. Provided that the court may, for any adequate and special reasons to be recorded in the judgment, impose a sentence of imprisonment for a term of less than 1 year and of fine of less than ₹ 5,000.

Penalty for subsequent offence: Whoever having been convicted of an offence under clause (b) of this section is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which shall not be less than 2 years but which may extend to 6 years with fine which shall not be less than 10,000 rupees. Provided that the court may, for any adequate and special reasons to be mentioned in the judgment, impose a sentence of imprisonment for a term of less than 2 years and of fine of less than 10,000 rupees.

- c. Any drug deemed to be spurious, but not being a drug referred to in clause (a) shall be punishable with imprisonment for a term which shall not be less than 5 years and with fine which shall not be less than 5,000 rupees. Provided that the court may, for any adequate and special reasons, to be recorded in the judgment, impose a

sentence of imprisonment for a term of less than 3 years but not less than one year.

Penalty for subsequent offence: whoever having been convicted of an offence under clause (c) of this section, is again convicted of an offence under that clause shall be punishable with imprisonment for a term which shall not be less than 6 years but which may extend to 10 years and with fine which shall not be less than 10,000 rupees.

- d. Any drug, other than a drug referred to in clause (a) or clause (b) or clause (c), in contravention of any other provision of this chapter or any rule made thereunder, shall be punishable with imprisonment for a term which shall not be less than 1 year but which may extend to 2 years and with fine. Provided that the court may, for any adequate and special reasons, to be recorded in the judgment imposes a sentence of imprisonment for a term of less than 1 year.

Penalty for subsequent offence: Whoever having been convicted of an offence under clause (d) of this section, is again convicted of an offence under that clause shall be punishable with imprisonment for a term which shall not be less than 2 years but which may extend to 4 years or with fine which shall not be less than 5,000 rupees, or both.

II. Penalty for Manufacture and Sale of Cosmetics

Whoever himself or by any other person on his behalf manufactures for sale for distribution, or sells, or stocks or exhibits or offers for sale:

- i. Any cosmetic deemed to be spurious shall be punishable with imprisonment for a term which may extend to 3 years and with fine.
- ii. Any cosmetic other than a cosmetic referred to in clause (i) above in contravention of any provision of this chapter or any rule made thereunder shall be

punishable with imprisonment for a term which may extend to 1 year or with fine which may extend to 1,000 rupees or both.

Penalty for subsequent offence: Whoever, having been convicted of an offence under above section is again convicted under that section, shall be punishable with imprisonment for a term which may extend to 2 years, or with fine which may extend to 2,000 rupees, or both.

III. Penalty for Non-disclosure of the Name of the Manufacturer

Whoever not disclosing the name of the manufacturer, or the place where the manufactured drug are kept shall be punishable with imprisonment for a term which may extend to one year or with fine which may extend to 1,000 rupees or both.

IV. Penalty for not Keeping Documents and for Non-disclosure of Information

Whoever not keeping records of manufacture or sale of drugs in the special manner shall be punishable with imprisonment for a term which may extend to 1 year or with fine which may extend to 1,000 rupees or both.

V. Penalty for Manufacture of Drugs or Cosmetics in Contravention of Section 26-A (Under Section 28-B)

Whoever himself or by any other person on his behalf manufactures or sells or distributes any drug or cosmetic is likely to involve any risk to human beings or animals or that any drug does not have the therapeutic value claimed or purported to be claimed for it or contains ingredients and in such quantity for which there is no therapeutic justification shall be punishable with imprisonment for a term which may extend to 3 years and shall also be liable to fine which may extend to 5,000 rupees.

VI. Penalty for Use of Government Analyst's Report for Advertising

Whoever uses any report of a test or analysis made by the Central Drugs Laboratory or by a government analyst, or any extract from such report, for the purpose of advertising any drug or cosmetic, shall be punishable with fine, which may extend to 5,00 rupees.

Penalty for subsequent offence: Whoever, having been convicted of an offence under above section is again convicted of an offence under the same section shall be punishable with imprisonment which may extend to 10 years with fine, or both.

MISCELLANEOUS PROVISIONS RELATED TO THE MANUFACTURE AND SALE

A. Confiscation:

1. Where any person has been convicted under the provision related to manufacture and sale of drugs for contravening any such provision related to manufacture and sale of drugs or any rule made thereunder as may be specified by rule made in this behalf, the stock of the drug or cosmetic in respect of which the contravention has been made shall be liable to confiscation and if such contravention is in respect of:
 - i. Manufacture of any drug deemed to be misbranded, adulterated or spurious under the provision related to manufacture and sale of drugs.
 - ii. Manufacture for sale, or for distribution, or stocking or exhibiting or offering for sale, or distribution of any drug without a valid license as required; any implements or machinery used in such manufacture, sale or distribution and any receptacles, packages or coverings in which such drug is contained and the animals, vehicles, vessels or other conveyances used in carrying such drug shall also be liable to confiscation.

2. Without prejudice to the provisions contained in above sub-section where the court is satisfied, on the application of an Inspector or otherwise and after such inquiry as may be necessary that the drug or cosmetic is not of standard quality or is misbranded, adulterated or spurious drug or misbranded or spurious cosmetic, such drug or, as the case may be, such cosmetic shall be liable to confiscation.
- B. *Cognizance of offence:* No prosecution under the provision related to manufacture and sale of drugs shall be instituted except by an Inspector or by the person aggrieved or by a recognised consumer association whether such person is a member of that association or not. No court inferior to that of a metropolitan magistrate or of a Judicial Magistrate of the first class shall try an offence punishable under the provision related to manufacture and sale of drugs. Nothing contained in this chapter shall be deemed to prevent any person from being prosecuted under any other law for any act or omission which constitutes an offence against this chapter.
- C. *Exemption:* The drugs specified in Schedule K shall be exempted from the provisions of Chapter IV (provisions related to the manufacture, sale and distribution of drugs and cosmetics) of the act and the rules made thereunder to the extent and subject to the conditions specified in that Schedule.
- DISPENSING AND COMPOUNDING OF DRUGS AND SUPPLY OF DRUGS**
- Dispensing and Compounding of Drugs**
- Any drug shall, if compounded or made on the licensee's premises be compounded or made under the direct and personal supervision of a registered pharmacist.
1. For the purpose of this rule the term 'Pharmacy' shall be held to mean to include every store or shop or other place:
- a. Where drugs are dispensed, that is, measured or weighed or mode up and supplied?
- b. Where prescriptions are compounded?
- c. Where drugs are prepared. or
- d. Which has upon it or displayed within it, or affixed to or used in connection with it, a sign bearing the word or words "pharmacy", "pharmacist," "dispensing chemist" or "pharmaceutical chemist"?
- e. Which, by sign, symbol or indication within or upon it gives the impression that the operations mentioned at (1), (2) and (3) are carried out in the premises?
- f. Which is advertised in terms referred to in (4) above?
2. The premises licensed for the retail sale of drugs may be described as:
- a. The description "**Drugstore**" shall be displayed by such licensees who do not require the services of a qualified person.
- b. The description "**Chemists and Drug-gists**" shall be displayed by such licensees who employ the services of a "registered pharmacist" but who do not maintain a "pharmacy" for compounding against prescriptions:
- c. The description "**Pharmacy**", "**Phar-macist**", "**Dispensing Chemist**" or "**Pharmaceutical Chemist**" shall be displayed by such licensees who employ the services of a "**Registered Phar-macist**" and maintain a "**Pharmacy**" for compounding against prescriptions:

For the purpose of this rule:

- i. "**Registered Pharmacist**" means a person who is a registered pharmacist as defined under the Pharmacy Act, 1948.

The provisions of sub-clause (i) shall not apply to those persons who are already approved as

"qualified person" by the Licensing Authority on or before 31st December 1969.

- ii. Date of expiry of potency means the date that is recorded on the container, label or wrapper as the date up to which the substance may be expected to retain potency not less than or not to acquire toxicity greater than that required or permitted by the prescribed test.
 - 3. In granting a license for a pharmacy the authority empowered to grant it shall have regard:
- a. To the average number of licenses granted during the period of 3 years immediately preceding.
 - b. To the occupation, trade or business ordinarily carried on by such applicant during the preceding 3 years.

Supply of Drugs and Record of Drugs

1. Any drug shall, if compounded or made on the licensee's premises be compounded or made under the direct and personal supervision of a registered pharmacist.
2. The supply, otherwise than by way of wholesale dealing, of any drug supplied on the prescription of a registered medical practitioner shall be affected only by or under the personal supervision of a registered pharmacist.
3. *The supply of any drug other than those specified in Schedule X on a prescription:*

The supply of any drug other than those specified in Schedule X on a prescription of a registered medical practitioner shall be recorded at the time of supply in a prescription register specially maintained for the purpose and the serial number of the entry in the register shall be entered on the prescription.

The following particulars shall be entered in the register:

- a. Serial number of the entry.
- b. The date of supply.

- c. The name and address of the prescriber.
- d. The name and address of the patient or the name and address of the owner of the animal if the drug supplied is for veterinary use.
- e. The name of the drug or preparation and the quantity or in the case of a medicine made up by the licensee, the ingredients and quantities thereof.
- f. In the case of a drug specified in Schedule C or Schedule H the name of the manufacturer of the drug, its batch number and the date of expiry of potency if any.
- g. The signature of the registered pharmacist by or under whose supervision the medicine was made up or supplied.

In the case of drugs which are not compounded in the premises and which are supplied from or in the original containers, the particulars specified in items (a) to (g) above may be entered in a cash or credit memo book, serially numbered and specially maintained for this purpose.

If the medicine is supplied on a prescription on which the medicine has been supplied on a previous occasion and entries made in the prescription register, it shall be sufficient if the new entry in the register includes a serial number, the date of supply, the quantity supplied and a sufficient reference to an entry in the register recording the dispensing of the medicine on the previous occasion.

It shall not be necessary to record the above details in the register or in the cash or credit memo particulars in respect of:

- a. Any drugs supplied against prescription under the employees state insurance Scheme if all the above particulars are given in that prescription.
- b. Any drug other than that specified in Schedule C or Schedule H if it is supplied in the original unopened container of the manufacturer and if the prescription is duly stamped at the time of supply with

the name of the supplier and the date on which the supply was made and on condition that the provisions this rule are complied with.

The option to maintain a prescription register or a cash or credit memo book in respect of drugs and medicines which are supplied from or in the original container, shall be made in writing to the licensing authority at the time of application for the grant or renewal of the license to sell by retail. The licensing authority may require records to be maintained only in prescription register if it is satisfied that the entries in the carbon copy of the cash or credit memo book are not legible.

4. I. *Supply of drug specified in Schedule C on prescription:* The supply by retail, otherwise than on a prescription of a drug specified in Schedule C shall be recorded at the time of supply either:
 - i. In a register specially maintained for the purpose in which the following particulars shall be entered:
 - a. Serial number of the entry.
 - b. The date of supply.
 - c. The name and address of the purchaser.
 - d. The name of the drug and the quantity thereof.
 - e. In the case of a drug specified in Schedule C, the name of the manufacturer, the batch number and the date of expiry of potency.
 - f. The signature of the person under whose supervision the sale was effected.
 - ii. In a cash or credit memo book, serially numbered containing all the particulars.

The entries in the carbon copy of the cash or credit memo which is retained by the licensee shall be maintained in a legible manner.

- II. The option to maintain a register or a cash or credit memo book shall be made in writing to the licensing authority at

the time of application for the grant or renewal of a license to sell by retail.

The licensing authority may require records to be maintained in a register if it is satisfied that the entries in the carbon copy of the cash/credit memo book are not legible.

- III. i. The supply by retail of any drug shall be made against a cash/credit memo which shall contain the following particulars:
 - a. Name, address and sale license number of the dealer.
 - b. Serial number of the cash/credit memo.
 - c. The name and quantity of the drug supplied.
 - ii. Carbon copies of cash/credit memos shall be maintained by the licensee as record.

- IV. *Records of purchase of a drug sold by retail:*

- i. Records of purchase of a drug intended for sale or sold by retail shall be maintained by the licensee and such records shall show the following particulars, namely:
 - a. The date of purchase.
 - b. The name and address of the person from whom purchased and the number of the relevant license held by him.
 - c. The name of the drug, the quantity and the batch number.
 - d. The name of the manufacturer of the drug.
- ii. Purchase bills including cash or credit memo shall be serially numbered by the licensee and maintained by him in a chronological order.

5. I. *The supply of drugs by wholesale:* Subject to the other provisions of these rules the supply of a drug by wholesale shall be made against a cash or credit memo bearing the name and address of the

licensee and his license number under the Drugs and Cosmetics Act in which the following particulars shall be entered:

- a. The date of sale.
- b. The name, address of the licensee to whom sold and his sale license number. In case of sale to an authority purchasing on behalf of government, or to a hospital, medical, educational or research institution or to a registered medical practitioner (RMP) for the purpose of supply to his patients the name and address of the authority, institution or the registered medical practitioner as the case may be.
- c. The name of the drug, the quantity and the batch number.
- d. The name of the manufacturer.
- e. The signature of the competent person under whose supervision the sale was effected.
- II. Carbon copies of cash or credit memos specified in clause (1) shall be preserved as records for a period of three years from the date of the sale of the drug.
- III. **Records of purchase of drugs sold by wholesale:**
 - i. Records of purchase of a drug intended for resale or sold by wholesale shall be maintained by the licensee and such records shall show the following particulars, namely:
 - a. The date of purchase.
 - b. The name, address and the number of the relevant license held by the person from whom purchased.
 - c. The name of the drug, the quantity and the batch number. and
 - d. The name of the manufacturer of the drug.
 - ii. Purchase bills including cash or credit memos shall be serially numbered by the licensee and maintained by him in a chronological order.
6. The licensee shall produce for inspection by an inspector appointed under the act on demand all registers and records maintained under these rules, and shall supply to the inspector such information as he may require for the purpose of ascertaining whether the provisions of the act and rules thereunder have been observed.
7. Except where otherwise provided in these rules, all registers and records maintained under these rules shall be preserved for a period of not less than 2 years from the date of the last entry therein.
8. Notwithstanding anything contained in this rule it shall not be necessary to record particulars in a register specially maintained for the purpose if the particulars are recorded in any other register specially maintained under any other law for the time being in force.
9. ***Substances specified in Schedule H or Schedule X:***
 - a. Substances specified in Schedule H or Schedule X shall not be sold by retail except on and in accordance with the prescription of a registered medical practitioner and in the case of substances specified in Schedule X, the prescriptions shall be in duplicate, one copy of which shall be retained by the licensee for a period of 2 years.
 - b. The supply of drugs specified in Schedule H or Schedule X to registered medical practitioners, hospitals, dispensaries and nursing homes shall be made only against the signed order in writing which shall be preserved by the licensee for a period of 2 years.
10. ***For the purposes of Schedule H or Schedule X a prescription:***
 - a. Shall be in writing and be signed by the person giving it with his usual signature and be dated by him.

- b. Specify the name and address of the person for whose treatment it is given, or the name and address of the owner of the animal if the drug is meant for veterinary use.
 - c. Indicate the total amount of the medicine to be supplied and the dose to be taken.
11. The person dispensing a prescription containing a drug specified in Schedule H and Schedule X shall comply with the following requirements in addition to other requirements of these rules:
 - a. The prescription must not be dispensed more than once unless the prescriber has stated thereon that it may be dispensed more than once.
 - b. If the prescription contains a direction that it may be dispensed a stated number of times or at stated intervals it must not be dispensed otherwise than in accordance with the directions.
 - c. At the time of dispensing there must be noted on the prescription above the signature of the prescriber the name and address of the seller and the date on which the prescription is dispensed.
- 11A. No person dispensing a prescription containing substances specified in Schedule H or X, may supply any other preparation, whether containing the same substance or not, in lieu thereof.
12. Substances specified in Schedule X kept in retail shop or premises used in connection therewith shall be stored:
 - a. Under lock and key in cupboard or drawer reserved solely for the storage of these substances.
 - b. In a part of the premises separated from the remainder of the premises and to which only responsible persons have access.
13. ***The Premises related to the retail sale of drugs:*** The description "Drugstore" shall be displayed by such licensees who do not require the services of a qualified person. The description "chemists and druggists" shall be displayed by such licensees who employ the services of a "registered pharmacist" but who do not maintain a "pharmacy" for compounding against prescriptions. The description "pharmacy", "pharmacist", "dispensing chemist" or "pharmaceutical chemist" shall be displayed by such licensees who employ the services of a "registered pharmacist" and maintain a "pharmacy" for compounding against prescriptions.
14. The licensee shall maintain an inspection book in Form 35 to enable an inspector to record his impressions and the defects noticed.
15. ***Provision related to sale of drug after expiration:*** No drug shall be sold or stocked by the licensee after the date of expiry of potency recorded on its container, label or wrapper, or in violation of any statement or direction recorded on such container, label or wrapper. Provided that any such drugs in respect of which the licensee has taken steps with the manufacturer or his representative for the withdrawal, reimbursement or disposal of the same, may be stocked after the date of expiration of potency pending such withdrawal, reimbursement or disposal, as the case may be, subject to the condition that the same shall be stored separately from the trade stocks and all such drugs shall be kept in packages or cartons, the top of which shall display prominently, the words "not for sale".
16. ***Provision related to the distribution of drugs to the medical profession as free sample:*** No drug intended for distribution to the medical profession as free sample which bears a label on the container as specified in Rule 96, and no drug meant

for consumption by the Employees' State Insurance Corporation, the Central Government Health Scheme, the Government Medical Stores Depots, the Armed Forces Medical Stores or other Government Institutions, which bears a distinguishing mark or any inscription on the drug or on the label affixed to the container thereof indicating this purpose shall be sold or stocked by the licensee on his premises.

Provided that this sub-rule shall not be applicable to licensees who have been appointed as approved chemists, by the State Government in writing, under the **Employees State Insurance Scheme**, or have been appointed as authorized agent or distributor, by the manufacturer in writing for drugs meant for consumption under the Central Government Health Scheme, the government medical stores depots, the armed forces medical stores or other government institutions for drugs meant for consumption under those schemes or have been appointed as authorized depots or carrying and forwarding agent by the manufacturer in writing, for storing free samples meant for distribution to medical profession. Subject to the conditions that the stock shall be stored separately from the trade stocks and shall maintain separate records of the stocks received and distributed by them.

17. *The supply by retail of drugs under the direct supervision of the "registered pharmacist":*

The supply by retail of any drug in a container other than the one in which the manufacturer has marketed the drug, shall be made only by dealers who employ the services of a "registered pharmacist" and such supply shall be made under the direct supervision of the "registered pharmacist" in an envelope or other suitable wrapper or container showing the following particulars on the label:

- Name of the drug.
- The quantity supplied.
- The name and address of the dealer.

18. *Provision related to the supply of drugs for treatment of animals (veterinary drugs):* The medicines for treatment of animals kept in a retail shop or premises shall be labeled with the words 'not for human use for treatment of animals only' and shall be stored:

- In a cupboard or drawer reserved solely for the storage of veterinary drugs.
- In a part of the premises separated from the remainder of the premises to which customers are not permitted to have access.

19. *The supply of drugs specified in Schedule X:*

- The supply of drugs specified in Schedule X shall be recorded at the time of supply in a register (bound and serially page numbered) specially maintained for the purpose and separate pages shall be allotted for each drug.
- The following particulars shall be entered in the said register, namely:
 - Date of transaction.
 - Quantity received, if any, the name and address of the supplier and the number of the relevant license held by the supplier.
 - Name of the drug.
 - Quantity supplied.
 - Manufacturer's name.
 - Batch no. or lot no.
 - Name and address of the patient purchaser.
 - Reference number of the prescription against which supplies were made.
 - Bill no and date in respect of purchases and supplies made by him.
 - Signature of the person under whose supervision the drugs have been supplied.

LABELLING AND PACKING OF DRUGS

Packaging is the science, art and technology of enclosing or protecting products for distri-

bution, storage, sale, and use. Packaging also refers to the process of design, evaluation, and production of packages. Packaging can be described as a coordinated system of preparing goods for transport, warehousing, logistics, sale, and end use. Packaging contains, protects, preserves, transports, informs and sells. In many countries it is fully integrated into government, business, institutional, industrial, and personal use. Package labelling or labelling is any written, electronic or graphic communications on the packaging or on a separate but associated label.

Packing of Drugs

1. The pack sizes of drugs meant for retail sale shall be as prescribed in Schedule P-1 to these rules.
2. The pack sizes of drugs not covered by the Schedule P-1 shall be as given below:

Unless specified otherwise in Schedule P-1.

- i. The pack sizes for tablets/capsules shall be—where the number of tablets (coated or uncoated)/capsules (hard or soft gelatin) is less than 10, such packing shall be made by the integral number for numbers above 10, the pack size of tablets/capsules shall contain multiples of 5.
- ii. The pack sizes for liquid oral preparations shall be 30 ml (paediatric only) 60 ml/ 100 ml/200 ml/450 ml.
- iii. The pack sizes for paediatric oral drops shall be 5 ml/10 ml/15 ml.
- iv. The pack sizes for eye/ear/nasal drops shall be 3 ml/5 ml/10 ml.
- v. The pack size for eye ointment shall be 3 gm/5 gm/10 gm.

Provided that the provisions of the pack sizes covered under this rule shall not apply to:

1. Pack sizes or dosage forms not covered by the foregoing provisions of this rule.
2. The imported formulations in finished form.
3. Preparations intended for veterinary use.
4. Preparations intended for export.

5. Vitamins/tonics/cough preparations/ antacids/laxatives in liquid oral forms, unit dose (including applicaps).
6. Pack sizes of dosage form meant for retail sale to hospitals, registered medical practitioners, nursing homes.
7. Physician's samples.
8. Pack sizes of large volume intravenous fluids.

Provided also that pack sizes of any of the new drug as and when approved by the licensing authority appointed under Rule 21 and if not covered under this rule, shall be examined for the purpose of approval with the specific justification by the said Licensing Authority. Provided further that oxytocin injection meant for sale shall be in single unit blister pack only.

Packings of drugs specified in Schedule X: The drugs specified in Schedule X shall be marketed in packings not exceeding:

- i. 100 unit doses in the case of tablets/ capsules.
- ii. 300 ml in the case of oral liquid preparations.
- iii. And 5 ml in the case of injections.

Provided that nothing in this rule shall apply to packing meant for use of a hospital or a dispensary subject to the conditions that:

- i. Such supplied are made by the manufacturers or distributors direct to the hospital/ dispensaries.
- ii. Hospital packs shall not be supplied to a retain dealer or to a registered medical practitioner.

Labelling of Drugs

The term labelling designates all labels and other written, printed or graphic matter up on or in any package or wrapper in which it is enclosed. The label states the name of the preparation, percentage content of drug of a liquid preparation, the amount of active ingredient of a

dry preparation, the volume of liquid to be added to prepare an injection or suspension from a dry preparation, the route of administration, a statement of storage condition and expiry date. Also label must indicate the name of manufacturer or distributors and carry an identifying lot number.

General labelling requirements: Manner of Labelling:

1. Subject to the provisions of these rules, the following particulars shall be either printed or written in indelible ink and shall appear in a conspicuous manner on the label of the innermost container of any drug and on every other covering which the container is packed, namely:
 - i. The name of the drug.

For this purpose, the proper name of the drug shall be printed or written in a more conspicuous manner than the trade name, if any, which shall be shown immediately after or under the proper name and shall be:

- a. For drugs included in the Schedule F or Schedule F₁, the name given therein.
- b. For drugs included in the India Pharmacopoeia or the Official Pharmacopoeia and official compendia of drug standards prescribed in the Rule 124, the name or synonym specified in the Respective Official Pharmacopoeias and official compendia of drug standards followed by the letters I.P. or, as the case may be, by the recognized abbreviations of the Respective Official Pharmacopoeias and official compendia of drug standards.
- c. For drugs included in the national formulary of India, the name or synonym specified therein followed by the letters 'N.F.I.'
- d. For other drugs, the international non-proprietary name, if any, published by the world health organization or where an international non-proprietary name is not published, the name descriptive of the true nature or origin of the substance.

ii. A correct statement of the net content in terms of weight, measure, volume, number of units of contents, number of units of activity, as the case may be, and the weight, measure and volume shall be expressed in metric system.

iii. The content of active ingredients.

This shall be expressed:

- a. For oral liquid preparations in terms of the content per single dose being indicated in 5 milliliters. Provided that where the dose is below 5 milliliters the contents of active ingredients may be expressed in terms of one milliliter, or fraction thereof. Provided further that where the single dose is more than 5 milliliters, the content of active ingredients shall be expressed in terms of minimum single dose as approved by the licensing authority.
- b. For liquid parenteral preparations ready for administration in terms of 1 milliliter or percentage by volume or per dose in the case of single dose container. Provided that if the preparation is contained in an ampoule it will be enough of the composition is shown on the label or wrapper affixed to any package in which such ampoule is issued for sale.
- c. For drugs in solid form intended for parenteral administration, in terms of units or weight per milligram or gram.
- d. For tablets, capsules, pills and the like, in terms of the content in each tablet, capsule, pill or other unit, as the case may be.
- e. For other preparations, in terms of percentage by weight or volume or in terms of unit age per gram or milliliter, as the case may be.

Provided that clause: (iii) shall not apply to the Pharmacopoeial Preparations where the composition of such preparation is specified in the Respective Pharmacopoeia and to a preparation included in the national formulary of India.

- iv. The name of the manufacturer and the address of the premises of the manufacturer where the drug has been manufactured. Provided that if the drug is contained in an ampoule or a similar small container, it shall be enough if only the name of the manufacturer are shown.
- v. Drugs specified in Schedule P and their preparations including combinations with other drugs shall bear on their labels the date of manufacture, and the date of expiry of potency, and the period between the date of manufacture and the date of expiry shall not exceed that laid down in the said Schedule under the conditions of storage specified therein. Drugs and their preparations not included in Schedule P shall bear on their labels the date of their manufacture and also the date of their expiry which shall not exceed 60 months from the date of manufacture. Provided that this period may be extended by the licensing authority in respect of any specified drug if satisfactory evidence is produced by the manufacturer to justify such an extension.
- vi. Drugs specified in Schedule C.
1. And their preparations including combinations with other drugs shall bear on the labels:
 - a. The date of manufacture.
 - b. Date of expiry of potency fixed by the manufacturer.
 - c. Where such drugs are imported, also the number of license under which the drug is imported, preceded by the words "import license". Provided that drugs in bulk form included in Schedule C₁ which are not ready for use and not included in Schedule P need not bear on the label the date of expiry of potency. Provided further that no reference shall be made to any other license number granted by any authority outside India on any label or container or in any covering in which the container is packed or in any other matter or advertisement enclosed herewith.
- vii. Every drug intended for distribution to the medical profession as a free sample shall, while complying with the labelling provisions under clauses (i) to (viii), further bear on the label of the container the words 'Physician's Sample—not to be sold' which shall be overprinted.
- viii. If any preparation contains not less than 3% by volume of alcohol the quantity of alcohol shall be stated in terms of the average percentage by volume of absolute alcohol in the finished products.
- ix. In addition to the other particulars which are required to be printed or written under these rules, the label of innermost container of the following categories of drugs and every other covering in which the container is packed shall bear a conspicuous red vertical line on the left side running throughout the body of the label which should not be less than 1mm in width and without disturbing the other conditions printed on the label under these rules, namely:
- Narcotics, analgesics, hypnotics, sedatives, tranquillisers, corticosteroids, hormones, hypoglycemics, antimicrobials, antiepileptics, antidepressants, anticoagulants, anticancer drugs and all other drugs falling under Schedules 'G', 'H', and 'X' whether covered or not in the above list.
- Provided that the provisions of this clause shall not apply to:
- a. Preparations intended for animal treatment.
 - b. Preparations intended for external use.
 - c. Ophthalmic preparations and ear drops.

Special Labelling Requirements and Drug Needing Cautionary Labelling	
Drugs	Particulars which should appear on label
Schedule G drugs	If the container of a medicine for internal use contains a substance specified in Schedule G shall be labeled with the words; 'Caution: It is dangerous to take this preparation except under medical supervision'—conspicuously printed and surrounded by a line within which there shall be no other words.
Schedule G (any drug)	Proper name, manufacturing or import license no. Batch No., Potency of unit, the date of expiry.
Schedule H drugs	If the container of a medicine for internal use contains a substance specified in Schedule H shall be labelled with the symbol Rx and conspicuously displayed on the left top corner of the label and be also labelled with the following words: Schedule H drug; Warning: To be sold by retail on the prescription of a registered medical practitioner only.'—If the container of a medicine for internal use contains a substance specified in Schedule H, and comes within the purview of the Narcotic Drugs and Psychotropic Substances Act, 1985 shall be labeled with the symbol NRx which shall be in red and conspicuously displayed on the left top corner of the label, and be also labeled with the following words; Schedule H drug; "Warning: To be sold by retail on the prescription of a registered Medical Practitioner only."
Schedule X drug	If the container of a medicine for internal use contains a substance specified in schedule X, shall be labeled with the symbol XRx which shall be in red conspicuously displayed on the left top corner of the label and be also labeled with the words : Schedule X drug; "Warning: To be sold by retail on the prescription of a registered medical practitioner only."
Schedule X drug (bulk form)	Substances specified in Schedule X in bulk form shall bear a label wherein they symbol XRx shall be given conspicuously in red letters.
Schedule C drugs	Proper name of substance in addition to patent or proprietary name, license no. Batch no., Lot no. Statements of potency in units, name and address of the manufacturer of the final product, date of manufacture, a test for maximum toxicity is prescribed a statement that it has passed the test, if any, date of expiry, nature and percentage of antiseptics, if any, precautions necessary for preserving the properties of the drugs.
Schedule C ₁ drugs: Schedule C ₁ drugs and their preparations including combinations with other drugs.	The date of manufacture, the date of expiry, import license no., if any.
Schedules F and F ₁	The prescribed name.
Schedule P drugs (any drugs)	Date of manufacture, date of expiry of potency.
Schedule W drugs (single ingredients)	Proper name (no trade name).
Medicines for animals (veterinary drugs)	The container of a medicine made up ready only for treatment of an animal shall be labelled conspicuously with the words 'not for human use; for animal treatment only' and shall bear a symbol depicting the head of a domestic animal.

Contd.

Contd.

<i>Drugs</i>	<i>Particulars which should appear on label</i>
Medicines containing methylated spirit if the medicine contains industrial methylated spirit,	The container of a medicine prepared for treatment of human ailments shall indicate this fact on the label and be labelled with the words "for external use only".
Preparations for external applications	The container of a embrocation, liniment, lotion, ointment, antiseptic cream, liquid antiseptic or other liquid medicine for external application shall be labeled with the word in capital 'for external use only'.
Non-sterile surgical ligature and suture	Every container of, and wrapper enclosing surgical ligature or suture other than a ligature or suture offered or intended to be offered for sale as sterile, shall bear a label on which are printed or written in a conspicuous manner in indelible red ink the words; "Non-sterile surgical ligature (suture)—not be used for operations upon the human body unless efficiently sterilized".
Patent or proprietary medicine containing vitamins for prophylactic or therapeutic use	"For prophylactic use"/"for therapeutic use".
Mechanical contraceptives	Perticulars specified in Schedule R, date of manufacture, date up to which it is expected to retain its properties, storage conditions.
Oral contraceptives	Date of manufacture.
Disinfectants	Grade and phenol coefficient and method of use.
Alcoholic preparations (any drug containing more than 3% v/v alcohol)	Statement of quantity of alcohol as average % of absolute alcohol by volume.
Coloured medicaments	Common name and % of colours
Drug samples	Drug for free distribution to the medical profession; the words 'physician's sample', 'not to be sold'.

Special Labelling Instructions for Particular type of Dispensed Dosage Form	
<i>Name of preparation</i>	<i>Labelling instructions</i>
Aerosol inhalations	<ul style="list-style-type: none"> • Pressurized containers keep away from heat source. • Shake before use. • Do not exceed the prescribed dose follow the instructions.
Capsules	<ul style="list-style-type: none"> • Swallow with a draught of water.
Creams	<ul style="list-style-type: none"> • For external use only. • Store in a cool place.
Dusting powders	<ul style="list-style-type: none"> • For external use only. • Not to be applied on open wound or to raw or weeping surface.
Ear drops	<ul style="list-style-type: none"> • For external use only.
Emulsions	<ul style="list-style-type: none"> • Shake the bottle before use.

Contd.

Contd.

Name of preparation	Labelling instructions
Enemas	<ul style="list-style-type: none"> • For rectal use only. • Shake well before use. • Warm to body temperature before use.
Eye drops	<ul style="list-style-type: none"> • To be used in 30 days after first opening
Eye-lotions	<ul style="list-style-type: none"> • To be used with 24 hrs after first opening.
Gargles and mouth washes	<ul style="list-style-type: none"> • Not to be swallowed in large amounts.
Granules	<ul style="list-style-type: none"> • To be dissolved or dispersed in water before taking.
Inhalations	<ul style="list-style-type: none"> • Not to be taken. Shake the bottle well before use.
Linctuses	<ul style="list-style-type: none"> • To be slipped and swallowed slowly without the addition of water.
Liniments and Lotions	<ul style="list-style-type: none"> • For external use only. • Shake the bottle before use. • Do not apply on broken skin.
Mixtures	<ul style="list-style-type: none"> • Shake the bottle before use. • To be taken only after diluting with water.
Nasal drops	<ul style="list-style-type: none"> • For nasal use only.
Ointments	<ul style="list-style-type: none"> • For external use only. • Sterile not to be used for injection.
Paints	<ul style="list-style-type: none"> • For external use only.
Passaries	<ul style="list-style-type: none"> • For vaginal use only. • Store in cool place. • For external use only.
Pastes	<ul style="list-style-type: none"> • For external use only.
Solutions	<ul style="list-style-type: none"> • For external use only. • Sterile not to be used for injection.
Suppositories	<ul style="list-style-type: none"> • For rectal use only. • For rectal use only. • Store in a cool place.
Tablets	
1. For soluble or dispersible tablets	<ul style="list-style-type: none"> • Dissolve or dispensed in water before taking. • Chew before swallowing.
2. For chewable tablets	<ul style="list-style-type: none"> • Do not crush or chew.
3. For sustain release, enteric coated or unpleasant tasting tablets.	

- d. Sterile preparations such as sutures, surgical dressings and preparations intended for parenteral use.
2. i. The particulars to be printed or written on the label of a mechanical contraceptive shall be as specified in Schedule R.
- ii. The following particulars, in addition to those specified under sub-rule (i) shall be either printed or written in indelible ink and shall appear in a conspicuous manner on the label of the innermost container and on every other covering in which the container of a contraceptive, other than a mechanical contraceptive, is packed, namely:
- The date of manufacture.
 - The date up to which the contraceptive is expected to retain its properties.
 - The storage conditions necessary for preserving the properties of the contraceptive up to the date indicated in sub-clause (i). Provided that for oral contraceptives it shall be sufficient to display on the label of the container the date of manufacture only.
3. The particulars prescribed in sub-rule:
- Shall be printed or written in indelible ink either on the label borne by a container of vaccine lymph or on a label or wrapper affixed to any package in which the container is issued for sale. The said particulars shall be indelibly marked on the sealed container of surgical ligature or suture or printed or written in indelible ink on a label enclosed therein.
 - Nothing in these rules shall be deemed to require the labelling of any transparent cover or of any wrapper, case or other covering used solely for the purpose of packing, transport or delivery.
 - Where be any provision of these rules any particulars are required to be displayed on a label on the container, such particulars may, instead of being displayed on a label, be etched, painted or otherwise indelibly marked on the container. Provided that, except where otherwise provided in these rules, the name of the drug or any distinctive letters intended to refer to the drug shall not be etched, painted or otherwise indelibly marked on any glass container other than ampoules.

LABELLING OF DISPENSED MEDICINES

The label on dispensed medicines has two main functions, one is to uniquely identify the contents of the container, and other is to ensure

Labelling Requirements for Eye Drop and Eye Ointment Container at the Time of Dispensing

S. no.	Requirement	Include on label
1	State route of administration	For external use only
2	Fully identify the product	The name and concentration of active ingredient (s)
3	Statement on preservation	Confirm presence or absence of preservative
4	Direction for use	Ex: Add one drop to each eye morning and evening.
5	Statement on in use expiry date	Day, month, year
6	Storage requirements	'Store in cool place' or 'Protect from light'
7	Identify patient	Patient's name
8	Date of dispensing	Day, month, year

that patients have clear and concise information. There are both legal and professional requirements which must be complied between labelling a dispensed medicine. It is the pharmacist responsibility to ensure that these requirements are satisfied and that all labelling is accurate. The regulation indicates the standard details which must appear on even label.

Standard requirements for labelling dispensed medicines: All labels must be type written or computer generated. The details, which must appear on the label of a dispensed medicine are:

- i. The name of the preparation.
- ii. The quality.
- iii. Instructions for the patient.
- iv. The patient name.
- v. The date of dispensing.
- vi. The name and address of the pharmacy.
- vii. Keep out of reach of children.

Instructions to the patient: There should be clear and complete instructions to the patient on how to take or use the preparation:

- a. **Direction:** The phrases such as 'to be taken' 'to be given' or 'to be used' are preferred to 'take' 'give' 'use'. The direction written on the label of a dispensed medicine should be simple and without any confusion.
- b. **Shake the bottle:** The emulsion suspension and aerosols need to be shaken immediately before its use, in order to ensure that the preparation is homogeneous so this instruction must appear on the label of such preparation.
- c. **Take with water:** Mixture which can cause gastrointestinal irritation or mixtures for adult patients having a dose 10 ml or more, should be diluted with water before taking it.
- d. **Expiry date:** The expiry date is that point in time when a pharmaceutical product is no longer within acceptable specifications for potency and stability. The date of expiry shall be in terms of month and year and it

shall mean that the drug is recommended till the last day of the month. The date of expiry shall be preceded by the words 'expiry date'.

Labelling of Parenterals

- Parenteral containers vary greatly in size from 1 ml ampoules to 3 liter bags. It is difficult to put much information on a label intended for a 1 ml ampoule and it is not important not to completely oblige the product from view.
- The USP states that the label must leave a sufficient area of the container uncovered for its full length of circumference to permit inspection of content.
- The BP requires that where appropriate the label must state the strength of the preparation in terms of amount of active ingredient in a suitable dose of volume. The label must also state the name of any added substance, the expiry date and storage conditions.
- Statement of storage condition is becoming increasingly important based on the temperature at which long term stability data have been generated.
- European regulating authority requires stability data generated at 25°C and 60% relative humidity.
- The FDA currently requires data at 30°C and 60% relative humidity. The requirements vary for different market depending upon the climatic condition.
- USP requires more information regarding added substances. It requires the percentage content of each ingredient or the amount of each ingredient in a specified volume. The USP requires the route of administration to be stated.
- The BP also has specific requirement for concentrated solution of injection. In this instance the label must state the name of the

concentrated solution that the solution must be diluted and the direction for preparation of the injection or infusion.

Labelling of Vitamin Containing Products

- The vitamin of pharmacopoeial preparation shall be stated on the label in metric units per dose unit. The amount of vitamins A, D and E may be stated in USP units.
- The label of nutritional supplement shall bear on identifying lot number, control number or batch number.

Labelling of Electrolytes

The concentration dosage of electrolytes for replacement therapy (e.g. sodium chloride or potassium chloride) shall be stated in the label in milliequivalents (mEq). The label of the product shall also indicate the quantity of ingredients in terms of weight or percentage concentration.

Labelling of Poisons

The basic labelling requirements are:

- The name of the substance.
- The name, address and telephone number of the supplier.
- An indication of general nature of the risk, e.g. toxic, corrosive, teratogenic.
- The symbols specified of the above risk, e.g. skull and cross bones.
- Risk phrases these are the general statements of properties of the substance, e.g. 'cause severe burns'.

Safety phrases these contain advice on what to do to avoid problems, e.g. 'wear suitable protective clothing', 'do not breathe vapor'.

OTHER PROVISIONS RELATED TO THE LABELLING OF DRUGS

A. *Use of letter I.P.:* The letters 'I.P.' and recognized abbreviations of Pharmacopoeias and official compendia of drug standards prescribed under these rules shall be entered on the label of the drug only for the purpose of

indicating that the drug is in accordance with standards set out in the Indian Pharmacopoeia or in any such Pharmacopoeia or official compendium of drug standards recognized under the rules.

B. *Prohibition against altering inscriptions on containers, labels or wrappers of drug:* No person shall alter, obliterate or deface any inscription or mark made or recorded by the manufacturer on the container, label or wrapper of any drug. Provided that nothing in this rule shall apply to any alteration, any inscription or mark made on the container, label or wrapper of any drug at the instance or direction or with the permission of the licensing authority.

C. *Prohibition of sale or distribution unless labeled:* Subject to the other provisions of these rules, no person shall sell or distribute any drug (including a patent or proprietary) unless it is labelled in accordance with these rules.

Exemption

Exemption of Certain Drugs from Certain Provisions of this Part (Labelling of Drugs)

1. Labels on packages or containers of drugs for export shall be adapted to meet the specific requirements of the law of the country to which the drug is to be exported but the following particulars shall appear in a conspicuous position on the innermost container in which the drug is packed and every other covering in which that container is packed:
 - a. Name of the drug.
 - b. The name, address of the manufacturer and the number of the license under which the drug has been manufactured.
 - c. Batch or lot number.
 - d. Date of expiry, if any.

Provided that where a drug, not classified under Schedule F, Schedule F₁ and Schedule X, blood products, narcotic and psychotropic Substances is required by the consignee to be not labeled with the name and address of the

manufacturer, the labels on packages or containers shall bear a code number as approved by the licensing authority.

2. A medicine made ready for treatment, whether after or without dilution, which is supplied on the prescription of a registered practitioner provided that it is labelled with the following particulars:
 - a. The name and address of the supplier.
 - b. The name of the patient and the quantity of the medicine.
 - c. The number representing serial number of the entry in the prescription register.
 - d. The dose, if the medicine is for internal use.
 - e. The words 'for external use only' if the medicine is for external application.

PROVISIONS RELATING TO AYURVEDIC, SIDDHA AND UNANI DRUGS

I. Ayurvedic, Siddha and Unani Drugs Technical Advisory Board

Ayurvedic, Siddha and Unani DTAB are constituted by Central Government under Section 33 C of the act.

1. The Central Government shall, by notification in the official gazette, constitute a board (to be called the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board) to advise the Central Government and the State Governments on technical matters relating to Ayurvedic, Siddha and Unani Drugs.
2. The Board shall consist of the following members, namely:

Ex-officio Members

- i. The Director General of Health Services.
- ii. The Drugs Controller, India.
- iii. The principal officer dealing with Indian Systems of Medicine in the ministry of Health.
- iv. The Director of the Central Drugs Laboratory, Calcutta.

Nominated Member

- v. One person holding the appointment of Government Analyst under Section 33 F, to be nominated by the Central Government.
- vi. One pharmacognocist to be nominated by the Central Government.
- vii. One phyto-chemist to be nominated by the Central Government.
- viii. Four persons to be nominated by the Central Government, two from amongst the members of the Ayurvedic Pharmacopoeia Committee, one from amongst the members of the Unani Pharmacopoeia Committee and one from amongst the members of the Siddha Pharmacopoeia Committee.
- ix. One teacher in *dravyaguna* and *bhaishajya kalpana*, to be nominated by the Central Government.
- x. One teacher in Ilm-Ul-advia and taklis-wa-dawa-sazi, to be nominated by the Central Government.
- xi. One teacher in *gunapadam* to be nominated by the Central Government.
- xii. Three persons, one each to represent the Ayurvedic, Siddha and Unani Drug industry, to be nominated by the Central Government.
- xiii. Three persons, one each from among the practitioners of Ayurvedic, Siddha and Unani-Tibb System of medicine to be nominated by the Central Government.
3. The Central Government shall appoint a member of the board as its Chairman.
4. The nominated members of the board shall hold office for three years but shall be eligible for renomination.
5. The Board may, subject to the previous approval of the Central Government, make bye-laws fixing a quorum and regulating its own procedure and conduct of all business to be transacted by it.

6. The functions of the board may be exercised notwithstanding any vacancy therein.
7. The Central Government shall appoint a person to be secretary of the board and shall provide the board with such clerical and other staff as the Central Government considers necessary.

II. The Ayurvedic, Siddha and Unani Drugs Consultative Committee

Consultative Committee: The Ayurvedic, Siddha and Unani Drugs Consultative Committee is constituted by Central Government under Section 33 D of the act.

1. The Central Government may constitute an advisory committee to be called as the Ayurvedic, Siddha and Unani Drugs Consultative Committee to advise the Central Government, the State Governments and the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board on any matter for the purpose of securing uniformity throughout India in the administration of this act in so far as it relates to Ayurvedic, Siddha or Unani Drugs.
2. The Ayurvedic, Siddha and Unani Drugs Consultative Committee shall consist of two persons to be nominated by the Central Government as representatives of that Government and not more than one representative of each state to be nominated by the State Government concerned.
3. The Ayurvedic, Siddha and Unani Drugs Consultative Committee shall meet when required to do so by the Central Government and shall regulate its own procedure.

III. The Ayurvedic, Siddha and Unani Government Analysts

A. Government analysts: The Ayurvedic, Siddha and Unani Government Analysts appointed by Central or State Government under Section 33 F of the act.

1. The Central Government or the State Government may, by notification in the official gazette, appoint such person as it thinks fit, having the prescribed qualification, to be government analysts for such areas as may be assigned to them by the Central Government or the State Government, as the case may be.
2. Notwithstanding anything contained in above sub-section, neither the Central Government nor the State Government shall appoint a Government Analyst any official not serving under it without the previous consent of the government under which he is serving.
3. No person who has any financial interest in the manufacture or sale of any drug shall be appointed to be a Government Analyst under this Section.

B. Qualifications: A person who is appointed as a Government Analyst under Section 33 F of the Act shall be a person possessing the qualifications prescribed in Rule 44 or a Degree in Ayurveda, Siddha or Unani System, as the case may be, conferred by a university, a State Government or statutory faculties, councils and boards of Indian Systems of Medicine recognized by the Central or State Government, as the case may be, for this purpose and has had not less than three years' postgraduate experience in the analysis of drugs in a laboratory under the control of:

- a. A Government Analyst appointed under the act.
- b. A chemical examiner to government.
- c. The head of an institution specially approved for the purpose by the appointing authority.

C. Duties:

1. The Government Analyst shall analyze or test or cause to be analyzed or tested such samples of Ayurvedic (including Siddha) or Unani Drugs as may be sent to him by Inspectors or any other persons or authority authorized by the Central Government or

State Government under the provisions related to Ayurvedic, Siddha and Unani Drugs of the act and shall furnish reports of the results of test or analysis in accordance with these rules.

2. A Government Analyst appointed under Section 33 F shall from time to time forward to the government reports giving the result of analytical work and research with a view to their publications at the discretion of the government.

D. Procedure: Procedure for dispatch of sample to Government Analyst and to receipt by the Government Analyst:

1. Sample for test or analysis shall be sent to the Government Analyst by registered post or by hand in a sealed package, enclosed together with a memorandum in Form 18-A in an outer addressed to the government analyst.
2. The package as well as the outer cover shall be marked with a distinguishing number.
3. A copy of the memorandum and a specimen impression of the seal used to seal the package shall be sent by registered post or by hand to the Government Analyst.
4. On the receipt of the package from an inspector, the Government Analyst or an officer authorized by him in writing in his behalf shall open the package and shall also record the conditions of the seals on the package.
5. After the test or analysis has been completed, one copy of the test results or analysis shall be supplied forthwith to the sender in Form 13-A shall also be sent simultaneously to the controlling authority and to the Drugs Controller, India.

Method of test or analysis to be employed in relation to Ayurvedic (including Siddha) or Unani Drugs: The method of test or analysis to be employed in relation to an Ayurvedic (Including Siddha) or Unani Drug shall be such as may be specified in the Ayurvedic, Siddha or

Unani pharmacopoeia, or if no such pharmacopoeias, such tests as the Government Analyst may employ, such tests being scientifically established to determine whether the drug contains the ingredients as stated on the label.

IV. The Ayurvedic, Siddha and Unani Licensing Authority

A. Licensing authority: Any application for the grant or renewal of a license for import, manufacturing, sale, etc. of Ayurvedic, Siddha and Unani Drugs is to be made to the licensing authority.

B. Qualifications: Qualification of the state drug licensing authority for licensing of Ayurveda, Siddha and Unani Drugs:

- a. The Ayurvedic, Siddha Unani qualifications as per Schedule II of CCIM Act, 1970 (the Indian Medicine Central Council Act, 1970)/ B Pharma (Ayurveda of a recognized university).
- b. At least 5 years experience in the Ayurveda, Siddha and Unani Drug manufacturing or testing of Ayurvedic, Siddha and Unani Drugs or enforcement of provisions relating to Ayurvedic Siddha and Unani Drugs of the Drugs and Cosmetics Act, 1940 and rules made there under or teaching/research on clinical practice of Ayurveda, Siddha and Unani system.

V. The Ayurvedic, Siddha and Unani Inspectors

A. Inspectors: The Ayurvedic, Siddha and Unani Inspectors appointed by Central or State Government under Section 33 G of the act.

- a. The Central Government or a State Government may, by notification in the official gazette, appoint such persons as it thinks fit, having the prescribed qualification, to be Inspectors for such areas as may be assigned to them by the Central Government or State Government as the case may be.
- b. The powers which may be exercised by an Inspector and the duties which may be

performed by him and the conditions, limitations or restrictions subject to which such powers and duties may be exercised or performed shall be such as may be prescribed.

- c. No person who has any financial interest in the manufacture or sale of any drug shall be appointed to be an Inspector under this section.
- d. Every inspector shall be deemed to be a public servant within meaning of Section 21 of the Indian Penal Code, 1860 and shall be officially subordinate to such authority as the government appointing him may specify in this behalf.

B. Qualifications: A person who is appointed an Inspector under Section 33 G shall be a person who:

- a. Has the qualifications laid down under Rule 49 and shall have undergone practical training in the manufacture of Ayurvedic (including Siddha) or Unani Drug, as the case may be.
- b. Has a degree in Ayurvedic or Siddha or Unani System or a Degree in Ayurveda Pharmacy, as the case may be, conferred by a University or State Government or a statutory faculty, council or board of Indian systems of medicine recognized by the Central Government or State Government for this purpose.
- c. Has a diploma in Ayurveda, Siddha or Unani Systems, as the case may be granted by the State Government or an institution recognized by the Central Government or a State Government for this purpose.

C. Duties: Duties of Inspectors specially authorised to inspect the manufacture of Ayurvedic (including Siddha) or Unani Drugs.

Subject to the instructions of the controlling authority, it shall be the duty of an inspector authorised to inspect the manufacture of Ayurvedic (including Siddha) or Unani Drugs:

- a. To inspect not less than twice a year, all premises licensed for the manufacture of Ayurvedic (including Siddha) or Unani Drugs within the area allotted to him and to satisfy himself that the conditions of the license and the provisions of the act and the rules made thereunder are being observed.
- b. To take samples of the drugs manufactured on the premises and send them for test or analysis in accordance with these rules.
- c. To institute prosecutions in respect of violation of the act and the rules made thereunder.

PROHIBITION OF MANUFACTURE AND SALE OF CERTAIN AYURVEDIC, SIDDHA AND UNANI DRUG

A. Regulation of manufacture for sale of Ayurvedic, Siddha and Unani Drugs: No person shall manufacture for sale or for distribution any Ayurvedic, Siddha or Unani Drug except in accordance with such standards, if any, as may be prescribed in relation to that drug.

B. Prohibition of manufacture and sale of certain Ayurvedic, Siddha and Unani Drug: From such date as the State Government may, by notification in the official gazette, specify in this behalf, no person, either by himself or by any other person on his behalf, shall:

- a. Manufacture for sale or for distribution:
 - i. Any misbranded, adulterated or spurious Ayurvedic, Siddha or Unani drugs.
 - ii. Any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof the true list of all the ingredients contained in it.
 - iii. Any Ayurvedic, Siddha or Unani Drug in contravention of any of the provisions related to the Ayurvedic, Siddha or Unani Drugs or any rule made thereunder.
- b. Sell, stock or exhibit or offer for sale or for distribution of any Ayurvedic, Siddha or

Unani Drug which has been manufactured in contravention of any of the provisions related to the Ayurvedic, Siddha or Unani Drug, or any rule made thereunder.

- c. Manufacture for sale or for distribution, any Ayurvedic, Siddha or Unani Drug, except under, and in accordance with the conditions of, a license issued for such purpose under this act by the prescribed authority. Provided that nothing in this section apply to vaidyas and hakims who manufacture Ayurvedic, Siddha or Unani Drug for the use of their own patients. Provided further that nothing in this section shall apply to the manufacture, subject to the prescribed conditions, of small quantities of any Ayurvedic, Siddha or Unani Drug for the purpose of examination, test or analysis.

C. Power of Central Government to prohibit manufacture, etc., of Ayurvedic, Siddha or Unani Drugs in public interest: If the Central Government is satisfied on the basis of any evidence or other material available before it that the use of any Ayurvedic, Siddha or Unani Drug is likely to involve any risk to human beings or animals or that any such drug does not have the therapeutic value claimed or purported to be claimed for it and that in the public interest it is necessary or expedient so to do then, that government may, by notification in the official gazette, prohibit the manufacture, sale or distribution of such drug.

MANUFACTURE FOR SALE OF AYURVEDIC (INCLUDING SIDDHA) OR UNANI DRUGS

Manufacture license: An application for the grant or renewal of a license to manufacture for sale any Ayurvedic (including Siddha) or Unani Drugs shall be made in Form 24-D to the licensing authority along with a fee of rupees sixty. In case of renewal the applicant may apply for the renewal of the license before its expiry or within one month of such expiry. The

applicant may apply for renewal after the expiry of one month but within three months of such expiry in which case of fee payable for renewal of such license shall be rupees 60 plus additional fee of rupees 30. A fee of rupees 15 shall be payable for a duplicate copy of a license issued under this rule, if the original license is defaced, damaged or lost.

Form of license: A license for the grant or renewal of license for the manufacture for sale any Ayurvedic (including Siddha) or Unani Drugs shall be issued in Form 25-D.

Conditions for the Grant or Renewal of a License

Before a license in Form 25-D is granted or renewed in Form 26-D the following conditions shall be complied with by the applicant, namely:

1. The manufacture of Ayurvedic (including Siddha) or Unani Drugs shall be carried out in such premises and under such hygienic conditions as are specified in Schedule T.
2. The manufacture of Ayurvedic (including Siddha) or Unani Drugs shall be conducted under the direction and supervision of competent technical staff consisting at least of one person, who is a whole-time employee and who possesses the following qualifications, namely:
 - a. A degree in Ayurveda or Ayurvedic Pharmacy, Siddha or Unani Systems of medicine, as the case may be, conferred by a university, a State Govt. or statutory facilities, councils and boards of Indian systems of medicine recognized by the Central Govt. or State Govt. for this purpose.
 - b. A diploma in Ayurveda, Siddha or Unani System of medicine granted by the State Govt. or an institution recognized by the Central Govt. for this purpose.
 - c. A graduate in pharmacy or pharmaceutical chemistry or chemistry or botany of a university recognized by the Central

Govt. with experience of at least two years in the manufacture of drugs pertaining to the Ayurvedic or Siddha or Unani System of medicine.

- d. A *vaid* or *hakim* registered in a state register of practitioners of indigenous system of medicines having experience of at least four years in the manufacture of Siddha or Unani Drugs.
- e. A qualification as pharmacist in Ayurvedic (including Siddha) or Unani System of medicine, possessing experience of not less than eight years in the manufacture of Ayurvedic or Siddha or Unani Drugs as may be recognized by the Central Govt.

The competent technical staff to direct and supervise the manufacture of Ayurvedic Drugs shall have qualifications in ayurveda and the competent technical staff to direct and supervise the manufacture of Siddha Drugs and Unani Drugs shall have qualifications in Siddha or Unani, as the case may be.

Conditions of License

A license in Form 25-D shall be subject to the conditions stated therein and to the following further conditions, namely:

- a. The license shall maintain proper records of the details of manufacture and of the tests, if any, carried out by him, or by any other person on his behalf, of the raw materials and finished products.
- b. The license shall allow an inspector appointed under the act to enter any premises

where the manufacture of a substance in respect of which the license is issued is carried on, to inspect the premises, to take samples of the raw materials as well as the finished products, and to inspect the records maintained under these rules.

- c. The license shall maintain an inspection book in Form 35 to enable an inspector to record his impressions and the defects noticed.

Duration of license: An original license in Form 25-D or a renewal license in Form 26-D, unless sooner suspended or cancelled shall be valid up to the 31st December, of the year following the year in which it is granted or renewal.

If the application for the renewal of a license is made before its expiry or within one month of its expiry, or if the application is made within 3 months of its expiry after payment of the additional fee of rupees 30, the license shall continue to be in force until orders are passed on the application. The license shall be deemed to have expired, if application for its renewal is not made within 3 months of its expiry.

LOAN LICENSE TO MANUFACTURE OF AYURVEDIC, SIDDHA OR UNANI DRUGS

An application for the grant or renewal of loan license to manufacture for sale of any Ayurvedic (including Siddha) or Unani Drugs shall be made in Form 24-E to the licensing authority along with a fee of rupees thirty. In the case of renewal the applicant may apply for the renewal of the license before its expiry or within one month of such expiry. In the case of renewal the

<i>Class of drugs</i>	<i>Standards to be complied with</i>
1. Single drugs included in Ayurvedic Pharmacopoeia.	<ol style="list-style-type: none"> 1. The standards for identity, purity and strength as given in editions of Ayurvedic Pharmacopoeia of India for the time being in force.
2. <i>Asavas and arishtas</i>	<ol style="list-style-type: none"> 2. The upper limit of alcohol as self generated alcohol should not exceed 12% v/v excepting those that are otherwise notified by the Central Government from time to time.

applicant may apply for the renewal one month, but within 3 months of such expiry in which case the fee payable for renewal of such license shall be rupees thirty plus an additional fee of rupees fifteen. A fee of rupees seven and fifty paise shall be payable for a duplicate copy of a license issued under this rule, if the original license is defaced, damaged or lost.

A loan license to manufacture for sale any Ayurvedic (including Siddha) or Unani Drugs shall be issued in Form 25-E.

A license under this rule shall be granted by the licensing authority after consulting such expert in Ayurvedic (including Siddha) or Unani System of medicine, as the case may be, which the State Govt. may approve in this behalf. The licensing authority shall, before the grant of a loan license satisfy himself that the manufacturing unit has adequate equipment and staff capacity for manufacture and facilities for testing, to undertake the manufacture on behalf of the applicant for a loan license.

Conditions of Loan License

A license in Form 25-E shall be subject to the following further conditions, namely:

- a. The license in Form 25-E shall be deemed to be cancelled or suspended, if the license owned by the licensee in Form 25-D whose manufacturing facilities have been availed of by the license is cancelled or suspended, as the case may be, under these rules.
- b. The licensee shall comply with the provisions of the act and of the rules and with such further requirements if any, as may be specified in any rules subsequently made under Chapter IV-A of the act, provided that where such further requirements are specified in the rules, these would come into force four months after publication in the official gazette.
- c. The licensee shall maintain proper records of the details of manufacture and of the tests, if any, carried out by him, or any other

person on his behalf, of the raw materials and finished products.

- d. The licensee shall allow an Inspector appointed under the act to inspect all registers and records maintained under these rules and shall supply to the Inspector such information as he may require for the purpose the ascertaining whether the provisions of the act and the rules have been observed.
- e. The licensee shall maintain an inspection book in Form-35 to enable an inspector to record his impressions and the defects noticed.

Duration of loan license: An original loan license in Form 25-E or a renewed loan license in Form 26-E, unless sooner suspended or cancelled, shall be valid up to the 31st December of all year following the year in which it is granted or renewed.

If the application for the renewal of a loan license is made in accordance with Rule 153-A, the loan license shall continue to be in force until orders are passed on the application. The license shall be deemed to have expired, if application for its renewal is not made within 3 months of its expiry.

SALE OF AYURVEDIC, SIDDHA OR UNANI DRUGS

A license is not necessary for the sale of any Ayurvedic, Siddha or Unani Drugs provide the drugs are manufactured by a person licensed to manufacture under the act.

Other Provisions Related to the Ayurvedic (Including Siddha) or Unani Drugs

A. Manufacture on more than one set of premises: If Ayurvedic (including Siddha) or Unani Drugs are manufactured on more than one set of premises, a separate application shall be made and a separate license shall be obtained in respect of each such set of premises.

B. Cancellation and suspension of licenses: The licensing authority may, after giving the

licensee an opportunity to show cause, within a period which shall not be less than fifteen days from the date of receipt of such notice, why such an order should not be passed, by an order in writing stating the reasons therefore, cancel a license issued under this part or suspend it for such period as he thinks fit, either wholly or in respect of some of the drugs to which it relates, if in his opinion, the licensee has failed to comply with any of the conditions of the license or with any provisions of the act or the rules made thereunder. A licensee whose license has been suspended or cancelled may appeal to the State Government within a period of 3 months from the date of receipt of the order, which shall, after considering the appeal, decide the same.

C. Identification of raw materials: Raw material used in the preparation of Ayurvedic (including Siddha) or Unani Drugs shall be identified and tested, wherever tests are available for their genuineness, and records of such tests as are

carried out for the purpose and the methods thereof shall be maintained.

D. Confiscation: Where any person has been convicted under the provisions relating to Ayurvedic, Siddha and Unani Drugs, the stock of the Ayurvedic, Siddha or Unani Drug, in respect of which the contravention has been made, shall be liable to confiscation.

OFFENCES AND PENALTIES

Penalty for Manufacture, Sale of Ayurvedic, Siddha or Unani Drug

Whoever himself or by any other person on his behalf:

1. Manufactures for sale or for distribution:
 - a. *Any Ayurvedic, Siddha or Unani Drugs:* Deemed to be adulterated, or without a valid license shall be punishable with imprisonment for a term which may extend to one year and with fine which shall not be less than 2,000 rupees.

THE SECOND SCHEDULE

Standards to be Complied with by Imported Drugs and by Drugs Manufactured for Sale, Void, Stocked or Exhibited for Sale or Distributed	
Class of drugs	Standard to be complied with
1. Patent or proprietary medicines other than homoeopathic medicines.	The formula or list of ingredients displayed in the prescribed manner on the label of the container and such other standards as may be prescribed.
Substances commonly known as vaccines, sera toxins, toxoids, antitoxins and antigens and biological products of such nature for human use or for veterinary use.	The standards maintained at the International Laboratory for Biological Standards, Stantans Serum Institute, Copenhagen and at the Central Veterinary Laboratory, Weybridge Surrey, U.K., and such other laboratories recognized by the World Health Organization from time to time, and such further standards of strength, quality and purity, as may be prescribed.
Substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction or vermin or insect which cause disease in human beings or animals.	Such standards may be prescribed.

Contd.

Standards to be Complied with by Imported Drugs and by Drugs Manufactured for Sale, Void, Stocked or Exhibited for Sale or Distributed

<i>Class of drugs</i>	<i>Standard to be complied with</i>
2. Homoeopathic medicines:	
a. Drugs included in the Homoeopathic Pharmacopoeia of India.	Standards of identity, purity and strength specified in the edition of the Homoeopathic Pharmacopoeia of the India for the time being and such other standards as may be prescribed.
b. Drugs not included in the Homoeopathic Pharmacopoeia of India, but which are included in the Homoeopathic Pharmacopoeia of United States of America or the United Kingdom or the German Homoeopathic Pharmacopoeia.	Standards of identity, purity and strength prescribed for the drug in the edition of such Pharmacopoeia for the time being in which they are given and such other standards as may be prescribed.
c. Drugs not included in the homoeopathic pharmacopoeia of India or the United States of America, or the United Kingdom or the German Homoeopathic Pharmacopoeia.	The formula or list of ingredients displayed in the prescribed manner on the label of the container and such other standards as may be prescribed by the Central Government.
3. Other drugs:	
a. Drugs included in the Indian Pharmacopoeia	Standards of identity, purity and strength specified in the edition of the Indian Pharmacopoeia for the time being in force and such other standards as may be prescribed. In case the standards of identity, purity and strength for drugs are not specified in the edition of the Indian Pharmacopoeia for the time being in force but are specified in the edition of the Indian Pharmacopoeia immediately preceding, the standards of identity, purity and strength shall be those occur in such immediately preceding edition of the Indian Pharmacopoeia and such other standards as may be prescribed.
b. Drugs not included in the Indian Pharmacopoeia but not included in the Official Pharmacopoeia of any other country.	Standards of identity, purity and strength specified for drugs in the edition of such official pharmacopoeia of any other country for the time being in force and such other standards as may be prescribed. In case the standards of identity, purity and strength for drugs are not specified in the edition of the official Pharmacopoeia for the time being in force but are specified in the edition immediately preceding, the standards of identity, purity and strength shall be those occurring in such immediately preceding edition of the official Pharmacopoeia and such other standards as may be prescribed.

Penalty for subsequent offence: Whoever being convicted of an offence under clause (a) of sub-section (1) is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which may extend to 2 years and fine which shall not be less than 2,000 rupees.

b. Any Ayurvedic, Siddha or Unani Drug deemed to be spurious shall be punishable with imprisonment for a term which shall not be less than 1 year but which may extend to 3 years and with fine which shall not be less than 5,000 rupees. The court may, for any adequate and special reasons to be mentioned in the judgment, impose a sentence of imprisonment for a term of less than one year and of fine of less than 5,000 rupees. or

Penalty for subsequent offence: Whoever being convicted of an offence under clause (b) of sub-section (1) is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which shall not be less than 2 years but which may extend to 6 years and with fine which shall not be less

than 5,000 rupees. Provided that the court may, for any adequate or special reasons to be mentioned in the judgment, impose a sentence of imprisonment for a term of less than 2 years and of fine of less than 5,000 rupees.

2. Contravenes any other provisions of this chapter or any rule made under this chapter, shall be punishable with imprisonment for a term which may extend to 3 months and with fine which shall not be less than 500 rupees.

Penalty for subsequent offence: Whoever being convicted of an offence under sub-section (2) of this section is again convicted of an offence under that sub-section, shall be punishable with imprisonment for a term which may extend to 6 months and with fine which shall not be less than 1,000 rupees.

STANDARDS OF AYURVEDIC, SIDDHA AND UNANI DRUGS

Standards to be complied with in manufacture for sale or for distribution of Ayurvedic, Siddha and Unani Drugs.

Homoeopathic Medicines are also Covered under Second Schedule 4 (A) Which are as Follows:

<i>Class of drugs</i>	<i>Standards to be complied with</i>
a. Drugs included in the Homoeopathic Pharmacopoeia of India.	Standards of identity, purity and strength of drugs given in the Homoeopathic Pharmacopoeia of India for the time being in force and such other standards as may be prescribed.
b. Drugs not included in the Homoeopathic Pharmacopoeia of India but which are included in the Homoeopathic Pharmacopoeia of the United States of America or the United Kingdom or the German Homoeopathic Pharmacopoeia.	Standards of identity, purity and strength prescribed for the drugs in the edition of such Pharmacopoeia for the time being in which they are given and such other standards as may be prescribed.
c. Drugs not included in the Homoeopathic Pharmacopoeia of India or the United States of America or the United Kingdom or the German Homoeopathic Pharmacopoeia.	The formula or list of ingredients displayed in the prescribed manner or the label of the container and such other standards as may be prescribed by the Central Government.

LABELLING, PACKING AND LIMIT OF ALCOHOL IN AYURVEDIC (INCLUDING SIDDHA) OR UNANI DRUGS

Labelling, Packing and Limit of Alcohol

The container and package of Ayurvedic (including Siddha) or Unani Drugs should be labelled with the following particulars:

- There shall be considerably displayed on the label of the container or package of an Ayurvedic (including Siddha) or Unani Drug, the true list of all the ingredients used in the manufacture of the preparation together with quantity of each of the ingredients incorporated therein and a reference to the method of preparation thereof as detailed in the standard text and adikarana, as are prescribed in the authoritative books specified in the first schedule to the act. Provided that if the list of ingredients contained in the medi-

cine is large and cannot be accommodated on the label, the same may be printed separately and enclosed with packing and reference be made to this effect on the label.

- The container of a medicine for internal use made up ready for the treatment of human ailments shall, if it is made up from a substance specified in Schedule E₁, be labelled conspicuously with the words 'Caution: To be taken under medical supervision both in English and Hindi language.
- Subject to the other provisions of these rules, the following particulars shall be either printed or written in indelible ink and shall appear in a conspicuous manner on the label of the innermost container of any Ayurvedic (including Siddha) or Unani Drug and on any other covering in which the container is packed namely:

Manufacture for Sale or for Distribution of Homoeopathic Medicines

S. no.	Category of drugs	Application form no.	License form no.	Fees for grant/renewal	Fee + penalty after expiry but within six months	Fees for duplicate copy of org. Lic.
1.	Mother tinctures and potentised preparations.	24-C	25-C	₹ 200 + ₹ 100 for 1st inspection or ₹ 50 in case of inspection for renewal of license.	₹ 200 + ₹ 100 p.m. or part thereof and inspection fee of ₹ 50.	₹ 50
2.	Potentised preparation.	24-C	25-C	₹ 200 + ₹ 100 for 1st inspection or ₹ 50 in case of inspection for renewal of license.	₹ 200 + ₹ 100 p.m. or part thereof and inspection fee of ₹ 50.	₹ 50
3.	Potentised preparations from back potencies by pharmacy which are licensed to sell homoeopathic medicines by retail.	24-C	25-C	₹ 200 + ₹ 100 for 1st inspection or ₹ 50 in case of inspection for renewal of license).	₹ 200 + ₹ 100 p.m. or part thereof and inspection fee of ₹ 50.	₹ 50
4.	Additional item.			₹ 50 for each additional item.		

- i. The name of the drug. For this purpose the name shall be the same as mentioned in the authoritative books included in the first schedule of the act.
 - ii. A correct statement of the net content in terms of weight, measure or number as the case may be. The weight and volume shall be expressed in metric system.
 - iii. The name and address of the manufacturer.
 - iv. The number of the license under which the drug is manufactured, the figure representing the manufacturing license number being preceded by the words 'Manufacturing license number' or 'Mfg. Lic. No.' or 'M.L.'
 - v. A distinctive batch number, that is to say, the number by reference to which details of manufacture of the particular batch from which the substance in the container is taken are recorded and are available for inspection, the figure representing the batch number being preceded by the words "batch No." or "Batch" or "Lot number" or "Lot no." or "Lot no." or "Lot" or any distinguishing prefix.
 - vi. The date of manufacture. For this purpose the date of manufacture shall be the date of completion of the final products, or the date of bottling or packing for issue.
 - vii. The words "Ayurvedic Medicine" or "Siddha Medicine" or "Unani Medicine" as the case may be.
 - viii. The words "for external use only" if the medicine is for external application.
 - ix. Every drug intended for distribution to the medical profession, as a free sample shall, while complying with the labelling provisions under clauses (i) to (viii), further bear on the label of the container the words "Physicians sample. Not to be sold" which shall be over-printed.
4. Nothing in these rules shall be deemed to require the labelling of any transparent cover or of any wrapper case or other covering used solely for the purpose of packing, transport or delivery.

EXEMPTION IN LABELLING AND PACKING OF AYURVEDIC (INCLUDING SIDDHA) AND UNANI DRUGS

Exemption in labelling and packing, provisions for export of Syurvedic (including Siddha) and Unani Drugs:

1. Labels and packages or containers of Ayurvedic, Siddha and Unani Drugs for export may be adapted to meet the specific requirements of the law of the country to which the said drug is to be exported, but the following particulars shall appear in conspicuous position on the container in which drug is packed and on every other covering in which that container is packed, namely:
 - i. Name of the Ayurvedic, Siddha and Unani Drug (single or compound formulations).

Sale of Homeopathic Medicines						
Category	Type sale	Application form	License form	Fees for grant/renewal	Fee + penalty after expiry but within six months	Fees for duplicate copy of org. Lic.
Homoeopathic Medicines	Whole-sale	19-B	20-D	₹ 250	₹ 250 + ₹ 50 p.m	₹ 50
	Retail sale	19-B	20-C	₹ 250	₹ 250 + ₹ 50 p.m.	₹ 50

- ii. The name, address of the manufacturer and the number of license under which the drug has been manufactured.
- iii. Batch or lot number.
- iv. Date of manufacture, along with the date for "Best for use before".
- v. Main ingredients, if required by the import country.
- vi. For export.

Provided that where Ayurvedic, Siddha and Unani single or compound drug not classified under first schedule or Schedule E₁, is required by the consignee to be not labeled with the name and address of the manufacturer, the labels on packages or containers shall bear a code number as approved by the licensing authority mentioned in Rule 152.

2. The provisions of Rule 161 shall not apply to a medicine made up "ready for treatment", whether after, or without, alteration, which is supplied on the prescription of a registered medical practitioner if the medicine is labeled with the following particulars, namely:
 - i. The name and address of the suppliers.
 - ii. The words "for external use only", if the medicine is for external application.

THE FIRST SCHEDULE

A. Ayurvedic and Siddha Systems

Name of the book Ayurveda and Siddha System.

B. Unani Tibba System

Name of the book Unani Tibba System.

PROVISIONS APPLICABLE TO THE HOMOEOPATHIC MEDICINES

Homoeopathic system of medicine is about two hundred years old in India first time it was introduced and patronised by Raja Ranjit Singh in 19th century in 1969. First time homoeopathic got a legal status and it was introduced in Drug and Cosmetics Act, 1940. The standard of

homoeopathic medicines recognized Drug and Cosmetics Act in June 1978. The Drug and Cosmetics Act regulate the import, manufacturer, distribution and sale of drugs. The Homoeopathic Acts and Rules are framed by subcommittee of drugs technical advisory board or homoeopathy. The Government Analysts, drug inspectors and import of homoeopathic medicines are governed by the same rule as applicable for modern medicine.

"Homoeopathic Medicines" include any drug which is recorded in homoeopathy proving or therapeutic efficacy of which has been established through long clinical experience as recorded in authoritative homoeopathic literature of India or abroad and which is prepared according to technique of homoeopathic pharmacy and covers combination of ingredients of such homoeopathic medicines but does not include a medicine which is administered by parenteral route.

Registered homoeopathic medical practitioner means a person who is registered in the central register or homoeopathy.

Quality of drugs: Quality of drugs for import and for manufacture is given in Chapter III (import of drugs and cosmetics) and IV (manufacture, sale and distribution of drugs and cosmetics) respectively. As per drugs and cosmetics act quality of drugs are given as follows:

Standards of Quality

Standard of quality means:

- a. In relation to drugs that the drug complies with the standard set out in the (second Schedule) and.
- b. In relation to a cosmetics that the cosmetics complies with such standard as may be prescribed.

Standard to be followed: Second Schedule covers the standards to be complied with by imported drugs manufactured for sale, sold, stocked or exhibited for sale or distributed.

Import: Rule 30-AA deals with import of homoeopathic medicines.

Homeopathic medicines can be imported into India without any license. No **new homoeopathic medicine** shall be imported except under and in accordance with the permission in writing of the licensing authority. The importer of a new homoeopathic medicine when applying for permission shall produce before the licensing authority such documentary and other evidence as may be required by the licensing authority for assessing the therapeutic efficacy of the medicine including the minimum provings carried out with it.

For the purpose of this rule, '**New Homoeopathic Medicine**' means:

- i. A homoeopathic medicine which is not specified in the Homoeopathic Pharmacopoeia of India or United States of America or of the United Kingdom or the German homoeopathic pharmacopoeia.
- ii. Which is not recognized in authoritative homoeopathic literature as efficacious under the conditions recommended.
- iii. A combination of homoeopathic medicines containing one or more medicines which are not specified in any of the Pharmacopoeias referred to in clause: (i) as homoeopathic medicines and also not recognized in authoritative homoeopathic literature as efficacious under the conditions recommended.

If homoeopathic medicines are manufactured in more than one set of premises a separate application shall be made and a separate license shall be obtained in respect of each such set of premises. Requirements of factory premises for manufacture of homoeopathic preparations are specified under Schedule M-I.

Application for license to manufacture homoeopathic medicines: Application for grant or renewal of licenses to manufacture for sale or for distribution of homoeopathic medicines shall be made to the licensing authority appoin-

ted by the State Government for the purpose of this Part (hereinafter in this part referred to as the licensing authority) and shall be made in Form 24-C.

Subject to the other provisions of these rules:

1. No 'New Homoeopathic Medicine' shall be manufactured unless it is previously approved by the licensing authority.
2. The manufacturer of 'New Homoeopathic Medicine', when applying to the licensing Authority mentioned in sub-rule (1) shall produce such documentary and other evidence as may be required by the licensing authority for assessing the therapeutic efficacy of the medicine including the minimum provings carried out with it.
3. While applying for a license to manufacture a 'New Homoeopathic Medicine' an applicant shall produce along with his application evidence that the 'New Homoeopathic Medicine' for the manufacture of which application is made has already been approved.

Form of license to manufacture homoeopathic medicines: License for manufacture of homoeopathic medicines is a license to manufacture potentised preparations from back potencies by Pharmacies who are already licensed to sell homoeopathic medicines by retail and shall be granted in Form 25-C.

Condition of License

A license in Form 25-C shall be subject to the conditions stated therein and to the following further conditions, namely:

- a. The license shall provide and maintain staff and premises as specified in Rule 85-E.
- b. The license shall allow an (inspector appointed under the act) to enter, with or without prior notice, any premises where the manufacture of a homoeopathic medicine in respect of which the license is issued is carried on, to inspect the premises and to take samples of the manufactured homoeopathic medicines.

- c. The license shall allow an inspector to inspect all registers and records maintained under these rules and shall supply to the inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and the rules made thereunder have been observed.
- d. The license shall maintain an inspection book in Form 35 to enable an inspector to record his impressions and defects noticed.
- e. The license shall comply with the following conditions in respect of the mother tinctures manufactured by him:
 - i. The crude drug used in the manufacture of the mother tincture shall be identified and records of such identification shall be kept for a period of five years.
 - ii. The total solids in the mother tincture shall be determined and records of such tests shall be kept for a period of five years.
 - iii. The alcohol content in the mother tincture shall be determined and records of the same shall be maintained for a period of five years.
 - iv. The containers of mother tincture shall preferably be of glass and shall be clean and free from any sort of impurities or adhering matter. The glass shall be natural as far as possible.

Application: Application for the grant or renewal of a license to sell, stock or exhibit or offer for sale or distribute homoeopathic medicines shall be made in Form 19-B to the licensing authority appointed by the State Government and shall be accompanied by a fee of rupees two hundred and fifty. If the original license is either defaced, damaged or lost, a duplicate copy thereof may be issued on payment of a fee of rupees 50.

Forms of licenses to sale drugs: A license to sell, stock or exhibit or offer for sale or distribute homoeopathic medicines by retail or by

wholesale shall be issued in Form 20-C or 20-D as the case may be.

Condition to be Satisfied before a License in Form 20-C or Form 20-D is Granted

1. A license in Form 20-C or Form 20-D to sell, stock or exhibit or offer for sale or distribute homoeopathic medicines shall not be granted to any person unless the authority empowered to grant the license is satisfied that the premises in respect of which the license is to be granted are clean and in the case of a license in Form 20-C the sale premises is in charge of a person who is or has been dealing in homoeopathic medicines and who is in the opinion of the licensing authority competent to deal in homoeopathic medicines.
2. Any person who is aggrieved by the order passed by the licensing authority under sub Rule (1) may within 30 days from the date the receipt of such order appeal to the State Government and the State Government may, after such enquiry into the matter as it considers necessary and after giving the appellant an opportunity for representing his case, make such order in relation thereto as it thinks fit.

Conditions of License

License in Form 20-C or 20-D shall be subject to the conditions stated therein and to the following further conditions, namely:

- a. The premises where the homoeopathic medicines are stocked for sale or sold are maintained in a clean condition.
- b. The sale of homoeopathic medicines shall be conducted under the supervision of a person, competent to deal in homoeopathic medicines.
- c. The licensee shall permit an inspector to inspect the premises and furnish such information as he may require for ascertaining whether the provisions of the act and

the rules made thereunder have been observed.

- d. The licensee in Form 20-D shall maintain records of purchase and sale of homoeopathic medicines containing alcohol together with names and addresses of parties to whom sold.
- e. The licensee in Form 20-C shall maintain records of purchase and sale of homoeopathic medicines containing alcohol. No records of sale in respect of homoeopathic potentised preparation in containers of 30 ml or lower capacity and in respect of mother tinctures made up in quantities up to 60 ml need be maintained.
- f. The licensee shall maintain an inspection book in Form 35 to enable an inspector to record his impressions and the defects noticed.

An original license or a renewed license unless it is sooner suspended or cancelled shall be valid for a period of five years on and from the date on which it is granted or renewed.

The licensing authority may, after giving the licensee an opportunity to show cause why

such an order should not be passed by an order in writing stating the reasons here for, cancel a license issued under this part or suspend it for such period as he thinks fit, if in his opinion, the licensee has failed to comply with any of the conditions of the license or with any provisions of the act or rules made thereunder.

A licensee whose license has been suspended or cancelled may, within 3 months of the date of the order, prefer an appeal against that order to the State Government, which shall decide the same.

LABELLING AND PACKING OF HOMOEOPATHIC MEDICINES

Manner of Labelling of Homoeopathic Medicines

1. The following particulars shall be either printed or written in indelible ink and shall appear in a conspicuous manner on the label of the innermost container of any homoeopathic medicine and on every other covering in which the container is packed:

License to Manufacture Cosmetics						
<i>S.no.</i>	<i>Particulars</i>	<i>Application form no.</i>	<i>License form no.</i>	<i>Fees for grant/renewal</i>	<i>Fee + penalty after expiry but within six months</i>	<i>Fees for duplicate copy of org. Lic.</i>
1.	Own manufacturing items for each category	31 up to 10	32	Lic. Fee of ₹ 2500 + insp. Fee of ₹ 1000 for every inspection or for renewal of license.	₹ 2500 + ₹ 400 p.m. or part thereof in addition to insp. fee of ₹ 1000.	₹ 250 ₹ 100 for each additional item subject to a maximum of ₹ 3000.
2.	Loan license items for each category	31-A up to 10	32-A	Lic. Fee of ₹ 2500 + insp. Fee of ₹ 1000 for every inspection or for renewal of license.	₹ 2500 + ₹ 400 p.m. or part thereof in addition to insp. fee of ₹ 1000.	₹ 100 for each additional item subject to a maximum of ₹ 3000.

Note: Fee for further application after rejection ₹ 250.

- i. The word 'homoeopathic medicine'.
- ii. The name of the medicine:
 - a. For drugs included in the homoeopathic pharmacopoeias of India or the United States of America or the United Kingdom or the German Homoeopathic Pharmacopoeia, the name specified in that Pharmacopoeia.
 - b. For other drugs, the name descriptive of the true nature of the drug.
- iii. The potency of the homoeopathic medicine—For this purpose the potency shall be expressed either in decimal, centesimal or millisimal systems.
- iiiA. In case of homoeopathic medicine containing two or more ingredients the name of each ingredient together with its potency and proportion expressed in metric system shall be stated on the label.
- iv. Name and address of the manufacturer when sold in original containers of the manufacturer. In case a homoeopathic medicine is sold in a container other than that of the manufacturer—the name and address of the seller.
- v. In case the homoeopathic medicine contains alcohol, the alcohol content in percentage by volume in terms of ethyl alcohol shall be stated on the label.

Provided that in case that the total quantity of the Pharmacopoeial homoeopathic medicine in the container is 30 milliliters or less, it will not be necessary to state the content of alcohol in the label.

2. In addition to the above particulars the labels of a homoeopathic mother tincture shall display the following particulars:
 - i. A distinctive batch number, that is to say, the number by reference to which details of manufacture of the particular batch from which the substance in the container is taken are recorded and are

available for inspection, the figures representing the batch number being preceded by the words "batch no." or "batch" or "lot number" or "lot no." or "lot" or any distinguishing prefix.

- ii. Manufacturing license number, the number being preceded by the words "manufacturing license number" or "Mfg. lic. no." or "M.L."

Explanation: This clause shall not apply to a homoeopathic mother tincture manufactured outside India.

3. No homoeopathic medicine containing a single ingredient shall bear a proprietary name on its label.

Prohibition of quantity and percentage: No homoeopathic medicine containing more than 12% alcohol v/v (ethyl alcohol) shall be packed and sold in packing or bottles of more than 30 millilitres, except that it may be sold to hospital/ dispensaries in packings or bottles of not more than 100 millilitres.

PROVISIONS APPLICABLE TO THE COSMETICS

Cosmetic means any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic. Cosmetics include skin-care creams, lotions, powders, perfumes, lipsticks, fingernail and toe nail polish, eye and facial makeup, permanent waves, colored contact lenses, hair colours, hair sprays and gels, deodorants, baby products, bath oils, bubble baths, bath salts, butters and many other types of products.

The manufacture of cosmetics is currently dominated by a small number of multinational corporations that originated in the early 20th century, but the distribution and sale of cosmetics is spread among a wide range of different businesses. The U.S. Food and Drug

Administration (FDA) which regulates cosmetics in the United States defines cosmetics as: "intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance without affecting the body's structure or functions." This broad definition includes, as well, any material intended for use as a component of a cosmetic product. The FDA specifically excludes soap from this category.

Provisions relating to import, manufacture, distribution and sale of cosmetics were included in the present act and rules in 1962.

IMPORT OF COSMETICS

Before any cosmetics are imported, a declaration signed by or on behalf of the manufacturer or by on behalf of the importer that the cosmetics comply with the provisions of Chapter III (provisions related to the import of drugs and cosmetics) of the act, and the rules made there under, shall be supplied to the collector of customs.

Cosmetics can also be imported in a way similar to that of drugs. All consignments of cosmetics sought to be imported shall be accompanied by an invoice or statement showing the name and quantities of each article of cosmetic included in the consignment and the name and address of the manufacturer. Cosmetics can also be imported in to India only through the point of entry specified for import of drugs.

Procedure: Procedure for the import of cosmetics:

1. If the officer appointed at the post of entry by the Central Government has reason to believe that any cosmetic contravenes any of the provisions of the act or the rules made thereunder he may take sample of the cosmetic from the consignment for inspection. If on examination of the sample defects are noticed the officer shall advise the collector of customs for further action to be taken.

2. If the suspected contravention of the provisions of the act or the rules is such as may have to be determined by test, the officer shall send the sample to the laboratory established for the purpose for performing such that the test report on such sample is received from the director of the said laboratory or any other officer of the laboratory empowered by him in this behalf with the approval of the Central Government.
3. If the importer gives an undertaking in writing not to dispose of the cosmetic without the consent of the collector of customs and to return the consignment or such portion thereof, he shall return the consignment or such portion thereof as may be required; the collector of customs shall make over the consignment to the importer.
4. If the importer who has given an undertaking under the proviso to sub-rule (1) is required by the collector of customs to return the consignment or portion thereof, he shall return the consignment or portion thereof within ten days of receipt of the notice.

IMPORT OF COSMETIC FOR PERSONAL USE

Small quantities of cosmetics the import of which is otherwise prohibited under Section 10 of the act, may be imported for personal use subject to the following conditions:

- i. The cosmetics shall form part of a passenger's baggage and shall be the property of and intended for, the bonafide use of the passenger.
- ii. The cosmetics shall be declared to the customs authorities, if they are so direct.

Exemption

Cosmetics as may be specified in Schedule D shall be exempted from the provisions of Chapter III (import of drugs and cosmetics) of the act and the rules made thereunder to the

extent and subject to the conditions specified in that schedule (see Schedule D).

Other Provisions Related to the Import of Cosmetics

A. Import of following classes of cosmetics is prohibited:

- i. Any cosmetic which is misbranded or spurious or not of standard quality.
- ii. Any cosmetic containing any ingredient which may render it un-safe or harmful for use under the directions indicated or recommended.
- iii. Any cosmetic whose import is prohibited under the rules.

B. Cosmetic to contain dyes, colours and pigments: No cosmetic shall contain dyes, colours and pigments other than those specified by the bureau of Indian standards and Schedule Q.

The permitted synthetic organic colours and natural organic colours used in the cosmetic shall not contain more than:

- i. 2 parts per million of arsenic calculated as arsenic trioxide.
- ii. 20 parts per million of lead calculated as lead.
- iii. 100 parts per million of heavy metals other than lead calculated as the total of the respective metals.

C. Import through points of entry: No cosmetic shall be imported into India except through the points of entry specified in Rule 43 A.

D. Prohibition of import of cosmetic containing hexachlorophene: No cosmetic containing hexachlorophene shall be imported.

E. Import of cosmetic lead or arsenic compound prohibited: No cosmetic shall be imported in which a lead or arsenic compound has been used for the purposes of colouring.

F. Import of cosmetics containing mercury compounds prohibited: No cosmetic shall be imported which contains mercury compounds.

MANUFACTURE OF COSMETIC FOR SALE OR FOR DISTRIBUTION

A license to manufacture cosmetic for sale or for distribution against application in Form 31, shall be granted in Form 32. If cosmetics are manufactured on more than one premise, a separate application for each such premise shall be made and a separate license shall be obtained for each such premises. Requirement of factory premises for manufacture of cosmetics are specified under Schedule M-II.

Application for license to manufacture cosmetics: Application for grant or renewal of license to manufacture any cosmetic for sale shall be made up to 10 items of each category of cosmetics categorized in Schedule M-II to the licensing authority appointed by the State Government for the purpose of this part (hereafter' in this part referred to as the licensing authority) in Form-31 and shall be accompanied by a fee of ₹ 2,500 and an inspection fee of ₹ 1,000 for every inspection thereof or for the purpose of renewal of license.

Conditions for the Grant or Renewal of a License in Form 32

Before a license in Form 32 is granted or renewed, the following conditions shall be compiled with by applicant:

1. The manufacture shall be conducted under the direction and personal supervision of a competent technical staff consisting of at least one person who is a whole time employee and who possesses any one of the following qualifications:
 - a. Holds a diploma in pharmacy approved by the Pharmacy Council of India under the Pharmacy Act, 1948.
 - b. Is registered under the Pharmacy Act, 1948.
 - c. Has passed the intermediate examination with chemistry as one of the subjects or an examination recognized

Form	
Form 44	Application for grant of permission to import or manufacture a new drug or to undertake clinical trial.
Form 45	Permission to import finished formulation of the new drug.
Form 45-A	Permission to import raw material (new bulk drug substance).
Form 46	Permission/approval for manufacture of new drug formulation.

by the licensing authority as equivalent to it.

2. The factory premises shall comply with the requirements and conditions specified in Schedule M-II.
3. The applicant shall either:
 - i. Provide and maintain adequate staff, premises and laboratory equipment for testing the cosmetic manufactured and the raw materials used in the manufacturing.
 - ii. Make arrangements with some institution approved by the licensing authority under Part XV-A of these Rules for such tests to be regularly carried out in this behalf by the institution.

LOAN LICENSE TO MANUFACTURE COSMETICS

A loan license to manufacture cosmetics for sale or for distribution against application in Form 31-A shall be granted in Form 32-A.

Conditions of License in Form 32-A

- a. This license and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
- b. Any change in the technical staff shall be forthwith reported to the licensing authority.
- c. If the licensee wants to manufacture for sale additional items he should apply to the licensing authority for the necessary endorsement to the license. This license shall be deemed to extend to the cosmetics so endorsed.

SALE OF COSMETICS

Cosmetics which do not contravene the provisions of the act and the rules may be sold without a license. Dealer are bound to disclose on demand the name and other particulars of the persons from whom they obtain cosmetics. Penalty for sale or distribution of cosmetics contravening the provisions of the act and rules are same as applicable for their manufacture.

OTHER PROVISIONS RELATED TO THE MANUFACTURE AND SALE OF COSMETICS

- A. *Report of result of test or analysis of cosmetics:* Test reports on samples of cosmetics taken for test or analysis under these rules shall be supplied in Form 34.
- B. *Standard for cosmetics:* Subject to the provisions of these rules, the standards for cosmetics shall be such as may be prescribed in Schedule S (see Schedule S).
- C. *Exemption of cosmetics not manufactured for consumption or sale in India:* From the provisions of this part: Labels on packages or containers of cosmetics not manufactured for consumption or sale in India shall be adapted to meet the specific requirements, if any, of the consignee. Provided that where a cosmetic is required by the consignee to be not labeled with the name and address of the manufacturer, the labels on packages or containers shall bear a code number as approved by the licensing authority.
- D. *Prohibition of sale or distribution:* Subject to other provisions of these rules, no person shall sell or distribute any cosmetic unless the

cosmetic, of Indian origin is manufactured by a licensed manufacturer and labelled and packed in accordance with these rules.

LABELLING, PACKING AND STANDARDS OF COSMETICS

Cosmetics whether imported or manufactured in India must be labeled in accordance with the following provisions:

Manner of labelling: Subject to other provisions of the rules, a cosmetic shall carry:

1. On both the inner and outer labels:
 - a. The name of the cosmetic.
 - b. The name of the manufacturer and complete address of the premises of the manufacturer where the cosmetic has been manufactured.

Provided that if the cosmetic is contained in a very small size container where the address of the manufacturer cannot be given, the name of the manufacturer and his principal place of manufacture shall be given along with pin code.

2. On the outer label-A declaration of the net contents expressed in terms of weight for solids, fluid measure for liquids, weight for semi solids, combined with numerical count if the content is sub-divided. Provided that this statement need not appear in case of a package of perfume, toilet water or the like the net content of which does not exceed 60 ml or any package of solid or semi-solid cosmetic the net content of which does not exceed 30 grams.
3. On the inner label, where a hazard exists:
 - a. Adequate direction for safe use.
 - b. Any warning, caution or special direction required to be observed by the consumer.
 - c. A statement of the names and quantities of the ingredients that are hazardous or poisonous.
4. A distinctive batch number, that is to say, the number by reference to which details of manufacture of the particular batch from

which the substance in the container is taken are recorded and are available for inspection, the figures representing the batch number being preceded by the letter "B", provided that this clause shall not apply to any cosmetic containing 10 grams or less if the cosmetic is in solid or semi-solid state, and 25 milliliters or less if the cosmetic is in a liquid state.

In the case of soaps, instead of the batch number, the month and year of manufacture of soap shall be given on the label.

5. Manufacturing license number, the number being preceded by the letter 'M'.
6. Where a package of a cosmetic has only one label, such label shall contain all the information required to be shown on both the inner and the outer labels, under these rules.

Prohibition against altering inscriptions on containers, labels or wrappers of cosmetics: No person shall alter, obliterate or deface any inscription or mark made or recorded by the manufacturer on the container, label or wrapper of any cosmetic. Provided that nothing in this rule shall apply to any alteration, inscription or mark made on the container, label or wrapper of any cosmetic at the instance or direction or with the permission of the licensing authority.

Labelling of hair dyes containing dyes, colours and pigments: Hair dyes containing para-phenylenediamine or other dyes, colours and pigments shall be labeled with the following legend in english and local languages and these shall appear on both the inner and the outer labels.

"Caution: This product contains ingredients which may cause skin irritation in certain cases and so a preliminary test according to the accompanying direction should first be made. This product should not be used for dyeing the eye-lashes or eye-brows, as such a use may cause blindness".

Each package shall also contain instructions in English and local languages on the following lines for carrying out the test:

"This preparation may cause serious inflammation of the skin in some cases and so a preliminary test should always be carried out to determine whether or not special sensitivity exists. To make the test, cleanse a small area of skin behind the ear or upon the inner surface of the forearm, using either soap and water or alcohol. Apply a small quantity of the hair dye as prepared for use to the area and allow it to dry. After 24 hours, wash the area gently with soap and water. If no irritation or inflammation is apparent, it may be assumed that no hypersensitivity to the dye exists. The test should, however, be carried out before each and every application. This preparation should on no account be used for dyeing eye-brows or eyelashes as severe inflammation of the eye or even blindness may result".

Special provisions relating to toothpaste containing fluoride:

- i. Fluoride content in toothpaste shall not be more than 1000 ppm and the content of fluoride in terms of ppm shall be mentioned on the tube and carton.
- ii. Date of expiry should be mentioned on tube and carton.

Standards for cosmetics: Standards for cosmetics in finished form are discussed in Schedule S (see Schedule S).

IMPORT OR MANUFACTURE OF NEW DRUG FOR CLINICAL TRIALS OR MARKETING

Definition of new drug: For the purpose of this part, new drug shall mean and include:

- a. A drug, as defined in the act including bulk drug substance which has not been used in the country to any significant extent under the conditions prescribed, recommended or suggested in the labelling thereof and has not been recognized as

effective and safe by the licensing authority for the proposed claims.

- b. A new drug already approved by the licensing authority for certain claims, which is now proposed to be marketed with modified or new claims, namely, indications, dosage, dosage form (including sustained release dosage form) and route of administration.
- c. A fixed dose combination of two or more drugs, individually approved earlier for certain claims, which are now proposed to be combined for the first time in a fixed ratio, or if the ratio of ingredients in an already marketed combination is proposed to be changed, with certain claims, viz. indications, dosage, dosage form (including sustained release dosage form) and route of administration.

For the purpose of this rule:

- i. All vaccines shall be new drugs unless certified otherwise by the licensing authority.
- ii. A new drug shall continue to be considered as new drug for a period of four years from the date of its first approval or its inclusion in the Indian Pharmacopoeia, whichever is earlier.

Application for Approval to Import or Manufacture of New Drug

Application for permission to import new drug and application for approval to manufacture new drug other than the drugs are classifiable under Schedules C and C₁.

1. No new drug shall be imported or manufactured for sale unless it is approved by the licensing authority. An application for the grant of approval to import or manufacture the new drug and its formulations shall be made in Form 44 to the licensing authority and shall be accompanied by a fee of 50,000 rupees. Whether in modified dosage form or with the new claims, is made, the fee to

accompany such subsequent application shall be 15,000 rupees.

Any application received after one year of the grant of approval for the import or manufacture for sale of the new drug, shall be accompanied by a fee of 15,000 rupees and such information and data as required by Appendix 1 or Appendix 1-A of Schedule Y, as the case may be.

2. The importer or manufacturer of a new drug under sub-rule (1) when applying for approval to the licensing authority mentioned in the same sub-rule, shall submit data as given in Appendix 1 to Schedule Y including the results of clinical trials carried out in the country in accordance with the guideline specified in Schedule Y and submit the report of such clinical trials in the same format given in Appendix II to the said Schedule.

The requirement of submitting the results of local clinical trials may not be necessary if the drug is of such nature that the licensing authority may, in public interest decide to grant such permission on the basis of data available from other countries.

The submission of requirements relating to animal toxicology, reproduction studies, teratogenic studies, perinatal studies, mutagenicity and carcinogenicity may be modified or relaxed in case of new drugs approved and marketed for several years in other countries if he is satisfied that there is adequate polished evidence regarding the safety of the drug, subject to the other provisions of these rules.

(2-A) The licensing authority after being satisfied that the drug if approved to be imported or manufactured as raw material (bulk drug substance) or as finished formulation shall be effective and safe for use in the country, may issue an import permission in Form 45 and/or Form 45-A and grant approval for manufacture in Form 46 and/or Form 46-A, as the case may be, subject to the conditions stated therein.

3. When applying for approval to manufacture a new drug or its preparations, to the State Licensing Authority, an applicant shall produce along with his application, evidence that the drug for the manufacture of which application is made has already been approved by the licensing authority.

Conditions for the grant of approval to import or manufacture of new drug are discussed below.

Conditions for Grant of Approval/permission in Form 45 or Form 46

Permission to import finished formulation of the new drug shall be issued in Form 45 and approval for manufacture of new drug formulation shall be issued in Form 46.

1. The formulation shall conform to the specifications approved by the licensing authority.
2. The proper name of the drug shall be printed or written in indelible ink and shall appear in a more conspicuous manner than the trade name, if any, which shall be shown immediately after or under the proper name on the label of the innermost container of the drug or every other covering in which the container is packed.
3. The label of the innermost container of the drug and every other covering in which the container is packed shall bear a conspicuous red vertical line on the left side running throughout the body of the label which shall not be less than 1 mm in width and without disturbing the other conditions printed on the label to depict it is prescription drug.
4. The label on the immediate container of the drug as well as the packing in which the container is enclosed should contain the following warning: "warning: To be sold by retail on the prescription of a only."
5. Post marketing surveillance study shall be conducted during initial period of two years

of marketing of the new drug formulation, after getting the protocol and the names of the investigator duly approved by the licensing authority.

6. All reported adverse reactions related to the drug shall be intimated to the Drugs Controller, India and licensing authority and regulatory action resulting from their review should be complied with.
7. No claims except those mentioned above shall be made for the drug without the prior approval of the licensing authority.
8. Specimen of the carton, labels, package insert that will be adopted for marketing the drug in the country shall get approved from the licensing authority before the drugs is marketed.
9. Each consignment of imported drug shall be accompanied by a test analysis report.

Conditions for Grant of Approval/Permission in Form 45-A

Permission to import raw material (new bulk drug substance) shall be issued in Form 45-A.

1. The raw material (new bulk drug substance) shall conform to the test specifications as approved by the licensing authority.
2. For manufacture of raw material (new bulk drug substance) or its formulation in the country, separate approval under Rule 122-B shall be obtained from the licensing authority.
3. The permission to import shall not be used to convey or imply that the raw material (new bulk drug) is categorized as "life saving or essential drug."

PERMISSION TO IMPORT OR MANUFACTURE FIXED DOSE COMBINATION

An application for permission to import or manufacture fixed dose combination of two or more drugs shall be made to the licensing authority in Form 44, accompanied by a fee of 15,000 rupees and shall be accompanied by such information and data as is required in Appendix VI of Schedule Y. The licensing authority after being satisfied that the fixed dose combination if approved to be imported or manufactured as finished formulation shall be effective and safe for use in the country, shall issue permission in Form 45 or Form 46, as the case may be, subject to the conditions stated therein.

APPLICATION FOR PERMISSION TO CONDUCT CLINICAL TRIALS FOR NEW DRUG/ INVESTIGATIONAL NEW DRUG

1. No clinical trial for a new drug, whether for clinical investigation or any clinical experiment by any institution, shall be conducted except under, and in accordance with, the permission, in writing, of the licensing authority.
2. An application for grant of permission to conduct:
 - a. Human clinical trials (Phase-I) on a new drug shall be made to the licensing authority in Form 44 accompanied by a fee of fifty thousand rupees and such information and data as required under Schedule Y.

Form	
Form 36	Application for grant or renewal of approval for carrying out tests on drugs cosmetics or raw materials used in the manufacture thereof on behalf of licensees for manufacture for sale of drugs cosmetics.
Form 37	Approval for carrying out tests on drugs cosmetics and raw materials used in their manufacture on behalf of licensees for manufacture for sale of drugs cosmetics

- b. Exploratory clinical trials (Phase-II) on a new drug shall be made on the basis of data emerging from Phase-I trial, accompanied by a fee of twenty five thousand rupees.
- c. Confirmatory clinical trials (Phase-III) on a new drug shall be made on the basis of the data emerging from Phase-II and where necessary, data emerging from Phase-I also, and shall be accompanied by a fee of 25,000 rupees.

Provided that no separate fee shall be required to be paid along with application for import/manufacture of a new drug based on successful completion of phases clinical trials by the applicant. Provided further that no fee shall be required to be paid along with the application by Central Government or State Government Institutes involved in clinical research for conducting trials for academic or research purposes.

3. The licensing authority after being satisfied with the clinical trials, shall grant permission in Form 45 or Form 45-A or Form 46 or Form 46-A, as the case may be subject to the conditions stated therein.

The licensing authority shall, where the data provided on the clinical trials is inadequate, intimate the applicant in writing, within 6 months from the date of such intimation or such extended period, not exceeding a further period of 6 months, as the licensing authority may, for reasons to be recorded in writing, permit, intimating the conditions which shall be satisfied before permission could be considered.

For the purpose of these rules investigational new drug means a new chemical entity or a product having therapeutic indication but which have never been earlier tested on human beings.

SPECIAL PROVISIONS RELATING TO BIOLOGICAL AND OTHER SPECIAL PRODUCTS

If any substance specified in Schedule C is advertised or sold as a proprietary medicine or

is contained in a medicine so advertised or sold, the proper name of the substance shall appear on the label in the manner prescribed in this part. For the purpose of this rule the expression "proper name" means the proper name stated in Schedule F or if no such name is stated, the name descriptive of the true nature and origin of the substance. Provided that in the case of veterinary biological product the expression "proper name" means the proper name stated in Schedule F₁ or if no such name is stated, the name or synonym given in the current edition for the time being of the British Pharmacopoeia (Veterinary), or, if no such name is stated either in Schedule F₁ or the British Pharmacopoeia (Veterinary), the name descriptive of the true nature and origin of the substance approved by the licensing authority.

No substance specified in Schedule C shall be sold or offered for sale unless it has been sealed in a previously sterilized container made of glass or any other suitable material approved for the purpose by the licensing authority appointed under Rule 21, in such manner as may, in the opinion of the licensing authority, suffice to preclude the access of bacteria. Provided that it shall not be necessary to use a previously sterilized container if the filled and sealed container is to be sterilized after the sealing and such sterilizing procedure would render the product sterile. However, the licensing authority may, for any special reasons, direct the licensee to pre-sterile such containers.

When any such substance is issued in liquid form in containers which are sealed in such a manner that portions of the contents can be withdrawn for use on different occasions, the liquid shall contain a sufficient proportion of some antiseptic to prevent the growth of any organisms which may be accidentally introduced in the process of removing a portion of the contents of the container. Provided that nothing in this sub-rule shall apply to a penicillin suspension in oil and water.

The container shall comply with such further requirements, if any, as are specified in Schedule F or Schedule F₁ as the case may be, in that behalf. The licensing authority may in the case of any particular preparation of any such substance dispense with any such substance dispense with any of the requirements of this rule or Schedule F or Schedule F₁ as the case may be, and may make such additional requirements, as having regard to the nature of the preparation, they may deem necessary.

Prohibition of sale of substance after prescribed Date: No person shall sell or exhibit for sale any substance specified in Schedule C after the date recorded on the container, label or wrapper as the date upto which the substance may be expected to retain a potency not less than, or not to acquire a toxicity greater than that required or permitted by the prescribed test as the case may be.

Standards: Every substance specified in Schedules C and C₁ intended for sale shall confirm with the standards of strength, quality and purity specified in these rules and in Schedule F or F₁, as the case may be, and the tests for determining such conformity shall be applied to samples taken from the final product after every manufacturing process has been completed.

Tests for Strength and Quality

1. The tests, if any, required for determining the strength and quality of each of the substances specified in Schedules C and C₁ shall be those set out in Schedule F or Schedule F₁ or as specified as the case may be.

Application of Tests for Sterility

The tests shall be applied:

- a. Two samples taken from each batch of the substance before the operation of filling and sealing the containers in which it is to be issued has commenced except preparations, which after being sealed in the containers are to be sterilized by heat,

in a manner satisfactory to the licensing authority.

- b. To the contents of sample containers when ready for issue.
 - 2. If at this examination no growth of micro-organisms is found in any tube, the sample may be treated as having passed the test.
- II. If at the examination of a growth of micro-organisms is visible, further samples may be taken and the tests may be repeated on the further samples taken but no container the contents of which form part of the batch shall be issued until such further samples have passed the test. The process of taking samples from the batch for a test may be repeated twice. Provided that if the same organism is visible in more than one test the batch shall be treated as not sterile and the material contained in the batch shall not be issued or used as part of a further batch unless and until it has been re-sterilized and has passed the tests.

Test for freedom from abnormal toxicity:

Each batch of serum should be tested for freedom for abnormal toxicity by giving a dose of 0.5 cc subcutaneously into a normal mouse/ not less than 5 cc subcutaneously or interperitoneally into a normal guinea pig. If no death or serious symptoms are produced in the animal within seven days, the serum is treated to have passed the test.

Test for pyrogens: Solution of substances intended for parenteral administration in large volumes (10 ml or more at a time) shall be pyrogen-free and tested for pyrogens. If water or any other adequate solvent is supplied along with the substances preparing such solutions, it shall also be pyrogen-free and tested for pyrogens.

Substances specified in Schedule C₁: The following provisions shall apply in the case of a substance specified in Schedule C₁:

- a. The container shall comply with the requirements, if any, specified in Schedule F

- or Schedule F₁, or as specified as the case may be.
- b. The substance shall conform to the standards of strength, quality and purity specified in Schedule F or Schedule F₁ or as specified, as the case may be and the tests for determining the strength, quality and purity of the substance shall be those specified in Schedule F or Schedule F₁ or as specified, as the case may be.
 - c. The tests for determining the strength, quality and purity of a substance specified in Schedule F or Schedule F₁, as the case may be applied to samples taken from the final product after each manufacturing process has been completed.
 - d. The substance should be stored in a cool place and away from light.

APPROVAL OF INSTITUTE FOR ANALYSIS

Approval of institutions for carrying out tests on drugs, cosmetics and raw materials used in their manufacture on behalf of licensees for manufacture for sale of drugs cosmetics:

Application for Grant for Testing Drugs and Cosmetics

1. Application for grant or renewal of approval for carrying out tests for identity, purity, quality and strength on drugs or cosmetics or the raw materials used in the manufacture thereof on behalf of licensees for manufacture for sale of drugs or cosmetics, shall be made in Form 36 to the licensing authority appointed by the State Government shall be accompanied by an inspection fee of 6,000 rupees in the case of testing of drugs specified in Schedules C and C₁ and rupees one thousand five hundred in the case of testing of drugs other than those specified in Schedules C and C₁, homoeopathic drugs and cosmetics.

If the applicant applied for renewal of approval after its expiry but within 6 months of

such expiry, the inspection fee payable shall be 6,000 rupees in the case of testing of drugs specified in Schedules C and C₁ and 1,500 rupees in the case of testing of drugs other than those specified in Schedules C and C₁, homoeopathic medicines and cosmetics plus an additional fee at the rate of 1,000 rupees per month.

2. A separate application shall be made for grant of approval for carrying out tests on additional categories of drugs or items of cosmetics and shall be accompanied by an inspection fee of 1,500 rupees in the case of drugs specified in Schedule C and Schedule C₁ and 1,000 rupees each in case of drugs other than those specified in Schedule C and Schedule C₁, homeopathic medicines and cosmetics.

Conditions for Grant or Renewal

Form on which approval to be granted for carrying out tests on drugs cosmetics on behalf of licensees for manufacture of drugs cosmetics and conditions for grant or renewal of such approval:

1. Approval for carrying out such tests of identity, purity, quality and strength of drugs or cosmetics as may be required under the provisions of these rules or behalf of licensee for manufacture of drugs or cosmetics shall be granted in Form 37.
2. Before approval in Form 37 is granted or renewed, the following conditions shall be compiled by the applicant:
 - i. The premises where the tests are being carried out shall be well lighted and properly ventilated except where the nature of tests of any drug or cosmetic warrants otherwise. Wherever necessary, the premises shall be air conditioned so as to maintain the accuracy and functioning of laboratory instruments or to enable the performance of special tests such as sterility tests, microbiological tests, etc.

- ii. The applicant shall provide adequate space having regard to the nature and number of samples of drugs or cosmetics proposed to be tested. Provided that the approving authority shall determine from time to time whether the space provided continues to be adequate.
3. If it is intended to carry out tests requiring the use of animals, the applicant shall provide for an animal house and comply with the following requirements:
 - a. The animal house shall be adequate in area, well lighted and properly ventilated and the animals undergoing tests shall be kept in air conditioned area.
 - b. The animals shall be suitably housed in hygienic surroundings and necessary provisions made for removal of excreta and foul smell.
 - c. The applicant shall provide suitable arrangements for preparation of animal feed.
 - d. The applicant shall provide suitable arrangements for quarantining of all animals immediately on their receipt in the institution.
 - e. The animals shall be periodically examined for their physical fitness.
 - f. The applicant shall provide for isolation of sick animals as well as animals under test.
 - g. The applicant shall ensure compliance with the requirements of the Prevention of Cruelty to Animal Act, 1960.
 - h. The applicant shall make proper arrangements for the disposal of the carcasses of animals in a manner as not to cause to public health.
4. The applicant shall provide and maintain suitable equipment having regard to the nature and number of samples of drugs or cosmetics intended to be tested which shall be adequate in the opinion of the approving authority.
5. The testing of drugs or cosmetics, as the case may be, shall be under the active direction of a person whose qualifications and experience are considered adequate in the opinion of the approving authority and who shall be held responsible for the reports of test or analysis issued by the applicant.
6. The testing of drugs or cosmetics, as the case may be, for identity, purity, quality and strength shall be carried out by persons whose qualifications and experience of testing are adequate in the opinion of the approving authority.
7. The applicant shall provide books of standard recognized under the provisions of the act and the rules made thereunder and such books of reference as may be required in connection with the testing or analysis of the products for the testing of which approval is applied for.

Conditions of Approval

An approval in Form 37 shall be subject to the following general conditions:

- a. The institution granted approval under this part (hereinafter referred to as the approved institution) shall provide and maintain an adequate staff and adequate premises and equipment as specified in Rule 150-C.
- b. The approved institution shall provide proper facilities for storage so as to preserve the properties of the samples of the samples to be tested by it.
- c. The approved institution shall maintain records of tests for identity, purity, quality and strength carried out on all samples of drugs or cosmetics and the results thereof together with the protocols of tests showing the readings and calculation in such form as to be available for inspection and such records shall be retained in the case of

substances for which an expiry date is assigned for a period of 2 years from the expiry of such date and in the case of other substances for a period of 6 years.

- d. The approved institution shall allow the Inspector appointed under this act to enter with or without prior notice, the premises where the testing is carried on and to inspect the premises and the equipment used for test and the testing procedures employed. The institution shall allow the inspectors to inspect the registers and records maintained under these Rules and shall supply to such Inspectors such information as they may require for the purpose of ascertaining whether the provisions of the act and rules made thereunder have been observed.
- e. The approved institution shall from time to time report to the approving authority any changes in the person-in-charge of testing of drugs or cosmetics or in the expert staff responsible for testing as the case may be and any material alteration in the premises or changes in the equipment used for the purposes of testing which have been made since the date of last inspection made on behalf of the approving authority before the grant or renewal of approval.
- f. The approved institution shall furnish reports of the results of test or analysis in Form 39.
- g. In case any sample of a drug or a cosmetic is found on test to be not of standard quality, the approved institution shall furnish the approving authority and the licensing authority of the state where the manufacturer and/or sender of the drug or cosmetic is located with copy of the test report on the sample with the protocols of tests applied.
- h. The approved institution shall comply with the provisions of the act and rules made thereunder and with each further requirement, if any, may be specified in the rules

subsequently made under Chapter IV of the act of which the approving authority has given the approved institution not less than 4 months notice.

- i. The approved institution shall maintain an Inspection book to enable the inspectors to record his impression or defects noticed.

Duration of approval: An approval granted in Form 37 or renewed in Form 38, unless sooner suspended or withdrawn, shall be valid for a period of five years on and from the date on which it is granted or renewed. If an application for the renewal of an approval in Form-37 is made before its expiry or if the application is made within 6 months of its expiry after the payment of the additional fee, the approval shall continue to be in force until orders are passed on the applications and the approval within 6 months of its expiry.

OTHER PROVISIONS RELATED TO THE APPROVAL OF INSTITUTE FOR ANALYSIS

A. Inspection before grant of approval: Before an approval in Form 37 is granted, the approved authority shall cause the institution at which the testing of drugs or cosmetics, as the case may be, is proposed to be carried out to be inspected jointly by the drugs inspectors of the central drugs standard control organization and the state drugs control organization who shall examine the premises and the equipment intended to be used for testing of drugs or cosmetics and inquire into the professional qualifications of the expert staff to be employed.

B. Report of inspection: The Drug inspector mentioned in Rule 150-F shall forward to the appointing authority a detailed report of the result of the inspection.

C. Procedure of approving authority: If the approving authority after such further enquiry, if any, as he may consider necessary, is satisfied that the requirements of the rules made under the act have been compiled with and that the conditions of the approval and the rules made

under the act will be observed, he shall grant an approval in Form 37. If the appointing authority is not so satisfied, he shall reject the application and shall inform the applicant of the reasons for such rejections and of the conditions, which must be satisfied before an approval could be granted.

D. Further application after rejection: If within a period of six months from the rejection for

approval, the applicant informs the approving authority that the conditions laid down have been satisfied and deposits inspection fee of rupees two hundred and fifty, the approving authority may, if, after causing a further inspection to be made, satisfied that the conditions for grant of approval have been complied with, grant the approval in Form 37.

E. Renewal: On an application being made for

SCHEDULES

SCHEDULES C and C ₁	
<i>Schedule C</i> <i>Biological and special products</i>	<i>Schedule C₁</i> <i>Other special products</i>
<ol style="list-style-type: none"> 1. Sera. 2. Solution of serum proteins intended for injection. 3. Vaccines for parenteral injections. 4. Toxins. 5. Antigen. 6. Antitoxins. 7. Neoarsphenamine and analogous substances used for the specific treatment of infective diseases. 8. Insulin. 9. Pituitary (posterior lobe) extract. 10. Adrenaline and solutions of salts of adrenaline. 11. Antibiotics and preparations thereof in a form to be administered parenterally. 12. Any other preparation which is meant for parenteral administration as such or after being made up with a solvent or medium or any other sterile product and which: <ol style="list-style-type: none"> a. Requires to be stored in a refrigerator. b. Does not require to be stored in a refrigerator. 13. Sterilized surgical ligature and sterilized surgical suture. 14. Bacteriophages. 15. Ophthalmic preparations. 16. Sterile disposable devices for single use only. 	<ol style="list-style-type: none"> 1. Drugs belonging to the digitalis groups and preparations containing drugs belonging to the digitalis group not in a form to be administered parentally. 2. Ergot and preparations containing ergot not in a form to be administered parentally. 3. Adrenaline and preparations containing adrenaline not in a form to be administered parenterally. 4. Fish liver oil and preparations containing fish liver oil. 5. Vitamins and preparations containing any vitamins not in a form to be administered parenterally. 6. Liver extract and preparations containing liver extract not in a form to be administered parenterally. 7. Hormones and preparations containing hormones not in a form to be administered parenterally. 8. Vaccine not in a form to be administered parenterally. 9. Antibiotics and preparations thereof not in a form to be administered parenterally. 10. <i>In vitro</i> blood grouping sera. 11. <i>In vitro</i> diagnostic devices for HIV, HbsAg and HCV.

renewal the approving authority may cause an inspection to be made and if satisfied that the conditions of the approval and the Rules made under the Act are and shall continue to be

observed shall issue a certificate of renewal in Form 38.

F. Withdrawal and suspension of approvals:
The approving authority may, after the approved

<i>Class of drugs</i>	<i>Extent and conditions of exemption</i>
Substances not intended for medicinal use	All provisions of chapter III of the act and rules thereunder subject to the conditions that if the substance is imported in bulk, the importer shall certify that the substance is imported for non-medicinal uses, and if imported otherwise than in bulk, each container shall bear a label indicating that the substance is not intended for medicinal use or is intended for some purposes other than medicinal use or is of commercial quality.
The following substances, which are used both as articles of food as well as drugs:	All provisions of Chapter III of the act and rules thereunder.
<ul style="list-style-type: none"> i. All condensed or powdered milk whether pure, skimmed or malted, fortified with vitamins and minerals. ii. Farex, oats, lactose and all other similar cereal preparations whether fortified with vitamins or otherwise excepting those for parenteral use. iii. Virol, bovril, chicken essence and all other similar predigested food. iv. Ginger, pepper, cumin, cinnamon and all other similar spices and condiments unless they are specifically labelled as conforming to the standards in the Indian pharmacopoeia or the official pharmacopoeias and the official compendia of the drug standards prescribed under the act and rules made thereunder. 	

institution an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefore, withdraw an approval granted under this Part

or suspend it for such period as he thinks fit either wholly or in respect of some of the categories of drugs or items of cosmetics to which it relates, if in his opinion the approved

A. Ayurvedic System

<i>I Drugs of vegetable origin</i>		<i>II Drugs of Animal origin</i>	
Ahipena	<i>Papaver somniferum</i> linn. Sarpa visha snake poison	Sarpa visha	Snake poison
Arka	<i>Calotropis gigantea</i> (linn.) R. Br. ex. Ait.	<i>III Drugs of mineral origin</i>	
Bhallataka	<i>Semecarpus anacardium</i> Linn. F	Gauripashana	Arsenic
Bhang	<i>Cannabis sativa</i> linn.	Hartala	Arsenosulphade
Danti	<i>Baliospermum monatanum</i> mull. Arg	Manahashila	Arsenosulphade
Dhattura	<i>Datura metel</i> linn.	Parada	Mercury
Gunj	<i>Abrus precatorius</i> linn.	Rasa karpura	Hydrargyri subchloridum
Jaipala	(Jayapala) <i>Croton tiglium</i> linn.	Tuttha	Copper sulphate
Langali	<i>Glorios asperba</i> linn.	Hingula	Cinnabar
Parasika	<i>Yavani Hyoseyamus inibar</i> linn.	Sindura	Red oxide of lead
Snuhi	<i>Euphorbia nerifolia</i> linn.	Girisindura	Red oxide of mercury
Vatsnabha	<i>Aconitum chasmantums tapfex</i> holm		
Vishamushti	<i>Strychnos nuxvomica</i> linn.		
Shringivisha	<i>Aconitum chasmanthum tapfex</i> holm.		

B. Siddha System

Abini	<i>Papaver Somniferum</i> linn.	Chadurakkalli	<i>Euphorbia antiquorum</i> linn.
Alari	<i>Nerium indicum</i> mill.	Karia polam	Aloe sp.
Azhavanam	<i>Lawsonia inermis</i> linn.	kattamanakkku	<i>Jatropha glandulifera</i> roxb.
Attru	<i>Citrullis colocynthis</i> Scharad.	Kattu thumatti	<i>Cucmis trigonus</i> roxb.
Anai kurni	<i>Adanathera pavonina</i> linn.	Kunri abrus	<i>Precotorusu</i> linn.
Ratta polam	<i>Adanathera pavonina</i> linn.	Cheran kottai	<i>Sernicorpus anacardium</i> linn.
Ilaikalli	<i>Euphorbia nerifolia</i> linn.	Thillai	<i>Exoeocoria agallocha</i> linn.
Eezhaththalari	<i>Plumeria acuminata</i> ait.	Nabi	<i>Aconitum ferox</i> wall.
Gomatthai	<i>Datuas tramorium</i> linn	Nervalam	<i>Croton tiglium</i> linn.
Etti	<i>Strychnos nuxvomica</i> linn.	Pugai elai	<i>Nicotiana tobacum</i> linn.
Ganja	<i>Cannabis sativa</i> linn.	Marukkarai	<i>Randia dumetorum</i> linn.
Kalappaik	<i>Kizhangu G loriosa superba</i> linn.	Mansevikkalli	<i>Euphorbia</i> sp.
Kodikkali	<i>Euphorbia tiruqalli</i> linn.		

C. Unani System			
<i>I Drugs of vegetable origin</i>		<i>III Drugs of mineral origin</i>	
Afiyun	<i>Papaver somniferum</i> linn.	Darchikna	Hydrargyri perchloridum
Baznul-ban	<i>Hyoscyamus niger</i> linn.	Hira	Diamond
Bish	<i>Aconitum chas manthum</i> <i>strappex holmas</i>	Ras kapoor	Hydrargyri subchloridum (calomel)
Bhang	<i>Canabis sativa</i> linn.	Shingruf	Hydrargyri isulphuratum
Charas	<i>Canabis sativa</i> linn.	Zangar	Cupri sub acetas
Datura seeds	<i>Datura metal</i> linn (seeds)	Sammul-far	Arsenic (white, yellow, black and red)
Kuchla	<i>Strychnos nuxvomica</i> linn.	(Abyaz, asfar, aswad and ahmar)	
Shokran	<i>Conium maculatum</i> linn	Tootiya	Copper sulphate
<i>II Drugs of animal origin</i>		Para	Hydrargyrum
Sanp (head)	<i>Snake</i> (head)	Hartal	Arsenic trisulphate (yellow)
Telni makkhi	<i>Mylabris cichori</i> linn mylabaris <i>pustulata thurd</i> mylabris macilenta		

institution has failed to comply with any of the conditions of the approval or with any provisions of the act or the rules made thereunder. Any approved institution whose approval has been suspended or withdrawn may within 3 months of the date of the order, appeal to the State Government which shall dispose of the appeal in consultation with a panel of competent persons appointed by it in this behalf and notified in the official gazette.

MISCELLANEOUS PROVISIONS RELATED TO THE DRUG AND COSMETIC ACT AND RULES

A. Offences and Penalties

I. *Offences by companies:* i. Where an offence under this act has been committed by a company, every person who at the time the offence was committed, was in charge of, and was responsible to the company for the conduct of business of the company,

as well as the company shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly.

ii. Notwithstanding anything contained in above sub-section, where an offence under this act has been committed by a company and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of, any director, manager, secretary or other officer of the company, such director, manager, secretary or other officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

II. *Offences by government departments:* Where an offence under Chapter IV (provisions related to manufacture, sale and distribution of drugs and cosmetics) or Chapter IVA (provisions related to

Ayurvedic, Siddha and Unani Drugs) has been committed by any department of government, such authority as is specified by the Central Government to be in-charge of manufacture, sale or distribution of drugs or where no authority is specified, the head of the department, shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly.

III. *Penalty vexatious search or seizure:* Any Inspector exercising powers under this Act or the Rules made thereunder, who:

- a. Without reasonable ground of suspicion searches any place, vehicle, vessel or other conveyance.
- b. Vexatiously and unnecessarily searches any person.
- c. Vexatiously and unnecessarily seizes any drug or cosmetic, or any substance or article, or any record, register, document or other material object.
- d. Commits, as such inspector, any other act, to the injury of any person without having reason to believe that such act is required for the execution of his duty, shall be punishable with fine which may extend to one thousand rupees.

IV. *Publication of sentences passed under this Act:* i. If any person is convicted of an offence under this act, the court before which the conviction takes place shall, on application made to it by the Inspector, cause the offender's name, place of residence, the offence of which he has been convicted and the penalty which has been inflicted upon him, to be published at the expense of such person in such newspapers or in such other manner as the court may direct.

ii. The expenses of such publication shall be deemed to form part of the cost relating to the conviction and shall be recoverable in the same manner as those costs are recoverable.

V. *Magistrate's power to impose enhanced penalties:* Notwithstanding anything contained in the Code of Criminal Procedure, 1973, it shall be lawful for any metropolitan magistrate or any judicial magistrate of the first class to pass any sentence authorized by this act in excess of his powers under the said code.

B. Protection of Action Taken in Good Faith

No suit, prosecution or other legal proceeding shall lie against any person for anything which is in good faith done or intended to be done under this act.

C. Rules to be Laid before Parliament

Every rule made under this act shall be laid as soon as may be after it is made before each house of parliament while it is in session for a total period of 30 days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both houses agree in making any modification in the rule or both houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be, so however that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.

D. Power to Give Directions

The Central Government may give such directions to any State Government as may appear to the Central Government to be necessary for

carrying into execution in the State any of the provisions of this Act or of any Rule or order made thereunder.

STANDARDS

Standards of Drugs

1. Drugs included in the Indian Pharmacopoeia:
 - a. The standards for identity, purity and strength shall be those as may be specified in the edition of the Indian Pharmacopoeia for the time being in force.
 - b. In case the standards for identity, purity and strength for drugs are not specified in the edition of the Indian Pharmacopoeia for the time being in force but are specified in the edition of the Indian Pharmacopoeia immediately preceding, the standards for identity, purity and strength shall be those occurring in such immediately preceding edition of the Indian Pharmacopoeia.
2. For other drugs (drugs not included in the Indian Pharmacopoeia):
 - a. The standards for identity, purity and strength shall be those as may be specified in the edition of the official Pharmacopoeia, for the time being in force, of any country to which the drug claims to comply with.
 - b. In case the standards for identity, purity and strength for drugs are not specified in the edition of such official Pharmacopoeia for the time being in force, but are expected in the edition immediately preceding, the standards for identity, purity and strength shall be those occurring in such immediately preceding edition of such Official Pharmacopoeia to which the drug claims to comply with.
 - c. For drugs for which standards are not included in the edition of the Official

Pharmacopoeia, for the time being in force, of any country or in edition immediately preceding, but included in the official compendia of drug standards, namely, the British Pharmaceutical codex or the national formulary of the United States, for the time being in force, to which the drug claims to comply with.

Standards for veterinary drugs: For drugs intended for veterinary use, the standards shall be those given in the current edition for the time being in force of the British Pharmacopoeia (veterinary).

Standards for patent or proprietary medicines: The standards for patent or proprietary medicines shall be those laid down in Schedule V and such medicines shall also comply with the standards laid down in the second Schedule to the act.

Standards for surgical dressings: The standards for surgical dressing shall be such as are laid down in Schedule F₂.

Standards for sterilised umbilical tapes: The standards for sterilised umbilical tapes shall be as laid down in Schedule F₃.

Standards for Substances (other than Food) Intended to Affect the Structure or any Function of Human Body

Contraceptives:

1. The standards for mechanical contraceptives shall be such as are laid down in Schedule R.
2. The standards which other contraceptives will have to comply with shall be in conformity with the formulae approved as safe and efficacious by the Central Government. Such formula shall be displayed on the label of every container of such contraceptive.

Standards for medical devices: The standards for the medical devices shall be such as are laid down in Schedule R₁.

Standards for Substances Intended to be Used for the Destruction of Vermin or Insects which Cause Disease in Human Beings or Animals

Disinfectants: The standards of disinfectants shall be such as are laid down in **Schedule O**.

Standards for ophthalmic preparations including homoeopathic ophthalmic preparations: The standards for ophthalmic preparations including homoeopathic ophthalmic preparations shall be those laid down in **Schedule FF**, and such preparations shall also comply with the standards set out in the second Schedule to the act.

LIST OF COLOURS PERMITTED TO BE USED IN DRUGS

A. No Drug Shall Contain a Colour other than Specified Below

1. **Natural colours:** Annatto, Carotene, Chlorophyll, Cochineal, Curcumin, Ted Oxide of Iron, Yellow Oxide of Iron, Titanium Dioxide, Black Oxide of Iron

2. **Artificial colours:** Caramel, Riboflavin

3. Coal tar colours

Green: Quinazarine Green S.S., alizarin Cyanine Green F., Fast Green F.C.F.

Yellow: Tartrazine, Sunset Yellow FCF, Quinoline Yellow WS

Red: Erythrosine, Eosin YS or Eosine G, Toney Red or Sudan III, Ponceau 4R, Carmoisine

Blue: Indigo Carmine, Brilliant Blue F.C.F.

Orange: Orange G

Brown: Resorcin Brown

Black: Naphthol Blue Balck

4. **Lakes:** The aluminum or calcium salts (lakes) of any of the water-soluble colours listed above.

B. The Label on the Container of a Drug Containing a Permitted Colour Shall Indicate the Common Name of the Colour

SCHEDULE D

The drugs specified in schedule D are exempted from the provisions regulating import of drugs, as follows:

SCHEDULE E

[Omitted as per GOI notification No. G.S.R. 462 (E) dt 22-6-1982]

SCHEDULE E1

List of poisonous substances under the Ayurvedic (including Siddha) and Unani Systems of medicine.

SCHEDULE G

Aminopterin, L-Asparaginase, Bleomycin, Busulphan; its salts, Carbutamide, Chlorambucil; its salts, Chlorothiazide and other derivatives of 1, 2, 4 benzothiadiazine, Chlorpropamide; its salts, Chlorthalidone and other derivatives of Chlorobenzene compound. (Cis-Platin), Cyclophosphamide; its salts, (Cytarabine), Daunorubicin, Di-Isopropyl Fluorophosphate, Disodium Stilbestrol Diprophosphate, Doxorubicin Hydrochloride, Ethacrylic acid, its salts, Ethosuximide, Glibenclamide, Hydantoin; its salts, its derivatives, their salts, Hydroxyurea, Insulin all types, Lomustine Hydrochloride, Mannomustine; its salts, Mercaptopurine; its salts, Metformin; its salts, Methylsuximide, Mustine, its salts, Paramethadione, Phenacetamide, Phenformin; its salts, 5-Phenylhydantoin; its alkyl and aryl derivatives, its salts, Primidone, Procarbazine Hydrochloride, Quinethazone, Sarcolysine, Sodium 2 Mercaptoethanesulfonate Tamoxifen Citrate, Testolactone, Thiotapec, Tolbutamide, Tretamine; its salts, Troxidone, Antihistaminic substances the following, their salts, their derivatives, salts of their derivatives., Antazoline, Bromodiphenhydramine, Buclizine, Chlorcyclizine, Chlorpheniramine, Clemizole, Cyproheptadine, Diphenhydramine, Diphenyl pyraline, Doxylamine Succinate, Isothipendyl, Mebhydroquin Napadisylate, Meclozine, Pheniramine, Promethazine, Thenalidine, Triprolidine, Substance being tetra-N-substituted derivatives of Ethylene Diamine or Prophylenediamine.

Note: Preparations containing the above substance excluding those intended for topical or external use are also covered by this schedule.

SCHEDULE H

Prescription Drugs

Acebutolol Hydrochloride, Aclarubicin Inj, Actilyse, Acyclovir, Adrenocorticotropic hormone (ACTH), Alclometasone Dipropionate, Allopurinol, Alphachymotrypsin, Alprazolam, Amantadine Hydrochloride, Amikacin, Amiloride Hydrochloride, Amineptine, Aminoglutethimide Tab, Aminosalicylic Acid, Amiodarone Hydrochloride, Amitriptyline, its salts, Amoscanate, Amoxapine, Amrinone Lactate, Analgin, Androgenic, Anabolic, Oestrogenic and Progestational Substances, Antibiotics, Aprotinin, Organic Compound of Arsenic for Injection, Articaine Hydrochloride, Astemizole, Atenolol, Atracurium Besylate Injection, Auranofin, Azathioprine, Barbituric acid, its salts, derivative of Barbituric acid, their salts, Bacampicillin, Benserazide Hydrochloride, Betahistine Dihydrochloride, Bethanidine Sulphate, Bezafibrate, Biclotymol, Biperiden Hydrochloride, Bitoscanate, Bleomycin Oil Suspension, Bromhexine Hydrochloride, Bromocriptine Mesylate, Budesonide, Bupivacaine Hydrochloride, Buspirone, Captoril, Carbidopa, Carbocisteine, Carbo-platin Injection, Carboquone, Carisoprodol, L.Carnitine, Cefadroxyl, Cefatoxime Sodium, Cefazolin Sodium, Ceftazidime Pentahydrate, Ceftizoxime Sodium Sterile, Cefuroxime, Cefuroxime Axetil, Centbutindole, Centchroman, Ciclopirox Olamine, Clindamycin, Cimetidine, Cinnarizine, Ciprofloxacin HCL Monohydrate/lactate, Chlordiazepoxide, its salts, Chlormezanone, Chlorpromazine, its salts, Chlorzoxazone, Clavulanic Acid, Clidinium Bromide, Clobetasol Propionate, Clobetazone 17-Butyrate, Clofazimine, Clofibrate, Clonidine Hydrochloride, Clopamide, Clostebol Acetate,

Clotrimazole, Codeine, its salts and derivatives, Colchicine, Corticosteroids, their esters, their derivatives and their dosage forms. Cotrimoxazole, Cyclanadelate, Cyclosporin Oral Solution, Danzol, Dapsone, its salts and derivatives, Desogestrol, Dextransomer, Dextropropoxyphene, its salts, Diazepam, Diazoxide, Diclofenac Sodium, Digoxine, Dilazep, Hydrochloride, Diltiazem, Dinoprostone, Diphenoxylate, its salts, Disopyramide, Domperidone, Dopamine Hydrochloride, Dothiepin Hydrochloride, Doxapram, Hydrochloride, Doxepin Hydrochloride, Econazole, Enalapril Maleate, Enfamilic Acid, Epinephrine, its salts, Epirubicine Inj., Ergot, alkaloids of, whether hydrogenated or not, their homologues, any salt of any substance, falling within this item. Estradiol succinate, Estramustine Phosphate Capsule. Ethacridine Lactate, Ethambutol Hydrochloride, Ethamsylate, Ethinyloestradiol, Ethionamide, Etomidate, Etoposide Cap. and Inj., Farmotidine, Flavoxate Hydrochloride, Flufenamic acid, its salts, its esters, their salts, Flunarizine Hydrochloride, Flupenthixol, Fluphenazine Enanthate and Decanoate, Flurazepam, Flurbiprofen, Flutamide, Fluoxetine Hydrochloride, Galanthamine, Hydrobromide, Gallamine, its salts, its quaternary compound, Gemfibrozil, Genodeoxycholic Acid, Gliclazide, Glucagon, Glycopyrrolate, Glydiazinamide Guanethidine, Gugulipid, Halogenated Hydroxyquinolines, Haloperidol, Heparin, Hepatitis B. Vaccine, Hyaluronidase, Hydrocortisone 17-Butyrate, Hydrotalcite, Hydroxyzine, its salts, Ibuprofen, Imipramine, its salts, Indapamide, Indomethacin, its salts, Insulin Human, Interferon Alpha Inj., Intralipid (intravenous Fat Emulsion), Iohexol Sterile Solution, Iopamidol Sterile Solution, Iopromide, Iron Preparation for parenteral use, Isocarboxazid, Isoflurane, Isonicotinic acid hydrazine and other hydrazine derivatives of isonicotinic acid, their, derivatives, their salts., Isosorbide, Dinitrate, Isosorbide Mononitrate, Isozsprine, Ketamine

Hydrochloride, Ketoconazole, Acetate, Ketoprofen, Labetalol Hydrochloride, Levarterenol, its salts, Levodopa, Lidoflazine, Lithium Carbonate, Lofepramine Decanoate, Loperamide, Lorazepam, Loxapine, Mebendazole, Mebeverine Hydrochloride, Medroxyprogesterone Acetate Tablets, Mefenamic Acid, its salts its ester, their salts, Megestrol Acetate, Meglumine Iocarmate, Melagenina Lotion, Mephenesin, its esters, Mephentermine, Mesterolone, Methicillin, Sodium, Methocarbamol, Metoclopramide, Metoprolol tartarate, Metrizamide, Metronidazole, Mexiletine Hydrochloride, Mianserin Hydrochloride, Miconazole, Minocycline Minoxidil, Mitoxantrone Hydrochloride, Mometasone Furoate, Morphazinamide Hydrochloride, Narcotic Drugs listed in the Narcotic Drugs and Psychotropic Substances Act 1985., Nadolol, Nalidixic Acid, Naproxen, Natamycin, Netilmicin Sulphate, Nicergoline, Nifedipine, Nimustine Hydrochloride, Nitrazepam, Nitroglycerin Injection, Norethisterone Enanthate Injection, Norfloxacin, Ofloxacin, Orphenadrine, its salts, Orthoclone Sterile, Oxazepam, Oxazolidine, its salts, Oxethazaine Hydrochloride, Oxolinic Acid, Oxprenolol Hydrochloride, Oxyfedrine, Oxymetazoline, Oxyphenbutazone, Oxytocin, Ozothine, Pancuronium Bromide, Para amino benzene sulphonamide its salts and derivatives, Para amino Salicylic acid, its salts, its derivatives, D-Penicillamine, Pentazocine, Pentoxyfylline, Pepleomycin Injection, Phenelzine, its salts, Phenothiazine, derivatives of and salts of its derivatives, Phenobarbital, Phenylbutazine, its salts, Pimozide, Pindolol, Piracetam, Piroxicam, Pituitary gland, the active principles of, not otherwise specified in this Schedule and their salts, Polidocanol Injection, Polyestradiol Phosphate Injection, Praziquantel, Prednimustine Tablets, Prednisolone Stearoylglycolate, Prenoxydiazin Hydrochloride, Promazine Hydrochloride, Propafenon Hydrochloride,

Propranolol Hydrochloride, Protristiline Hydrochloride, Pyrazinamide, Pyrvinium, its Salts, Quinidine Sulphate, Ranitidine, Rauwolfia alkaloids, their salts, derivatives of the alkaloids of rauwolfia, their salts, Reproterol Hydrochloride, Rosoxacin, Salbutamol Sulphate, Salicylazosulphapyridine, Satranidazole, Septopal Beads and Chains, Serratio Peptidase, Sisomicin Sulphate, Sodium Cromoglycate, Sodium Hyaluronate Solution, Sodium and Meglumine Iothalamate, Sodium Valproate, Sotalol, Spectinomycin Hydrochloride, Spironolactone, Sucralfate, Sulphadoxine, Sulphamethoxine, Sulphamethoxypyridazine, Sulphaphenazole, Sulprostone Injection, Teratol Hydrochloride, Terbutaline Sulphate, Terfenadine, Terizidine, Testosterone Undecanoate, Tiaprofenic Acid, Timolol Maleate, Tinazoline, Tinidazole, Thiacetazone, Thiomepacate, its salts, Tobramycin, Tranylcypromine, its salts, Trazodone, Tretinoin, Trifluoperazine, Trifluoperadol Hydrochloride, Trimetazidine Dihydrochloride, Trimipramine, Tripotassium Dicitrate, Bismuthate, Urokinase, Vasopressin, Vecuronium Bromide Injection, Verapamil Hydrochloride, Xipamide, Zidovudine Cap.

- Note:** 1. Preparations exempted under proviso to para 2 of note to Schedule X shall also be covered by this Schedule.
 2. Preparations containing the above substances excluding those intended for topical/or external use are also covered by this schedule. The inclusion of a substance in Schedule H does not imply or convey that substance is exempted from the provisions of Rule 122-A.

SCHEDULE J

Diseases and ailments (by whatever name described) which a drug may not purport to prevent or cure or make claims to prevent or cure.
 1. AIDS, 2. Angina Pectoris, 3. Appendicitis, 4. Arteriosclerosis, 5. Baldness, 6. Blindness,

7. Bronchial Asthma, 8. Cancer and Benign tumour, 9. Cataract, 10. Change in colour of the hair and growth of new hair, 11. Change of Foetal sex by drugs, 12. Congenital malformations, 13. Deafness, 14. Diabetes, 15. Diseases and disorders of uterus, 16. Epileptic-fits and psychiatric disorders, 17. Encephalitis, 18. Fairness of the skin, 19. Form and structure of breast, 20. Gangrene, 21. Genetic disorders, 22. Glaucoma, 23. Goitre, 24. Hernia, 25. High/low Blood Pressure, 26. Hydrocele, 27. Insanity, 28. Increase in brain capacity and improvement of memory, 29. Improvement in height of children/adults, 30. Improvement in size and shape of the sexual organ and in duration of sexual performance, 31. Improvement in the strength of the natural teeth, 32. Improvement in vision, 33. Jaundice/ Hepatitis/Liver disorders, 34 Leukaemia, 35. Leucoderma, 36. Maintenance or improvement of the capacity of the human being for sexual pleasure, 37. Mental retardation, subnormalities and growth, 38. Myocardial infarction, 39. Obesity, 40. Paralysis, 41. Parkinsonism, 42. Piles and Fistulae, 43. Power to rejuvenate, 44. Premature ageing, 45. Premature greying of hair, 46. Rheumatic Heart Diseases, 47. Sexual Impotence, Premature ejaculation and spermatorrhoea, 48. Spondylitis, 49. Stammering, 50. Stones in gallbladder, kidney, bladder, 51. Vericose vein.

SCHEDULE M (GOOD MANUFACTURING PRACTICES)

“Good Manufacturing Practice” or “GMP” is part of a quality system covering the manufacturing and testing of active pharmaceutical ingredients, diagnostics, foods, pharmaceutical products, and medical devices. GMPs are guidelines that outline the aspects of production and testing that can impact the quality of a product. Many countries have legislated that pharmaceutical and medical device companies must follow GMP procedures, and have created their own GMP guidelines that correspond with their legislation.

Although there are a number of them, all guidelines follow a few basic principles:

- Manufacturing processes are clearly defined and controlled. All critical processes are validated to ensure consistency and compliance with specifications.
- Manufacturing processes are controlled, and any changes to the process are evaluated. Changes that have an impact on the quality of the drug are validated as necessary.
- Instructions and procedures are written in clear and unambiguous language (good documentation practices).
- Operators are trained to carry out and document procedures.
- Records are made, manually or by instruments, during manufacture that demonstrate that all the steps required by the defined procedures and instructions were in fact taken and that the quantity and quality of the drug was as expected. Deviations are investigated and documented.
- Records of manufacture (including distribution) that enable the complete history of a batch to be traced are retained in a comprehensible and accessible form.
- The distribution of the drugs minimizes any risk to their quality.
- A system is available for recalling any batch of drug from sale or supply.
- Complaints about marketed drugs are examined, the causes of quality defects are investigated, and appropriate measures are taken with respect to the defective drugs and to prevent recurrence.

GMP guidelines are not prescriptive instructions on how to manufacture products. They are a series of general principles that must be observed during manufacturing. When a company is setting up its quality program and manufacturing process, there may be many ways it can fulfill GMP requirements. It is the company’s responsibility to determine the most effective and efficient quality process.

Good manufacturing practices and requirements of premises, plant and equipment for pharmaceutical products: Quality of drugs is essentially the responsibility of manufacturers and it has assumed significant importance in view of post GATT scenario. The Good Manufacturing Practice (GMP) guidelines are a means to assure this very quality of drugs. GMP regulations were introduced in the form of amended Schedule M in 1988. The Schedule M has again been amended in a major way by the Drugs and Cosmetics (8th Amendment) Rules 2001 w. e. f. 11th December 2001 and embraces rules 71, 74, 76 and 78 under the D and C Rules, 1945. These rules shall not apply to the manufacturers that are presently licensed to manufacture drugs for the period up to the 31st December 2003. This period has been allowed intentionally so that the manufacturers could equip themselves to meet the newly imposed stringent requirements. To achieve the objectives listed below, each licensee shall evolve appropriate methodology, systems and procedures which shall be documented and maintained for inspection and reference; and the manufacturing premises shall be used exclusively for production of drugs and no other manufacturing activity shall be undertaken therein.

PART I—FACTORY PREMISES

Part I ideal with good manufacturing practices relating to factory premises.

Good manufacturing practices for premises and materials.

1. General Requirements

A. Location and surroundings: The factory building(s) for manufacture of drugs shall be so situated and shall have such measures as to avoid risk of contamination from external environmental including open sewage, drain, public lavatory or any factory which product disagreeable or obnoxious odour, fumes,

excessive soot, dust, smoke, chemical or biological emissions.

B. Building and premises: The buildings used for the factory shall be designed, constructed, adapted and maintained to suit the manufacturing operations so as to permit production of drugs under hygienic conditions. They shall conform to the conditions laid down in the Factories Act, 1948. The premises used for manufacturing, processing, warehousing, packaging labelling and testing purposes shall be:

- i. Compatible with other drug manufacturing operations that may be carried out in the same or adjacent area/section.
- ii. Adequately provided with working space to allow orderly and logical placement of equipment, materials and movement of personnel so as to:
 - a. Avoid the risk of mix-up between different categories of drugs or with raw materials, intermediates and in-process material.
 - b. Avoid the possibilities of contamination and cross-contamination by providing suitable mechanism.
- iii. Designed/constructed/maintained to prevent entry of insects, pests, birds, vermins, and rodents. Interior surface (walls, floors and ceilings) shall be smooth and free from cracks, and permit easy cleaning, painting and disinfection.
- iv. Air-conditioned, where prescribed for the operations and dosage forms under production. The production and dispensing areas shall be well lighted, effectively ventilated, with air control facilities and may have proper air handling units (wherever applicable) to maintain conditions including temperature and, wherever necessary, humidity, as defined for the relevant product. These conditions shall be appropriate to the category of drugs and nature of the operation. These

shall also be suitable to the comforts of the personnel working with protective clothing, products handled, operations undertaken within them in relation to the external environment. These areas shall be regularly monitored for compliance with required specifications.

- v. Provided with drainage system, as specified for the various categories of products, which shall be of adequate size and so designed as to prevent back flow and/or prevent insects and rodents entering the premises. Open channels shall be avoided in manufacturing areas and, where provided, these shall be shallow to facilitate cleaning and disinfection.

C. Water supply: There shall be validated system for treatment of water drawn from own or any other source to render it potable in accordance with standards specified by the bureau of Indian standards or local municipality, as the case may be, so as to produce purified water conforming to pharmacopoeial specification. Purified water so produced shall only be used for all operations except washing and cleaning operations where potable water may be used. Water shall be stored in tanks, which do not adversely affect quality of water and ensure freedom from microbiological growth. The tank shall be cleaned periodically and records maintained by the licensee in this behalf.

D. Disposal of waste: The disposal of sewage and effluents (solid, liquid and gas) from the manufactory shall be in conformity with the requirements of Environment Pollution Control Board. All bio-medical waste shall be destroyed as per the provisions of the Bio-Medical Waste (Management and handling) Rules, 1996. additional precautions shall be taken for the storage and disposal of rejected drugs. Records shall be maintained for all disposal of waste. Provisions shall be made for the proper and safe storage of waste materials awaiting disposal.

Hazardous, toxic substances and flammable materials shall be stored in suitably designed and segregated, enclosed areas in conformity with Central and State legislations.

2. Warehousing Area

Adequate areas shall be designed to allow sufficient and orderly warehousing of various categories of materials and products like starting and packaging materials, intermediates, bulk and finished products, products in quarantine, released, rejected, returned or recalled, machine and equipment spare parts and change items. Warehousing areas shall be designed and adapted to ensure good storage conditions. They shall be clean, dry and maintained with acceptable temperature limits, where special storage conditions are required (e.g. temperature, humidity), these shall be provided, monitored and recorded. Storage areas shall have appropriate house-keeping and rodent, pests and vermin control procedures and records maintained. Proper racks, bins and platforms shall be provided for the storage of materials. Receiving and dispatch bays shall protect materials and products from adverse weather conditions. Where quarantine status is ensured by warehousing in separate earmarked areas in the same warehouse or store, these areas shall be clearly demarcated. Any system replacing the physical quarantine, shall give equivalent assurance of segregation. Access to these areas shall be restricted to authorized persons. There shall be a separate sampling area in the warehousing area for active raw materials and excipients. If sampling is performed in any other area, it shall be conducted in such a way as to prevent contamination, cross-contamination and mix-up. Segregation shall be provided for the storage of rejected, recalled or returned materials or products. Such areas, materials or products shall be suitably marked and secured. Access to these areas and materials shall be restricted. Highly hazardous, poisonous

and explosive materials such as narcotics, psychotropic drugs and substances presenting potential risks of abuse, fire or explosion shall be stored in safe and secure areas. Adequate fire protection measures shall be provided in conformity with the rules of the concerned civic authority. Printed packaging materials shall be stored in safe, separate and secure areas. Separate dispensing areas for β (Beta) lactum, sex hormones and cytotoxic substances or any such special categories of product shall be provided with proper supply of filtered air and suitable measures for dust control to avoid contamination. Such areas shall be under differential pressure. Sampling and dispensing of sterile materials shall be conducted under aseptic conditions conforming to grade A, which can also be performed in a dedicated area within the manufacturing facility. Regular checks shall be made to ensure adequate steps are taken against spillage, breakage and leakage of containers. Rodent treatments (pest control) should be done regularly and at least once in a year and record maintained.

3. Production Area

The production area shall be designed to allow the production preferably in uni-flow and with logical sequence of operations. In order to avoid the risk of cross-contamination, separate dedicated and self-contained facilities shall be made available for the production of sensitive pharmaceutical products like penicillin or biological preparations with live micro-organisms. Separate dedicated facilities shall be provided for the manufacture of contamination causing and potent products such as beta-lactum, sex hormones and cytotoxic substances. Working and in-process space shall be adequate to permit orderly and logical positioning of equipment and materials and movement of personnel to avoid cross contamination and to minimize risk of omission or wrong application of any manufacturing and control measures.

Pipe-work, electrical fittings, ventilation openings and similar services lines shall be designed, fixed and constructed to avoid creation of recesses. Services lines shall preferably be identified by colours and the nature of the supply and direction of the flow shall be marked/indicated.

4. Ancillary Areas

Rest and refreshment rooms shall be separate from other areas. These areas shall not lead directly to the manufacturing and storage areas. Facilities for changing, storing clothes and for washing and toilet purposes shall be easily accessible and adequate for the number of users. Toilets, separate for males and females. Maintenance workshops shall be separate and away from production areas. Areas housing animals shall be isolated from other areas.

5. Quality Control Area

Quality control laboratories shall be independent of the production areas. Separate areas shall be provided each for physicochemical, biological, microbiological or radioisotope analysis. Separate instrument room with adequate area shall be provided for sensitive and sophisticated instruments employed for analysis. Quality control laboratories shall be designed appropriately for the operations to be carried out in them. Adequate space shall be provided to avoid mix-ups and cross contamination. Sufficient and suitable storage space shall be provided for test samples, retained samples, reference standards, reagents and records. The design of the laboratory shall take into account the suitability of construction materials and ventilation. Separate air handling units and other requirements shall be provided for biological, microbiological and radioisotopes testing areas. The laboratory shall be provided with regular supply of water of appropriate quality for cleaning and testing purpose. Quality Control Laboratory shall be divided into

separate sections, i.e. for chemical, microbiological and wherever required, biological testing. These shall have adequate area for basis installation and for ancillary purposes. The microbiology section shall have arrangements such as airlocks and laminar airflow workstation, wherever considered necessary.

6. Personnel

The manufacture shall be conducted under the direct supervision of competent technical staff with prescribed qualifications and practical experience in the relevant dosage and/or active pharmaceutical products. The head of the quality control laboratory shall be independent of the manufacturing unit. The testing shall be conducted under the direct supervision of competent technical staff who shall be whole time employees of the licensee. Personnel for quality assurance and quality control operations shall be suitably qualified and experienced. Written duties of technical and quality control personnel shall be laid and following strictly. Number of personnel employed shall be adequate and in direct proportion to the workload. The licensee shall ensure in accordance with a written instruction that all personnel in production area or into quality control laboratories shall receive training appropriate to the duties and responsibility assigned to them. They shall be provided with regular in-service training.

7. Health, Clothing and Sanitation of Workers

The personnel handling beta-lactum antibiotics shall be tested for penicillin sensitivity before employment and those handling sex hormones, cytotoxic substances and other potent drugs shall be periodically examined for adverse effects. These personnel should be moved out of these sections (except in dedicated facilities), by rotation, as a health safeguard. Prior to employment, all personnel, shall undergo medical examination including eye examination

and shall be free from tuberculosis, skin and other communicable or contagious diseases thereafter, they should be medically examined periodically, at least once a year. All persons prior to and during employment shall be trained in practices which ensure personnel hygiene. A high level of personal hygiene shall be observed by all those engaged in the manufacturing processes. Instructions to this effect shall be displayed in change rooms and other strategic locations. No person showing, at any time, apparent illness or open lesions which may adversely affect the quality of products, shall be allowed to handle starting materials, packing materials, in-process materials, and drug products until his condition is no longer judged to be a risk. All employees shall be instructed to report about their illness or abnormal health condition to their immediate supervisor so that appropriate action can be taken. Direct contact shall be avoided between the unprotected hands of personnel and raw materials, intermediate or finished, unpacked products. All personnel shall wear clean body coverings appropriate to their duties. Smoking, eating, drinking, chewing or keeping plants, food, drink and personal medicines shall not be permitted in production, laboratory, storage and other areas where they might adversely influence the product quality.

8. Manufacturing Operations and Controls

All manufacturing operations shall be carried out under the supervision of technical staff approved by the licensing authority. Each critical step in the process relating to the selection, weighing and measuring of raw material addition during various stages shall be performed by trained personnel under the direct personal supervision of approved technical staff. The contents of all vessels and containers used in manufacture and storage during the various manufacturing stages shall be conspicuously labeled with the name of the product, batch number, batch size and stage of manu-

facture. Each label should be initialled and dated by the authorised technical staff. Products not prepared under aseptic conditions are required to be free from pathogens like salmonella, escherichia coli, pyocyanea, etc.

Precautions against mix-up and cross-contamination:

- The licensee shall prevent mix-up and cross-contamination of drug material and drug product (from environmental dust) by proper air-handling system, pressure differential, segregation, status labelling and cleaning. Proper records and standard operating procedures thereof shall be maintained.
- The licensee shall ensure processing of sensitive drugs like beta-lactum antibiotics, sex hormones and cytotoxic substances in segregated areas or isolated production areas within the building with independent air-handling unit and proper pressure differential. The effective segregation of these areas shall be demonstrated with adequate records of maintenance and services.
- To prevent mix-ups during production stages, materials under process shall be conspicuously labeled to demonstrate their status. All equipment used for production shall be labeled with their current status.
- Packaging lines shall be independent and adequately segregated. It shall be ensured that all left-overs of the previous packaging operations, including labels, cartons and caps are cleared before the closing hour.
- Before packaging operations are begun, steps shall be taken to ensure that the work area, packaging lines, printing machines, and other equipment are clean and free from any products, materials and spillages. The line clearance shall be performed according to an approximate check-list and recorded.
- The correct details of any printing (for example, batch numbers or expiry dates)

done separately or in the course of the packaging shall be rechecked at regular intervals. All printing and overprinting shall be authorized in writing.

- The manufacturing environment shall be maintained at the required levels of temperature, humidity and cleanliness.
- Authorized persons shall ensure change-over into specific uniforms before undertaking any manufacturing operations including packaging.
- There shall be segregated enclosed areas, secured for recalled or rejected material and for such materials which are to be reprocessed or recovered.

9. Sanitation in the Manufacturing Premises

The manufacturing premises shall be cleaned and maintained in an orderly manner, so that it is free from accumulating waste, dust, debris and other similar material. A validated cleaning procedure shall be maintained. The manufacturing areas shall not be used for storage of materials, except for the material being processed.

A routine sanitation program shall be drawn up and observed, which shall be properly recorded and which shall indicate:

- a. Specific areas to be cleaned and cleaning intervals.
- b. Cleaning procedure to be followed, including equipment and materials to be used for cleaning.
- c. Personnel assigned to and responsible for the cleaning operation.

The adequacy of the working and in-process storage space shall permit the orderly and logical positioning of equipment and materials so as to minimize the risk of mix-up between different pharmaceutical products or their components to avoid cross contamination, and to minimise the risk of omission or wrong application of any of the manufacturing or control steps. Production areas shall be well lit,

particularly where visual on-line controls are carried out.

10. Raw Materials

The licensee shall keep an inventory of all raw materials to be used at any stage of manufacture of drugs and maintain records as per Schedule U. All incoming materials shall be quarantined immediately after receipt or processing. All materials shall be stored under appropriate conditions and in an orderly fashion to permit batch segregation and stock rotation by a 'first in/first expiry'-'first-out' principle. All incoming materials shall be checked to ensure that the consignment corresponds to the order placed. All incoming materials shall be purchased from approved sources under valid purchase vouchers. Wherever possible, raw materials should be purchased directly from the producers. Authorized staff appointed by the licensee in this behalf, which may include personnel from the Quality Control Department, shall examine each consignment on receipt and shall check each container for integrity of package and seal. Damaged containers shall be identified, recorded and segregated. If a single delivery of material is made up of different batches, each batch shall be considered as a separate batch for sampling, testing and release.

Raw materials in the storage area shall be appropriately labeled. Labels shall be clearly marked with the following information:

- a. Designated name of the product and the internal code reference, where applicable, and analytical reference number.
- b. Manufacturer's name, address and batch number.
- c. The status of the contents, e.g. quarantine, under test, released, approved, rejected.
- d. The manufacturing date, expiry date and re-test date.

There shall be adequate separate areas for materials "under test", "approved" and "rejected" with arrangements and equipment to allow dry,

clean and orderly placement of stored materials and products, wherever necessary, under controlled temperature and humidity. Containers from which samples have been drawn shall be identified. Only raw materials which have been released by the Quality Control Department and which are within their shelf-life shall be used. It shall be ensured that shelf life of formulation product shall not exceed with that of active raw materials used. It shall be ensured that all the containers of raw materials are placed on the raised platforms racks and not placed directly on the floor.

11. Equipment

Equipment shall be located, designed, constructed, adapted and maintained to suit the operations to be carried out. The layout and design of the equipment shall aim to minimize the risk of errors and permit effective cleaning and maintenance in order to avoid cross contamination, build-up of dust or dirt and, in general any adverse effect on the quality of products. Each equipment shall be provided with a logbook, wherever necessary. Balances and other measuring equipment of an appropriate range, accuracy and precision shall be available in the raw material stores, production and in process control operations and these shall be calibrated and checked on a scheduled basis in accordance with standard operating procedures and records maintained. The parts of the production equipment that come into contact with the product shall not be reactive, additive or adsorptive to an extent that would affect the quality of the product. To avoid accidental contamination, wherever possible, non-toxic, edible grade lubricants shall be used and the equipment shall be maintained in a way that lubricants do not contaminate the products being produced. Defective equipment shall be removed from production and quality control areas or appropriately labeled.

12. Documentation and Records

Documentation is an essential part of the Quality Assurance System and, as such, shall be related to all aspects Good Manufacturing Practices (GMP). Its aim is to define the specifications for all materials, method of manufacture and control, to ensure that all personnel concerned with manufacture know the information necessary to decide whether or not to release a batch of drug for sale and to provide an audit trail that shall permit investigation of the history of any suspected defective batch.

Documents designed, prepared, reviewed and controlled, wherever applicable, shall comply with these rules. Documents shall be approved, signed and dated by appropriate and authorized persons. Documents shall specify the title, nature and purpose. They shall be laid out in an orderly fashion and be easy to check. Reproduced documents shall be clear and legible. Documents shall be regularly reviewed and kept up-to-date. Any alteration made in the entry of a document shall be signed and dated. The records shall be made or completed at the time of each operation in such a way that all significant activities concerning the manufacture of pharmaceutical products are traceable. Records and associated Standard Operating Procedures (SOP) shall be retained for at least one year after the expiry date of the finished product. Data may be recorded by electronic data processing systems or other reliable means, but Master Formulae and detailed operating procedures relating to the system in use shall also be available in a hard copy to facilitate checking of the accuracy of the records.

13. Labels and other Printed Materials

Labels are absolutely necessary for identification of the drugs and their use. The printing shall be done in bright colours and in a legible manner. The label shall carry all the prescribed details about the product.

All containers and equipment shall bear appropriate labels. Different colour coded tablets shall be used to indicate the status of a product (for example, under test, approved, passed, rejected). To avoid chance of mix-up of printed packaging materials, product leaflets, related to different products, shall be stored separately. Prior to release, all labels for containers, cartons and boxes and all circulars, inserts and leaflets shall be examined by the Quality Control Department of the licensee. Prior to packaging and labelling of a given batch of a drug, it shall be ensured by the licensee that samples are drawn from the bulk and duly tested, approved and released by the quality control personnel.

Records of receipt of all labelling and packaging materials shall be maintained for each shipment received indicating receipt, control reference numbers and whether accepted or rejected. Unused coded and damaged labels and packaging materials shall be destroyed and recorded. The label or accompanying document of reference standards and reference culture shall indicate concentration, lot number, potency, date on which containers was first opened and storage conditions, where appropriate.

14. Quality Assurance

This is a wide-ranging concept concerning all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that products are of the quality required for their intended use.

The system of quality assurance appropriate to the manufacture of pharmaceutical products shall ensure that:

- a. The pharmaceutical products are designed and developed in a way that takes account of the requirement of Good Manufacturing Practices (herein referred as GMP) and other associated codes such as those of Good

- Laboratory Practices (hereinafter referred as GLP) and Good Clinical Practices (herein-after referred as GCP).
- Adequate arrangements are made for manufacture, supply and use of the correct starting and packaging materials.
 - Adequate controls on starting materials, intermediate products, and bulk products and other in-process controls, calibrations, and validations are carried out.
 - The finished product is correctly processed and checked in accordance with established procedures.
 - The pharmaceutical products are not released for sale or supplied before authorized persons have certified that each production batch has been produced and controlled in accordance with the requirements of the label claim and any other provisions relevant to production, control and release of pharmaceutical products.

15. Self-inspection and Quality Audit

It may be useful to constitute a self-inspection team supplemented with a quality audit procedure for assessment of all or part of a system with the specific purpose of improving it.

To evaluate the manufacturer's compliance with GMP in all aspects of production and quality control, concept of self-inspection shall be followed. The manufacturer shall constitute a team of independent, experienced, qualified persons from within or outside the company, who can audit objectively the implementation of methodology and procedures evolved. The procedure for self-inspection shall be documented indicating self-inspection results; evaluation, conclusions and recommended corrective actions with effective follow up program. The recommendations for corrective action shall be adopted. The program shall be designed to detect shortcomings in the implementation of good manufacturing practice and to recommend the necessary corrective actions.

Written instructions for self-inspection shall be drawn up which shall include the following:

Personnel premises including personnel facilities, maintenance of buildings and equipment, storage of starting materials and finished products, equipment, production and in-process controls, quality control, documentation, sanitation and hygiene, validation and revalidation programmes, calibration of instruments or measurement systems, recall procedures, complaints management labels control, results of previous self-inspections and any corrective steps taken.

16. Quality Control System

Quality control shall be concerned with sampling, specifications, testing, documentation, release procedures which ensure that the necessary and relevant tests are actually carried and that the materials are not released for use, nor products released for sale or supply until their quality has been judged to be satisfactory. It is not confined to laboratory operations but shall be involved in all decisions concerning the quality of the product. It shall be ensured that all quality control arrangements are effectively and reliably carried out the department as a whole shall have other duties such as to establish evaluate, validate and implement all quality control procedures and methods.

Every manufacturing establishment shall establish its own quality control laboratory managed by qualified and experienced staff. The area of the quality control laboratory may be divided into chemical, instrumentation, microbiological and biological testing. Adequate area having the required storage conditions shall be provided for keeping reference samples. The quality control department shall evaluate, maintain and store reference samples. Standard operating procedures shall be available for sampling, inspecting and testing of raw materials, intermediate bulk finished products and packing materials and, wherever necessary, for monitoring environmental conditions.

There shall be authorized and dated specifications for all materials, products, reagents and solvents including test of identity, content, purity and quality. These shall include specifications for water, solvents and reagents used in analysis. No batch of the product shall be released for sale or supply until it has been certified by the authorized person (s) that it is in accordance with the requirements of the standards laid down. Reference/retained samples from each batch of the products manufactured shall be maintained in quantity which is at least twice the quantity of the drug required to conduct all the tests, except sterility and pyrogen/bacterial endotoxin, test performed on the active material and the product manufactured. The retained product shall be kept in its final pack or simulated pack for a period of three months after the date of expiry. Assessment of records pertaining to finished products shall include all relevant factors, including the production conditions, the results of in process testing, the manufacturing (including packaging) documentation, compliance with the specification for the finished product, and an examination of the finished pack. Assessment records should be signed by the in-charge of production and countersigned by the authorised quality control personnel before a product is released for sale or distribution. Quality control personnel shall have access to production areas for sampling and investigation, as appropriate. The quality control department shall conduct stability studies of the products to ensure and assign their shelf life at the prescribed conditions of storage. All records of such studies shall be maintained. The in-charge of quality assurance shall investigate all product complaints and records thereof shall be maintained. All instruments shall be calibrated and testing procedures validated before these are adopted for routine testing. Periodical calibration of instrument and validation of procedures shall be carried out.

Each specification for raw materials, intermediates, final products, and packing materials shall be approved and maintained by the Quality Control Department. Periodic revisions of the specifications shall be carried out wherever changes are necessary. Pharmacopoeiae, reference standards, working standards, references, spectra, other reference materials and technical books, as required, shall be available in the quality control laboratory of the licensee.

17. Specification

For raw materials and packaging materials:
They shall include:

- a. The designated name and internal code reference.
- b. Reference, if any, to a pharmacopoeial monograph.
- c. Qualitative and quantitative requirements with acceptance limits.
- d. Name and address of manufacturer or supplier and original manufacturer of the material.
- e. Specimen of printed material.
- f. Directions for sampling and testing or reference to procedures.
- g. Storage conditions.
- h. Maximum period of storage before re-testing.

For product containers and closures:

- i. All containers and closures intended for use shall comply with the pharmacopoeial requirements. Suitable validated test methods, sample sizes, specifications, cleaning procedure and sterilization procedure, wherever indicated, shall be strictly followed to ensure that these are not reactive, additive, absorptive or leach to an extent that significantly affects the quality or purity of the drug. No second hand or used containers and closures shall be used.

- ii. Whenever bottles are being used, the written schedule of cleaning shall be laid down and followed. Where bottles are not dried after washing, they should be rinsed with deionised water or distilled water, as the case may be.

For in-process and bulk products—Specifications for in-process material, intermediate and bulk products shall be available. The specifications should be authenticated.

For finished products: Appropriate specifications for finished products shall include:

- a. The designated name of the product and the code reference.
- b. The formula or a reference to the formula and the pharmacopoeial reference.
- c. Directions for sampling and testing or a reference to procedures.
- d. A description of the dosage form and package details.
- e. The qualitative and quantitative requirements, with the acceptance limits for release.
- f. The storage conditions and precautions, where applicable.
- g. The shelf-life.

For preparation of containers and closures: The requirements mentioned in the Schedule do not include requirements of machinery, equipments and premises required for preparation of containers and closures for different dosage forms and categories of drugs. The suitability and adequacy of the machinery, equipment and premises shall be examined taking into consideration the requirements of each licensee in this respect.

18. Master Formula Records

There shall be master formula records relating to all manufacturing procedures for each product and batch size to be manufactured. These shall be prepared and endorsed by the competent technical staff, i.e. head of production and quality control. The master formula shall include:

- a. The name of the product together with product reference code relating to its specifications.
- b. The patent or proprietary name of the product along with the generic name, a description of the dosage form, strength, composition of the product and batch size.
- c. Name, quantity, and reference number of all the starting materials to be used. Mention shall be made of any substance that may 'disappear' in the course of processing.
- d. A statement of the expected final yield with the acceptable limits, and of relevant intermediate yields, where applicable.
- e. A statement of the processing location and the principal equipment to be used.
- f. The methods, or reference to the methods, to be used for preparing the critical equipments including cleaning, assembling, calibrating, sterilizing.
- g. Detailed stepwise processing instructions and the time taken for each step.
- h. The instructions for in-process control with their limits.
- i. The requirements for storage conditions of the products, including the container, labelling and special storage conditions where applicable.
- j. Any special precautions to be observed.
- k. Packing details and specimen labels.

19. Packing Records

There shall be authorised packaging instructions for each product, pack size and type.

These shall include or have a reference to the following:

- a. Name of the product.
- b. Description of the dosage form, strength and composition.
- c. The pack size expressed in terms of the number of doses, weight or volume of the product in the final container.
- d. Complete list of all the packaging materials required for a standard batch size, including

- quantities, sizes and types with the code of reference number relating to the specifications of each packaging material.
- e. Reproduction of the relevant printed packaging materials and specimens indicating where batch number and expiry date of the product have been applied.
 - f. Special precautions to be observed, including a careful examination of the area and equipment in order to ascertain the line clearance before the operations begin.
 - g. Description of the packaging operation, including any significant subsidiary operations and equipment to be used.
 - h. Details of in-process controls with instructions for sampling and acceptance.
 - i. Upon completion of the packing and labelling operation, reconciliation shall be made between number of labelling and packaging units issued, number of units labeled, packed and excess returned or destroyed. Any significant or unusual discrepancy in the numbers shall be carefully investigated before releasing the final batch.

20. Batch Packaging Records

A batch packaging record shall be kept for each batch or part batch processed. It shall be based on the relevant parts of the packaging instructions, and the method of preparation of such records shall be designed to avoid transcription errors. Before any packaging operation begins, check shall be made and recorded that the equipment and the work stations are clear of the previous products, documents or materials not required for the planned packaging operations, and that the equipment is clean and suitable for use.

21. Batch Processing Records

There shall be batch processing record for each product. It shall be based on the relevant parts of the currently approved master formula. The

method of preparation of such records included in the master formula shall be designed to avoid transcription errors. Before any processing begins, check shall be performed and recorded to ensure that the equipment and work station are clear of previous products, documents or materials not required for the planned process are removed and the equipment is clean and suitable for use.

During processing, the following information shall be recorded at the time each action is taken and the record shall be dated and signed by the person responsible for the processing operations:

- a. The name of the product.
- b. The number of the batch being manufactured.
- c. Dates and time of commencement, of significant intermediate stages and of completion of production.
- d. Initials of the operator of different significant steps of production and where appropriate, of the person who checked each of these operations.
- e. The batch number and/or analytical control number as well as the quantities of each starting material actually weighed.
- f. Any relevant processing operation or event and major equipment used.
- g. A record of the in-process controls and the initials of the person (s) carrying them out, and the results obtained.
- h. The amount of product obtained after different and critical stages of manufacture (yield).
- i. Comments or explanations for significant deviations from the expected yield limits shall be given.
- j. Notes on special problems including details, with signed authorization, for any deviation from the master formula.
- k. Addition of any recovered or reprocessed material with reference to recovery or reprocessing stages.

22. Standard Operating Procedures (SOPs) and Records, Regarding

22.1 Receipt of Materials

1. There shall be written standard operating procedures and records for the receipt of each delivery of raw, primary and printed packaging material.
2. The records of the receipts shall include.
 - a. The name of the material on the delivery note and the number of containers.
 - b. The date of receipt.
 - c. The manufacturer's and/or supplier's name.
 - d. The manufacturer's batch or reference number.
 - e. The total quantity, and number of containers, and quantity in each container received.
 - f. The control reference number assigned after receipt.
 - g. Any other relevant comment or information.
3. There shall be written standard operating procedures for the internal labelling, quarantine and storage of starting materials, packaging materials and other materials, as appropriate.
4. There shall be standard operating procedures available for each instrument and equipment and these shall be placed in close proximity to the related instrument and equipment.

22.2 Sampling

1. There shall be written standard operating procedures for sampling which include the person (s) authorized to take the samples.
2. The sampling instruction shall include:
 - a. The method of sampling and the sampling plan.
 - b. The equipment to be used.
 - c. Any precautions to be observed to avoid contamination of the material or any deterioration in its quality.
 - d. The quantity of samples to be taken.

- e. Instructions for any required sub-division or pooling of the samples.
- f. The types of sample containers to be used.
- g. Any specific precautions to be observed, especially in regard to sampling of sterile and hazardous materials.

22.3. Batch Numbering

1. There shall be standard operating procedures describing the details of the batch (lot) numbering set up with the objective of ensuring that each batch of intermediate, bulk or finished product is identified with a specific batch number.
2. Batch numbering standard operating Procedures applied to a processing stage and to the respective packaging stage shall be same or traceable to demonstrate that they belong to one homogeneous mix.
3. Batch number allocation shall be immediately recorded in a logbook or by electronic data processing system. The record shall include date of allocation, product identity and size of batch.

22.4. Testing

There shall be written procedures for testing materials and products at different stages of manufacture, describing the methods and equipment to be used. The tests performed shall be recorded.

22.5 Records of Analysis

1. The records shall include the following data:
 - a. Name of the material or product and the dosage form.
 - b. Batch number and, where appropriate the manufacturer and/or supplier.
 - c. Reference to the relevant specifications and testing procedures.
 - d. Test results, including observations and calculations, and reference to any specifications (limits).
 - e. Dates of testing.

- f. Initials of the persons who performed the testing.
 - g. Initials of the persons who verified the testing and the detailed calculations.
 - h. A statement of release or rejection.
 - i. Signature and date of the designated responsible person.
2. There shall be written standard operating procedures and the associated records of actions taken for:
- a. Equipment assembly and validation.
 - b. Analytical apparatus and calibration.
 - c. Maintenance, cleaning and sanitation.
 - d. Personnel matters including qualification, training, clothing, hygiene.
 - e. Environmental monitoring.
 - f. Pest control.
 - g. Complaints.
 - h. Recalls made.
 - i. Returns received.

23. Reference Samples

Each lot of every active ingredient, in a quality sufficient to carryout all the tests, except sterility and pyrogens/bacterial endotoxin test, shall be retained for a period of 3 months after the date of expiry of the last batch produced from that active ingredient. Samples of finished formulations shall be stored in the same or simulated containers in which the drug has been actually marketed.

24. Reprocessing and Recoveries

Where reprocessing is necessary, written procedures shall be established and approved by the Quality Assurance Department that shall specify the conditions and limitations of repeating chemical reactions. Such reprocessing shall be validated. If the product batch has to be reprocessed, the procedure shall be authorized and recorded. An investigation shall be carried out into the causes necessitating re-processing and appropriate corrective measures shall be taken for prevention of recurrence. Re-processed batch shall be

subjected to stability evaluation. Recovery of the product residue may be carried out, if permitted, in the master production and control records by incorporating it in subsequent batches of the product.

25. Distribution Records

Prior to distribution or dispatch of given batch of a drug, it shall be ensure that the batch has been duly tested, approved and released by the quality control personnel. Records for distribution shall be maintained in a manner such that finished batch of a drug can be traced to the retain level to facilitate prompt and complete recall of the batch, if and when necessary.

26. Validation and Process Validation

Validation studies shall be an essential part of good manufacturing practices and shall be conducted as per the pre-defined protocols. These shall include validation of processing, testing and cleaning procedures. A written report summarizing recorded results and conclusions shall be prepared, documented and maintained. Processes and procedures shall be established on the basis of validation study and undergo periodic revalidation to ensure that they remain capable of achieving the intended results. Critical processes shall be validated, prospectively for retrospectively. When any new master formula or method of preparation is adopted, steps shall be taken to demonstrate its suitability for routine processing. The defined process, using the materials and equipment specified shall be demonstrated to yield a product consistently of the required quality. Significant changes to the manufacturing process, including any changes in equipment or materials that may affect product quality and/or the reproducibility of the process, shall be validated.

27. Product Recalls

A prompt and effective product recall system of defective products shall be devised for timely

information of all concerned stockists, wholesalers, suppliers, upto the retail level within the shortest period. The licensee may make use of both print and electronic media in this regard. There shall be an established written procedure in the form of standard operating procedure for effective recall of products distributed by the licensee. Recall operations shall be capable of being initiated promptly so as to effectively reach at the level of each distribution channel. The distribution records shall be readily made available to the persons designated for recalls. The designated person shall record a final report issued, including reconciliation between the delivered and the recovered quantities of the products. The effectiveness of the arrangements for recalls shall be evaluated from time to time. The recalled products shall be stored separately in a secured segregated area pending final decision on them.

28. Complaints and Adverse Reactions

All complaints thereof concerning product quality shall be carefully reviewed and recorded according to written procedures. Each complaint shall be investigated/evaluated by the designated personnel of the company and records of investigation and remedial action taken thereof shall be maintained. Reports of serious adverse drug reactions resulting from the use of a drug along with comments and documents shall be forthwith reported to the concerned licensing authority. There shall be written procedure describing the action to be taken, recall to be made of the defective product.

29. Site Master File

The licensee shall prepare a succinct document in the form of site master file containing specific and factual good manufacturing practices about the production and/or control of pharmaceutical manufacturing preparations carried out at the licensed premises. It shall contain the following:

General Information

- a. Brief information of the firm.
- b. Pharmaceutical manufacturing activities as permitted by the licensing authority.
- c. Other manufacturing activities, if any, carried out on the premises.
- d. Type of product licensed for manufacture with flow charts mentioning procedure and process flow.
- e. Number of employees engaged in the production, quality control, storage and distribution.
- f. Use of outside scientific, analytical or other technical assistance in relation to.
- g. Manufacture and analysis.
- h. Short description of the quality management system of the firm.
- i. Products details registered with foreign countries.

Personnel

- a. Organizational chart showing the arrangement for quality assurance including production and quality control.
- b. Qualification, experience and responsibilities of key personnel.
- c. Outline for arrangements for basic and in-service training and how the records are maintained.
- d. Health requirements for personal engaged in production.
- e. Personal hygiene requirements, including clothing.

Premises

- a. Simple plan or description of manufacturing areas drawn to scale.
- b. Nature of construction and fixtures / fittings.
- c. Brief description of ventilation systems. More details should be given for critical areas with potential risk of airborne contamination (schematic drawing of systems). Classification of the rooms used for the manufacture of sterile products should be mentioned.

- d. Special areas for the handling of the highly toxic, hazardous and sensitizing materials.
- e. Brief description of water system (schematic drawings of systems), including sanitation.
- f. Description of planned preventive maintenance programs for premises and of the recording system.

Equipment

- a. Brief description of major equipment used in production and quality control laboratories (a list of equipment required).
- b. Description of planned preventive maintenance programs for equipment and of the recording system.
- c. Qualification and calibration including the recording systems and arrangements for computerized systems validation.

Sanitation

Availability of written specifications and procedures for cleaning manufacturing areas and equipments.

Documentation

- a. Arrangements for the preparation, revision and distribution of.
- b. Necessary documentation for the manufacturer.
- c. Any other documentation related to product quality that is not mentioned elsewhere (e.g. microbiological controls about air and water).

Production

- a. Brief description of production operations using, wherever possible, flow sheets and charts specifying important parameters.
- b. Arrangements for the handling of starting materials, packaging materials, bulk and finished products, including sampling, quarantine, release and storage.
- c. Arrangements for the handling of rejected materials and products.

- d. Brief description of general policy for process validation.

Quality Control

Description of the quality control system and of the activities of the Quality Control Department. Procedures for the release of the finished products.

Loan License Manufacture and Licensee

Description of the way in which compliance of good manufacturing practices by the loan licensee shall be assessed.

Distribution, Complaints and Product Recall

- a. Arrangements and recording system for distribution.
- b. Arrangements for handling of complaints and product recalls.

Self-inspection

Short description of the self-inspection system indicating whether an outside, independent and experienced external export was involved in evaluating the manufacturer's compliance with good manufacturing practices in all aspects of production.

Export of Drugs

- a. Products exported to different countries.
- b. Complaints and product recall, if any.

PART I A

Specific requirements for manufacture of sterile products, parenteral preparations (small volume injectables and large volume parenterals) and sterile ophthalmic preparations.

The general requirements as given in Part I of this schedule relating to requirements of good manufacturing practices for premises and materials for pharmaceutical products shall be complied with, mutatis mutandis, for the manufacture of sterile products, parenteral preparations (small volume injectables and large

volume parenterals) and sterile ophthalmic preparations. In addition to these requirements, the following specific requirements shall also be followed, namely:

1. **General:** Sterile products, being very critical and sensitive in nature, a very high degree of precautions, prevention and preparations needed. Dampness, dirt and darkness are to be avoided to ensure aseptic conditions in all areas. There shall be strict compliance in the prescribed standards especially in the matter of supply of water, air, active materials and in the maintenance of hygienic environment.
2. **Building and civil works:** The building shall be built on proper foundation with standardized materials to avoid cracks in critical areas like aseptic solution preparation, filling and sealing rooms. Location of services like water, steam, gases, etc. shall be such that their servicing or repairing shall not pose any threat to the integrity of the facility. The manufacturing areas shall be clearly separated into support areas (e.g. washing and component preparation areas, storage areas, etc.) preparation areas (e.g. bulk manufacturing area, non-aseptic blending areas, etc.) change areas and aseptic areas.

In Aseptic Areas

- a. Walls, floors and ceiling should be impervious, non-shedding, non-flaking and non-cracking. Flooring should be unbroken and provided with a cove both at the junction between the wall and the floor as well as the wall and ceiling.
- b. Walls shall be flat and ledges and recesses shall be avoided. Wherever other surfaces join the wall (e.g. sterilizers, electric sockets, gas points, etc.) these shall flush the walls.
- c. Ceiling shall be solid and joints shall be sealed. Light-fittings and air-grills shall flush with the walls and not hanging from the ceiling, so as to prevent contamination.

- d. There shall be no sinks and drains in grade A and grade B areas.
- e. Doors shall be made of non-shedding material. These may be made preferably of aluminium or steel material. Wooden doors shall not be used. Doors shall open towards the higher pressure area so that they close automatically due to air pressure.
- f. Windows shall be made of similar material as the doors, preferably with double panel and shall be flush with the walls. If fire escapes are to be provided, these shall be suitably fastened to the walls without any gaps.
- g. The furniture used shall be smooth, washable and made of stainless steel or any other appropriate material other than wood.

The manufacturing and support areas shall have the same quality of civil structure described above for aseptic areas, except the environmental standards which may vary in the critical areas. Change rooms with entrance in the form of air-locks shall be provided before entry into the sterile product manufacturing areas and then to the aseptic area. Separate exit space from the aseptic areas is advisable. Change rooms to the aseptic areas shall be clearly demarcated into 'black', 'gray' and 'white rooms' with different levels of activity and air cleanliness. The 'black' change room shall be provided with a hand-washing sink. The sink and its drain in the unclassified (first) change rooms may be kept clean all the time. For communication between aseptic areas and non-aseptic areas, intercom telephones or speakers shall be used. These shall be minimum in number. Material transfer between aseptic areas and outside shall be through suitable airlocks or pass-boxes. Personal welfare areas like rest rooms, tea room, canteen and toilets shall be outside and separated from the sterile product manufacturing area. Animal houses shall be away from the sterile product manufacturing area and shall not share a common

entrance or air handling system with the manufacturing area.

3. **Air handling system (central air-conditioning):** Air handling units for sterile product manufacturing areas shall be different from those for other areas. Critical areas, such as the aseptic filling area, sterilized components unloading area and change room conforming to grades B, C and D respectively shall have separate air handling units. The filter configuration in the air handling system shall be suitably designed to achieve the Grade of air as given in Table 2.3.
- a. In order to reach the B, C and D air grades, the number of air changes shall be related to the size of the room and the equipment and personnel present in the room. The air system shall be provided with the appropriate filters such as HEPA for Grade A, B and C the maximum permitted number of particles in the "at rest" condition shall approximately be as under:

Grade A corresponds with class 100 or M 3.5 or ISO class 5.

Grade B with class 1000 or M 4.5 or ISO Class 6.

Grade C with class 10,000 or M 5.5 or ISO Class 7.

Grade D with class 100,000 or M 6.5 or ISO Class 8.

- b. The requirement and limit for the area shall depend on the nature of the operation carried out.
- c. Type of operations to be carried out in the various grades is given in Tables 3.4 and 3.5 as under.

4. **Environmental monitoring:** There shall be written environmental monitoring program. All environmental parameters shall be verified and established at the time of installation and thereafter monitored at periodic intervals. The recommended frequencies of periodic monitoring shall be as follows:

- a. Particulate monitoring in air—6 monthly.
- b. HEPA filter integrity testing (smoke testing)—yearly.
- c. Air change rates—6 monthly.
- d. Air pressure differentials—daily.
- e. Temperature and humidity—daily.

Table 2.3: Airborne particulate classification for manufacture of sterile products

Grade	At rest (b)		In operation (a)	
	Maximum number of permitted particles per cubic metre equal to or above			
A	0.5 µm 3520	5 µm 29	0.5 µm 3500	5 µm 29
B (a)	35,200	293	3,52,000	2,930
C (a)	3,52,000	2,930	35,20,000	29,300
D (a)	35,20,0000	29,300	Not defined (c)	Not defined (c)

Table 2.4: Types of operations to be carried out in the various grades for aseptic preparations

Grade	Types of operations for aseptic preparations
A	Aseptic preparation and filling
B	Background room conditions for activities requiring grade A
C	Preparation of solution to be filtered
D	Handling of components after washing

Table 2.5: Types of operations to be carried out in the various grades for terminally sterilized products

<i>Grade</i>	<i>Types of operations for terminally sterilized products</i>
A	Filling of products, which are usually at risk.
B	Placement of filling and sealing machines, preparation of solutions when usually at risk. Filling of product when unusually at risk.
C	Moulding, blowing (pre-forming) operations of plastic containers, preparations of solutions and components for subsequent filling.

- f. Microbiological monitoring by settle plates and/or swabs in aseptic areas—daily, and at decreased frequency in other areas.

Note: The above frequencies of monitoring shall be changed as per the requirements and load in individual cases.

There shall be a written environmental monitoring program and microbiological results shall be recorded. Recommended limits for microbiological monitoring of clean areas “in operation” are as given in Table 2.6.

Notes:

- a. These are average values.
- b. Individual settle plates may be exposed for not less than two hours in Grades B, C and D areas and for not less than thirty minutes in Grade A area.

Appropriate action shall be taken immediately if the result of particulate and microbiological monitoring indicates that the counts exceed the limits. The Standard operating procedures shall contain corrective action. After major engineering modification to the HVAC system of any area, all monitoring shall be re-performed before production commences.

5. **Garments:** This section covers garments required for use by personnel working only in aseptic area. Outdoor clothing shall not be brought into the sterile areas. The garments shall be made of non-shedding and tight weave material. Cotton garments shall not be used. The garments shall shed virtually no fibers or particulate matter. The clothing and its quality shall be adopted to the process and the work place and worn in such a way as to protect the product from contamination. Garments shall be single piece with fastenings at cuffs, neck and at legs to ensure close fit. Only clean, sterilized and protective garments shall be used at each work session where aseptic filtration and filling operations are undertaken and at each work shift for products intended to be sterilized, post-filling. The mask and gloves shall be changed at every work session in both instances. Gloves shall be made of latex or other suitable plastic materials and shall be powder free. The footwear shall be of suitable plastic or

Table 2.6: Recommended limits for microbiological monitoring of clean areas “in operation”

<i>Grade</i>	<i>Air sample cfu/m²</i>	<i>Settle plates (dia. 90 mm. cfu/2 hrs.</i>	<i>Contact plates (dia. 55 mm) cfu per plate</i>	<i>Glove points (five fingers) cfu per glove</i>
A	<1	<1	<1	<1
B	10	5	5	5
C	100	50	25	—
D	500	100	50	—

rubber material and shall be daily cleaned with a bactericide. Safety goggles or numbered glasses with side extension shall be used inside aseptic areas. These shall be sanitized by a suitable method. Garment changing procedures shall be documented and operators trained in this respect. A full size mirror shall be provided in the final change room for the operator to verify that he is appropriately attired in the garments. Periodic inspection of the garments shall be done by responsible staff.

6. **Sanitation:** There shall be written procedures for the sanitation of sterile processing facilities. Employees carrying out sanitation of aseptic areas shall be trained specifically for this purpose. Different sanitizing agent shall be used in rotation and the concentrations of the same shall be as per the recommendations of the manufacturer. Distilled water freshly collected directly from the distilled water plant or water maintained above 70°C from the re-circulation loop shall be used for dilution of disinfectants. Alternatively, distilled water sterilized by autoclaving or membrane filtration shall be used. The dilution shall be carried out in the 'white' change room. Where alcohol or isopropyl alcohol is used for dilution of disinfectants for use as hand sprays, the preparation of the same shall be done in the bulk preparation area and diluted solution membrane filtered into suitable sterile containers held in aseptic area. Diluted disinfectants shall bear the label 'use before', based on microbiological establishment of the germicidal properties. Formaldehyde or any other equally effective fumigant is recommended for the fumigation of aseptic areas or after major civil modifications. There shall be standard operating procedures for this purpose. Cleaning of sterile processing facilities shall be undertaken

with air-suction devices or with non-linting sponges or clothes. Air particulate quality shall be evaluated on a regular basis and record maintained.

7. **Equipment:** The special equipment required for manufacturing sterile products includes component like washing machines, steam sterilizers, dry heat sterilizers, membrane filter assemblies, manufacturing vessels, blenders, liquid filling machines, powder filling machines, sealing and labelling machines, vacuum testing chambers, inspection machines, lyophilisers, pressure vessels, etc. suitable and fully integrated washing sterilizing filling lines may be provided, depending upon the type and volume of activity. Unit-sterilizers shall be double-ended with suitable inter-locking arrangements between the doors. Filling machines shall be challenged initially and then at periodic intervals by simulation trials including sterile media fill. Standard operating procedures and acceptance criteria for media fills shall be established, justified and documented. Special simulation trial procedures shall be developed, validated and documented for special products like ophthalmic ointments. The construction material used for the parts which are in direct contact with products and the manufacturing vessels may be stainless steel or borosilicate glass (if glass containers) and the tubing shall be capable of being washed and autoclaved. On procurement, installation qualification of each of the equipment shall be done by engineers with the support of production and quality assurance personnel. Equipment for critical processes like aseptic filling and sterilizers shall be suitably validated according to a written program before putting them to use. Standard Operating Procedures shall be available for each equipment for its calibration and operation

and cleaning. Gauges and other measuring devices attached to equipment shall be calibrated at suitable intervals against a written program.

8. **Water and steam systems:** Potable water meeting microbiological specification of not more than 500 cfu/ml and indicating absence of individual pathogenic micro-organisms, *Escherichia coli*, *Salmonella*, *Staphylococcus aureus* and *Pseudomonas aeruginosa* per 100 ml sample shall be used for the preparation of purified water. Purified water prepared by de-mineralization shall meet the microbiological specification of not more than 100 cfu per ml and indicate absence of pathogenic microorganisms in 100 ml. Purified water shall also meet IP specification for chemical quality. Water for Injection (hereinafter as WFI) shall be prepared from potable water or purified water meeting the above specifications by distillation. Water for Injection shall meet microbiological specification of not more than 10 cfu per 100 ml. WFI shall also meet IP specification for Water for Injection and shall have an endotoxin level of not more than 0.25 EU/ml. bulk solutions of liquid parenterals shall be made in WFI. Final rinse of product containers and machine parts shall be done with WFI. Disinfectant solutions for use in aseptic areas shall be prepared in WFI. Water for Injection for the manufacture of liquid injectables shall be freshly collected from the distillation plant or from a storage or circulation loop where the water has been kept at above 70°C. At the point of collection, water may be cooled using suitable heat exchanger. Water for non-injectable sterile products like eye drops shall meet IP specifications for purified water. In addition, microbiological specification of not more than 10 cfu per 100 ml and absence of *Pseudomonas aeruginosa* and

Enterobacter coli in 100 m shall also be met. Water for Injection shall be stored in steam jacketed stainless steel tanks of suitable size and the tanks shall have hydrophobic bacterial retention with 0.2 μ vent filters. The filters shall be suitably sterilized at periodic intervals. There shall be a written procedure and program for the sanitation of different water systems including storage tanks, distribution lines, pumps and other related equipment. Records of sanitation shall be maintained. There shall be written microbiological monitoring program for different types of water. The results shall justify the frequency of sampling and testing. Investigation shall be carried out and corrective action taken in case of deviation from prescribed limits. Steam coming in contact with the product, primary containers and other product contact surfaces shall be sterile and pyrogen free. The steam condensate shall meet microbiological specification of not more than 10 cfu per 100 ml the condensate shall also meet IP specification for water for injection and shall have an endotoxin levels of not more than 0.25 EU/ml there shall be a suitable schedule for the monitoring of steam quality.

9. **Manufacturing process:** Manufacture of sterile products shall be carried out only in areas under defined conditions. Bulk raw materials shall be monitored for bio-burden periodically. Bio-burden of bulk solution prior to membrane filtration shall be monitored periodically and a limit of not more than 100 cfu per ml is recommended. The time between the start of the preparation of the solution and its sterilization or filtration through a microorganism retaining filter shall be minimized. Gases coming in contact with the sterile product shall be filtered through two 0.22 μ hydrophobic filters connected in-series. These

filters shall be tested for integrity. Gas cylinders shall not be taken inside aseptic areas. Washed containers shall be sterilized immediately before use. Sterilized containers, if not used within an established time, shall be rinsed with distilled or filtered purified water and re-sterilized. Each lot of finished product shall be filled in one continuous operation. In each case, where one batch is filled in using more than one operation, each lot shall be tested separately for sterility and held separately till sterility test results are known. Special care shall be exercised while filling products in powder form so as not to contaminate the environment during transfer of powder to filling machine-hopper.

10. **Form-fill-seal technology or blow, fill-seal technology:** Form-fill-seal units are specially built automated machines in which through one continuous operation, containers are formed from thermoplastic granules, filled and then sealed. Blow, fill-seal units are machines in which containers are moulded/blown (preformed) in separate clean rooms, by non-continuous operations.

Note:

- i. These shall be installed in at least Grade C environment.
- ii. These shall comply with the limits as recommended in table IV.

Form-fill-seal/blow, fill-seal machines used for the manufacture of products for terminal sterilization shall be installed in at least Grade C environment and the filling zone within the machine shall fulfill grade A requirements.

Terminally sterilized products: Preparation of primary packaging material such as glass bottles, ampoules and rubber stoppers shall be done in at least Grade D environment. Where there is unusual risk to the product from microbial contamination, the above operation shall be done in Grade C environment. All the

process used for component preparation shall be validated. Filling of products requiring terminal sterilization shall be done under Grade A environment with a Grade C background. Preparation of solutions, which are to be sterilized by filtration, shall be done in grade C environment, and if not to be filtered, the preparation of materials and products shall be in a grade A environment with Grade B in background.

Filtration (membrane):

- i. Solutions for large volume parenterals shall be filtered through a non-fibre releasing, sterilizing grade cartridge/membrane filter of nominal pore size of $0.22\ \mu$ for aseptic filling whereas $0.45\ \mu$ porosity shall be used for terminally sterilized products.
- ii. A second filtration using another $0.22\ \mu$ sterilizing grade cartridge/membrane filter shall be performed immediately prior to filling. Process specifications shall indicate the maximum time during which a filtration system may be used with a view to precluding microbial build-up to levels that may affect the microbiological quality of the large volume parenterals.
- iii. The integrity of the sterilized filter shall be verified and confirmed immediately after use by an appropriate method such as bubble point, diffusive flow or pressure hold test.

Sterilization (autoclaving): Before any sterilization process is adopted, its suitability for the product and its efficacy in achieving the desired sterilizing conditions in all parts of each type of load pattern to be processed shall be demonstrated by physical measurements and by biological indicators, where appropriate. All the sterilization process shall be appropriately validated. The validity of the process shall be verified at regular intervals, but at least annually. Whenever significant modifications have been made to the equipment and product, records shall

be maintained thereof. The sterilizer shall be double ended to prevent mix-ups. Periodic bio-burden monitoring of products before terminal sterilization shall be carried out and controlled to limits specified for the product in the Master Formula. The use of biological indicators shall be considered as an additional method of monitoring the sterilization. These shall be stored and used according to the manufacturer's instructions. Their quality shall be checked by positive controls. If biological indicators are used, strict precautions shall be taken to avoid transferring microbial contamination from them. There shall be clear means of differentiating 'sterilized' and 'un-sterilized' products. Sterilization records shall be available for each sterilization run and may also include thermographs and sterilization monitoring strips. They shall be maintained as part of the batch release procedure.

Sterilization (by dry heat): Each heat sterilization cycle shall be recorded on a time, temperature chart of a suitable size by appropriate equipment of the required accuracy and precision. The position of temperature probes used for controlling and/or recording shall be determined during the validation and, where applicable, shall also be checked against a second independent temperature probe located in the same position. The chart shall form a part of the batch record. Container mapping may also be carried out in the case of large volume parenterals. Chemical or biological indicators may also be used, but shall take the place of physical validation. Sufficient time shall be allowed for the load to reach the required temperature before measurement of sterilization time commences. This time shall be separately determined for each type of load to be processed. After the high temperature phase of a heat sterilization cycle, precautions shall be taken against contamination of sterilized load during cooling. Any cooling fluid or gas in contact with the product shall be sterilized unless it can be shown that any leaking container would not be approved for use. Air

inlet and outlets shall be provided with bacterial retaining filters. The process used for sterilization by dry heat shall include air-circulation within the chamber and the maintenance of a positive pressure to prevent the entry of non-sterile air. Air inlets and outlets should be provided with microorganism retaining filters. Where this process of sterilization by dry heat is also intended to remove pyrogens, challenge tests using endotoxins would be required as part of the validation process.

Sterilization (by moist heat): Both the temperature and pressure shall be used to monitor the process. Control instrumentation shall normally be independent of monitoring instrumentation and recording charts. Where automated control and monitoring systems are used for these applications, these shall be validated to ensure that critical process requirements are met. System and cycle faults shall be registered by the system and observed by the operator. The reading of the independent temperature indicator shall be routinely checked against the chart-recorder during the sterilization period. For sterilizers fitted with a drain at the bottom of the chamber, it may also be necessary to record the temperature at this position throughout the sterilization period. There shall be frequent leak tests done on the chamber during the vacuum phase of the cycle. The items to be sterilized, other than products in sealed containers, shall be wrapped in a material which allows removal of air and penetration of steam but which prevents re-contamination after sterilization. All parts of the load shall be in contact with the sterilizing agent at the required temperature of the required time. No large volume parenteral shall be subjected to steam sterilization cycle until it has been filled and sealed. Care shall be taken to ensure that the steam used for sterilization is of a suitable quality and does not contain additives at a level which could cause contamination of the product or equipment.

Completion/finalisation of sterile products:

All unit operations and processes in the manufacture of a batch shall have a minimum time specified and the shortest validated time shall be used from the start of a batch to its ultimate release for distribution. Containers shall be closed by appropriately validated methods. Containers closed by fusion, e.g. glass or plastic ampoules shall be subjected to 100% integrity testing. Samples of other containers shall be checked for integrity according to appropriate procedures.

Containers sealed under vacuum shall be tested for required vacuum conditions. Filled containers parenteral products shall be inspected individually for extraneous contamination or other defects. When inspection is done visually, it shall be done under suitably controlled conditions of illumination and background. Operators doing the inspection shall pass regular eyesight checks with spectacles, if worn, and be allowed frequent rest from inspection. Where other methods of inspection are used, the process shall be validated and the performance of the equipment checked at suitable intervals. Results shall be recorded.

11. Product containers and closures: All containers and closures intended for use shall comply with the pharmacopoeial and other specified requirements. Suitable sample sizes, specifications, test methods, cleaning procedures and sterilization procedures, shall be used to assure that containers, closures and other component parts of drug packages are suitable and are not reactive, additive, adsorptive or leachable or presents the risk of toxicity to an extent that significantly affects the quality or purity of the drug. No second hand or used containers and closures shall be used. Plastic granules shall also comply with the pharmacopoeial requirements including physicochemical and biological tests. All containers and closures shall be

rinsed prior to sterilization with Water for Injection according to written procedure. The design of closures, containers and stoppers shall be such as to make cleaning, easy and also to make airtight seal when fitted to the bottles. It shall be ensured that containers and closures chosen for a particular product are such that when coming into contact they are not absorbed into the product and they do not affect the product adversely. The closures and stoppers should be of such quality substances as not to affect the quality of the product and avoid the risk of toxicity. Whenever glass bottles are used, the written schedule of cleaning shall be laid down and followed. Where bottles are not dried after washing, these shall be finally rinsed with distilled water or pyrogen free water, as the case may be, according to written procedure. Individual containers of parenteral preparations, ophthalmic preparations shall be examined against black/white background fitted with diffused light after filling, so as to ensure freedom from foreign matters.

Glass bottles: Shape and design of the glass bottle shall be rational and standardized. Glass bottles made of USP Type-I and USP Type-II glass shall only be used. Glass bottles shall not be reused. Before the use, USP Type-II bottles shall be validated for the absence of particulate matter generated over a period of the shelf-life of the product and shall be regularly monitored after the production, following statistical sampling methods. USP Type-III glass containers may be used for non-parenteral sterile products such as otic solutions.

Plastic containers: Pre-formed plastic containers intended to be used for packing of large volume parenteral shall be moulded in-house by one-continuous operation through an automatic machine. Blowing, filling and sealing (plugging) operation shall be conducted in

room (s) conforming to requirements as mentioned in table III. Entry to the area where such operations are undertaken, shall be through a series of airlocks. Blowers shall have an air supply which is filtered through $0.22\text{ }\mu$ filters. Removal of runners and plugging operations shall be conducted under a laminar airflow workstation.

Rubber stoppers: The rubber stoppers used for large volume parenterals shall comply with specifications prescribed in the current edition of the Indian pharmacopoeia.

12. Documentation: The manufacturing records relating to manufacture of sterile products shall indicate the following details:

(1) Serial number of the batch manufacturing record, (2) Name of the product, (3) Reference to master formula record, (4) Batch/lot number, (5) Batch/lot size, (6) Date of commencement of manufacture and date of completion of manufacture, (7) Date of manufacture and assigned date of expiry, (8) Date of each step in manufacturing, (9) Names of all ingredients with the grade given by the quality control department, (10) Quality of all ingredients, (11) Control reference numbers for all ingredients, (12) Time and duration of blending, mixing, etc. whenever applicable, (13) pH of solution whenever applicable, (14) Filter integrity testing records, (15) Temperature and humidity records whenever applicable, (16) Records of plate-counts whenever applicable, (17) Results of pyrogen and/or bacterial endotoxin and toxicity, (18) Results of weight or volume of drug filled in containers, (19) Bulk sterility in case of aseptically filled products, (20) Leak test records, (21) Inspection records, (22) Sterilization records including autoclave leakage test records, load details, date, duration, temperature, pressure, etc. (23) Container washing records, (24) Total number of containers filled, (25) Total numbers of containers rejected at each stage, (26) Theoretical yield, permissible yield, actual yield and variation thereof, (27) Clarification for

variation in yield beyond permissible yield, (28) Reference numbers of relevant analytical reports, (29) Details of reprocessing, if any, (30) Name of all operators carrying out different activities, (31) Environmental monitoring records, (32) Specimens of printed packaging materials, (33) Records of destruction of rejected containers printed packaging and testing, (34) Signature of competent technical staff responsible for manufacture and testing.

PART I B

Specific requirements for manufacture of oral solid dosage forms (tablets and capsules)

The general requirements as given in Part I of this schedule relating to requirements of good manufacturing practices for premises and materials for pharmaceutical products shall be complied with, mutatis mutandis, for the manufacture of oral solid dosage forms (tablets and capsules). In addition to these requirements, the following specific requirement shall also be followed, namely:

1. General: The processing of dry materials and products creates problems of dust control and cross-contamination. Special attention is therefore, needed in the design, maintenance and use of premises and equipment in order to overcome these problems. Wherever required, enclosed dust control manufacturing systems shall be employed. Suitable environmental conditions for the products handled shall be maintained by installation of air-conditioning wherever necessary. Effective air-extraction systems, with discharge points situated to avoid contamination of other products and processes shall be provided. Filters shall be installed to retain dust and protect the factory and local environment. Special care shall be taken to protect against subsequent contamination of the product by particles of metal or wood. The use of metal detector is recommended. Wooden equipment

should be avoided. Screens, sieves, punches and dies shall be examined for wear and tear or for breakage before and after each use. All ingredients for a dry product shall be sifted before use unless the quality of the input material can be assured. Such sifting shall normally be carried out at dedicated areas. Where the facilities are designed to provide special environmental conditions of pressure differentials between rooms, these conditions shall be regularly monitored and any specification results brought to the immediate attention of the production and quality assurance department which shall be immediately attended to care shall be taken to guard against any material lodging and remaining undetected in any processing or packaging equipment. Particular care shall be taken to ensure that any vacuum, compressed air or air-extraction nozzles are kept clean and that there is no evidence lubricants leaking into the product from any part of the equipment.

2. Sifting, mixing and granulation: Unless operated as a closed system, mixing, sifting and blending equipments shall be fitted with dust extractors. Residues from sieving operations shall be examined periodically for evidence of the presence of unwanted materials. Critical operating parameters like time and temperature for each mixing, blending and drying operation shall be specified in a master formula, monitored during processing, and recorded in the batch records. Filter bags fitted to fluid-bed drier shall not be used for different products, without being washed in-between use. With certain highly potent or sensitizing products, bags specific to one product only shall be used. Air entering the drier shall be filtered. Steps shall be taken to prevent contamination of the site and local environment by dust in the air leaving the drier due to close positioning of the air-inlets and

exhaust. Granulation and coating solutions shall be made, stored and used in a manner which minimizes the risk of contamination or microbial growth.

3. Compressions (tablets): Each tablets compressing machine shall be provided with effective dust control facilities to avoid cross-contamination. Unless the same product is being made on each machine, or unless the compression machine itself provides its own enclosed air controlled environment, the machine shall be installed in separate cubicles. Suitable physical procedural and labelling arrangements shall be made to prevent mix-up of materials, granules and tables on compression machinery. Accurate and calibrated weighting equipment shall be readily available and used for in-process monitoring of tablet weight variation. Procedures used shall be capable of detecting out-of-limits tablets. At the commencement of each compression run and in case of multiple compression points in a compression machine, sufficient individual tablets shall be examined at fixed intervals to ensure that a tablet from each compression station or from each compression point has been inspected for suitable pharmacopoeial parameters like 'appearance', 'weight variation', 'disintegration', 'hardness', 'friability' and 'thickness'. The results shall be recorded as a part of the batch documentation.

Tablets shall be de-dusted, preferably by automatic device and shall be monitored for the presence of foreign materials besides any other defects. Tablets shall be collected into clean, labeled containers. Rejected or discarded tablets shall be isolated in identified containers and their quality recorded in the batch manufacturing record. In-process control shall be employed to ensure that the products remain within specification. During compression, samples of tablets shall be taken at regular intervals of not greater

than 30 minutes to ensure that they are being produced in compliance with specified in-process specification. The tablets shall also be periodically checked for additional parameters such as 'appearance', 'weight variation', 'disintegration', 'hardness', 'friability' and 'thickness' and contamination by lubricating oil.

4. **Coating (tablets):** Air supplied to coating pans for drying purposes shall be filtered air and of suitable quality. The area shall be provided with suitable exhaust system and environmental control (temperature, humidity) measures. Coating solutions and suspensions shall be made afresh and used in a manner, which shall minimize the risk of microbial growth. Their preparation and use shall be documented and recorded.
5. **Filling of hard gelatin capsule:** Empty capsules shells shall be regarded as 'drug component' and treated accordingly. They shall be stored under conditions which shall ensure their safety from the effects of excessive heat and moisture.
6. **Printing (tablets and capsules):** Special care shall be taken to avoid product mix-up during any printing of tablets and capsules. Where different products, or different batches of the same product, are printed simultaneously, the operations shall adequately be segregated. Edible grade colours and suitable printing ink shall be used for such printing. After printing, tablets and capsules shall be approved by quality control before release for packaging or sale.
7. **Packaging (strip and blister):** Care shall be taken when using automatic tablet and capsule counting, strip and blister packaging equipment to ensure that all 'rogue' tablets, capsules or foils from packaging operation are removed before a new packaging operation is commenced. There shall be an independent recorded check of the equipment before a new batch of tablets or capsules is handled. Uncoated tablets shall be packed

on equipment designed to minimize the risk of cross-contamination. Such packaging shall be carried out in an isolated area when potent tablets or beta-lactum containing tablets are being packed. The strips coming out of the machine shall be inspected for defects such as misprint, cuts on the foil, missing tablets and improper sealing. Integrity of individual packaging strips and blisters shall be subjected to vacuum test periodically to ensure leak proofness of each pocket strip and blister and records maintained.

PART I C

Specific requirements for manufacture of oral liquids (syrups, elixirs, emulsions and suspensions)

The general requirements as given in Part I of this Schedule relating to requirements of good manufacturing practices for premises and Materials for pharmaceutical products shall be complied with, mutatis mutandis, for the manufacture of (syrups, elixirs, emulsions and suspensions). In addition to these requirements, the following specific requirements shall also be followed, namely:

1. **Building and equipment:** The premises and equipment shall be designed, constructed and maintained to suit the manufacturing of oral liquids. The layout and design of the manufacturing area shall strive to minimize the risk of cross-contamination and mix-ups.

Manufacturing area shall have entry through double door airlock facility. It shall be fly proof by the use of 'fly catcher' and/or 'air curtain'. Drainage shall be of adequate size and have adequate traps, without open channels and design shall be such as to prevent back flow. Drains shall be shallow to facilitate cleaning and disinfecting. The production area shall be cleaned and sanitized at the end of every production process. Tanks, containers, pipe work and pumps shall be designed and installed so that they can be easily cleaned and

sanitized. Equipment design shall be such as to prevent accumulation of residual microbial growth or cross-contamination. Stainless steel or any other appropriate material shall be used for parts of equipments coming in direct contact with the products. The use of glass apparatus shall be minimum. Arrangements for cleaning of containers, closures and droppers shall be made with the help of suitable machines/devices equipped with the high pressure air, water and steam jets. The furniture used shall be smooth, washable and made of stainless steel.

2. Purified water: The chemical and microbiological quality of purified water used shall be specified and monitored routinely. The microbiological evaluation shall include testing for absence of pathogens and shall not exceed 100 cfu/ml (as per Appendix 12.5 of IP 1996.). There shall be a written procedure for operation and maintenance of the purified water system. Care shall be taken to avoid the risk of microbial proliferation with appropriate methods like recirculation, use of UV treatment, treatment with heat and sanitizing agent. After any chemical sanitisation of the water systems, a flushing shall be done to ensure that the sanitizing agent has been effectively removed.

3. Manufacturing: Manufacturing personnel shall wear non-fiber shedding clothing to prevent contamination of the product. Materials likely to shed fiber like gunny bags or wooden pallets shall not be carried into the area where products or cleaned-containers are exposed. Care shall be taken to maintain the homogeneity of emulsion by use of appropriate emulsifier and suspensions by use of appropriate stirrer during filling. Mixing and filling processes shall be specified and monitored. Special care shall be taken at the beginning of the filling process, after stoppage due to any interrup-

tion and at the end of the process to ensure that the product is uniformly homogeneous during the filling process. The primary packaging area shall have an air supply which is filtered through 5 micron filters. The temperature of the area shall not exceed 30°C. When the bulk product is not immediately packed, the maximum period of storage and storage conditions shall be specified in the master formula. The maximum period of storage time of a product in the bulk stage shall be validated.

PART I D

Specific requirements for manufacture of topical products, i.e. external preparations (creams, ointments, pastes, emulsions, lotions, solutions, dusting powders and identical products)

The general requirements as given in Part I of this schedule relating to requirements of good manufacturing practices for premises and materials for pharmaceutical products shall be complied with, mutatis mutandis, for the manufacture of topical products, i.e. external preparations (creams, ointments, pastes, emulsions, lotions, solutions, dusting powders and identical products used for external applications). In addition to these requirements, following specific requirements shall also be followed, namely:

1. The entrance to the area where topical products are manufactured should be through a suitable airlock. Outside the airlock, insectocutors shall be installed.
2. The air to this manufacturing area shall be filtered through at least 20 μ air filters and shall be air-conditioned. The area shall be ventilated.
3. The area shall be fitted with an exhaust system of suitable capacity to effectively remove vapours, fumes, smoke, floating dust particles.

4. The equipment used shall be designed and maintained to prevent the product from being accidentally contaminated with any foreign matter or lubricant.
5. No rags or dusters shall be used in the process of cleaning or drying the process equipment or accessories used.
6. Water used in compounding shall be purified water IP.
7. Powders, wherever used, shall be suitably sieved before use.
8. Heating vehicles and a base like petroleum jelly shall be done in separate mixing area in suitable stainless steel vessels, using steam, gas, electricity, solar energy, etc.
9. A separate packing section may be provided for primary packaging of the products.

PART I E

Specific requirements for manufacture of metered-dose-inhalers (MDIs)

The general requirements as given in Part I of this schedule relating to requirements of good manufacturing practices for premises and materials for pharmaceutical products shall be complied with, mutatis mutandis, for the manufacture of Metered-Dose-Inhalers (MDIs).

In addition to these requirements, the following specific requirements shall also be followed, namely:

1. **General:** Manufacture of metered-dose-inhalers shall be done under conditions which shall ensure minimum microbial and particulate contamination. Assurance of the quality of components and the bulk product is very important. Where medicaments are in suspended state, uniformity of suspension shall be established.
2. **Building and civil works:** The building shall be located on a solid foundation to reduce risk of cracking walls and floor due to the movement of equipment and machinery. All building surfaces shall be impervious, smooth and non-shedding. Flooring shall be

continuous and provided with a cove between the floor and the wall as well as the wall to the ceiling. Ceiling shall be solid, continuous and covered to walls. Light fittings and air-grills shall be flush with the ceiling. All service lines requiring maintenance shall be erected in such a manner that these accessible from outside the production area. The manufacturing area shall be segregated into change rooms for personnel, container preparation area, bulk preparation and filling area, quarantine area and spray testing and packing areas. Secondary change rooms shall be provided for operators to change from factory clothing to special departmental clothing before entering the manufacturing and filling area. Separate area shall be provided for de-cartoning of components before they are air washed. The propellants used for manufacture shall be delivered to the manufacturing area distribution system by filtering them through 2 μ filters. The bulk containers of propellants shall be stored, suitably identified, away from the manufacturing facilities.

3. **Environmental conditions:** Where products or clean components are exposed, the area shall be supplied with filtered air of Grade C. The requirements of temperature and humidity in the manufacturing area shall be decided depending on the type of product and propellants handled in the facility. Other support area shall have comfort levels of temperature and humidity. There shall be a difference in room pressure between the manufacturing area and the support areas and the differential pressure shall be not less than 15 pascals (0.06 inches or 1.5 mm water gauge). There shall be a written schedule for the monitoring of environmental conditions. Temperature and humidity shall be monitored daily.

4. **Garments:** Personnel in the manufacturing and filling section shall wear suitable single-piece garment made out of non-shedding, tight weave material. Personnel in support areas shall wear clean factory uniforms. Gloves made of suitable material having no interaction with the propellants shall be used by the operators in the manufacturing and filling areas. Preferably, disposable gloves shall be used. Suitable department-specific personnel protective equipment like footwear and safety glasses shall be used wherever hazard exists.
5. **Sanitation:** There shall be written procedures for the sanitation of the MDIs manufacturing facility. Special care should be taken to handle residues and rinses of propellants. Use of water for cleaning shall be restricted and controlled. Routinely used disinfectants are suitable for sanitizing the different areas. Records of sanitation shall be maintained.
6. **Equipment:** Manufacturing equipment shall be of closed system. The vessels and supply lines shall be of stainless steel. Suitable check weights spray testing machines and labelling machines shall be provided in the department. All the equipment shall be suitably calibrated and their performance validated on receipt and thereafter periodically.
7. **Manufacture:** There shall be approved Master Formula Records for the manufacture of metered dose inhalers. All propellants, liquids and gases shall be filtered through 2 μ filters to remove particles. The primary packing material shall be appropriately cleaned by compressed air suitably filtered through 0.2 μ filter. The humidity of compressed air shall be controlled as applicable. The valves shall be carefully handled and after de-cartoning, these shall be kept in clean, closed containers in the filling room. For suspensions, the bulk shall be kept stirred continuously. In-process, controls shall include periodical checking of weight of bulk formulation filled in the containers. In a two-shot-filling process (liquid filling followed by gaseous filling), it shall be ensured that 100% check on weight is carried out. Filled containers shall be quarantined for a suitable period established by the manufacturer to detect leaking containers prior to testing, labelling and packing.
8. **Documentation:** In addition to the routine good manufacturing practices documentation, manufacturing records shall show the following additional information:
 1. Temperature and humidity in the manufacturing area.
 2. Periodic filled weights of the formulation.
 3. Records of rejections during on line check weighing.
 4. Records of rejection during spray testing.

PART I F

Specific requirements of premises, plant and materials for manufacture of active pharmaceutical ingredients (bulk drugs)

The general requirements as given in part I of this schedule relating to requirements of good manufacturing practices for premises and materials for pharmaceutical products shall be complied with, mutatis mutandis, for the manufacture of active pharmaceutical ingredients (bulk drugs).

In addition to these requirements, the following specific requirements shall also be followed, namely:

1. **Building and civil works:** Apart from the building requirements contained Part I, general note, the active pharmaceutical ingredients facilities for manufacture of hazardous reactions, beta-lactum antibiotics. Steroids and steroid hormones/cytotoxic substances shall be provided in confined areas to prevent contamination of the other

drugs manufactured. The final stage of preparation of a drug, like isolation/filtration/drying/milling/sieving and packing operations shall be provided with air filtration systems including prefilters and finally with a 5 micron filter. Air handling systems with adequate number of air changes per hour or any other suitable system to control the air borne contamination shall be provided. Humidity/temperature shall also be controlled for all the operations wherever required. Air filtration systems including pre-filters and particulate matter retention air filters shall be used, where appropriate, for air supplies to production areas. If air is re-circulated to production areas, measures shall be taken to control re-circulation of floating dust particles from production. In areas where air contamination occurs during production, there shall be adequate exhaust system to control contaminants. Ancillary area shall be provided for boiler-house. Utility areas like heat exchangers, chilling workshop, store and supply of gases shall also be provided. For specified preparation like manufacture of sterile products and for certain antibiotics, sex hormones, cytotoxic and oncology products, separate enclosed areas shall be designed. The requirements for the sterile active pharmaceutical ingredient shall be in line with the facilities required for formulation to be filled aseptically.

2. Sterile products: Sterile active pharmaceutical ingredient filled aseptically shall be treated as formulation from the stage wherever the process demands like crystallization, lyophilisation, filtration, etc. all conditions applicable to formulations that are required to be filled aseptically shall apply mutatis mutandis for the manufacture of sterile active pharmaceutical ingredients involving stages like filtration crystallization and lyophilisation.

3. Utilities/services: Equipment like chilling plant, boiler, heat exchangers, vacuum and gas storage vessels shall be serviced, cleaned, sanitized and maintained at appropriate intervals to prevent malfunctions or contamination that may interfere with safety, identity, strength, quality or purity of the drug product.

4. Equipment design, size and location: Equipment used in the manufacture, processing, packing or holding of an active pharmaceutical ingredient shall be of appropriate design, adequate size and suitably located to facilitate operations for its intended use and for its cleaning and maintenance. If the equipment is used for different intermediates and active pharmaceutical ingredients, proper cleaning before switching from one product to another becomes particularly important. If cleaning of a specific type of equipment is difficult, the equipment may need to be dedicated to a particular intermediate or active pharmaceutical ingredient.

The choice of cleaning methods, detergents and levels of cleaning shall be defined and justified. Selection of cleaning agents (e.g. solvents) should depend on:

- a. The suitability of the cleaning agent to remove residues of raw materials, intermediates, precursors, degradation products and isomers, as appropriate.
- b. Whether the cleaning agent leaves a residue itself.
- c. Compatibility with equipment construction materials like centrifuge/filtration, dryer/fluid bed dryer, rotocone proton dryer, vacuum dryer, frit mill, multi-mill/jet mills/sewetters cut sizing.
- d. Test for absence of intermediate or active pharmaceutical ingredient in the final rinse.

Written procedures shall be established and followed for cleaning and maintenance of

equipment, including utensils used in the manufacture, processing, packing or holding of active pharmaceutical ingredients. These procedures shall include but should not be limited to the following:

- a. Assignment of responsibility for cleaning and maintaining equipment.
- b. Maintenance and cleaning program schedules, including where appropriate, sanitizing schedules.
- c. A complete description of the methods and materials used to clean and maintain equipment, including instructions for de-assembling and reassembling each article of equipment to ensure proper cleaning and maintenance.
- d. Removal or obliteration of previous batch identification.
- e. Protection of clean equipment from contamination prior to use.
- f. Inspection of equipment for cleanliness immediately before use.
- g. Establishing the maximum time that may elapse between completion of processing and equipment cleaning as well as between cleaning and equipment reuse.

Equipment shall be cleaned between successive batches to prevent contamination and carry-over of degraded material or contaminants unless otherwise established by validation. As processing approaches the final purified active pharmaceutical ingredient, it is important to ensure that incidental carry over between batches does not have adverse impact on the established impurity profile. However, this does not generally hold good for any biological, active pharmaceutical ingredient where many of the processing steps are accomplished aseptically and where it is necessary to clean and sterilize equipment between batches.

5. **In-process controls:** In-process control for chemical reactions may include the following:

- a. Reaction time or reaction completion.
- b. Reaction mass appearance, clarity, completeness or pH solutions.
- c. Reaction temperature.
- d. Concentration of a reactant.
- e. Assay or purity of the product.
- f. Process completion check by TLC/any other means.

In-process control for physical operations may include the following:

- a. Appearance and colour.
- b. Uniformity of the blend.
- c. Temperature of a process.
- d. Concentration of a solution.
- e. Processing rate or time.
- f. Particle size analysis.
- g. Bulk/tap density.
- h. pH determination.
- i. Moisture content.

6. **Product containers and closures:** All containers and closures shall comply with the pharmacopoeial or any other requirement, suitable sampling methods, sample sizes, specifications, test methods, cleaning procedures and sterilization procedures, when indicated, shall be used to assure that containers, closures and other component parts of drug packages are suitable and are not reactive, additive, adsorptive or leachable to an extent that significantly affects the quality or purity of the drug. The drug product container shall be tested or re-examined as appropriate and approved or rejected and shall be identified and controlled under a quarantine system designed to prevent their use in manufacturing or processing operations for which these are unsuitable. Container closure system shall provide adequate protection against foreseeable external factors in storage/transportation and use that may cause deterioration or contamination of the active pharmaceutical ingredient. Bulk containers and

closures shall be cleaned and, where indicated by the nature of the active pharmaceutical ingredient, sterilized to ensure that they are suitable for their intended use.

The container shall be conspicuously marked with the name of the product and the following additional information concerning:

- Quality and standards, if specified.
- Manufacturing license number/drug master file number (whichever applicable), batch number.
- Date of manufacture and date of expiry.
- Method for container disposal (label shall give the methodology, if required).
- Storage conditions, if specified and name and address of the manufacturer, if available.

Areas for different operation of active pharmaceutical ingredients (bulk drugs) section shall have appropriate area which may be suitably partitioned for different operations.

PART II

Requirements of plant and equipment

Part II deals with the plant and equipment for manufacture of drugs.

- External preparations:** The following equipments are recommended for the manufacture of 'External Preparations', i.e. ointments, emulsion, lotions, solutions, pastes, creams, dusting powders and such identical products used for external applications whichever is applicable, namely: (i) Mixing and storage tanks (stainless steel), (ii) Jacketted kettle (steam, gas or electrically heated), (iii) Mixer (electrically operated), (iv) Planetary mixer, (v) A colloid mill or a suitable emulsifier, (vi) A triple roller mill or an ointment mill, (vii) Liquid filling equipment (electrically operated), (viii) Jar or tube filling equipment (electrically operated).

Area:

- A minimum area of thirty square meters for basic installation of ten square meters for Ancillary area is recommended.
- Areas for formulations meant for external use and internal use shall be separately provided to avoid mix-up.

- Oral liquid preparations:** The following equipments are recommended for the manufacture of oral/internal use preparations, i.e. syrups, elixirs, emulsions and suspensions, whichever is applicable, namely: (i) Mixing and storage tanks (stainless steel), (ii) Jacketted kettle / stainless steel tank (steam, gas or electrically heated), (iii) Portable stirrer (electrically operated), (iv) A colloid mill or suitable emulsifier (electrically operated), (v) Suitable filtration equipment (electrically operated), (vi) Semi-automatic/automatic bottle filling machine, (vii) Pilfer proof cap sealing machine, (viii) Water distillation unit or deioniser, (ix) Clarity testing inspection units.

Area: A minimum area of 30 square meters for basic installation and 10 square meters for ancillary area is recommended.

- Tablets:** The tabletting section shall be free from dust and floating particles and may be air-conditioned.

For this purpose, each tablet machine shall be isolated into cubicles and connected to a vacuum dust collector or an exhaust system. For effective operations, the tablet production department shall be divided into four distinct and separate sections as follows:

- Mixing, granulation and drying section.
- Tablet compression section.
- Packaging section (strip/blister machine wherever required).
- Coating section (wherever required).

The following electrically operated equipments are recommended for the manufacture

of compressed tablets and hypodermic tablets, in each of the above sections, namely:

- a. Granulation-cum-drying section:
(i) Disintegrator and sifter, (ii) Powder mixer, (iii) Mass mixer/Planetary mixer/rapid mixer granulator, (iv) Granulator, (v) Thermostatically controlled hot air oven with trays (preferably mounted on a trolley)/fluid bed dryer, (vi) Weighing machines.
- b. Compression section: (i) Tablet compression machine, single/multi punch/rotatory, (ii) Punch and dies storage cabinets, (iii) Tablet deduster, (iv) Tablet Inspection unit/belt, (v) Dissolution test apparatus, (vi) In-process testing equipment like single pan electronic balance, hardness tester, friability and disintegration test apparatus, (vii) Air-conditioning and dehumidification arrangement (wherever necessary).
- c. Packaging section: (i) Strip/blister packaging machine, (ii) Leak test apparatus (vacuum system), (iii) Tablet counters (wherever applicable), (iv) Air-conditioning and dehumidification arrangement (wherever applicable).

Area: A minimum area of 60 square meters for basic installation and 20 square meters for Ancillary area is recommended for un-coated tablets.

- d. Coating section: (i) Jacketted kettle (steam, gas or electrically heated for preparing coating suspension), (ii) Coating pan (stainless steel), (iii) Polishing pan (where applicable), (iv) Exhaust system (including vacuum dust collector), (v) Air-conditioning and dehumidification arrangement, (vi) Weighing balance.

The coating section shall be made dust free with suitable exhaust system to remove excess

powder and fumes resulting from solvent evaporation. It shall be air-conditioned and dehumidified wherever considered necessary.

Area: A minimum additional area of 30 square meters for coating section for basic installation and 10 square meters for Ancillary area is recommended.

Separate area and equipment for mixing, granulation, drying, tablet compression, coating and packing shall be provided for penicillin group of drugs on the lines indicated above. In case of operations involving dust and floating particles, care shall be exercised to avoid cross-contamination. The manufacture of hypodermic tablets shall be conducted under aseptic conditions in a separate air-conditioned room, the walls of which shall be smooth and washable. The granulation, tableting and packing shall be done in this room. The manufacture of effervescent and soluble/dispersible tablets shall be carried out in air-conditioned and dehumidified areas.

4. **Powders:** The following equipment is recommended for the manufacture of powders, namely: (i) Disintegrator, (ii) Mixer (electrically operated), (iii) Sifter, (iv) Stainless steel vessels and scoops of suitable sizes, (v) Filling equipment (electrically operated), (vi) Weighing balance. In the case of operation involving floating particles of fine powder, suitable exhaust system shall be provided. Workers should be provided with suitable masks during operation.

Area: A minimum area of 30 square meters is recommended to allow for the basic installations. Where the actual blending is to be done on the premises, an additional room shall be provided for the purpose.

5. **Capsules:** For the manufacture of capsules, separate enclosed area suitably air-conditioned and dehumidified with an airlock arrangement shall be provided. The following equipment is recommended for

filling hard gelatin capsules, namely: (i) Mixing and blending equipment (electrically or power driven), (ii) Capsules filling units (preferably semi-automatic or automatic filling machines), (iii) Capsules counters (wherever applicable) (iv) Weighing balance, (v) Disintegration test apparatus, (vi) Capsule polishing equipment. Separate equipment and, filling and packaging area shall be provided in penicillin and non-penicillin sections. In case of operations involving floating particles of fine powder, a suitable exhaust system shall be provided. Manufacture and filling shall be carried out in airconditioned area. The room shall be dehumidified.

Area: A minimum area of 25 square meters for basic installation and 10 square meters for Ancillary area each for penicillin and non-penicillin sections is recommended.

6. Surgical dressing: The following equipment is recommended for the manufacture of surgical dressings other than Absorbent Cotton Wool, namely: (i) Rolling machine, (ii) Trimming machine, (iii) Cutting equipment, (iv) Folding and pressing machine for gauze, (v) Mixing tanks for processing medicated dressing, (vi) Hot air dry oven, (vii) Steam sterilizer or dry heat sterilizer or other suitable equipment, (viii) Work tables/benches for different operations.

Area: A minimum area of 30 square meters is recommended to allow for the basic installations. In case medicated dressings are to be manufactured, another room with a minimum area of 30 square meters shall be provided.

7. Ophthalmic preparations: For the manufacture of ophthalmic preparations, separate enclosed areas with airlock arrangement shall be provided. The following equipment is recommended for the manufacture under aseptic conditions of eye-ointment, eye-lotions and other prepara-

tions for external use, namely: (i) Thermospatially controlled hot air ovens (preferably double ended), (ii) Jacketted kettle/stainless steel tanks (steam, gas or electrically heated), (iii) Mixing and storage tanks of stainless steel/Planetary mixer, (iv) Colloid mill or ointment mill, (v) Tube filling and crimping equipment (semi-automatic or automatic filling machines), (vi) Tube cleaning equipment (air jet type), (vii) Tube washing and drying equipment, if required, (viii) Automatic vial washing machine, (ix) Vial drying oven, (x) Rubber bung washing machine, (xi) Sintered glass funnel, Seitz filter and filter candle (preferably cartridge and membrane filters), (xii) Liquid filling equipment (semi-automatic or automatic filling machines), (xiii) Autoclave (preferably ventilator autoclave), (xiv) Air conditioning and dehumidification arrangement (preferably centrally air-conditioned and dehumidification system), (xv) Laminar airflow units.

Area:

- A minimum area of 25 square meters for basic installation and 10 square meters for Ancillary area is recommended. Manufacture and filling shall be carried out in air-conditioned areas under aseptic conditions. The rooms shall be further dehumidified as considered necessary if preparations containing antibiotics are manufactured.
 - Areas for formulations meant for external use and internal use shall be separately provided to avoid mix-up.
- 8. Pessaries and suppositories:** The following equipment is recommended for manufacture of Pessaries and Suppositories, namely: (i) Mixing and pouring equipment, (ii) Moulding equipment, (iii) Weighing devices.

Area: A minimum area of 20 square meters is recommended to allow for the basic installation.

9. **Inhalers and vitrallae:** The following equipment is recommended for manufacture of inhalers and vitrallae, namely:
 (i) Mixing equipment, (ii) Graduated delivery equipment for measurement of the medicament during filling, (iii) Sealing equipment,

Area: An area of minimum 20 square meters is recommended for the basic installations.

10. **Rewraping of drugs and pharmaceutical chemicals:** The following equipment is recommended for repacking of drugs and pharmaceutical chemicals, namely:
 (i) Powder disintegrator, (ii) Powder sifter (electrically operated), (iii) Stainless steel scoops and vessels of suitable sizes, (iv) Weighing and measuring equipment, (v) Filling equipment (semi-automatic automatic machines), (vi) Electric sealing machine.

Area: An area of minimum 30 square meters is recommended for the basic installation. In case of operations involving floating particles of fine powder, a suitable exhaust system shall be provided.

11. **Parenteral preparations:** The whole operation of manufacture of parenteral preparations (small volume injectables and large volume parenterals) in glass and plastic containers may be divided into the following separate areas/rooms, namely:

- 11.1 **Parenteral preparations in glass containers:** The following equipment is recommended for different above-mentioned areas, namely:

- a. **Water management area:** (i) De-ionised water treatment unit, (ii) Distillation (multi-column with heat ex-changers) unit, (iii) Thermostatically controlled water storage tank, (iv) Transfer pumps, (v) Stainless steel service lines for carrying water into user areas.

- b. **Containers and closures preparation area:**
 (i) Automatic rotary ampoule/vial/bottle washing machine having separate air, water distilled water jets, (ii) Automatic closures washing machine, (iii) Storage equipment for ampoules, vials, bottles and closures, (iv) Dryer/sterilizer (double ended), (v) Dust proof storage cabinets, (vi) Stainless steel benches/stools.
- c. **Solution preparation area:** (i) Solution preparation and mixing stainless steel tanks and other containers, (ii) Portable stirrer, (iii) Filtration equipment with cartridge and membrane, filters/bacteriological filters, (iv) Transfer pumps, (v) Stainless steel benches/stools.
- d. **Filling, capping and sealing area:** (i) Automatic ampoule/vial/bottle filling, sealing and capping machine under laminar airflow workstation, (ii) Gas line (Nitrogen, Oxygen, Carbon dioxide) wherever required, (iii) Stainless steel benches/stools.
- e. **Sterilization area:** (i) Steam sterilizer preferably with computer control for sterilization cycle along with trolley sets for loading/unloading containers before and after sterilization, (ii) Hot air sterilizer (preferably double ended), (iii) Pressure leak test apparatus.
- f. **Quarantine area:** (i) Storage cabinets, (ii) Raised platforms/steel racks.
- g. **Visual inspection area:** (i) Visual inspection units (preferably conveyor belt type and composite white and black assembly supported with illumination), (ii) Stainless steel benches/stools.
- h. **Packaging area:** (i) Batch coding machine (preferably automatic), (ii) Labelling unit (preferably conveyor belt type), iii. Benches/stools.

Area: (i) A minimum area of 150 square meters for the basic installation and an ancillary

area of 100 square meters for Small Volume Injectables are recommended. For Large Volume Parenterals, an area of 150 square meters each for the basic installation and for ancillary area is recommended. These areas shall be partitioned into suitable enclosures with airlock arrangements, (ii) Areas for formulations meant for external use and internal use shall be separately provided to avoid mix-up, (iii) Packaging materials for large volume parenteral shall have a minimum area of 100 square meters.

11.2 Parenteral preparations in plastic containers by Form-Fill-Seal/blow, fill-seal technology: The whole operation of manufacture of large volume parenteral preparations in plastic containers including plastic pouches by automatic (all operations in one station) Form-Fill-Seal machine or by semi-automatic blow moulding, filling-cum-sealing machine may be divided into following separate areas/rooms, namely:

The following equipment is recommended for different above mentioned areas namely:

- a. Water management area: (i) De-ionised water treatment unit, (ii) Distillation unit (multi column with heat exchangers), (iii) Thermostatically controlled water storage tank, (iv) Transfer pumps, (v) Stainless steel service lines for carrying water into user areas.
- b. Solution preparation area: (i) Solution preparation and storage tanks, (ii) Transfer pumps, (iii) Cartridge and membrane filters.
- c. Container moulding-cum-filling and sealing area: (i) Sterile form-fill-seal machine (all operations in one station with built-in laminar airflow workstation having integrated container output conveyor belt through pass box).

Arrangement for feeding plastic granules through feeding-cum-filling tank into the machine.

- d. *Sterilization area:* Super heated steam sterilizer (with computer control for sterilization cycle along with trolley sets for loading/unloading containers for sterilization).
- e. *Quarantine area:* Adequate number of platforms/racks with storage system.
- f. *Visual inspection area:* Visual inspection unit (with conveyor belt and composite
- g. *Packaging area:* (i) Pressure leak test apparatus (pressure belt or rotating disc type), (ii) Batch coding machine (preferably automatic), (iii) Labelling unit (preferably conveyor belt type).

Area: (i) A minimum area of 250 square meters for the basic installation of an Ancillary area of 150 square meters for large volume parenteral preparations in plastic containers by Form-Fill-Seal technology is recommended. These areas shall be partitioned into suitable enclosures with airlock arrangements, (ii) Areas for formulations meant for external use and internal use shall be separately provided to avoid mix-up, (iii) Packaging materials for large volume parenteral shall have a minimum area of 100 square meters.

SCHEDULE M I

1. Requirements of Factory Premises for Manufacture of Homoeopathic Preparations

A. Location and surroundings: The factory shall be situated in a place which shall not be adjacent to an open sewage drain, public lavatory or any factory which produces a disagreeable or obnoxious odour or fumes or large quantities of soot, dust or smoke. The factory shall be located in a sanitary place, away from filthy surroundings.

B. Buildings: The part of the building used for manufacturing shall not be used for a sleeping place and no sleeping place adjoining to it shall communicate therewith except through open air

or through an intervening open space. The walls of the room in which manufacturing operations are carried out shall, upto a height of six feet from the floor, be smooth, waterproof and shall be capable of being kept clean. The flooring shall be smooth, and even washable and shall be such as not to permit retention or accumulation of dust. There shall be no chinks or crevices in the walls or floor. The building used for the factory shall be constructed so as to permit production under hygienic conditions laid down in the Factories Act, 1948.

C. Water supply: The water used in manufacture shall be pure and drinkable quality, free from pathogenic microorganisms.

D. Disposal of waste: There should be adequate arrangement for disposal of wastewater and other residues from the laboratory. The rooms should be airy and clean and the temperature of the room should be moderately comfortable.

E. Health, clothing and sanitary requirement of the staff: All workers shall be free from contagious or obnoxious disease. Their clothing shall consist of a white or coloured uniform suitable to the nature of the work and the climate and shall be clean. Adequate facilities for personal cleanliness, such as clean towels, soap and hand scrubbing brushes, shall be provided separately for each sex. The workers shall be required to wash and change into clean footwear before entering the rooms where the manufacturing operations are carried on. Workers shall be required to wear either a clean cap or a suitable headgear so as to avoid any possibility of contamination by air or perspiration.

F. Medical services: The manufacturer shall provide adequate facilities for first-aid, medical inspection of workers at the time of employment and periodically check-up thereafter at least once a year.

G. Working benches: Working benches shall be provided for carrying out operations such as filling, labelling, packing, etc. such benches shall

be fitted with smooth, impervious tops capable of being washed.

H. Container management: Where operations involving use of containers such as bottles, phials and jars are conducted, there shall be adequate arrangements separated from potentiation chamber for washing, cleaning and drying such containers, with suitable equipment for the purpose. Wherever these are attended manually adequate precaution of perfection in respect of cleanliness and avoidance of pollutants shall be taken.

2. Requirements of Plant and Equipment

Mother tinctures: External tinctures and mother solution section: The following plant and equipment shall be provided namely:

- i. Disintegrator.
- ii. Sieved separator.
- iii. Balances and fluid measures.
- iv. Chopping boards and knives.
- v. Macerators with lids.
- vi. Percolators with lids and regulated discharge.
- vii. Moisture determination apparatus or other suitable arrangement.
- viii. Filtering arrangement.
- ix. Mixing vessels and suitable non-metallic storage containers.
- x. Portable stirrers.
- xi. Water still.

Note:

An area of 55 sq. meters is recommended for basic installations.

Potentisation section:

1. The following arrangements are recommended for container for closure preparation section namely:
 - i. Washing tanks with suitable brushing arrangement manual or mechanical.
 - ii. Purified water rinsing tank.
 - iii. Closure macerating or washing tanks.
 - iv. Drying chambers.

An area of 20 sq. meters is recommended for basic installation.

2. The following arrangements are recommended for potency preparation section, namely:
 - i. Working tables with washable top.
 - ii. Facilities for separate storage of different grades of back potencies.
 - iii. Suitable measuring devices for discharge of drug and diluent in potentisation vial.
 - iv. Potentiser with counter or suitable manual arrangement.

3. The Following Arrangement are Recommended

- i. Triturating machine for suitable device.
- ii. Disintegrator.
- iii. Mass mixer.
- iv. Granulator.
- v. Oven.
- vi. Tableting punches or machines.
- vii. Kettle (Steam/gas/electrically heated) for preparation solution.
- viii. Dryers.
- ix. Sieved separator, tablet counters and balances.

Note:

Tablet section shall be free from dust and floating particles.

An area of 55 sq. meters is recommended for basis installations.

4. Ointments and Lotion Section

The following arrangements are recommended namely:

- i. Mixing tank.
- ii. Kettle (steam, gas or electrically heated).
- iii. Suitable powder mixer.
- iv. Ointment mill.
- v. Filling equipment or arrangement.

An area of 20 sq. meters is recommended for basic installation.

5. Syrups and Tonics

The following arrangements are recommended namely:

- i. Mixing and storage tank.
- ii. Portable mixer.
- iii. Filtering equipment.
- iv. Water still/deioniser.
- v. Filling and sealing equipment.

An area of 20 sq. meters is recommended for basic installations.

6. Ophthalmic Preparations

The following equipment is recommended for manufacture under aseptic conditions of eye-ointments, eye drops, eye-lotion and other preparations for external use, namely:

- i. Hot air oven electrically heated with thermostatic control.
- ii. Colloid mill or ointment mill.
- iii. Kettle (gas or electrically heated) with suitable mixing arrangement.
- iv. Tube filling equipment.
- v. Mixing and storage tanks of stainless steel or of other suitable material.
- vi. Sintered glass funnel, Seitz filter or filter candle.
- vii. Liquid filling equipment.
- viii. Autoclaves—Adequate precaution should be taken to ensure that the finished product is sterile.

An area of 20 sq. meters is recommended for basic installations.

7. Adequate Arrangements for Space and Equipment should make for Labelling and Packing

SCHEDULE M II

Requirement of factory premises for manufacture of cosmetics: Due to the increasing popularity of the cosmetics the government of India has shown its serious concern in their manufacture as evident from the introduction

of Schedule M II in August 1992 laying down the requirements of factory premises, plants and equipments for the manufacture of cosmetics.

I. General Requirements

1. ***Location and surroundings:*** The factory shall not be located in a sanitary place and hygienic conditions shall be maintained in the premises. Premises shall not be used for residence or be interconnected with residential area. It shall be well-ventilated and clean.
2. ***Buildings:*** The buildings used for the factory shall be constructed so as to permit production under hygienic conditions and not to permit entry of insects, rodents, flies, etc. The walls of the room in which manufacturing operations are carried out, shall up to a height of six feet from the floor, be smooth, waterproof and capable of being kept clean. The flooring shall be smooth, and even washable and shall be such as not to permit retention or accumulation of dust.
3. ***Water supply:*** The water used in manufacture shall be of potable quality.
4. ***Disposal of water:*** Suitable arrangements shall be made for disposal of waste water.
5. ***Health, clothing and sanitary requirements of the staff:*** All workers shall be free from contagious or infectious diseases. They shall be provided with clean uniforms, masks, headgears, and gloves wherever required. Washing facilities shall also be provided.
6. ***Medical services:*** Adequate facilities for first aid shall be provided.
7. Working benches shall be provided for carrying out operations such as filling, labelling, packing, etc. such benches shall be fitted with smooth, impervious tops capable of being washed.
8. Adequate facilities shall be provided for washing and drying of glass containers if

the same are to be used for packing the product.

II. Requirement of Plant and Equipment

The following equipment, area and other requirements are recommended for the manufacture of:

1. ***Powders:*** Face powder, make-up, cake compacts, face packs, masks and rouges, etc.
Equipment:
 - a. Powder mixer of suitable type provided with a dust collector.
 - b. Perfume and colour blender.
 - c. Sifter with sieves of suitable mesh size.
 - d. Ball mill or suitable grinder.
 - e. Trays and scoops (stainless steel).
 - f. Filling and sealing equipment provided with dust extractor.
 - g. For compacts:
 - i. A separate mixer.
 - ii. Compact pressing machine.
 - h. Weighing and measuring devices.
 - i. Storage tanks.

An area of 15 square meters is recommended. The section is to be provided with adequate exhaust fans.

2. ***Creams:*** lotions, emulsions, pastes, cleaning milks, shampoos, pomade, brilliantine, shaving creams and hair-oils, etc.
 - a. Mixing and storage tanks of suitable materials.
 - b. Heating kettle—steam, gas or electrically heated.
 - c. Suitable agitator.
 - d. Colloidal mill or homogeniser (wherever necessary).
 - e. Triple roller mill (wherever necessary).
 - f. Filling and sealing equipment.
 - g. Weighing and measuring devices.

An area of 25 square meters is recommended.

3. ***Nail polishes and nail lacquers:***

Equipment:

- a. A suitable mixer.

- b. Storage tanks.
- c. Filling machine—hand operated or power driven.
- d. Weighing and measuring devices.

An area of 15 square meters is recommended. The section shall be provided with flameproof exhaust system.

Premises: The following are the special requirements related to nail polishes and nail lacquers:

- a. It shall be suited in an industrial area.
- b. It shall be separate from other cosmetic manufacturing areas by metal/brick partition up to ceiling.
- c. Floors, walls, ceiling and doors shall be fireproof.
- d. Smoking, cooking and dwelling shall not be permitted and no naked flame shall be brought in the premises.
- e. All electrical wiring and connections shall be concealed and main electric, switch shall be outside the manufacturing area.
- f. All equipment, furniture and light fittings in the section shall be flameproof.
- g. Fire extinguisher like foam and dry powder and sufficient number of buckets containing sand shall be provided.
- h. All doors of the section shall open outwards.

Storage: All explosive solvents and ingredients shall be stored in metal cupboards or in a separate enclosed area.

Manufacture:

- a. Manufacture of lacquer shall not be undertaken unless the above conditions are complied with.
- b. Workers shall be asked to wear shoes with rubber soles in the section.

Other requirements: No objection certificate from the local Fire Brigade Authorities shall be furnished.

4. Lapsticks and lipgloss:

Equipment:

- a. Vertical mixer.
- b. Jacketted kettle—steam, gas or electrically heated.
- c. Mixing vessel (stainless steel).
- d. Triple roller mill/ball mill.
- e. Moulds with refrigeration facility.
- f. Weighing and measuring devices.

An area of 15 square meters is recommended.

5. Depilatories:

Equipment:

- a. Mixing tanks.
- b. Mixer.
- c. Triple roller mill or homogeniser (where necessary).
- d. Filling and sealing equipment.
- e. Weighing and measuring devices.
- f. Moulds (where necessary).

An area of 10 square meters is recommended.

6. Preparations used for eyes:

Such preparations shall be manufactured under strict hygienic conditions to ensure that these are safe for use.

- i. Eyebrows, eyelashes, eyeliners

Equipment:

- a. Mixing tanks.
- b. A suitable mixer.
- c. Homogeniser (where necessary).
- d. Filling and sealing equipment.
- e. Weighing and measuring devices.

An area of 10 square meters is recommended.

ii. Kajal and surma

Equipment:

- a. Base sterilizer.
- b. Powder sterilizer (dry heat oven).
- c. Stainless steel tanks.
- d. A suitable mixer.
- e. Stainless steel sieves.
- f. Filling and sealing arrangements.
- g. Weighing and measuring devices.
- h. Homogeniser (where necessary).
- i. Pestle and Mortar (for Surma).

An area of 10 square meters with a separate area of 5 square meters for base sterilization is recommended.

Other Requirements for (i) and (ii)

- a. False ceiling shall be provided wherever required.
- b. Manufacturing area shall be made fly proof. An airlock or an air curtain shall be provided.
- c. Base used for *Kajal* shall be sterilized by heating the base at 150°C for required time in a separate enclosed area.
- d. The vegetable carbon black powder shall be sterilized in a drying oven at 120°C for required time.
- e. All utensils used for manufacture shall be of stainless steel and shall be washed with detergent water, antiseptic liquid and again with distilled water.
- f. Containers employed for '*Kajal*' shall be cleaned properly with bactericidal solution and dried.
- g. Workers shall put on clean overalls and use hand gloves wherever necessary.

7. Aerosol:

Equipment:

- a. Air-compressor (wherever necessary).
- b. Mixing tanks.
- c. Suitable propellant filling and crimping equipments.
- d. Liquid filling unit.
- e. Leak testing equipment.
- f. Fire extinguisher (wherever necessary).
- g. Suitable filtration equipment.
- h. Weighing and measuring devices.

An area of 15 square meters is recommended.

Other requirements: No objection certificate from the local Fire Brigade Authorities shall be furnished.

8. Alcoholic fragrance solutions:

Equipment:

- a. Mixing tanks with stirrer.
- b. Filtering equipment.
- c. Filling and sealing equipment.

- d. Weighing and measuring devices.

An area of 15 square meters is recommended.

9. Hair dyes:

Equipment:

- a. Stainless steel tanks.
- b. Mixer.
- c. Filling unit.
- d. Weighing and measuring devices.
- e. Masks, gloves and goggles.

An area of 15 square meters with proper exhaust is recommended.

10. Tooth powders and toothpastes, etc:

- i. Tooth-powder in general

Equipment:

- a. Weighing and measuring devices.
- b. Dry mixer (powder blender).
- c. Stainless steel sieves.
- d. Powder filling and sealing equipments.

An area of 15 square meters with proper exhaust is recommended.

- ii. Toothpastes

Equipment:

- a. Weighing and measuring devices.
- b. Kettle—steam, gas or electrically heated (where necessary).
- c. Planetary mixer with de-aerator system.
- d. Stainless steel tanks.
- e. Tube filling equipment.
- f. Crimping machine.

An additional area of 15 square meters with proper exhaust is recommended.

- iii. Tooth-powder (black)

Equipment:

- a. Weighing and measuring devices.
- b. Dry mixer powder blender.
- c. Stainless steel sieves.
- d. Powder filling arrangements.

An area of 15 square meters with proper exhaust is recommended. Areas for manufacturing "Black" and "White" tooth powders should be separate.

11. *Toilet soaps:*

Equipment:

- a. Kettles/pans for saponification.
- b. Boiler or any other suitable heating arrangement.
- c. Suitable stirring arrangement.
- d. Storage tanks or trays.
- e. Driers.
- f. Amalgamator/chipping machine.
- g. Mixer.
- h. Triple roller mill.
- i. Granulator.
- j. Plodder.
- k. Cutter.
- l. Pressing, stamping and embossing machine.
- m. Weighing and measuring devices.

A minimum area of 100 square meters is recommended for the small-scale manufacture of toilet soaps.

The areas recommended above are for basic manufacturing of different categories of cosmetics. In addition to that separate adequate space for storage of raw materials, finished products, packing materials shall be provided in factory premises.

The above requirements of the Schedule are made subject to modification at the direction of the Licensing Authority, if he is of the opinion that having regard to the nature and extent of the manufacturing operations it is necessary to relax or alter them in the circumstances of a particular case.

The above requirements do not include requirements of machinery, equipments and premises required for preparation of containers and closers of different categories of cosmetics. The licensing authority shall have the discretion to examine the suitability and adequacy of the machinery, equipments and premises for the purpose of taking into consideration of the requirements of the license.

Schedule M-II specifies equipments and space required for certain categories of cosmetics only.

There are other cosmetics items, viz. *Attars*, perfumes, etc. which are not covered in the above categories. The licensing authority shall, in respect of such items or categories of cosmetics have the discretion to examine the adequacy of factory premises, space, plant and machinery and other requisites having regard to the nature and extent of the manufacturing operations involved and direct the licensee to carry on necessary modification in them.

Areas for formulations are meant for external use and areas for formulations are meant for internal use, shall be separately provided to avoid mix-up even though they are from the same category of formulations.

Adoption of above good manufacturing practices to the manufacture of cosmetics shall go a long way ensuring better quality cosmetics to consumer.

SCHEDULE M III

Requirements of factory premises for manufacture of medical devices

1. General Requirements

Location and surroundings: The factory building(s) shall be located in a sanitary place and hygienic conditions shall be maintained in the premises. Premises shall not be used for residence or be interconnected with residence. It shall be well ventilated and clean.

Buildings: The buildings used for the factory shall be constructed so as to permit production under hygienic conditions and not to permit entry of insects, rodents, flies, etc. The walls of the rooms in which manufacturing operations are carried out, shall be up to a height of six feet from the floor, be smooth, waterproof and capable of being kept clean. The floor shall be smooth, and even washable and shall be such as not to permit retention or accumulation of dust.

Water supply: The water used in manufacture shall be of potable quality.

Disposal of waste: Suitable arrangements shall be made for disposal of waste water.

Health, clothing and sanitation of workers:

All workers shall be free from contagious or infectious diseases. They shall be provided with clean uniforms, masks, headgears and gloves wherever required. Washing facilities shall also be provided.

Medical services: Adequate facilities for first-aid shall be provided.

Work benches shall be provided for carrying out operations such as moulding, assembling, labelling, packing, etc. such benches shall be fitted with smooth impervious tops capable of being washed. Adequate facilities shall be provided wherever required for cleaning, washing, drying of different containers of devices. The premises shall be kept under controlled conditions of temperature and humidity so as to prevent any deterioration in the properties of materials and products due to storage and process conditions.

2. Requirements for Manufacture of Medical Devices

The process of manufacture of medical devices shall be conducted at the licensed premises, wherever required, and shall be divided into the following separate operations/sections:

1. Moulding (wherever manufacture of medical devices is to start from granules).
2. Assembling (include cutting, washing and drying, sealing, packing, labelling, etc.).
3. Raw materials.
4. Storage area.
5. Washing, drying and sealing area (wherever required).
6. Sterilization.
7. Testing facilities.

The following equipments and space are recommended for the basic manufacture of different categories of medical devices.

A. Sterile Disposable Perfusion and Blood Collection Sets

1. Moulding:

- a. Injection moulding machine.

- b. Extruder machine.
- c. PVC resin compounding machine.

2. Assembling:

- a. Hand pressing machine for filter fixing a drip chamber.
- b. Bag sealing machine.
- c. Compressor machine.
- d. Leak testing bench.
- e. PVC Tube cutting machine.
- f. Tube winding machine (wherever necessary).
- g. Welding machine (wherever necessary).

An area of 30 square meters for moulding and 15 square meters for assembling are recommended for basic installation. The assembling area shall be air-conditioned provided with HEPA filters. The moulding section shall, if necessary, have proper exhaust system.

Note: An additional area of 20 square meters is recommended for any extra category.

B. Sterile Disposable Hypodermic Syringes

1. Moulding:

- a. Granulator.
- b. Injection moulding machine.
- c. Weighing devices.

2. Assembling:

- a. Blister pack machine.
- b. Vacuum dust cleaner.
- c. Rubber-tip washing machine.
- d. Foil stamping or screen printing equipment.

An area of 30 square meters for moulding and 15 square metres for assembling are recommended for basic installation. The assembling area shall be air-conditioned provided with HEPA filters. The moulding section, shall, if necessary, have proper exhaust system.

Note: An additional area of 20 square meters is recommended for any extra category.

C. Sterile Disposable Hypodermic Needles

1. Moulding:

- a. Needle grinding and leveling machine.

- b. Electro polishing machine.
- c. Cutting machine.
- d. Injection moulding machine.
- e. Needle pointing deburrine machine.
- f. Air-compressor.

2. Assembling:

- a. Needle cleaning machine with magnetic separator.
- b. Blister packing machine.
- c. Needle inspection unit.

An area of 30 square meters for moulding and 15 square meters for assembling are recommended for basic installation. The assembling area shall be air-conditioned provided with HEPA filters. The molding section shall, if necessary, have proper exhaust system.

Note: An additional area of 20 square meters is recommended for any extra category.

3. Raw materials:

The licensee shall keep an inventory of all raw materials to be used at any stage of manufacture of devices and shall maintain records as per Schedule U. All such raw materials shall be identified and assigned control reference number. They shall be conspicuously labeled indicating the name of the material, control reference number, name of the manufacturer and be specially labeled "Under Test" or "Approved" or "Rejected". The under test, approved or rejected materials shall appropriately be segregated. These shall be tested for compliance with required standards of quality.

A minimum area of 10 square meters shall be provided for storage of raw materials.

4. Storage area:

The licensee shall provide separate storage facilities for quarantine and sterilized products. An area not less than 10 square metres shall be provided for each of them.

5. Washing, drying and sealing area:

The licensee shall provide wherever required adequate equipments like water distillation still, deionizer, washing machine. Drying oven with

trays for washing, drying and sealing of medical device. An area not less than 10 square metres shall be provided.

6. Sterilization:

The licensee shall provide requisite equipments with required controls and recording device for sterilization of medical devices by ethylene oxide gas in his own premises or may make arrangements with some Institution approved by the Licensing authority for sterilization. The products sterilized in this manner shall be monitored to assure acceptable levels of residual gas and its degradation products. An area of 10 square meters is recommended for basic installation of such facility.

Provided that the above equipment may not be required in case the licensee opts for sterilization of medical devices by ionising radiation.

7. Testing facilities:

The licensee shall provide testing laboratory for carrying out chemical and physicochemical testing of medical devices and of raw materials used in its own premises.

Provided that the licensing authority shall permit the licensee in the initial stage to carry out testing of sterility, pyrogens, toxicity on their products from the approved testing institutions but after one renewal period of licensee shall provide testing facilities of all such tests in their own premises.

8. Records:

The licensee shall maintain records of different manufacturing activities with regard to each stage of manufacture in-process control, assembling, packing, batch records for the quantity of devices manufactured from each lot of blended granules, duration of work, hourly quantum of production in respect of each item as well as record of each sterilizing cycle of the gaseous method employed.

Note: The above requirements of machinery, equipments, space, qualifications are made subject to the modification at the discretion of the licensing authority, if he is of the opinion

that having regard to the nature and extent of the manufacturing operations it is necessary to relax or alter them in the circumstances of a particular case.

SCHEDULE N

List of minimum equipment for the efficient running of a pharmacy.

The Schedule N prescribes the following minimum requirements:

1. **Entrance:** The front of a pharmacy shall bear an inscription "pharmacy" in front.
2. **Premises:** The premises of a pharmacy shall be separated from rooms for private use. The premises shall be well built, dry, well lit and ventilated and of sufficient dimensions to allow the goods in stock especially medicaments and poisons to be kept in a clearly visible and in an appropriate manner. The area of the section to be used as dispensing department shall not be less than 6 square meters for one pharmacist working therein with additional 2 square meters for each additional pharmacist. The height of the premises shall be at least 2.5 meters. The floor of the pharmacy shall be smooth and washable. The walls shall be plastered or tiled or oil painted so as to maintain smooth, durable and washable surface devoid of holes, cracks and crevices. A pharmacy shall be provided with ample supply of good quality of water. The dispensing department shall be separated by a barrier to prevent the admission of the public.
3. **Furniture and apparatus:** Pharmacy shall contain furniture of required size and suitable apparatus. The drugs and chemicals shall be kept in suitable containers to prevent their deterioration. Every container shall be labeled as the name of drug as per pharmacopoeia. Dispensing bench shall be impervious and washable.

Poisonous drugs shall be stored in cupboard with lock and key and marked with the word 'poison' in red letters on white backgrounds.

Containers of all concentrated/water soluble solution shall bear special label or marked with the words "to be diluted".

4. **List of minimum equipment/apparatus:** A pharmacy shall be provided with the following minimum apparatus and book—necessary for making of official preparations and prescriptions:

Apparatus:

1. Balance, dispensing sensitivity 30 mg,
2. Balance, counter capacity 3 kg, sensitivity 1 gm,
3. Beakers, lipped assorted sizes,
4. Bottles, prescription, ungraduated assorted sizes,
5. Corks assorted sizes and tapers,
6. Cork extractor,
7. Evaporating dishes, porcelain,
8. Filter paper,
9. Funnels glass,
10. Litmus paper, blue and red,
11. Measure glasses cylindrical 10 ml, 25 ml, 100 ml and 500 ml,
12. Mortars and pestles, glass,
13. Mortars and pestles, Wedgwood,
14. Ointment pots with bakelite or suitable caps,
15. Ointment slab, porcelain,
16. Pipettes, graduated, 2 ml, 5 ml and 10 ml,
17. Ring, stand (retort) iron, complete with rings,
18. Rubber stamps and pad,
19. Scissors.
20. Spatulas, rubber or vulcanite,
21. Spatulas, stainless steel,
22. Spirit lamp,
23. Glass stirring rods,
24. Thermometer, 0°C to 200°C,
25. Tripod stand,
26. Watch glasses,
27. Water bath,
28. Water distillation still in case Eye drops and Eye-lotions are prepared,
29. Weights metric 1 mg to 100 gm
30. Wire gauze,
31. Pill finisher, boxwood,
32. Pill machine,
33. Pill boxe,
34. Suppository mould.

Books:

1. The Indian Pharmacopoeia (current edition).
2. National Formulary of Indian (current edition).
3. The Drugs and Cosmetics Act, 1940.
4. The Drugs and Cosmetics Rules, 1945.
5. The Pharmacy Act, 1948.
6. The Dangerous Drugs Act, 1930.
6. **General provisions:** A pharmacy shall be conducted under the continuous personal supervision of a registered pharmacist whose name shall be displayed conspicuously in

the premises. The pharmacist shall always put on clean white overalls (apron). The premises and fittings of the pharmacy shall be properly kept and everything shall be in good order and clean. All records and registers shall be maintained in accordance with the laws in force.

Any container taken from the poison cupboard shall be replaced therein immediately after use and the cupboard should be locked. The keys of the poison cupboard shall be kept in the personal custody of the responsible person. Medicaments when supplied shall have labels conforming to the provisions of laws in force.

SCHEDULE S

Standards for cosmetics

Standards for cosmetics in finished form.

The following cosmetics in finished form shall conform to the Indian standards specifications laid down from time to time by the Bureau of Indian Standards (BIS).

SCHEDULE V

Standards for patent or proprietary medicines

1. *Standards for patent or proprietary medicines, containing vitamins:* Patent or proprietary medicines containing vitamins for prophylactic, therapeutic or paediatric use shall contain the vitamins in quantities not less than and not more than those specified under the act and rules.

1. Skin powders
2. Skin powder for infants
3. Tooth powder
4. Toothpaste
5. Skin creams
6. Hair oils
7. Shampoo, soap-based
8. Shampoo, synthetic-detergent based
9. Hair creams
10. Oxidation hair dyes, liquid
11. Cologne
12. Nail polish (nail enamel)
13. After shave lotion
14. Pomades and brilliantines

2. *General standards for different categories of patent or proprietary medicines:* In the case of Pharmaceutical products containing several active ingredients, the selection shall be such that the ingredients do not interact with one another and do not affect the safety and therapeutic efficacy of the product. The combination shall not also lead to analytical difficulties for the purpose of assaying the content of such ingredient separately. The substances added as additives shall be innocuous, shall not affect the safety or therapeutic efficacy of the active ingredients, and shall not affect the assays and identity tests in the amount present. Subject to the provisions of these rules, patent or proprietary medicines shall comply with the following standards, namely:

- I. Patent or proprietary medicines shall comply with the general requirements of the dosage form under which it falls as given in the Indian Pharmacopoeia. If the dosage form is not included in the Indian Pharmacopoeia, but is included in any other pharmacopoeia, prescribed for the purpose of the Second Schedule to the Act, it shall comply with the general requirements of the dosage of such pharmacopoeia. Without prejudice to the generality of the foregoing requirements, general requirements shall include compliance with colour

15. Depliatories chemicals
16. Shaving creams
17. Cosmetic pencils
18. Lipstick
19. Toilet soap
20. Liquid toilet soap
21. Baby toilet soap
22. Shaving soap
23. Transparent toilet soap
24. Lipsalve IS: 10284
25. Powder hair dye IS: 10350
26. Bindi (liquid) IS: 10998
27. Kum kum powder IS: 10999
28. Henna powder IS: 11142

consistency, clarity, stability, freedom from contamination with foreign matter or fungal growth, defects like chipping and capping of tablets, cracking of the coating, mottled appearance and other characteristic defects that can be perceived by visual inspection.

- II. Without prejudice to the generality of the following paras, dosage forms of patent or proprietary medicines shall comply with the following requirements, namely:
- Tablets:** Medicines shall comply with requirements for tablets as laid down in the Indian Pharmacopoeia. The nature of coating shall be indicated on the label. Permitted colours may however, be added and declared on the label. Nature of tablets, such as uncoated, sugar coated or film coated shall be declared on the label.
 - Capsules:** Medicines shall comply with the requirements for capsules laid down in the Indian Pharmacopoeia. However, the capsules shall be free from distortion or shape, discolouration and other physical defects like leakage of powder from joints, pinholes or cracks in the capsules.
 - Liquid oral dosage forms:** Emulsions and suspensions shall disperse uniformly on shaking. Homogeneous solutions shall contain no sediments. The volume of the product (net content) in the container shall be not less than the labeled volume. The limit for ethanol content of pharmaceutical products shall be not less than 90% and not more than 110% of the labeled contents.
 - Injections:** Medicines shall comply with the requirements for injections as laid down in the Indian Pharmacopoeia.
 - Ointments:** Medicines shall comply with the requirements for injections as laid down in the Indian Pharmacopoeia.

III. The contents of active ingredients, other than vitamins, enzymes and antibiotics, in patent or proprietary medicines shall be not less than 90% and not more than 110% of the labeled content. However, for enzymes and vitamins, only for lower limit of 90% shall apply. In all dry formulations containing antibiotics, the limit shall be 90 to 130% of the labeled contents and in case of liquid antibiotic formulations, the limit shall be 90 to 140% of labeled contents.

Fiducial limits for error for microbiological assay of antibiotics may be estimated depending upon the design of assay procedure. Methods, used for assaying active ingredients shall employ the same basic principles and shall use same organisms as given in the latest edition of the Indian Pharmacopoeia or shall follow any other methods as approved by the authority competent to grant license to manufacture.

- All patent or proprietary medicines containing aspirin shall be subjected to "free salicylic acid test" and the limit of such acid shall be 0.75%. Except in case of soluble type aspirin in which case the limit of such acid shall be 3%.
- Patent or proprietary medicine to be tested for pyrogen shall be tested by injecting into rabbits not less than the human dose of the medicine based on body weight of a 60 kg human being. Methodology selected shall be indicated in the protocol but the dose shall be not greater than 5 times the human dose based on body weight of 60 kg for man.
- In injectable patent or proprietary medicines, the test for freedom from toxicity, shall be performed as described in the Indian Pharmacopoeia. Dose selected shall be indicated in the protocol but the dose shall not be less than five times the human dose based on body weight of 60 kg human being.

SCHEDULE W

Name of drugs which shall be marketed under generic name only

Analgin, aspirin and its salts, chlorpromazine and its salts, ferrous sulphate, piperazine and its salts.

SCHEDULE X

List of drugs whose import, manufacture and sale, labelling and packaging are governed by special provisions. Amobarbital, Amphetamine, Barbital, Cyclobarbital, Dexamphetamine, Ethchlorvynol, Glutethimide, Meprobamate, Methamphetamine, Methylphenidate, Methylphenobarbital, Pentobarbital, Phencyclidine, Phenmetrazine, Secobarbital.

SCHEDULE Y**Requirement and guidelines on clinical trials for import and manufacture of new drug****1. Clinical Trials**

i. *Nature of trials:* The clinical trials required to be carried out in the country before a new drug is approved for marketing depend on the status of the drug in other countries. If the drug is already approved/ marketed, Phase III trials usually are required. If the drug is not approved/ marketed trials are generally allowed to be initiated at one phase earlier to the phase of trials in other countries.

For new drug substances discovered in other countries Phase I trials are not usually allowed to be initiated in India unless Phase I data from other countries are available. However, such trials may be permitted even in the absence of Phase I data from other countries if the drug is of special relevance to the health problem of India. For new drug substances discovered in India, clinical trials are required to be carried out in India right from phase I though Phase III, permission to carry out these trials is generally given in stages, considering the data emerging from earlier phase.

ii. *Permission for trials:* Permission to initiate clinical trials with a new drug may be obtained by applying in Form 12 for a test license (TL) to import or manufacture the drug under the rules. Data appropriate for the various phases of clinical trials to be carried out should accompany the application. In addition, the protocol for proposed trials, case report forms to be used, and the names of investigators and institutions should also be submitted for approval. The investigators selected should possess appropriate qualifications and experience and should have such investigations facilities as are germane to the proposed trials protocol. Permission to carry out clinical trials with a new drug is issued along with a test license in Form 11.

It is desirable that protocols for clinical trials be reviewed and approved by the institution's ethical committee. Since such committees at present do not exist in all institutions, the approval granted to a protocol by the ethical committee of one institution will be applicable to use of that protocol in other institutions which do not have an ethical committee. In case none of the trial centers/institutions has an ethical committee, the acceptance of the protocol by the investigator and its approval by the drugs controller (India) or any officer as authorized by him to do so will be adequate to initiate the trials.

For new drugs having potential for use in children, permission for clinical trials in the paediatric age group is normally given after phase III trials. If the drug is of value primarily in a disease of children, early trials in the paediatric age group may be allowed.

iii. *Responsibilities of sponsor/investigator:* Sponsors are required to submit to the licensing authority an annual status report on each clinical trial, namely, ongoing, completed, or terminated. In case a trial is terminated, reason for this should be stated. Any unusual, unexpected or serious Adverse Drug Reaction (ADR) detected

during a trial should be promptly communicated by the sponsor to the licensing authority and the other investigators. In all trials an informal, written consent required to be obtained from each volunteer/patient in the prescribed Forms which must be signed by the patient/volunteer and the chief investigator.

For filling the application for permission to market a new drug substance the data under following headings is required.

1. Chemical and pharmaceutical information.
2. Animal toxicology.
 - a. Acute toxicology
 - b. Long-term toxicity
 - c. Reproduction studies:
 - i. Fertility studies.
 - ii. Teratogenicity studies.
 - iii. Perinatal studies.
 - d. Local toxicity.
 - e. Mutagenicity and carcinogenicity.
3. Animal pharmacology.
4. Human/clinical pharmacology(phase I).
5. Explanatory trials (Phase II).
6. Confirmatory trials (Phase III).
7. Special studies.
8. Submission of reports.
9. Regulatory status in other countries.
10. Marketing information.
11. Post-marketing surveillance study.

Phase I (human/clinical pharmacology): The objective of Phase I of trials is to determine the maximum tolerated dose in humans, pharmacodynamic effects, adverse reactions, if any, with their nature and intensity; and pharmacokinetic behaviour of the drug as far as possible. These studies are carried out in healthy adult males, using clinical, physiological and biochemical observations. At least two subjects should be used on each dose. Phase I trials are usually carried out by investigators trained in clinical pharmacology and having the necessary facilities to closely observe and monitor the subjects. These may be carried out at one or two centers.

Phase II (explanatory trials): In Phase II trial a limited number of patients are studied carefully to determine possible therapeutic use, effective dose range and further evaluation of safety and pharmacokinetics. Normally 10–12 patients should be studied at each dose level. These studies are usually limited to 3–4 centres and carried out by clinicians specialized in the concerned therapeutic areas and having adequate facilities to perform the necessary investigations for efficacy and safety.

Phase III (confirmatory trials): The purpose of these trials is to obtain sufficient evidence about the efficacy and safety of the drug in a larger number of patients, generally in comparison with a standard drug and/or a placebo as appropriate. These trials may be carried out by clinicians in the concerned therapeutic areas, having facilities appropriate to the protocol. If the drug is already approved/marketed in other countries, Phase III data should generally be obtained on at least 100 patients distributed over 3–4 centres primarily to confirm the efficacy and safety of the drug, in Indian patients when used as recommended in the product monograph for the claims made. If the drug is a new drug substance discovered in India and not marketed in any other country, Phase III data should be obtained at least 500 patients distributed over 10–15 centres. In addition, data on adverse drug reactions observed during clinical use of the drug should be collected in 1000–2000 patients; such data may be collected through clinicians who give written consent to use the drug as recommended and to provide a report on its efficacy and adverse reactions in the treated patients. The selection of clinicians for such monitoring and supply of drug to them will need approval of the licensing authority.

Special Studies

A. These include studies on solid oral dosage form, such as, bio-availability and dissolution studies. These are required to be submitted on

the formulations manufactured in the country. B. These include studies to explore additional aspects of the drug, e.g. use in elderly patients or patients with renal failure, secondary or ancillary effects, interactions, etc.

The reports of completed clinical trials shall be submitted by the applicant duly signed by the investigator with a stipulated period of time. The applicant should do so even if he is no longer interested to market the drug in the country unless there are sufficient reasons for not doing so. It is important to state if any restrictions have been placed on the use of the drug in any other country, e.g. dosage limited, exclusion of certain age groups, warnings about adverse drug reaction, etc. Likewise, if the drug

has been withdrawn from any country specially by a regulatory directive, such information should be furnished along with reasons and their relevance, if any, to India.

The product monograph should comprise the full prescribing information necessary to enable a physician to use the drug properly. It should include description, actions, indications, dosage precaution, drug interactions, warnings and adverse reactions. On approval of a new drug, the importer or the manufacturer shall conduct post-marketing surveillance study of that new drug after getting the protocols and the names of the investigators approved by the licensing authority during the initial period of two years of marketing.

DESIGN OF LABELS ACCORDING TO THE D AND C ACT AND RULES

Specimen label of Schedule G Drug

10 × 10 Tablets

Rx

PRIMIDONE TABLETS USP

(Anticonvulsant)

Composition: Each tablet contains:

Primidone USP 250 mg

Schedule 'G' Drug

Caution: It is dangerous to take this preparation except under medical supervision

Dosage: As directed by the physician.

Store at 20–25°C (68°F–77°F).

Dispense in well-closed container with child resistant closure.

Warning: As with all medications, keep out of reach of the children.

Mfg. Lic. No.: 25/2/92

Batch. No.:

Mfg. Date:

Exp. Date:

MRP Rs: (Inclusive of all taxes)

Manufactured by:

PIRAMAL HEALTHCARE LTD.

Dist-Dhar Madhya Pradesh

Mumbai 400030

Specimen Label of Insulin (Schedule G)

10 c

INSULIN

80 Units/cc

Schedule 'G' Drugs

Caution: It is dangerous to take this preparation except under medical supervision.

Dosage: As directed by the physician.

Mfg. Lic. No.:

Batch. No.:

MRP not to exceed Rs:Local tax extra

Mfg. Date:

Exp. Date:

Manufactured by:

PQR PHARMA PVT. LTD.

Mumbai 400030

Specimen Label of Schedule H Drug

Rx

10 × 10 Tablets

ATENALOL TABLETS USP

Composition: Each film-coated tablet contains:

Atenolol USP 25 mg

Schedule 'H' Drug

Warning: To be sold by retail on the prescription of a registered medical practitioner only

Dosage: One tablet daily or as directed by the physician.

Store at controlled room temperature, 20–25°C.

Dispense in well-closed, light resistant container.

Warning: As with all medications, keep out of the children.

Mfg. Lic. No.: G1430

Batch. No.:

MRP Rs:(Inclusive of all taxes)

Mfg. Date:

Exp. Date:

Manufactured by:

UNIQUE PHARMACEUTICAL LABORATORIES

(A Div. of J.B. Pharmaceuticals Ltd.)

Mumbai 400030

Specimen Label of Schedule H Drug for Parenteral Use

Rx

100 ml

METRONIDAZOLE INJECTION IP

Composition: Each 100 ml contains:

Metronidazole IP 500 mg

Sterile, nonpyrogenic, isotonic, single dose container

Schedule H Drug

Warning: To be sold by retailers on the prescription of a registered medical practitioner only

Caution: Even invisible damage to bottle caused during storage or transit may result in contamination, do not use if leak found on squeezing or contents not clear and return for replacement.

Dosage: Injection (100 ml) slowly by i. v. route over period of 20–30 minutes.

To be repeated every 8 hours or as directed by the physician.

Mfg. Lic. No.: G/28A/4348A

Batch No.: 11W0052

Max retail price Rs: Inclusive of all taxes

Mfg. Date:

Exp. Date:

Manufactured by:

J. B. CHEMICALS AND PHARMACEUTICAL LTD.

Panoli-394116, Dis-Bharuch

Specimen Label of Eye Drop (Schedule H)

Rx

5 ml

MOXIFLOXACIN EYE DROPS

Composition:

Moxifloxacin hydrochloride e.q. to moxifloxacin 0.5% w/v

Hydroxypropyle-methylcellulose IP 0.25% w/v

Sterile aqueous vehicle q.s.

Dosage: As directed by the physician.

Keep in a cool and dark place.

Schedule H Drug

Warning: To sold by retailers on the prescription of an ophthalmologist only

Not for injection

For external use only

- Warning: 1. If irritation persists or increases discontinue the use and consult physician.
 2. Do not touch the droppers tip or other dispensing tip any surface since this may contaminate solution.
 3. Use the solution within one month after opening the vial.

Mfg. Lic. No.: 29/US/SC/P-2007

Batch. No.: 10SC42

MRP Rs:(Inclusive of all taxes)

Mfg. Date:

Exp. Date:

Manufactured by:

AKUMS DRUGS AND PHARMACEUTICAL LTD.

Haridwar-249403

Specimen Label of Schedule X Drug

10 × 10 Tablets

XR_X**METHAMPHETAMINE HYDROCHLORIDE TABLETS USP**

(Anticonvulsant)

Composition: Each tablet contains:

Methamphetamine hydrochloride USP 5 mg

Schedule 'X' Drug

Warning: To be sold by retailers on the prescription of a registered medical practitioner only

Dosage: See package inserts or as directed by the physician.

Do not accept if seal over bottle is opening broken or missing.

Dispense in well-closed light resistant container with child resistant closure.

Store at 20–25°C (68°F–77°F). Protect from light.

Warning: As with all medications, keep out of reach of the children.

Mfg. Lic. No.:

MRP Rs: (Inclusive of all taxes)

Batch. No.:

Mfg. Date:

Exp. Date:

Manufactured by:

Name and Address of pharmacy

Specimen Label of Schedule X Drug for Parenteral UseXR_X**PHENOBARBITONE SODIUM INJECTION USP**

Composition: Each 100 ml contains:

Phenobarbitone sodium USP 500 mg

Schedule 'X' Drug

Warning: To be sold by retailers on the prescription of a registered medical practitioner only

Dosage: As directed by the physician.

The injected should be discarded if any precipitate is observed.

Mfg. Lic. No.:

MRP Rs:(Inclusive of all taxes)

Batch. No.:

Mfg. Date:

Exp. Date:

Manufactured by:

Name and Address of Pharmacy

Specimen Label of Schedule H Drug under Narcotic Drug and Psychotropic Substance ActNR_X

10 Tablets

ESOMEPRAZOLE MAGNESIUM DELAYED RELEASE TABLETS

ES-OD20

Composition: Each enteric-coated tablet contains:

Esomeprazole magnesium

equivalent to esomeprazole20 mg

Excipientsq.s.

Schedule 'H' Drug

Warning: To be sold by retailer on the prescription of registered medical practitioner only

Dosage: As directed by the physician.

Store in a cool, dry and dark place.

Mfg. Lic. No.:

Batch. No.:

MRP Rs:(Inclusive of all taxes)

Mfg. Date:

Exp. Date:

Manufactured by:

Name and Address of Pharmacy

Specimen Label of Schedule H Drug Falling under Narcotic Drug and Psychotropic Substance ActNR_X

10 Tablets

NIMESULIDE FLAVOURED DISPERSIBLE TABLETS BP

[Nimu Disp]

Composition: Each uncoated flavored tablet contains:

Nimesulide BP 100 mg

Schedule 'H' Drug

Warning: To be sold by retailer on the prescription of MRP only

Dosage: As directed by the physician.

Store on a cool, dry and dark place.

Mfg. Lic. No.:

Batch. No.:

MRP Rs: (Inclusive of all taxes)

Mfg. Date:

Exp. Date:

Manufactured by:

Name and Address of Pharmacy.

Specimen Label of Schedule X Drug for Parenteral UseXR_X**PHENOBARBITONE SODIUM INJECTION USP**

Composition: Each 100 ml contains:

Phenobarbitone sodium USP 500 mg

Schedule 'X' Drug

Warning: To be sold by retailer on the prescription of a registered medical practitioner only

Dosage: As directed by the physician.

The injected should be discarded if any precipitable is observed.

Mfg. Lic. No.:

Batch. No.:

MRP Rs: (Inclusive of all taxes)

Mfg. Date:

Exp. Date:

Manufactured by:

Name and Address of Pharmacy

Specimen Label of Hair Dye

Rx

40 ml

HAIR DYE

Composition:

It contains 4% paraphenylenediamine

Direction for use: Apply as directed

Poison

For external use only

Caution: This product contains ingredients which may cause skin irritation in certain cases and so a preliminary test according to accompanying direction should first be made. This product should not be used for dying eyelashes, eyebrow as such use cause blindness.

Warning: Keep the product away from reach of the children.

Mfg. Lic. No.:

Batch. No.:

MRP Rs:(Inclusive of all taxes)

Mfg. Date:

Exp. Date:

Manufactured by:

XYZ PVT. LTD. MUMBAI

CHAPTER

3

The Medicinal and Toilet Preparations (Excise Duties) Act, 1955 and Rules, 1956

INTRODUCTION

The Medicinal and Toilet Preparations (Excise Duties) Act was passed in 1955 and the Rules were passed in 1956 to provide for the collection of levy and collection of duties of excise on medicinal and toilet preparations containing alcohol, narcotic drugs or narcotics. The Act extends to whole of India. It came into force on such date (1st April 1957), as the Central Government may, by notification in the official gazette, appoint.

This act has been enacted with a view to provide for the levy of the collection of duties of excise on medicinal and toilet preparation containing alcohol and other narcotic drugs. The manufacture of alcoholic and other narcotic preparations can be undertaken only under the authority of a license granted for this purpose.

The rules made under the act given the procedures which have to be followed for the manufactured under bond, manufacture without bond, manufacture of homoeopathic and ayurvedic preparations containing alcohol, issue of preparations, issue of preparations from bonded laboratories and inter-state movements of excisable preparations, etc. The rules also state, the powers duties and responsibilities of various officers entrusted with the proper implementation of the act.

Importance of alcohol in the manufacture of drugs: Alcohol has always been a fascinating friend of the mankind. Alcohol posses excellent

solvent properties beside its preservative effect and hence it has found a very important place in the manufacture of drugs and medicines. Drinking alcohol is an abuse where its use in toilet preparations can be considered as a luxury. In addition to these, it is also used in research laboratories. It is therefore essential that alcohol that is being used for medicinal purposes be subjected to a lower rate of excise duty. In order to prevent misuse of alcohol meant for medicinal purpose, it is essential to control its issue and transport on government level. Prior to the enactment of this act, each state in India had an excise manual and a rule of its own. Thus differences existed in the rates of excise duty for the same item in different states leading to large scale interstate smuggling of such preparations. The Act was passed mainly to curb this evil. The Act has since superseded all state laws in force prior to its commencement and now only such rules of the State which are not inconsistent with the provisions of this act are valid.

Medicinal and Toilet Preparations (Excise Duties) Act

Alcohol is used in manufacture of many pharmaceutical and toilet preparations, the alcohol required for this may be obtained from government at a lower rate of excise duty than required for alcoholic beverages, since the Government charges a very high percent of duty in the later case. Manufacture of alcohol is controlled by Central and State Governments.

Objectives

The Medicinal and Toilet Preparations (Excise Duties) Act, 1955 was passed with the following objectives:

- To provide for the collection of levy and duties of excise on medicinal and toilet preparations containing alcohol, opium, Indian hemp or other narcotic drugs or narcotics.
- To provide for uniformity in the rules and rates of excise duties leviable on such preparations through the country.

DEFINITIONS

- a. "**Alcohol**" means ethyl alcohol of any strength and purity having chemical compositions $C_2H_5 OH$.
- b. "**Collecting Government**" means the Central Government or, as the case may be, the State Government which is entitled to collect the duties levied under this act.
- c. "**Dutiable Goods**" means the medicinal and toilet preparations specified in the schedule as being subject to the duties of excise levied under this Act.

Dutiable goods said to be manufactured in bond within the meaning of this section if they are allowed to be manufactured without payment of any duty of excise leviable under any law for the time being in force in respect of alcohol, opium, Indian hemp or other narcotic drug or narcotic which is to be used as an ingredient in the manufacture of such goods.

- d. "**Excise Officer**" means an officer of the Excise Department of any State and includes any person empowered by the Collecting Government to exercise all or any of the powers of an excise officer under this Act.
- e. "**Manufacture**" includes any process incidental or ancillary to the completion of the manufacture of any dutiable goods.
- f. "**Medicinal Preparation**" includes all drugs which are a remedy or "prescription" prepared for internal or external

use of human beings or animals and all substances intended to be used for or in the treatment, mitigation or prevention of disease in human beings or animals.

- g. "**Narcotic Drug**" or "**Narcotic**" means a substance which is coca leaf, or coca derivative, or opium or derivative of opium, or Indian hemp and shall include any other substance, capable of causing or producing in human beings dependence, tolerance and withdrawal syndromes and which the Central Government may, by notification in the official gazette, declare to be a narcotic drug or narcotic.
- h. "**Toilet Preparation**" means any preparation which is intended for the use in toilet of the human body or in perfuming apparel of any description, or any substance intended to cleanse, improve or alter the complexion, skin, hair or teeth, and includes deodorants and perfumes.
- i. "**Absolute Alcohol**" means alcohol conforming to the British Pharmacopoeial specification for dehydrated alcohol.
- j. "**Bonded Manufactory**" means the premises or any part of the premises approved and licensed for the manufacture and storage of medicinal and toilet preparations containing alcohol, opium, Indian hemp and other narcotic drugs or narcotics on which duty has not been paid.
- k. "**Non-bonded Manufactory**" means the premises or any part of the premises approved and licensed for the manufacture and storage of medicinal and toilet preparations containing alcohol, opium, Indian hemp and other narcotic drugs or narcotics on which duty has been paid.
- l. "**Chemical Examiner**" means the chemical examiner to the State Government and includes such other officer whom the State Government or the Central Government may at any time appoint as chemical examiner.
- m. "**Denatured Spirit**" or "**Denoted Alcohol**" means alcohol of any strength which has

- been rendered unfit for human consumption by the addition of substances approved by the Central Government or by the State Government with the approval of the Central Government.
- n. "**Excise Commissioner**" means the Head of the Excise administration of a State and includes a Prohibition Commissioner and also an officer designated in any State as Prohibition or Excise Director.
 - o. "**Finished Store**" means that portion of a non-bonded or bonded manufactory which is set apart for the storage of its finished preparations.
 - p. "**Gauge**" means to determine the quantity of alcohol or dutiable goods contained in, or taken from, any cask or receptacle or to determine the capacity of any cask or receptacle.
 - q. "**Laboratory**" means that part of a non-bonded or bonded manufactory in which the actual manufacture of dutiable goods takes place.
 - r. "**Manufacturer**" means a person to whom a license has been granted for the manufacture of dutiable goods.
 - s. "**Quarter**" means a period of 3 months beginning with 1st January, 1st April, 1st July, or 1st October.
 - t. "**Rectified Spirit**" means plain undenatured alcohol of strength not less than 50.00 over proof and includes absolute alcohol.
 - u. "**Restricted Preparation**" means every medicinal preparation specified in the schedule and includes every preparation declared by the Central Government as restricted preparation under the Rules.
 - v. "**Unrestricted Preparation**" means any medicinal preparation containing alcohol but other than a restricted preparation or a spurious preparation.
 - w. "**Spirit Store**" means that portion of the bonded or non-bonded manufactory which is set apart for the storage of alcohol, opium, Indian hemp and other narcotic

drugs or narcotic purchased free of duty or at prescribed rates of duty specified in the schedule to the act.

- x. "**Standard Preparation**" means a preparation other than a 'sub-standard preparation'.
- y. A "**Sub-standard Preparation**" is:
 - i. A pharmacopoeial preparation in which the amount of any of the various ingredients is below the minimum that the pharmacopoeial composition would require.
 - ii. A proprietary medicine which does not conform to the formula or the list of ingredients disclosed on the label on the container or on the container.
- z. '**Warehouse**' means any place or premises licensed under Rule 70.

THE SCHEDULE

Medicinal and Toilet Preparations

A. Medicinal Preparations

- Allopathic medicinal preparations.
- Medicinal preparations in Ayurvedic, Unani or other indigenous systems of medicine.
- Homoeopathic preparations Rs. 20 per containing alcohol litre of pure alcohol content.

B. Toilet Preparations

Toilet preparations containing one hundred per alcohol or narcotic drug or narcotic. cent. advalorem or rupees twenty per litre of pure alcohol content whichever is higher.

For the purposes of this schedule, "pure alcohol content", in relation to a preparation, means the ethyl alcohol content in the preparation expressed as ethyl alcohol of 100% by volume at 150°C.

APPOINTMENT OF OFFICERS AND DELEGATION OF POWERS TO THEM

- A. **Excise Officer:** The State Government may appoint such number of excise officers as it

thinks fit to exercise all or any of the powers conferred or to discharge all or any of the duties imposed by the act or these rules and define the jurisdiction of every such officer.

The Excise Commissioner: May perform all or any of the duties, or exercise all or any of the powers assigned to any excise officer under these rules.

B. Functions of excise officer:

- To supervise the manufacturing of alcoholic preparations.
- To take the sample from the finished preparations and send them to the chemical examiner for the determination of alcoholic strength.
- To issue alcoholic preparations from the bonded laboratory on which duty has not been paid.

STANDING COMMITTEE

Standing Committee and its Functions

A. Constitution: The standing committee referred to in Rule 60 shall consist of the following as its members:

- i. The Drugs Controller of the Government of India.
- ii. The Chief Chemist, Central Revenues Control Laboratory.
- iii. One pharmacologist to be nominated by the Central Government.
- iv. The Adviser in Indigenous Systems of Medicine, Ministry of Health, Family Planning and Urban Development.

B. Functions: The committee shall advise the Central Government on all matters connected with the technical aspects of the administration of the act and their Rules and, in particular, on the question whether:

- i. A particular preparation is entitled to be treated, or to continue to be treated, as a genuine medicinal or toilet preparation for the purposes of the act.
- ii. Whether it should be treated, or continue to be treated, as a restricted or an unrestricted preparation.

The committee may tender such advice, on the motion of the Central Government and may make such investigation as it or the Central Government considers necessary and the Central Government may take, on such advice, such decision as that Government thinks fit.

For the purpose of such investigation, four samples of 227 ml each or such other quantity of the preparation as may be considered necessary shall be taken.

The Standing Committee shall before declaring a preparation as a restricted preparation, grant, if the person concerned so desires, an opportunity of being heard in the matter. Where a member of the Standing Committee is unable for any reason to attend the meeting of that committee, he may nominate an officer subordinate to him to attend the meeting on his behalf.

LEVY AND COLLECTION OF DUTIES

A. Duties of excise to be levied and collected on certain goods: There shall be levied duties of excise, at the rates specified in the schedule, on all dutiable goods manufactured in India. The duties aforesaid shall be leviable:

- a. Where the dutiable goods are manufactured in bond, in the state in which such goods are released from a bonded warehouse for home consumption, whether such State is the state of manufacture or not.
- b. Where dutiable goods are not manufactured in bond, in the state in which such goods are manufactured.

B. Rebate of duty on alcohol supplied for manufacture of dutiable goods: Where alcohol opium, Indian hemp or other narcotic drug or norcotic had been supplied to a manufacturer or any dutiable goods for use as an ingredient of such goods by, or under the authority of, the collecting Government and a duty or excise on the goods so supplied had already been recovered by such Government under any law for the time being in force, the collecting Government shall, on an application being made

to it in this behalf, grant in respect of the duty of excise leviable under this Act, a rebate to such manufacturer of the excess, if any, of the duty so recovered over the duty leviable under this Act.

C. Recovery of duty: Every person who manufactures any dutiable goods, or who stores such goods in a warehouse shall pay the duty or duties leviable on such goods under the Act, at such time and place and to such person as may be designated in, or under the authority of these rules, whether the payment of such duty or duties is secured by bond or otherwise.

LICENSING

Manufacturing of alcoholic and narcotic preparations can only be undertaken under the authority of a license granted for the purpose and such a license is issued only if the requisite license for the manufacture of drugs under drugs and cosmetics act and rules has been first obtained. Application for the license or for its renewal is to be made to licensing authority who is the excise commissioner in the case of a bonded manufactory or warehouse and in other cases, such officer as the State Government may authorize in this behalf. A separate application is to be made if more than one kind of license is desired. Where the applicant has more than one place of business, he should obtain and separate license in respect of each such place of business. The application for the license should be submitted in the prescribed form accompanied with the prescribed fee, at least two months before the proposed date of commencement of the manufacture. In case of renewal such application shall be submitted at least one month before the commencement of the year for which it is required.

Every such application for grant or renewal of license shall, where a fee is prescribed in the sub-joined table, be accompanied by a treasury chalan showing payment of such fee (Table 3.1).

A. Form of license—limitations:

1. Every license granted or renewed under these rules shall be in such one of the proper

forms of license as may be appropriate, shall have reference only to the premises, if any, described in the license, and shall be for a period not exceeding one year but in no case shall such period extend beyond 31st March next following the date of commencement of the license.

2. Every license shall be deemed to have been granted or renewed personally to the licensee and no license shall be sold or transferred.
3. Where a licensee sells or transfers his business to another person, the purchaser or the transferee shall obtain a fresh license under these rules but it shall be granted free of fee for the residue of the period covered by the original license.
4. If the holder of a license wishes to enter into partnership in regard to the business covered by the license he shall do so after obtaining the previous sanction of the licensing authority and his license shall thereafter be suitably amended. Where a partnership is entered into, the partner as well as the original holder of the license shall be bound by the conditions of that license.
5. If a partnership is dissolved, every person who was a partner immediately before such dissolution shall send a report of the dissolution to the licensing authority within ten days thereof.
6. If during the currency of a license the licensee desires to transfer his business to new premises he shall intimate his intention to the licensing authority at least fifteen days in advance, specifying the address of the new premises, and get his license suitably amended. The license shall, thereupon, hold good in respect of the new premises.

B. Such application applicable for applying for a license to manufacture medicinal and toilet preparations in a bonded/non-bonded manufactory: such application should contain the following particulars:

1. The name or names and address and addresses of the applicant or applicants. In case of a firm, the name and address of

Table 3.1: License fee payable per annum

The details of license fee are as follows:

<i>Purpose of license</i>	<i>License fee for manufacture</i>	
	<i>Under bond (₹)</i>	<i>Outside bond (₹)</i>
A. Allopathic medicinal preparations and toilet preparations containing alcohol where consumption of alcohol is:		
i. 125 L.P. liters or less per annum	...	10
ii. More than 125 L.P. liters but less than 500 L.P. liters per annum	...	25
iii. 500 L.P. liters or more per annum		200
iv. Less than 4000 L.P. liters per annum	100	
v. More than 4000 L.P. liters per annum	200	
B. Non-alcoholic medicinal and toilet preparations containing opium, Indian hemp, or other narcotic drug or narcotic	10	10
C. Homeopathic preparations containing alcohol where consumption of alcohol is:		
i. 125 L.P. liters or less per annum	...	10
ii. More than 125 L.P. liters but less than 500 L.P. liters per annum	...	25
iii. Less than 4000 L.P. liters per annum	100	25
iv. More than 4000 L.P. liters per annum	200	
D. Medicinal preparations in Ayurvedic, Unani or other indigenous system of medicines containing alcohol and which are prepared by distillation or to which alcohol has been added	25	25
E. Bonded warehouse	25	
F. Manufacture of medicinal preparations containing alcohol by hospitals, dispensaries and other charitable institutions eligible for exemption from duty	...	nil

- every partner. In case of a company, its registered name and address, the names and addresses of its directors, managers and managing agents.
2. Name and address of the place and the site on which the bonded or non-bonded laboratory is situated or to be constructed.
 3. The amount of capital proposed to be invested.
 4. Approximate date from which the applicant desires to start the manufacture if the required license is granted.
 5. The number and full description of the vats, still and other permanent apparatus

- and machinery which the applicant wishes to set up.
6. The maximum quantities in L.P. liters of alcohol and alcoholic content in unfinished and finished preparations likely to remain in the laboratory at any one time. Maximum quantities by weight of opium, Indian hemp or other narcotic drug and their content in unfinished and finished preparations likely to remain in the laboratory at one time.
 7. In case of bonded laboratory, whether the proposed bonded manufactory will require the services of a whole-time or part-time excise officer.
 8. A list of all preparations, that the licensee proposes to manufacture showing.
 - a. The percentage or proportion of alcohol in such preparation containing alcohol.
 - b. The quantities of opium, Indian hemp or other narcotic drugs in terms of weight in preparations containing these substances.
 9. The kind and number of licenses held by the applicant under the Drug and Cosmetics Act, 1940.
 10. Site and evaluation plans of the manufactory building or buildings showing the location of the different rooms with doors and windows therein.
 11. In case of a firm, a true copy of the partnership-deed. And in case of a company, the list of the directors and managers together with copies of memorandum of association.
- Disposal of application for license to manufacture medicinal and toilet preparation in a bonded/non-bonded manufactory by the licensing authority:*** On receipt of an application, licensing authority shall cause such enquiries to be made as it may deem necessary including enquiries into the following:
- i. The qualifications and previous experience of technical personnel engaged in the manufacturing operation.
 - ii. The equipment of the bonded and non-bonded manufactory.
 - iii. Soundness of the applicant's financial position.
 - iv. Suitability of the proposed building for the establishment of manufactory.
- After satisfying that the applicant is eligible for the issue of a license, the licensing authority (the Excise Commissioner) shall issue a license and approve the plans of building submitted along with the application by the applicant. After constructing the building and establishing the laboratory as per the approved plans, the planning authority shall verify the plans to ascertain whether the construction is as per the approved plans or not. In some cases where security is required to be furnished the licensing authority shall fix the amount of such security before granting the license. The security shall be either in cash or in interest bearing securities like government promissory notes, national saving certificates, etc.
- C. Revocation and suspension of license:*** Any license granted under these rules may be revoked or suspended by the licensing authority if the holder, or any person in his employ, is found to have committed a breach of the conditions thereof or of any of the provisions of the Act or these Rules or has been convicted of an offence under the Indian Penal Code 1860. Such revocation or suspension shall be made until the holder of the license has been given a reasonable opportunity of showing cause against the action proposed to be taken. Every such order shall be in writing and shall specify the reasons for the suspension or revocation and shall be communicated to the licensee. Where a license is revoked or suspended under this rule the holder of the license shall not be entitled to claim from the Central or State Government any compensation or refund of license fee for such cancellation or suspension.
- Refund of license-fee:*** The license applied for is refused, the license-fee paid, if any, with the application shall be refunded. If the applicant surrenders his license at any time either before

the commencement of the license or during the currency of the license, he shall forfeit any claim for refund of such license-fee in full or in proportion to the period not availed of.

MANUFACTURE OF MEDICINAL AND TOILET PREPARATIONS

Supply of rectified spirit: Rectified spirit shall ordinarily be supplied to a manufacturer from a distillery or a spirit warehouse of the State in which the manufactory is situated. The manufacturer, however, is not precluded from obtaining his requirements of rectified spirit from sources situated outside the State. Wastage in transit of rectified spirit if, in any particular case it is proved to the satisfaction of the Excise Commissioner that the loss is bona rule and not due to negligence or connivance on the part of the manufacturer, the duty payable in respect of such loss may be waived in full or in part according to the merits of the case. Except with the prior sanction of the State Government the concession in this rule shall not be applicable to issues of rectified spirit made to non-bonded manufactories.

Mode of manufacture: Manufacture of medicinal and toilet preparations containing alcohol shall be permitted in bond without payment of duty as well as outside bond. In the case of manufacture in bond alcohol on which duty has not been paid shall be used under excise supervision and in the case of manufacture outside bond, only alcohol on which duty has already been paid shall be used.

There are two modes of manufacture of medicinal and toilet preparations containing alcohol.

A. Manufacture in bond.

B. Manufacture outside bond.

A. Manufacture in bond: Manufacture in bond of medicinal and toilet preparations containing alcohol, opium, Indian hemp and other narcotic drugs and narcotics: Rectified spirit shall be issued without previous payment of duty for the manufacture of medicinal and toilet

preparations containing alcohol subject to the condition that the manufacturer enters into a bond in Form B-1 with sufficient security towards due payment of duty and observance of the rules.

I. Essentials of a Bonded Manufactory/ Construction of Bonded Laboratory

Bonded laboratory—General description:

- i. A bonded manufactory shall make provision for the following:
 - i. One plain spirit store unless the manufactory is attached to a distillery or a rectified spirit warehouse from which rectified spirit is made available as and when necessary.
 - ii. At least one large room for manufacturing medicinal preparations.
 - iii. One or more rooms for storing finished medicinal preparations.
 - iv. Separate arrangement for manufacture of toilet preparations.
 - v. The storage of finished toilet preparations.
 - vi. Accommodation with necessary furniture near the bonded premises for the officer-in-charge.

There shall be only one main entrance in the laboratory and one door to each of its compartments. All the doors shall be secured with excise ticket locks during the absence of the officer-in-charge.

- vii. Malleable iron rods not less than 19 mm. in thickness, set not more than 102 mm. apart, embodied in brick work up to a depth of at least 51 mm. and covered on the inside with strong wire netting or expanded metal of a mesh not exceeding 25 mm. in diameter of length in every window of the bonded premises.
- viii. A board on which the name of the room and a serial number, if any, are legibly painted in oil colour on the outside of every such room in the manufactory.
- ix. All pipes from sinks or wash-basins inside manufactory premises dischar-

ging into drains forming part of the general drainage system of the premises.

- x. All gas and electric connections with the licensed premises so fixed as to admit of the supply of gas or electricity being cut off and all the regulators or switches being securely locked at the end of the day's work.
- xi. All vessels intended to hold alcohol and other liquid preparations should bear a distinctive serial number with their full capacity marked indelibly.
- xii. The alcohol storage vessels shall bear the excise ticket lock.
- xiii. The laboratory can be opened only in the presence of the Excise officer-in-charge.
- 2. The Central Government may in special cases relax any of the provisions of clause (i) to (x) of sub-rule (1) (Figs 3.1 and 3.2).

All the end of the day's work it shall be closed with the excise ticket locks (refer the plans of the typical bonded laboratory).

II. Manufacture of Alcoholic Preparations

a. **Arrangement of receptacles in a bonded manufactory:** The permanent vessels for the storage of alcohol, opium Indian, hemp and other narcotic drugs and narcotics received under bond and all the finished preparation on which duty has not been paid shall be secured with excise ticket locks. All vessels intended to hold alcohol and liquid preparations shall be gauged by the officer-in-charge. They shall each bear a distinctive serial number and their full capacities distinctly and indelibly marked on them. A record of these details shall be kept in Form R.G.-I. Table shall be computed to show contents at an inch and tenth of an inch of the depth of each such vessel.

b. **Rectified spirit—Procurement:** Indent for rectified spirit: Rectified spirit required for manufacturing medicinal and toilet preparations shall be obtained on an indent in Form I.D.-1 countersigned by the officer-in-charge, from any distillery or spirit warehouse approved by the excise commissioner, the original being sent by the licensee of the bonded manufactory to the distiller the duplicate sent through the officer-

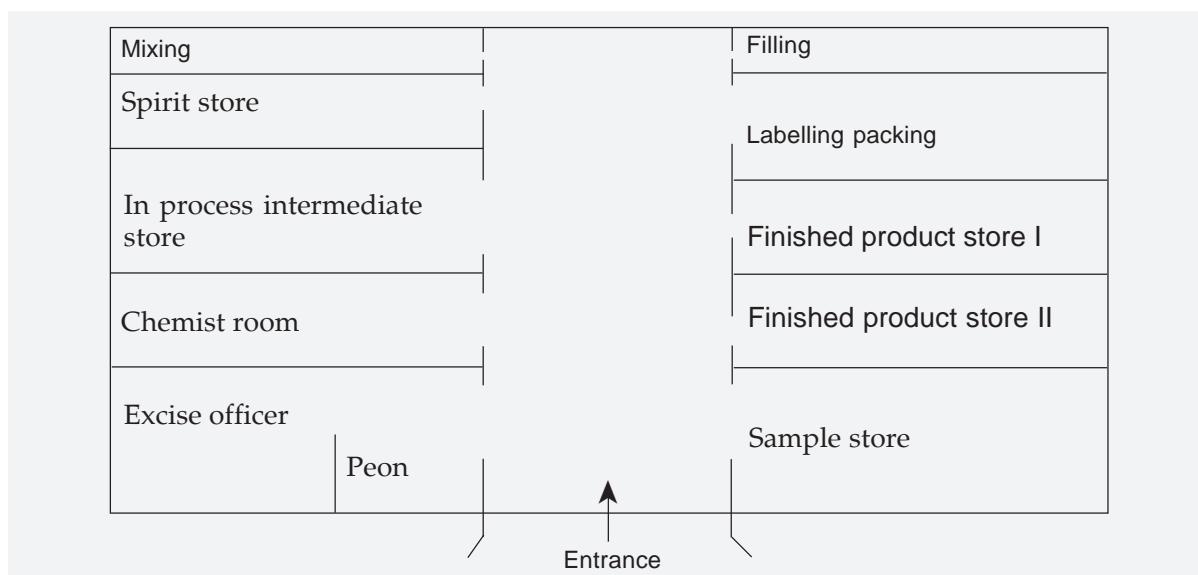


Fig. 3.1: Plan 1 of a typical bonded manufactory

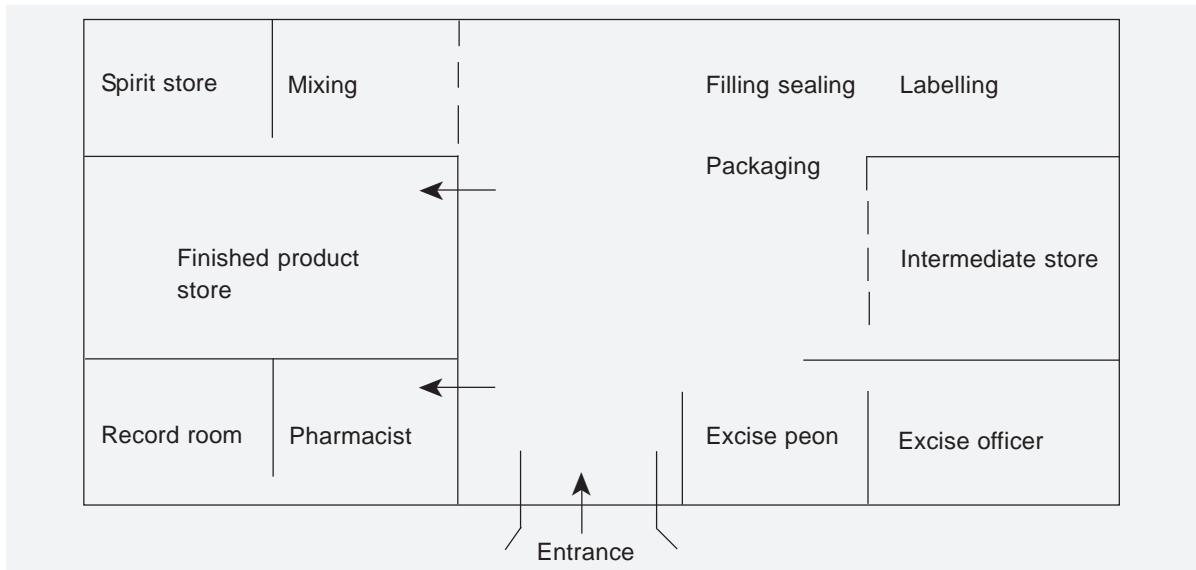


Fig. 3.2: Plan 2 of a typical bonded manufactory

in-charge to the distillery or spirit warehouse officer and the triplicate retained as office copy. The cost price of such rectified spirit shall be paid by the licensee of the bonded manufactory to the distiller. If the distillery or warehouse officer has received from the officer-in-charge of the bonded manufactory the duplicate of the indent, he shall issue the spirit required under bond, under the appropriate permit in the form in vogue in the State for transport of rectified spirit and send the advice portion of such permit to the officer-in-charge.

Verification of rectified spirit: Consignments of rectified spirit received under bond shall be verified in volume and strength and the receipt of such supply shall be entered in register in Form R.G.-2. Subject to the provision of Rule 19 duty at the rate levied by the State Government on alcoholic liquors on all wastages shall be paid by the licensee of the bonded manufactory into a Government treasury on receipt of a demand from the officer-in-charge and a copy of the treasury receipt shall be sent to the distillery officer who shall thereupon make the necessary adjustment in his register.

After the rectified spirit received has been verified, it shall be stored in one or more vessels in the spirit store. If, in any particular case, it is proved to the satisfaction of the excise commissioner that the loss is bona fide and not due to negligence or connivance on the part of the manufacturer, the duty payable in respect of such loss may be waived in full or in part according to the merits of the case.

c. **Rectified spirit:** Issued for manufacturing from the spirit store: Rectified spirit shall be issued from the spirit store against the requisition in specified form. The manufacturer calculates his requirements of spirit as per the approved formula and gives the indent slip to the officer-in-charge. The manufacturer keeps all other ingredients of the preparation ready. The officer-in-charge shall then issue the spirit and in his presence the spirit is immediately mixed with other ingredients of the preparations. Rectified spirit shall be issued from the spirit store to the laboratory of the manufactory on a requisition of the licensee, which shall be made in Form RQ-1, but only in such quantities as are in conformity with the

formulae laid down in the relevant pharmacopoeia or the formula of the patent and proprietary medicines displayed on the label of the container in the manner prescribed in the Drugs Rules, 1945, for the time being in force, for the particular preparation for which the alcohol is required.

Every time the percolator, or other vessel intended for alcohol is charged there shall be attached to it a label showing the following particulars:

- i. The name and batch number of the preparation.
- ii. The description and quantity of alcohol placed in it from time to time.
- iii. The date of removal of the preparation and the quantity of such preparation removed.

d. *Indent for opium, Indian hemp and other narcotic drugs and narcotics, their storage and issue for manufacture:* Indent for opium shall be made to the nearest sub-treasury or the Government Opium Factory, Ghazipur or to the warehouse or to the place of storage approved by the State Government. The supply of Indian hemp and other narcotics shall also be indented for from the nearest Government warehouse in the same Form. The supply of opium, Indian hemp, narcotic drugs and other narcotics shall be made under permit. On their receipt in the bonded manufactory they shall be verified and accounted for in the register in Form R.G.-2 as in the case of alcohol. Opium, Indian hemp, narcotic drugs and other narcotic obtained by the licensee free of duty shall be stored separately in the spirit store and secured by excise ticket locks. They shall be issued for the manufacture of medicinal preparations only on a requisition in Form R.Q.-1 by the licensee as in the case of alcohol.

e. *Storage of finished products:* Medicinal and toilet preparation shall on completion of production be stored in bulk in jars or bottles each containing not less than 2,273 ml. Such preparations ready for issue may be filled in bottles or containers of not less than 57 ml. content. Every container of a finished

preparation shall bear a label showing the name of the preparation, its batch number, its alcoholic strength and the name of the manufacturer. The label of each container of a preparation stored in bulk shall, in addition, indicate the actual contents in litres, its alcoholic strength and the date of storage. The containers shall be kept so arranged in suitable racks as to allow ready identification of each batch. Any goods stored may be left in the store room for a period of three years or for such extended period as the Excise Commissioner may, in each case, allow. The owner of the bonded laboratory shall, before the expiry of the period of three years or the extended period, if any, clear the same for consumption in the State on payment of excise duty or for removal in bond to a bonded warehouse or for exportation.

f. *Sampling, filling, packaging, etc.:*

1. As soon as the production (i.e. manufacture) of the medicinal or toilet preparation is completed, free samples (227 ml) are taken with permission of the officer-in-charge for analysis of medicaments and alcohol strength in his own laboratory.
2. Any sampled quantity left over after analysis shall be destroyed in the presence of the officer-in-charge.
3. The Excise officer also may collect two samples from each batch and send one sample for analysis to the chemical examiner. All samples sent for analysis should be in sealed containers.
4. Details of the samples removed are entered in the register.
5. Medicinal and toilet preparations after determining the alcohol strength shall be filled or subdivided into the bottles, labelled, packed and kept in the finished product store room batch wise. After paying the excise duty, the goods shall be removed outside the bonded laboratory with the permission of the officer-in-charge for the distribution and sale.
6. If the alcohol strength of the preparation is found to be more than 3% proof degree or

below the lowest allowable limit, its issue from the bonded laboratory shall be withheld. The licensee may be allowed to adjust the alcoholic strength off the preparation in a suitable manner with the previous approval of the excise commissioner, provided such process does not affect the therapeutic or toilet properties of the preparation.

g. Deficiency noticed in the finished store: A record shall be kept of all deficiencies in bulk content of any finished medicinal or toilet preparation in store by the officer-in-charge in Form R.G.-4, and a report of all such deficiencies, shall be submitted by him at the end of each quarter to the Excise Commissioner. All such loss in the absence of a satisfactory explanation from the licensee shall be subject to levy of duty on the quantity so lost at penal rates which shall not be more than double the rates prescribed. If the excise commissioner is satisfied that the deficiency reported was due to natural or unavoidable causes, and if he is satisfied that the alcoholic preparation has not gone into consumption, he may remit the duty.

h. Disposal of sub-standard preparations: A finished medicinal or toilet preparation which is or is suspected to have deteriorated in quality may, if the manufacturer so desires, be destroyed with the permission of the Excise Commissioner in the presence of the officer-in-charge and relevant entries made in the register in Form R.G.-4. The Excise Commissioner may, on an application made to him by the manufacturer, allow him to re-process a sub-standard preparation. Excise duty shall not be levied on the preparation so destroyed provided the Excise Commissioner is satisfied that the deterioration of the preparation, or in the alternative its improper manufacture, was due to reasons beyond the control of the licensee.

i. Disposal of recovered alcohol: Alcohol recovered in course of production of a medicinal or toilet preparation or distilled separately from the mark of such preparation may be used for subsequent production of the same preparation

provided such alcohol is collected separately and accounted for separately. In cases where the alcohol recovered from a preparation liable to duty at the lower rate is sought to be used in the manufacture of a preparation subject to higher rate of duty, the duty on the preparation so manufactured shall be collected or made leivable on determination of the spirit strength of the preparation. An account of recovered alcohol in a recovered alcohol vat shall be maintained by the officer-in-charge in Form R.G.-2. Recovered alcohol declared by the licensee to be unfit for use shall be destroyed by him in the presence of the officer-in-charge on submission of written application. No rebate of duty shall be allowed on recovered alcohol so destroyed.

j. Wastage in manufacture: The State Government may, from time to time, fix the percentage of wastage in the production of a particular medicinal or toilet preparation. Any wastage that exceeds the allowable limit and is not properly accounted for shall be charged with the duty together with such penalty not exceeding the duty leivable thereon as the Excise Commissioner may deem fit. If the alcohol in strength of a preparation is found by the Chemical Examiner to exceed the highest allowable limit by more than 3 proof degrees or to be below the lowest allowable limit, its issue from the bonded manufactory, shall be withheld. The licensee may be allowed to adjust the alcoholic strength or the medicaments or the ingredients of such a batch of preparation in a suitable manner with the previous approval of the Excise Commissioner provided the process employed does not impair the therapeutic or toilet properties of the preparation in any way. A sample of the preparation shall be sent to the Chemical Examiner for analysis after adjusting the spirit or medicaments or other ingredients, and issue of the adjusted batch of such preparation shall be allowed only when the Chemical Examiner's report has been found to be satisfactory. When an excess of more than 20 proof degrees over the strength declared by the licensee of any batch of preparation is found by the Chemical Examiner, the true strength, as

ascertained by the Chemical Examiner, shall be entered in the batch account in Form R.G.-3, and the reason for this alteration shall be briefly noted in the remarks column, and the excess duty due from the licensee or any quantity issued from the batch on payment of such duty to the credit of the Central Government (in the case of Union territories) or the State Government prior to the receipt—the Chemical Examiner's report, shall be realized by the officer-in-charge with the previous sanction of the Excise Commissioner. No refund or abatement of excess duty shall be allowed on any quantity of a batch of preparation issued on payment of such duty and prior to the receipt of the Chemical Examiner's report, if the strength is found to be lower than that declared by the licensee.

k. Issue of alcoholic preparations from a bonded manufactory/laboratory: Issues of alcoholic preparations and preparations containing opium, Indian hemp or other narcotic drugs and narcotics shall be made from a bonded manufactory on payment of duty. The licensee shall present before the officer-in-charge an application in Form A.R.-2 signed by him or by his authorized representative. The officer-in-charge shall, after checking the entries and realizing the duty payable, allow the required quantities to be removed after issuing a permit. If the licensee is also an account-holder as provided for in Rule 9, duty leviable on alcohol preparations and preparations containing opium, Indian hemp or other narcotic drugs and narcotics to be issued from a bonded manufactory shall be debited in the account-current before the preparations are removed from the bonded premises.

l. Preparation exempted from duty payment: Supply of medicinal preparations containing alcohol, manufactured in India and supplied directly from bonded laboratory to the following places is exempted from paying excise duty:

1. To hospitals and dispensaries working under Central or State Government.
2. To hospitals dispensaries subsidized by the Central or State Government.

3. To charitable hospitals dispensaries under the control and management of local body.
4. To medical stores depot of Central or State Government.
5. To Institutions which supply medicines freely to the poor and certified to that effect by the principal medical officer of the district.

If in the supply of any medicinal preparation made direct to all or any of the institution any loss or shortage is detected at the destination, the manufacturer or the licensee of a warehouse, as the case may be, shall be liable to pay duty on such loss or shortage at the rate in force on the date on which such loss or shortage is detected made known to the proper officer. If it is proved to the satisfaction of the Excise Commissioner that the loss or shortage was due to circumstances over which the manufacturer or licensee, as the case may be, had no control, the Excise Commissioner may remit the whole or part of duty payable.

m. Remission of duty in case of loss of due to accident: In case of any accidental loss of alcohol in a bonded manufactory (otherwise than by theft). Due to reasons beyond the control of the licensee, the duty on the alcohol so lost shall be remitted with the approval of the Excise Commissioner.

B. Non-bonded laboratory (manufacture outside bond): Manufacture outside bond of medicinal and toilet preparations containing alcohol, opium, Indian hemp and other narcotic drugs and narcotics.

When spirit is obtained from the distillery after paying the duty, execution of a bond does not arise. Preparations that are manufactured using this duty-paid alcohol are known as manufactured without bond or outside bond and the laboratory is called Non-bonded laboratory. However, following other condition is to be compiled with.

I. Issue of License

1. A license is required from the Excise Commissioner. Application to be made in the prescribed form.

2. The prescribed fee shall be paid into the treasury and the challan attached with application.
3. Plan of the laboratory building and the list of equipments and vats to be used are to be submitted.
4. The capital proposed to be invested in the business and the maximum quantity of alcohol likely to remain in the premises at any one time shall also be indicated to the licensing authority.
5. Details about the constitutions of the firm.

II. Non-bonded Laboratory—General Description

The laboratory building shall have the following:

1. The portion of the non-bonded manufactory used as "laboratory" shall be separated from that used for other purpose.
2. The windows of the "spirit store", "laboratory" and "finished store" shall be fitted with malleable iron bars not less than 19 mm. in thickness, set not more than 102 mm. apart and fixed in the brick-work to a depth of at least 51 mm. at each end. On the inside of each window there shall be securely fastened to the bars stout wire-netting the aperture of which shall not exceed 25 mm. in diameter.
3. There shall be only one entrance to the non-bonded manufactory and one door each to the "laboratory", "spirit", "store", and "finished store".
4. All pipes from sinks and wash-basins inside the manufactory premises shall discharge into closed drains forming part of the general drainage system of the premises.
5. All electric and gas connections with the licensed premises shall be so fixed as to admit of the supply of electricity or gas being cut off and the regulators or switches being securely locked out at the end of day's work.
6. There shall be separate "spirit store" for the rectified spirit purchased at the duty of Rs. 1.10 paise, Rs. 3.85 paise and Rs. 15.50 paise per London proof litre.

7. There shall be separate finished stores for medicinal and toilet preparations falling under each item of the schedule to the act.
8. All alterations in arrangement of building and plants shall be made only with the previous sanction of the Excise Commissioner.
9. The State Government may relax all or any of the provisions of Clauses. (i) to (viii) in the case of small manufacturers whose annual consumption of alcohol does not exceed 500 litres and also in the case of those who prepare medicinal preparation for dispensing to their patients only and not for sale.

III. Opening and Closing Hours

The work of manufacture and sale in the non-bonded manufactory shall be conducted between the hours of sunrise and sunset and on such days and hours as may be fixed by the Excise Commissioner. The premises shall remain closed from the hours of sunset to sunrise each day.

IV. Receptacles

1. The permanent vessels for the storage of alcohol and finished preparations containing alcohol in the non-bonded manufactory shall be gauged accurately and tables shall be computed to show the contents of every 20 mm and 2 mm of its depth.
2. The receptacles for the storage of finished preparations in the finished store shall be of metal, porcelain or glass as may be convenient and necessary.
3. Each permanent vessel shall bear a distinctive serial number, its full capacity, and the purpose for which it is to be used, distinctly and indelibly marked on it. A record of these details shall be kept in the register in the Form R.G.-1.
4. All receptacles containing alcohol, tinctures, liquid extracts or other alcoholic medicinal or toilet preparations, in the laboratory shall

have affixed to them labels signed by the manufacturer or his authorized representative showing the batch number, the name of the preparations and the quantity of alcohol added in the receptacles during the course of manufacture.

5. Labels placed on macerators and percolators or carboys shall show the quantity of proof-spirit contained in them on each occasion and shall be destroyed when they are emptied and cleaned.
6. Labels on bottles filled for removal shall show among other details, which the manufacturer may require, the alcoholic contents in proof-strength and the average percentage of absolute alcohol it contains.

V. Indent for Rectified Spirit-duty Paid/ Obtained Duty Paid Spirit

Rectified spirit required for manufacturing medicinal and toilet preparations shall be obtained on an indent prepared in triplicate, Form I.D.-1, from any distillery or spirit warehouse approved by the Excise Commissioner, the original being sent by the licensee of the manufactory to the distiller or spirit warehouse keeper, the duplicate to the officer-in-charge of the distillery or spirit warehouse through the proper officer and the triplicate retained by the licensee as office copy. The cost of such rectified spirit shall be paid by the licensee of the manufactory to the distiller or spirit warehouse-keeper. The licensee shall credit the duty payable on the spirit indented for into a Government treasury of the collecting Government and enclose the chalan in token of such payment, to the duplicate copy of the indent. The treasury officer shall send an advice of such payment to the officer-in-charge of the distillery or spirit warehouse. The officer-in-charge of the distillery or spirit warehouse, after satisfying himself that the correct amount of duty has been paid, as evidenced by the chalan enclosed by the licensee and the advice of such payment received, from the treasury officer, shall order the issue of rectified spirit required. The rectified spirit shall

be brought from the distillery or spirit warehouse to the manufactory covered by a permit issued by the officer-in-charge of the distillery or spirit warehouse. All such permits shall be filed along with respective indents.

Where the manufactory as well as the warehouse from which rectified spirit is to be obtained is located within the same State, the licensee may authorize the owner of the distillery or warehouse to pay the duty on his behalf before the issue of rectified spirit. On such authorization the owner of the distillery or warehouse shall pay the amount of duty into a Government treasury to the credit of the collecting Government or in such manner as may be prescribed by the excise commissioner.

Rectified spirit procurement (rate of duty):

1. Rate of duty for:
 - a. Allopathic medicinal preparations containing alcohols which are not capable of being consumed as ordinary alcoholic beverages ₹ 10/lit.
 - b. Allopathic medicinal preparations containing alcohol which is known active ingredients consumed as ordinary alcoholic beverages ₹ 20/lit.
 - c. Other allopathic medicinal preparations containing alcohols which are capable of being consumed as ordinary alcoholic beverages ₹ 80/lit.
2. Indent for procurement shall be made in the prescribed form in triplicate, and countersigned by the proper officer of the excise department. The original with the cost of spirit sent to the distiller. The duplicate copy is sent through the proper officer to the distillery Excise officer, along with the challan in token of the duty paid into the treasury. The officer-in-charge of the distillery, after satisfying himself that correct amount of duty has been paid, shall order to issue rectified spirit with the transit permit.
3. The consignment of the spirit received shall be transferred to the respective spirit store immediately and entered in the register.

VI. Indent for Opium, Indian Hemp and Other Narcotic Drugs and Narcotics, their Storage and Issue for Manufacture

Indent for opium shall be made to the nearest sub-treasury or to the Government Opium Factory, Ghazipur, or to the warehouse or place of storage approved by the State Government in Form I.D.-1. The supply of Indian hemp, narcotic drugs and other narcotics shall be indented for from the nearest Government warehouse or place of storage approved by the State Government in the same form. The supply of opium, Indian hemp and other narcotic drugs and narcotics shall be made under permit. On their receipt in the non-bonded manufactory they shall be verified and accounted for in the register in Form R.G.-2. Opium, Indian hemp and other narcotic drugs and narcotics obtained by the licensee free of duty shall be stored separately in the spirit store. Every time opium, Indian hemp other narcotic drugs and narcotics are issued from the spirit store of the laboratory, such issues shall be accounted for in the register in Form R.G.-2.

VII. Manufacture, Storage and Sale to be Carried on only in the Licensed Premises of the Non-bonded Manufactory

The manufacture and storage of all preparations shall be carried on in the licensed premises only. Each preparation manufactured shall be registered and shall bear a distinctive serial number, which shall be known as its batch number in the register in Form R.G.-3. This register shall also show the receipt and disposal of all rectified spirit, opium, Indian hemp and other narcotic drugs and narcotics drawn from the spirit store and the quantity of finished preparation manufactured there from. All finished preparations shall be transferred from the "laboratory" to the "finished store" and shall be so arranged that the checking of stock of every batch of preparation from the accounts register "in Form R.G.-4" is facilitated. Finished preparations made from rectified spirit obtained at different rates of duty shall be kept separately

in the finished store. Every preparation stored in bulk shall be measured into the storage vessel to the nearest fluid ounce by the manufacturer and sealed. When any of the contents of a vessel, in which the preparations are stored in bulk are removed, the manufacturer shall enter on the stock card attached thereto the quantity taken out and the manner of disposal with his signature and date.

VIII. Sampling

Samples to be taken by the excise officer at least once a month for analysis: The excise officer, in whose jurisdiction the manufactory is situated, shall, without previous notice to the manufacturer, take samples of not less than 13% and not more than 15% (save in exceptional circumstances) of the total number of the medicinal and toilet preparations containing alcohol from the finished stocks at least once every month and forward them to the chemical examiner for analysis and report whether the alcoholic contents thereof tally with the percentage of alcohol shown on the labels affixed to the bottles. If the proof strength reported by the Chemical Examiner is more than 3% proof spirit than the strength declared by the manufacturer on the labels pasted on such bottles, the manufacturer is liable to a penalty at the rate of 10 times the difference in duty in the quantity so manufactured but not exceeding ₹ 2,000. If such differences are found to occur frequently, the excise commissioner may order the cancellation of the license held by the manufacturer. Samples of finished products may also be taken at any time by the Excise Commissioner, and such other Excise Officer authorized by the Excise Commissioner in this behalf. All such samples shall be taken by the officer personally and in the presence of the manufacturer or his authorized agent.

Procedure to be followed in taking samples: A sample shall be of 227 ml. or such quantity as may be fixed by the Excise Commissioner. Every sample shall be taken in duplicate. The cork of every bottle in which sample is kept shall be fixed

with the officer's personal seal or the official seal and the name of the preparations and batch number shall be stated on label attach to each such bottle. The label of the bottle shall be signed by the officer taking the sample. The manufacturer, if he so desires shall be allowed to affix his own seal and sign the labels. The duplicate samples shall be kept securely under lock and key in a cupboard (to be provided by the manufacturer) until the result of the analysis has been reported, save in the case in which the Chemical Examiner has asked for another sample either to replace the previous sample despatched to him or to repeat the analysis. Duplicate samples, to which no further reference is needed, shall be promptly returned to the manufacturer. The samples to be sent for examination shall be carefully placed in a case and securely fastened with tape or wire to be supplied by the manufacturer and shall be sealed by the officer taking the samples, with the personal seal or the official seal, and despatched without delay, at the expense of the manufacturer, to the Chemical Examiner. A letter advising the despatch of the sample shall be sent to the Chemical Examiner in duplicate. The letter shall contain besides other information a facsimile of the seal used. The Chemical Examiner shall acknowledge the receipt of the sample in the duplicate copy to the dispatching officer.

IX. Accounts

Correct and up-to-date accounts in prescribed printed registers to be maintained.

The manufacturer shall maintain up-to-date, correct and proper accounts in the relevant register and deliver to the proper officer, by the 5th of each month, a monthly return of transactions of business. The manufacturer shall also furnish such statements as may be required by the Excise Commissioner or by any officer empowered by him in this behalf. All the account registers shall be obtained by the manufacturer at his cost from the respective Taluqa office or Excise Office or such other office authorized to sell such registers.

Returns: The manufacturer shall maintain correct and proper accounts up-to-date in the relevant registers and submit to the proper officer by 5th of each month (known as return).

X. Employees

The manufacturer shall furnish to the Excise Commissioner and the proper officer, a list containing the names of the manager or assistant manager employed by him and of all other employees whose duties require them to another non-bonded manufactory. He shall promptly inform the Excise Commissioner and the proper officer of any changes which he may choose to make in the list from time to time. No person other than the person whose name is contained in the list shall enter the manufactory without the special permission of the proper officer.

XI. Inspection

The non-bonded laboratory shall be open to inspection by the Excise Officer of that area. The officer shall inspect the laboratory at least once every month. The State Government may authorize any officer of the prohibition, land revenue, medical and public health departments to inspect non-bonded laboratory.

CLASSIFICATION OF MEDICINAL AND TOILET PREPARATIONS CONTAINING ALCOHOL

Manufacture of Allopathic, Homeopathic and Ayurvedic Preparations

I. Allopathic Preparations/Patent and Proprietary Preparations

Allopathic preparations are medicinal preparations made according to the modern system of medicines and fall under the following two categories:

- i. Official allopathic preparations which are made strictly in accordance with the formulae given in the official current editions of the under-mentioned Pharmacopoeias:

1. The British Pharmacopoeia.
2. The British Pharmaceutical Codex.
3. The Indian Pharmacopoeia.
4. The United States Pharmacopoeia.
5. The National Formulary of the United States.
6. Any other Pharmacopoeia that may be recognized under the Drugs Act, 1940, by the Government of India.
7. Veterinary Codex recognized by the Government of India.
8. International Pharmacopoeia.
9. The State Pharmacopoeia of the Union of Soviet Socialist Republics.
- ii. Non-official allopathic preparations which are prepared according to allopathic system of medicine and conform strictly to the formula displayed on the label.

Restricted and unrestricted medicinal preparations: Maintenance of restricted list of preparations:

1. A list of medicinal preparations which are considered as capable of being misused as ordinary alcoholic beverage, hereinafter referred to as **Restricted Preparations**, is given in the Schedule.

All other medicinal preparations being manufactured from a date prior to 1st April, 1957, shall be considered to be not capable of being misused as ordinary alcohol beverages hereinafter referred to as **Unrestricted Preparations**.

2. If, however, a preparation falling in the unrestricted category is found to be widely used as ordinary alcoholic beverage, Central Government may, on the request of a State Government or *suomotu*, refer the matter to the Standing Committee. The Central Government shall, if so advised by the said Committee, declared the preparation as a restricted preparation and the item or sub-item or both in the Schedule to the Act under which the preparation falls, and thereupon include the said preparation in the Schedule.

3. Medicinal preparation other than official allopathic preparations which are manufactured in India for first time on and subsequent to 1st April, 1957, shall be presumed to be restricted preparations unless declared to the contrary by Central Government on the advice of the Standing Committee. Any manufacturer, intending to produce a new alcohol preparation other than an official allopathic preparation, shall submit the samples of such preparation with the receipt to the State Government. The State Government shall forward such request with receipts to the Central Government for a decision. The Central Government shall refer the matter to the Standing Committee and in accordance with the advice tendered by it declare the category in which the preparation should be placed and the item or sub-item or both in the Schedule to the Act under which the preparation falls. The decision of the Central Government shall be communicated to all State Governments. In case the preparation is declared to be an unrestricted preparation it shall be included in the schedule on unrestricted preparations.

The advice of the Standing Committee shall be communicated within a reasonable time and in no case later than 6 months from the date of submission of sample to the committee.

II. Homoeopathic Preparations

Mode of manufacture: American, British and general pharmacopoeias that are in vogue at present in the various States, shall be recognized as standard pharmacopoeia or for homoeopathic preparation for the purpose of these rules until such time as the Central Government evolves its own pharmacopoeia.

Preparation with narcotic ingredients: Preparations containing opium, Indian hemp and other narcotic drugs and narcotics. The Rules in respect of alcoholic medicinal and toilet preparations shall, as far as may be, apply to

preparations containing opium, Indian hemp, and other narcotic drugs and narcotics.

III. Ayurvedic Preparations

Types of preparation: Asavas and aristas are the principal types of Ayurvedic preparations in which alcoholic contents is self-generated and not added to such.

Pharmacopoeia for Ayurvedic preparations: Until a standard Ayurvedic Pharmacopoeia has been evolved by the Central Government, the Pharmacopoeias that are in the various States shall be recognized as standard Ayurvedic Pharmacopoeias.

Classification of preparation containing self-generated alcohol for purposes of levy of duty: No duty shall be levied on Ayurvedic preparations containing self-generated alcohol in which the alcoholic content does not exceed 2% proof spirit. Where the percentage of proof spirit is in excess of 2% duty will be leviable under the Schedule to the Act according as the preparations are capable of being consumed as ordinary alcoholic beverage or not. Provided that Ayurvedic practitioner registered under any law for the time being in force in any State where there is no such registration of Ayurvedic practitioners, such practitioners, as are proved to satisfaction of the Excise Commissioner to be of good standing, shall be allowed to manufacture and dispense Ayurvedic preparations, excepting those prepared by distillation or by addition of alcohol as such during the process of manufacture or to the finished product, free of duty subject to the following conditions:

- a. Practitioners shall take out license on payment of fee of Re 1 per L.P. liter in the manner hereinafter stated.
- b. Such preparations shall be used only for the patients of the practitioners and shall not be for sale to the general public.
- c. The practitioner shall allow drawing of samples by Excise Officer to ensure that the preparations contain only self-generated alcohol.

d. Daily account shall be maintained of all the preparations manufactured and dispensed giving particulars of names and addresses of the patients of the practitioners.

Levy of duty on Ayurvedic preparations made by distillation or to which alcohol is added at any stage of manufacture: For purpose of duty Ayurvedic preparations, made by distillation or to which alcohol is added at any stage of manufacture, shall be treated as alcoholic preparations capable of being used as ordinary alcoholic beverages.

WAREHOUSING OF ALCOHOLIC PREPARATIONS

A. Establishment and licensing: The manufacturers or dealers in dutiable goods may establish bonded warehouses anywhere in India. No duty paid goods and no goods other than dutiable goods shall be deposited in such bonded warehouses. The Excise Commissioner shall license a private warehouse for the storage of dutiable goods on which duty has not been paid and may direct in what manner and on what terms such goods shall be stored and how and in what manner such warehouse shall be secured by locks or fastenings. The Excise Commissioner shall require the licensee to furnish a bond in Form B-2 with such surety or sufficient security, in such amount and under such conditions, as the Excise Commissioner approves binding the licensee to pay duty on the goods deposited therein and for the due and safe removal of such goods to another warehouse and for the due observance of the terms, conditions and requirements of the Act, these rules and any other rule made hereunder in respect of the same.

B. Receipt of goods at warehouse and owner's power to deal with warehoused goods: All goods brought for warehousing shall be produced to the officer-in-charge of the warehouse, if any, or the proper officer, together with the relative transport and shall be weighed, gauged and proved, wherever necessary, in his presence and assessed to duty prior to entry into

the warehouse and the quantity and description of the goods, the marks and numbers of the packages, the number and date of the permit and the amount of duty leviable thereon shall be noted in the warehouse register in Form R.G.-5. All goods received into the warehouse shall be kept separate from other goods until the receipt account has been taken by the officer-in-charge or the proper officer, as the case may be.

With the sanction of the officer-in-charge or the proper officer, as the case may be, and in accordance with such instructions as the Excise Commissioner may, from time to time, issue in writing in this behalf, any owner of goods lodged in a warehouse may sort, separate, pack and re-pack the goods and make such alterations therein as may be necessary for the preservation, sale or disposal thereof. After the goods have been so separated and repacked in such manner as may be ordered by the Excise Commissioner, the officer-in-charge or the proper officer, as the case may be, may, at the owner's request, cause or permit any damaged goods remaining after such repacking to be destroyed subject to such limitations as the Excise Commissioner may, from time to time, impose and may remit the duty assessed thereon.

C. Goods not to be taken out of warehouse except as provided by these rules: No goods shall be removed from any warehouse except on payment of duty or for removal to any other warehouse or for export and on presentation of a written application prescribed in Rule 81 or Rule 98, as the case may be.

D. Periods for which goods may remain in warehouse under bond: Any goods warehoused may be left in the warehouse in which they are deposited for a period of three years or such extended period as the Excise Commissioner in each case allow. The owner of any such goods remaining in the warehouse shall, before the expiry of the period mentioned above, clear the same for consumption in the State after payment

of duty or for removal in bond to another bonded warehouse or for exportation.

E. Mode for calculating quantity of goods warehoused: The quantity of goods contained in any package warehoused may be calculated by weight, measure, gauge, proof strength, or in such other manner as the Excise Commissioner may direct.

F. Power to remit duty on warehoused goods lost or destroyed: If any goods lodged in a warehouse are lost or destroyed by unavoidable accident, the Excise Commissioners may remit the duty thereon. Provided that if any goods are so lost or destroyed, notice thereof shall be given to the officer-in-charge of the warehouse or the proper officer immediately on discovery of such loss or destruction.

G. Responsibility of the licensee of the warehouse: The licensee of the warehouse in respect of goods lodged therein, shall be responsible for their due reception therein and delivery there from and for their safe custody while deposited therein, according to the quantity or weight reported by the officer who has assessed the goods.

H. Monthly returns: Within seven days after the close of each month, every licensee shall submit to the Excise Commissioner a monthly return showing the quantity of dutiable goods received, the quantity transferred to another warehouse under bond, the quantity removed on payment of duty and such other particulars as the State Government may by general or special order require.

I. Clearance on payment of duty: When the licensee desires to remove goods on payment of duty, he shall make an application in Form A.R.-2, in triplicate, to the officer-in-charge or the proper officer, as the case may be, at least twelve hours before he is intended to remove the goods. The officer shall, thereupon, assess the amount of duty leviable on the goods and on production of evidence that the sum has been paid into a treasury or the sum has been debited to the account-current, as the case may be, shall allow the goods to be cleared.

EXPORT OF ALCOHOLIC PREPARATIONS

Export of alcoholic preparations:

- i. Under claim for rebate of duty
- ii. Under bond (directly from the bonded laboratory without payment of duty):

A. Method of export: Duty-paid goods shall be exported under claim for rebate of duty. Goods under bond for payment of duty shall be sent to the place of export under bond for their due export.

Application to be submitted: The exporter shall present to the officer-in-charge or the proper officer, as the case may be, an application in triplicate in Form A.R.-3, if the goods are to be exported by land and in Form A.R.-4, if the goods are to be exported by sea or air or by parcel post. The officer-in-charge or the proper officer shall send the original to the customs officer or the border examiner or the postmaster, as the case may be, at the place of export, deliver the duplicate to the consignor and retain the triplicate as office copy. A separate application shall be submitted in respect of each consignment.

B. Examination of goods prior to despatch:

1. **Export under bond:** When goods from a bonded manufactory or warehouse are to be exported, the cases or packages in which such goods are packed, shall be legibly marked in ink or oil colour (or in such other durable manner as the Excise Commissioner may in any particular case allow), with a progressive number commencing with No.1 for each year, with the owner's name and special mark, if any, the total quantity of dutiable goods with their alcoholic contents in London-proof litres.
2. **Export of duty paid goods:** The owner of a non-bonded manufactory or a wholesale dealer, who wants to export duty paid goods shall give 48 hours notice to the proper officer, for supervising packing of the goods to be exported. The manufacturer or wholesale dealer shall present the entire consignment to be exported to the proper officer. The said officer shall take samples

from each kind of dutiable goods to be exported and shall allow the despatch of the goods subject to fulfilling further conditions laid down in sub-rule (3). Thereafter, he shall send the samples to the Chemical Examiner for analysis. On receipt of the analysis report of the Chemical Examiner, the proper officer shall enter the alcoholic content in London-proof litres of the goods packed as ascertained by analysis in the duplicate copy of the application which the owner shall present to him before its presentation to the Excise Commissioner for claiming rebate of excise duty.

3. After verifying the particulars entered in the application, and, in the case of duty-paid goods, after satisfying himself that the goods are identifiable as the goods, in respect of which the payment of duty cited in the application was made, the officer-in-charge or the proper officer, as the case may be, shall get the following particulars noted in the body of each package:
 - a. Name and address of the consignee.
 - b. Description of the goods.
 - c. Total quantity of the goods packed.
 - d. Alcoholic content of the goods in London-proof litres as declared by the manufacturer.
 - e. Gross weight of the package.

And shall then sell each package with his official seal in such a manner that the package cannot be tampered with without breaking the seal. The said officer shall endorse all copies of the application, shall specify the period within which the goods shall be actually exported and return the duplicate to the consignor, who, after dispatching the goods shall enter the number and date of the railway receipt or bill of lading in the duplicate copy and shall communicate these particulars to the proper officer for entry in the other copies.

C. Examination at the place of export: On arrival at the place of export by post have been sealed, the exporter shall present the duplicate application, together with the packet or packets

to which it refers, to the postmaster at the office of booking.

On arrival at the place of export, the goods shall be presented, together with the duplicate application, to the Customs Collector, Border Examiner, or any officer, of customs or land customs duly appointed for the purpose. The consignment shall be carefully examined and check-weighed and if the seals are intact and the case or the packages correspond with the description given in the application, and the particulars stated in the duplicate application and the original received from the officer at the place of despatch agree in all respects, the Customs Collector, Border Examiner, or any such officer of customs shall allow export and shall then certify on the duplicate application that the goods have been duly exported (citing in the case of exports by sea or air, the shipping bill number and date and other particulars of export) and return it to the exporter.

D. Further procedure in respect of goods exported by parcel post: Where the goods are exported by post, the postmaster of the post office of final despatch from India shall certify on the duplicate applications that the goods covered by the application have been duly exported out of India and shall return it, through the postmaster at the post office of booking to the exporter. The original application shall be returned to the officer-in-charge of the proper officer with the certificate of export.

INTER-STATE TRANSPORT OF ALCOHOLIC PREPARATIONS

Inter-State Movement of Medicinal and Toilet Preparations containing alcohol, opium, Indian hemp and other narcotic drugs and narcotics.

A. Mode of Inter-State movement: Dutiable goods manufactured under bond or stored in a bonded warehouse in any State, unless exempted from payment of duty may be removed from such State to any other State:

- i. After payment of duty in the first mentioned State.

ii. In bond, in the manner hereinafter prescribed for movement from one bonded warehouse to another.

B. Movement from one bonded warehouse to another bonded warehouse bond for due arrival and re-warehousing: When warehoused goods are to be removed from one warehouse to another, the consignor or the consignee of the goods shall, before the goods are removed, enter into a bond in Form B-4 with sufficient security as the Excise Commissioner may prescribe, for a sum equal, at least, to double the duty chargeable on such goods for the due arrival and re-warehousing thereof at the warehouse of destination within such time as the officer-in-charge of the warehouse of removal directs.

C. Remover may enter into a general bond: The Excise Commissioner may permit any person, to remove warehoused goods from one warehouse to another, by entering into a general bond in Form B-4, with such surety or sufficient security in such amount and under such condition, as the Excise Commissioner approved for the removal, from time to time, of any goods from one warehouse to another and for the due arrival and re-warehousing thereof at the warehouse of destination within such time as the officer-in-charge of the warehouse of removal directs.

D. Procedure in respect of goods removed from one warehouse to another: The application for removal of goods from one warehouse to another in triplicate shall be presented by the consignor to the officer-in-charge of the warehouse removal at least 24 hours before the intended removal together with such other information as the Excise Commissioner may, by general or special rules or order, require. Such officer shall then take account of the goods, and after completing the removal certificate on all the copies of the application, shall send the duplicate to the officer-in-charge of the warehouse of destination, and hand over the triplicate to the consignor for despatch to the consignee. He shall also over-deliver to the consignor a transport permit. On arrival of the goods at the warehouse of

destination, the consignee shall present them together with the triplicate application and the transport permit to the office-in-charge of such warehouse, who shall, after taking account of the goods, complete the re-warehousing certificate on the duplicate and the triplicate application and return the duplicate to the officer-in-charge of the officer-in-charge of the warehouse of removal, and the triplicate to the consignee for the despatch to the consignor. The consignor shall present the triplicate application duly endorsed with such certificate to the officer-in-charge of the warehouse of removal within ninety days of the date of issue of the transport permit.

E. Failure to present triplicate application: If the consignor fails to present the triplicate application to the office-in-charge of the warehouse of removal in the manner laid down above, and the duplicate application endorsed with the re-warehousing certificate has also not been received by such officer, from the officer-in-charge of the warehouse of destination, the consignor shall, upon a written demand being made by the former officer, pay the duty leviable on such goods within 10 days of the notice of demand and if the duty is not so paid, he shall not be permitted to make fresh removals of any warehoused goods from one warehouse to another until the duty is paid or until the triplicate application is so presented or the duplicate application is so received. Where such duty has been paid, it shall be refunded to the consignor, either on his presentation of his triplicate application to, or on the receipt of the duplicate application by the officer at the warehouse of removal, duly endorsed as provided above, with a certificate by the officer-in-charge of the warehouse of destination that the goods covered by the application have been satisfactorily re-warehoused.

F. Procedure on failure to pay duty: If the owner fails to pay any sum demanded under any of the preceding rules, the officer authorized in this behalf by the State Government may forthwith either proceed upon the bond executed by the

owner of such goods, or cause such portion as he thinks fit of such goods (if any) in the warehouse, on account of which the money is due, to be detained with a view to recovering the demand; and if the demand is not discharged within ten days from the date of such detention, due notice thereof being given to the owner, the goods so detained may be sold by public auction duly advertised in the official gazette, or in such other manner as the Excise Commissioner may, in any particular case direct.

The net proceeds of the sales of any goods so detained shall be adjusted against the amount due under the bond and the effect of such adjustment shall be recorded and if there is any surplus remaining after such adjustment, the surplus shall be paid to the owner of the goods.

Procedure

Procedure of Entry, Search, Seizure and Investigation

A. Inspection: Authorized officers to have free access to premises, equipment, stocks and accounts of dealers in dutiable goods. Any officer authorised in writing by the Excise Commissioner in this behalf, shall have free access at all reasonable times to any premises licensed under these rules and to any place where dutiable goods are manufactured, stored or kept for sale, and may, with or without notice to the owner, inspect the building, the plant, the machinery, the stocks and the accounts, and may at any time check the records made of the goods stocked in, or removed from the manufactory, warehouse or place of their transfer within a manufactory to that part of the premises, if any, in which they are to be used for the manufacture of any other commodity, whether for the purpose of testing accuracy of any return submitted under these rules, or of informing himself as to any particulars regarding which information is required for the purpose of the Act or these rules.

B. Power to detain person and examine goods/ detention of person: Any Excise Officer duly

empowered by the State Government may stop and detain any person found carrying or removing any dutiable goods for the transport of which a permit or other transport document is required by these rules, and may examine the goods and may require the production of a permit or other document authorizing the removal thereof. If a permit or other prescribed document is produced agreeing with the goods in all respects, the officer may endorse thereon the time and place of his examination thereof.

C. Power to stop, enter and search: Any Excise Officer not below the rank of a sub-inspector of excise may stop and search any vessel, car or other means of conveyance for dutiable goods, and enter and search at any time by day or by night any land, building, any enclosed place, premises, vessel, conveyance or other place upon or in which he has reason to believe that dutiable goods are stored, manufactured or carried or in contravention of the provisions of the Act or these rules, and in case of resistance break open any door and remove any other obstacle to his entry, open and search into such land, building and closed places, premises, vessel, conveyance or other place.

D. Seizure: Any Excise Officer not below the rank of a sub-inspector of excise may seize and remove or detain any goods in respect of which, it appears to him, the duty should have been, but has not been, levied or that contravention of the provisions of the Act or these rules has occurred. He may also seize and remove or detain any receptacle, packages or coverings, in which such goods or articles are contained, and animals, vehicles, vessels or other conveyance used in carrying such goods or articles and any implements and machinery used in the manufacture of such goods.

E. Summons and notices: Manner of service. Any Excise Officer not below the rank of a sub-inspector of excise may summon any person whose attendance he considers necessary either to give evidence or to produce documents or any other things, in any enquiry which such officer is making for any of the purposes of the

Act or the Rules. Every summon or notice issued under the Act or the Rules shall be in writing in duplicate, and shall state the purpose for which it is issued, and shall be signed by the officer issuing it, and shall also bear his official seal, if he has any and shall be served by tendering a copy of it to the persons summoned, or if he cannot be found, by affixing a copy of it to some conspicuous part of the house in which he is known to have last resided, or carried on business or personally worked for gain.

F. Service of notice: Notice not void for error. No notice shall be deemed void on account of an error in the name or designation of any person referred to therein, unless such error has produced a material misconception of the intended intimation.

G. Disposal of things seized: The owner or person having the charge of any animal seized and detained shall provide from day-to-day for its keep while detained, and if he fails to do so, such animal may be sold by public auction, and the expenses (if any) incurred on account of it defrayed from the proceeds of the sale. When anything is seized an order for its release is subsequently passed and owner does not, within a period of one month, appear to claim such thing and tender the duties, penalties and charge (if any) due in respect thereof, it may be sold by public auction and such duties, penalties, and charges will be defrayed from the proceeds of the sale. Surplus proceeds of a sale under these rules shall, if not claimed by the owner of the things seized within a period of three months from the date of such sale be forfeited, to the collecting Government.

H. Disposal of persons arrested: Every person arrested under this Act shall be forwarded without delay to the nearest Excise Officer empowered to send persons so arrested to a Magistrate or if there is no such excise officer within a reasonable distance to the officer-in-charge of the nearest police station. The officer-in-charge of a police station to whom any person is forwarded shall either admit him to bail to appear before a Magistrate having jurisdiction

or in default of bail forward him without delay in custody to such Magistrate.

I. **Prosecution:** No prosecutions under the Act shall be instituted except by an Excise Officer not below the rank of a sub-inspector of excise.

J. **Arrests:** Any Excise Officer not below the rank of a sub-inspector of excise may arrest any person whom he has reason to believe to be liable to punishment under the Act or any person who, on demand by him refuse to give his name and residence, or who gives his name and address which such officer has reason to believe to be false. All arrests and seizures made under these rules shall be in conformity with the provisions of the Act and the Rules.

K. **Power of adjudication of confiscation and penalty:** Where by these rules anything is liable to confiscation or any person is liable to penalty such confiscation or penalty shall be adjudged by the Excise Commissioner. The State Government may confer on any Excise Officer the power to adjudge confiscation or penalty and may prescribe the limit within which such power may be exercised. A breach of these rules shall, where no other penalty is provided herein, be punishable with a penalty which may extend to 1000 rupees and with confiscation of the goods in respect of which such breach is committed.

L. **Composition of offences:** The Excise Commissioner, or any Excise Officer specially empowered by him in this behalf, may accept from any person whose property is liable to confiscation under this Act or these Rules or who is reasonably suspected of having committed an offence under the Act a sum of money not exceeding two thousand rupees 2000 in lieu of confiscation of goods or of punishment for breach of any provisions of the Act or of the Rules.

M. **Confiscation:** When any goods or articles are liable to confiscation for breach of any of the provisions of the Act or these Rules, any alcohol, drugs or materials by means of which the breach has been committed and of any receptacle, packages or covering in which such goods or

articles are contained and the animals, vehicles, vessels or other conveyances used in carrying such goods or articles and any implements or machinery used in the manufacture of such goods shall be liable to confiscation. When anything is confiscated under these rules, such things shall thereupon vest in the collecting Government. The officer adjudging confiscation shall take and hold possession of the things confiscated, and every officer of police, on the requisition of such officer, shall assist him in taking and holding such possession.

N. **Appeals and Revision:** An appeal against an order of an officer other than an Excise Commissioner made in exercise of the powers conferred on him by the Act or these Rules shall lie to the Excise Commissioner of the State concerned. An appeal against an order passed by the Excise Commissioner shall lie to the State Government. If between the dates of the order or decision appealed against and the date of the hearing of the appeal, the officer who passed the order or decision is promoted to be the officer to hear such appeal, such appeal shall be heard by an officer superior in ranks to such officer. Every appeal under this rule should be filed within three months of the date of the decision or order appealed against an order passed in appeal under this rule shall, subject to the power of revision. The Central Government may, on the application of any person aggrieved by any decision or order passed under the Act or these Rules, and from which no appeal lies, reverse or modify such decision or order. Every application shall be filed within 6 months of the date of the decision or order appealed against. Every appeal or application for revision shall be accompanied by a copy of the decision or order by which the appellant, or applicant as the case may be, is aggrieved.

OTHER PROVISIONS

A. **Power of excise officer to arrest:** Any excise officer duly empowered by rules made in this behalf may arrest any person whom he has reason to believe to be liable to punishment

under this Act. Any person accused or reasonably suspected of committing an offence under this Act or any Rules made there under, who, on demand of any excise officer duly empowered by Rules made under this Act, refuses to give his name and residence, or who gives a name or residence which such officer has reason to believe to be false may be arrested by such officer in order that his name and residence may be ascertained.

B. Punishment for connivance at offences: Any owner or occupier of land or any agent of such owner or occupier in-charge of the management of the land, who willfully connives at any offence against the provisions of this Act or any rules made there under shall, for every such offence, be punishable with imprisonment for a term which may extend to six months, or with fine which may extend to 500 rupees, or with both.

C. Inquiry how to be made by excise officers against arrested persons forwarded to them: When any person is forwarded to an excise officer empowered to send persons so arrested to a Magistrate, the Excise Officer shall proceed to inquire into the charge against him. The Excise Officer may exercise the same powers, and shall be subject to the same provisions, as the officer-in-charge of a police station may exercise and is subject to under the Code of Criminal Procedure, 1898, when investigating a cognizable case.

All officers exercising any powers under the act shall exercise their powers as to ensure that every person who is arrested and detained in custody is produced before the nearest magistrate within a period of twenty-four hours of such arrest excluding the time necessary for the journey from the place of arrest to the court of the Magistrate.

D. Vexatious search, seizure by excise officer: Any officer exercising powers under this Act or under the Rules made there under who:

- Without reasonable ground of suspicion searches or causes to be searched any place, conveyance or vessel.

- Vexatiously and unnecessarily detains, searches or arrests any person.
- Vexatiously and unnecessarily seizes the moveable property of any person on pretence of seizing or searching for any article liable to confiscation under this act.
- Commits, as such officer, any other act to the injury of any person, without having reason to believe that such act is required for the execution of his duty, shall, for every such offence, be punishable with fine which may extend to 200 rupees.

Any person willfully and maliciously giving false information and so causing an arrest or a search to be made under this Act shall be punishable with imprisonment for a term which may extend to two years, or with fine which may extend to 2000 rupees, or both.

E. Failure of excise officers on duty: Any excise officer who ceases or refuses to perform, or withdraws himself from the duties of his office, unless he had obtained the express written permission of his superior officer or has given such superior officer 2 month's notice in writing of his intention or has other lawful excuse, shall be punishable with imprisonment for a term which may extend to 3 months, or with fine which may extend to 3 months pay, or both.

F. Bar of suits: No suit or other legal proceeding shall lie against the collecting Government or against any officer in respect of any order passed in good faith or any act in good faith done or ordered to be done under this Act. No suit, prosecution or other legal proceeding shall be instituted against the collecting Government or against any officer for anything done or ordered to be done under this Act after the expiration of 6 months from the accrual of the cause of action or from the date of the act or order complained of.

G. Repeals and savings: If, immediately before the commencement of this act, there is in force in any State any law corresponding to this Act, that law is hereby repealed. Provided that all rules made, notifications issued, licenses or

permits granted, powers conferred under any law hereby repealed shall, so far as they are not inconsistent with this Act, have the same force and effect as if they had been respectively made, issued, granted or conferred under this Act and by the authority empowered hereby in that behalf.

OFFENCES AND PENALTIES

The following punishments are given for various offences under this Act:

1. **Failure to observe conditions of a license or to pay excise duty:** A person, who fails to observe any conditions of the license granted to him or fails to pay the excise duty, shall be liable to punishment with imprisonment up to 6 months or to fine up to 2,000 rupees or both.
2. **False information:** Any person who willfully gives the false information which leads to the arrest of person or to search any premises shall be liable to punishment with imprisonment up to 2 years or to fine up to 2,000 rupees or both.
3. **Disorderly keeping of stocks and accounts:** Any person, who is not maintaining stocks and accounts in the proper manner, shall be liable to fine up to ₹ 2,000.
4. **Offences with respect to warehousing:** An owner or any one of his employee, who commits any one of the following offences, shall be liable to a fine up to ₹ 2,000.
 - a. Opens any lock or door in the absence of Excise officer.
 - b. Make any alteration in the warehouse without previous consent of the Excise Commissioner.
 - c. Removes goods in contravention of the Rules.
5. **Obstruction to officers:** An owner or any person, who willfully obstructed the duties of Excise officer shall be liable to a fine up to ₹ 5,000.
6. **General penalty:** Breach of any of the Rules made under this Act (where no penalty is

provided for such breach) shall be punishable with a fine up to ₹ 1000.

7. **Failure of excise officer to do duty:** Any Excise officer who fails to do his duty or refuses to obey the order of his superiors, shall be liable to imprisonment up to 3 months or a fine up to 3 months salary or both.
8. **Disclosure of information by Excise Officer:** Any officer, who discloses any official information, shall be liable to a fine up to ₹ 1,000.

MISCELLANEOUS

A. **Excise Commissioner may require a fresh declaration:** If the Excise Commissioner at any time requires a new declaration to be made in any case, he shall cause a written notice, addressed to the person who signed the existing declaration, to be delivered. At the declared premises, and at the expiration of fourteen days from the delivery of the notice the existing declaration shall, without prejudice to any liability incurred, be void and the license granted to the owner in respect of the premises shall be suspended.

B. **Stocks of dutiable goods to be stored in an orderly manner:** The Excise Commissioner may also require the licensed person or keeper of the warehouse, to maintain stock cards in respect of the separate lots and to leave an accessible passage free of packages in the middle of the warehouse or other place of storage and a similar passage along the walls of such warehouse or other place of storage at right angles to the aforesaid passage, so as to facilitate counting, and may require that each separate lot or consignment shall be clearly marked with the number and date of the document under which the goods were admitted to the place of storage, the number of the relevant record in stock card, account or warehouse register and such other identifying particulars as he may direct. Breach of this shall be punishable with a penalty which may extend to ₹ 1,000.

C. Account of stock of goods in a manufactory or ware house to be taken and balance to be struck: As often as the Excise Commissioner may deem it necessary or proper, and at least once in every year, the stock of dutiable goods remaining in a manufactory or warehouse or store-room licensed or approved for the storage of such goods shall be counted, weighed, measured, proved, gauged or otherwise ascertained in the presence of the proper officer or the officer-in-charge, as the case may be, and if the quantity so ascertained is less than the quantity which ought to be found in such premises, the owner of such goods shall, unless the deficiency be accounted for to the satisfaction of such officer, be liable to pay the duty leviable on such deficiency; and shall also be liable to a penalty which may extend to ten times the duty chargeable on such goods as are found deficient or a sum of ₹ 2,000 whichever is less.

D. Restriction of removal of goods: Dutiable goods shall not be delivered from a bonded manufactory or a bonded warehouse licensed under these rules before six o'clock in the forenoon or after six o'clock in the afternoon, nor at any hour on Sundays and closed holidays, except with the permission of the Excise Commissioner and under such conditions, as the Commissioner may, by general or special order, direct.

E. Registers and stock accounts: How registers and stock accounts to be maintained:

1. Where any person is required by these rules to maintain any register or a stock account in respect of goods manufactured or stored by him, he shall:
 - i. At the time of making any entry, insert the date when the entry is made.
 - ii. Correctly keep such account or register in the manner required and shall not cancel, obliterate, or alter any entry therein, except for correction of any errors, with the sanction and in the presence of the proper officer or the officer-in-charge, as the case may be,

and shall not make any entry therein which is untrue in any particulars.

- iii. Keep the account or register all time ready for the inspection of the Excise Officers, and shall permit any such officer to inspect it and make any such minute therein or any extract there from, as the officer thinks fit, and shall, at any time, if demanded, send that minute or extract to that officer.
2. Any person who fails to enter the required particulars within the time prescribed in the relevant rules, or who fails to keep such account or register, as the case may be, or to deliver it up to the Excise Officer on demand or who obstructs or hinders such officer in making any minute therein or extract there from, or conveys away or conceals it, or destroys or tears out any leaf there from, or makes any false entry therein or fraudulently alters any entry therein, shall be liable to a penalty which may extend to 2,000 rupees and all the goods of which due entry has not been made in such account or register shall be liable to confiscation.

F. Provision and maintenance of weighing and measuring apparatus: The weights, measures, and gauging and proving instruments shall be of the denominations as may be specified by the Excise Commissioner by general or special order. The licensed dealer shall maintain and keep the scales, weights, measures, and gauging and proving instruments in such proper and convenient place in his manufactory, warehouse, or other premises as the proper officer or the officer-in-charge approves, so that they shall be at all times ready for the use of officers. The dealer shall permit every officer to the scales, weights, measures and gauging and proving instruments for the purpose aforesaid and shall, with his servants and workmen whenever required by such officer, weigh or measure, or assist him in weighing, measuring and gauging, as he requires, and in taking account of any such goods in his warehouse. For

any refusal or neglect on the part of a licensee to comply with any of the provisions of this rule, he shall be liable to a penalty which may extend to one thousand rupees (1,000 rupees).

G. Provision and maintenance of locks: Where any warehouse, room, place, vessel, or fitting belonging to any person licensed to deal in dutiable goods is by these rules, or by any general or special order of the Excise Commissioner, directed to be secured or locked, the licensee shall, to the satisfaction of the proper officer-in-charge, as the case may be, provide, affix, repair and renew all fastenings requisite for the purpose of enabling officers to affix locks thereto or otherwise to secure them. If the licensee or warehouse-keeper fails so to do, the proper officer may provide, affix, repair or renew the fastenings, and the expense thereof shall be paid on demand by the licensee or warehouse-keeper, as the case may be. All requisite excise ticket or keys shall be provided by the collecting Government. If any licensee

or warehouse-keeper fails on demand to pay the expenses of providing, affixing, repairing or renewing, fastenings or if any licensee or warehouse-keeper, or his servant or workman, wilfully destroys or damages any such fastening, or any lock-lable, or improperly obtains access into any warehouse, room, place, vessel or fitting, or has any fastening vessel or fitting so constructed, that the security intended to be obtained by any lock or fastening may be defeated, the licensee or warehouse keeper shall be liable to a penalty which may extend to 2,000 rupees.

H. Goods, plant and machinery chargeable with duty not paid: Any officer duly authorized by general or special order of the Excise Commissioner may detain such goods, materials, preparations, plant, machinery, vessels, utensils, and articles until such duties or any sums recoverable in lieu thereof are paid or recovered, and such direction shall have effect notwithstanding any change in the ownership of the trade or business.

The Narcotic Drugs and Psychotropic Substances Act, 1985 and Rules

INTRODUCTION

All systems of medicine are based on natural drugs but a large number of synthetic drugs have found their way in the allopathic or the modern system of medicine. Amongst the drugs obtained from natural sources, the vegetable drugs have been most valuable ones and are known to the mankind since the history of cultivation. Cocoa, opium and hemp though excellent drugs are habit forming substances and as such their unrestricted use are dangerous from the social point of view. Because of this, Government of different countries though it fit to impose restriction of their use to bona fide medical purposes only. Prior to the passage of the Narcotic Drugs and Psychotropic Substances Act, 1985, the statutory control over Narcotics Drug in India was mainly exercised through a number of Central and State enactment namely the Opium Act, 1857, the Opium Act, 1878 and the Dangerous Drug Act, 1930.

With the passage of time and the developments in the field of illicit drugs traffic and drug abuse at national and international level, many deficiencies in the existing laws became evident. These are the followings:

- The scheme of penalties under the present Act was not sufficiently deterrent to meet the challenge of well-organized gangs of smugglers. The Dangerous Drug Act, 1930 provided for a maximum term of imprisonment of 4 years with no maximum punishment being prescribed. This resulted in the letting off of drug traffickers with nominal punishment.

- The existing central laws did not provide the officers of a number of important agencies like Narcotics, Customs, and Central Excise, etc. with the power of investigation of offences.

- Since the enactment of the above laws, a vast body of international law in the field of narcotics had evolved through various international treaties and protocol to which the Government of India was a party. Hence it was obligatory on the part of the Government to update its laws.

- During recent years, new drugs of addition (psychotropic drugs) had appeared on the scene and posed serious problems to the government. Hence, there was a need to frame a suitable act in order to control over such substances.

Hence, the Narcotic Drugs and Psychotropic Substances Act, 1985 has been passed to consolidate and amend the law relating to narcotic drugs, to make stringent provisions for the control and regulation of operations relating to narcotic drugs and psychotropic substances to provide for the forfeiture of property derived from, or used in, illicit traffic in narcotic drugs and psychotropic substances, to implement the provisions of the International Conventions on Narcotic Drugs and Psychotropic Substances and for matters connected therewith.

The Act and Rules extend to the whole of India. It shall come into force on 14th November, 1985 and different dates may be appointed for different provisions of this act and for different States and any reference in any such provision to the commencement of this Act shall be construed in relation to any State as a reference to the coming into force of that provision in that State.

Salient Features of the NDPS Act, 1985

Basic features of The Narcotic Drugs and Psychotropic Substances Act, 1985.

The NDPS Act, 1985 sets out the statutory framework for drug law enforcement in India. The main elements of the control regime mandated by the Act are as follows:

- a. The cultivation, production, manufacture, possession, sale, purchase, transportation, warehousing, consumption, inter-State movement, transhipment and import and export of narcotic drugs and psychotropic substances is prohibited, except for medical or scientific purposes and in accordance with the terms and conditions of any license, permit or authorization given by the Government.
- b. The Central Government is empowered to regulate the cultivation production, manufacture, import, export, sale, consumption, use, etc. of narcotic drugs and psychotropic substances.
- c. State Governments are empowered to permit and regulate possession and inter-State movement of opium, poppy straw, the manufacture of medicinal opium and the cultivation of cannabis excluding hashish (Section 10).
- d. All persons in India are prohibited from engaging in or controlling any trade whereby narcotic drugs or psychotropic substances are obtained outside India and supplied to any person outside India except with the previous authorization of the Central Government and subject to such

conditions as may be imposed by the Central Government.

- e. The Central Government is empowered to declare any substance, based on an assessment of its likely use in the manufacture of narcotics drugs and psychotropic substances as a controlled substance.
- f. Assets derived from drugs trafficking are liable to forfeiture (Chapter V-A).
- g. Both the Central Government and State Governments are empowered to appoint officers for the purposes of the Act.

The NDPS Act is in effect, a comprehensive code not only for the control and regulation of narcotic drugs and psychotropic substances but also for the control of selected chemicals—commonly known as precursors, which can be used in the illicit manufacture of narcotic drugs and psychotropic substances, as well as for the investigation and forfeiture of drug related assets.

Objectives

The main objectives of The Narcotic Drugs and Psychotropic Substances Act, 1985 are as follows:

- To consolidate and amend the existing laws relating to narcotic drugs.
- To make stringent provisions for the control and regulation of operations relating to narcotic drugs and psychotropic substances.
- To considerably enhance the penalties particularly for trafficking offences.
- To make provisions for the implementations of International conventions relating to narcotic drugs and psychotropic substances to which India is a party.

DEFINITIONS

1. “Addict” means a person addicted to any narcotic drug or psychotropic substance.
2. “Board” means the Central Board of Excise and Customs constituted under the Central Boards of Revenue Act, 1963.

3. "**Cannabis (hemp)**" means:
- Charas, that is, the separated resin, in whatever form, whether crude or purified, obtained from the cannabis plant and also includes concentrated preparation and resin known as hashish oil or liquid hashish.
 - Ganja, that is, the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops), by whatever name they may be known or designated.
 - Any mixture, with or without any neutral material, of any of the above forms of cannabis or any drink prepared therefrom.
4. "**Cannabis Plant**" means any plant of the genus cannabis.
5. "**Coca Derivative**" means:
- Crude cocaine, that is, any extract of coca leaf which can be used, directly or indirectly, for the manufacture of cocaine.
 - Egonine and all the derivatives of egonine from which it can be recovered.
 - Cocaine, that is, methyl ester of benzoyl-egonine and its salts.
 - All preparations containing more than 0.1% of cocaine.
6. "**Coca Leaf**" means:
- The leaf of the coca plant except a leaf from which all egonine, cocaine and any other egonine alkaloids have been removed.
 - Any mixture thereof with or without any neutral material, out does not include any preparation containing not more than 0.1% of cocaine.
7. "**Coca Plant**" means the plant of any species of the genus *Frythroxylon*.
8. "**Controlled Substance**" means any substance which the Central Government may, having regard to the available information as to its possible use in the production or manufacture of narcotic drugs or psychotropic substances or to the provisions of any International Convention, by notification in the Official Gazette, declare to be a controlled substance.
9. "**Conveyance**" means a conveyance of any description whatsoever and includes any aircraft, vehicle or vessel.
10. "**Illicit Traffic**", in relation to narcotic drugs and psychotropic substances, means:
- Cultivating any coca plant or gathering any portion of coca plant.
 - Cultivating the opium poppy or any cannabis plant.
 - Engaging in the production, manufacture, possession, sale, purchase, transportation, warehousing, concealment, use or consumption, import inter-state, export inter-state, import into India, export from India or transhipment, of narcotic drugs or psychotropic substances.
 - Dealing in any activities in narcotic drugs or psychotropic substances other than those referred to in sub-clauses (a) to (b).
 - Handling or letting out any premises for the carrying on of any of the activities referred to in sub-clauses (a) to (d), other than those permitted under this Act, or any Rule or order made, or any condition of any license, term or authorization issued, thereunder, and includes:
 - Financing, directly or indirectly, any of the aforementioned activities.
 - Abetting or conspiring in the furtherance of or in support of doing any of the aforementioned activities.
 - Harboiring persons engaged in any of the aforementioned activities.

In the context of 'illicit traffic' in relation to narcotic drugs and psychotropic substances the Central Government has specified the "small quantity" of the following drugs: Heroin or brown Sugar of Smack (250 mg), Hahish or

Charas (5 g) Opium (% g), Cocain (125 mg), Ganja (500 g).

11. "International Convention" means:

- a. The Single Convention on Narcotic Drugs, 1961 adopted by the United Nations Conference at New York in March, 1961.
 - b. The Protocol, amending the convention mentioned in sub-clause (a), adopted by the United Nations Conference at Geneva in March, 1972.
 - c. The Convention on Psychotropic Substances, 1971 adopted by the United Nations Conference at Vienna in February, 1971.
 - d. Any other international convention, or protocol or other instrument amending an international convention, relating to narcotic drugs or psychotropic substances which may be ratified or acceded to by India after the commencement of this Act.
- 12. 'Commercial Quantity'**, in relation to Narcotic Drugs and Psychotropic substances means any quantity specified by the Central Government by notification in Official Gazette.
- 13. 'Controlled Substance'** means any substance which the Central Government may, having regard to the available information as to its possible use in the production or manufacture of narcotic drugs or psychotropic substances or to the provisions of any International Convention, by notification in the official gazette, declare to be controlled substances.
- 14. 'Small Quantity'** in relation to the Narcotic Drugs and Psychotropic Substances means any quantity specified by the Central Government.
- 15. "Manufacture"**, in relation to Narcotic Drugs or Psychotropic Substances, includes:
- a. All processes other than production by which such drugs or substances may be obtained.

- b. Refining of such drugs or substances.
- c. Transformation of such drugs or substances.

- d. Making of preparation (otherwise than in a pharmacy on prescription) with or containing such drugs or substances.

16. "Manufactured Drug" means:

- a. All coca derivatives, medicinal cannabis, opium derivatives and poppy straw concentrate.
- b. Any other narcotic substance or preparation which the Central Government may, having regard to the available information as to its nature or to a decision, if any, under any International Convention, by notification in the Official Gazette, declare not to be a manufactured drug.

17. "Medicinal Cannabis", that is, medicinal hemp, means any extract or tincture of cannabis (hemp).

18. "Narcotics Commissioner" means the Narcotics Commissioner appointed under Section 5.

19. "Narcotic Drug" means coca leaf, cannabis (hemp), opium, poppy straw and includes all manufactured drugs.

20. "Opium" means:

- a. The coagulated juice of the opium poppy.
- b. Any mixture, with or without any neutral material, of the coagulated juice of the opium poppy, but does not include any preparation containing not more than 0.2% of morphine.

21. "Opium Derivative" means:

- a. Medicinal opium, that is, opium which has undergone the processes necessary to adapt it for medicinal use in accordance with the requirements of the Indian Pharmacopoeia or any other pharmacopoeia notified in this behalf by the Central Government, whether in powder form or granulated or otherwise or mixed with neutral materials.

- b. Prepared opium, that is, any product of opium obtained by any series of operations designed to transform opium into an extract suitable for smoking and the dross or other residue remaining after opium is smoked.
- c. Phenanthrene alkaloids, namely, morphine, codeine, thebaine and their salts.
- d. Diacetylmorphine, that is, the alkaloid also known as dia-morphine or heroin and its salts.
- e. All preparations containing more than 0.2% of morphine or containing any diacetylmorphine.
- 22. **"Opium Poppy"** means:
 - a. The plant of the species *Papaver somniferum* L.
 - b. The plant of any other species of *Papaver* from which opium or any phenanthrene alkaloid can be extracted and which the Central Government may, by notification in the Official Gazette, declare to be opium poppy for the purposes of this Act.
- 23. **"Poppy Straw"** means all parts (except the seeds) of the opium poppy after harvesting whether in their original form or cut, crushed or powdered and whether or not juice has been extracted therefrom.
- 24. **"Poppy Straw Concentrate"** means the material arising when poppy straw has entered into a process for the concentration of its alkaloids.
- 25. **"Preparation"**, in relation to a narcotic drug or psychotropic substance, means any one or more such drugs or substances in dosage form or any solution or mixture, in whatever physical state, containing one or more such drugs or substances.
- 26. **"Crop Year"** means the period beginning on the 1st October of any year to the 30th September of the following year.
- 27. **"Production"** means separation of opium, poppy straw, coca leaves or cannabis from the plants from which they are obtained.
- 28. **"Psychotropic Substance"** means any substance, natural or synthetic, or any natural material or any salt or preparation of such substance or material included in the list of psychotropic substances specified in the schedule.
- 29. **"To Import Inter-State"** means to bring into a State or Union territory in India from another State or Union territory in India.
- 30. **"To Import into India"**, with its grammatical variations and cognate expressions, means to bring into India from a place outside India and includes the bringing into any port or airport or place in India of a narcotic drug or a psychotropic substance intended to be taken out of India without being removed from the vessel, aircraft, vehicle or any other conveyance in which it is being carried.
- 31. **"To Export from India"**, with its grammatical variations and cognate expressions, means to take out of India to a place outside India.
- 32. **"To Export Inter-State"** means to take out of a State or Union territory in India to another State or Union territory in India.
- 33. **"To Transport"** means to take from one place to another within the same State or Union territory.
- 34. **"Use"** in relation to narcotic drugs and psychotropic substances, means any kind of use except personal consumption.
- 35. Words and expressions used herein and not defined but defined in the Code of Criminal Procedure, 1973 have the meanings respectively assigned to them in that Code.

AUTHORITIES AND OFFICERS

A. Measures by Central Government:

1. The Central Government shall take all such measures for the purpose of preventing and combating abuse of narcotic drugs and psychotropic substances and the illicit traffic therein.

2. The measures which the Central Government may take under above sub-section include measures with respect to all or any of the following matters, namely:
 - a. Coordination of actions by various officers, State Governments and other authorities under this act, or under any other law for the time being in force in connection with the enforcement of the provisions of this act.
 - b. Obligations under the International Conventions.
 - c. Assistance to the concerned authorities in foreign countries and concerned international organizations with a view to facilitating coordination and universal action for prevention and suppression of illicit traffic in narcotic drugs and psychotropic substances.
 - d. Identification, treatment, education, after-care, rehabilitation and social re-integration of addicts.
 - e. Such other matters as the Central Government deems necessary or expedient for the purpose of securing the effective implementation of the provisions of this Act and preventing and combating the abuse of narcotic drugs and psychotropic substances and illicit traffic therein.
3. The Central Government may, if it considers it necessary or expedient so to do for the purposes of this Act, by order, published in the Official Gazette, constitute an authority or a hierarchy of authorities by such name or names as may be specified in the order for the purpose of exercising such of the powers and functions of the Central Government under this Act and for taking measures with respect to such of the matters as may be mentioned in the order, and subject to the supervision and control of the Central Government and the provisions of such order, such authority or authorities may exercise the powers and take the measures so mentioned in the order as if

such authority or authorities had been empowered by this Act to exercise those powers and take such measures.

B. Officers of Central Government: The Central Government shall appoint a Narcotics Commissioner and may also appoint such other officers with such designations as it thinks fit for the purposes of this Act. The Narcotics Commissioner shall, either by himself or through officers subordinate to him, exercise all powers and perform all functions relating to the superintendence of the cultivation of the opium poppy and production of opium and shall also exercise and perform such other powers and functions as may be entrusted to him by the Central Government. The officers appointed shall be subject to the general control and direction of the Central Government, or, if so directed by that Government, also of the Board or any other authority or officer.

C. Power of Central Government to add to or omit from the list of psychotropic substances: The Central Government may, if satisfied that it is necessary or expedient so to do on the basis of:

- a. The information and evidence which has become available to it with respect to the nature and effects of, and the abuse or the scope for abuse of, any substance (natural or synthetic) or natural material or any salt or preparation of such substance or material.
- b. The modifications or provisions (if any) which have been made to, or in, any International Convention with respect to such substance, natural material or salt or preparation of such substance or material, by notification in the Official Gazette, add to, or, as the case may be, omit from, the list of psychotropic substances specified in the Schedule such substance or natural material or salt or preparation of such substance or material.

D. The Narcotic Drugs and Psychotropic Substances Consultative Committee:

1. The Central Government may constitute, by notification in the Official Gazette, an

advisory committee to be called "the narcotic drugs and psychotropic substances Consultative Committee" to advise the Central Government on such matters relating to the administration of this act as are referred to it by that Government from time to time.

2. The Committee shall consist of a Chairman and such other members, not exceeding twenty, as may be appointed by the Central Government.
3. The Committee shall meet when required to do so by the Central Government and shall have power to regulate its own procedure.
4. The Committee may, if it deems it necessary so to do for the efficient discharge of any of its functions, constitute one or more sub-committees and may appoint to any such sub-committee, whether generally or for the consideration of any particular matter, any person (including a non-official) who is not a member of the Committee.
5. The term of office of, the manner of filling casual vacancies in the offices of and the allowances, if any, payable to, the Chairman and other members of the Committee, and the conditions and restrictions subject to which the Committee may appoint a person who is not a member of the Committee as a member of any of its sub-committees, shall be such as may be prescribed by rules made by the Central Government.

E. Narcotics Commissioner: The Narcotics Commissioner and such other officer as may be appointed by the Central Government under Act to supervise cultivation of opium poppy and production of opium and to implement various other provisions. The State Government may appoint suitably designated officers deemed necessary to implement the provisions of the Act in their territories.

F. National fund for control of drug abuse:

1. The Central Government may, by notification in the official Gazette, constitute a

fund to be called the National Fund for control of drug abuse (hereafter in this chapter referred to as the fund) and there shall be credited thereto:

- a. An amount which the Central Government may, after due appropriation made by Parliament by law in this behalf, provide.
- b. The sale proceeds of any property.
- c. Any grants that may be made by any person or institution.
- d. Any income from investment of the amounts credited to the Fund under the aforesaid provisions.
2. The Fund shall be applied by the Central Government to meet the expenditure incurred in connection with the measures taken for combating illicit traffic in, or controlling abuse of, narcotic drugs and psychotropic substances for all.
3. The Central Government may constitute a Governing body as it thinks fit to advise that Government in regard to the application of the fund.
4. The Governing Body shall consist of a Chairman (not below the rank of an additional secretary to the Central Government) and such other members not exceeding six as the Central Government may appoint.
5. The Governing body shall have the power to regulate its own procedure.

The Central Government shall, as soon as may be, after the end of each financial year, cause to be published in the Official Gazette, a report giving an account of the activities financed during the financial year, together with a statement of accounts.

G. Officers of State Government:

1. The State Government may appoint such officers with such designations as it thinks fit for the purposes of this act.
2. The officers appointed shall be subject to the general control and direction of the State Government, or, if so directed by that Government, also of any other authority or officer.

PROHIBITION, CONTROL AND REGULATION

The Government prohibits the various operations such as cultivation, manufacture, possession, sale, purchase, transport, import, export, etc. in relation to all the narcotic drugs and psychotropic substances except for scientific purposes.

A. Prohibition of certain operations/operations totally prohibited:

1. No person shall:
 - a. Cultivate any coca plant or gather any portion of coca plant.
 - b. Cultivate the opium poppy or any cannabis plant.
 - c. Produce, manufacture, possess, sell, purchase, transport, warehouse, use, consume, import inter-state, export inter-state, import into India, export from India or tranship any narcotic drug or psychotropic substance, except for medical or scientific purposes and in the manner and to the extent provided by the provisions of this Act or the Rules or orders made thereunder and in a case where any such provision, imposes any requirement by way of license, permit or authorization also in accordance with the terms and conditions of such license, permit or authorization.
 2. The prohibition against the cultivation of the cannabis plant for the production of ganja or the production, possession, use, consumption, purchase, sale, transport, warehousing, import inter-state and export inter-state of ganja for any purpose other than medical and scientific purpose shall take effect only from the date which the Central Government may, by notification in the Official Gazette, specify in this behalf. Nothing in this section shall apply to the export of poppy straw for decorative purposes.
- B. Power of Central Government to permit, control and regulate:**
1. The Central Government may, by rules: Permit and regulate:
 - i. The cultivation, or gathering of any portion (such cultivation or gathering being only on account of the Central Government) of coca plant, or the production, possession, sale, purchase, transport, import inter-state, export inter-state, use or consumption of coca leaves.
 - ii. The cultivation (such cultivation being only on account of Central Government) of the opium poppy.
 - iii. The production and manufacture of opium and production of poppy straw.
 - iv. The sale of opium and opium derivatives from the Central Government factories for export from India or sale to State Government or to manufacturing chemists.
 - v. The manufacture of manufactured drugs (other than prepared opium) but not including manufacture of medicinal opium or any preparation containing any manufactured drug from materials which the maker is lawfully entitled to possess.
 - vi. The manufacture, possession, transport, import inter-state, export inter-state, sale, purchase, consumption or use of psychotropic substances.
 - vii. The import into India and export from India and transhipment of narcotic drugs and psychotropic substances.
 2. In particular and without prejudice to the generality of the foregoing power, such rules may:
 - i. Empower the Central Government to fix from time to time the limits within which licenses may be given for the cultivation of the opium poppy.
 - ii. Require that all opium, the produce of land cultivated with the opium poppy, shall be delivered by the cultivators to the officers authorised in this behalf by the Central Government.
 - iii. Prescribe the forms and conditions of licenses for cultivation of the opium

- poppy and for production and manufacture of opium; the fees that may be charged therefore, the authorities by which such licenses may be granted, withheld, refused or cancelled and the authorities before which appeals against the orders of withholding, refusal or cancellation of licenses shall lie.
- iv. Prescribe that opium shall be weighed, examined and classified according to its quality and consistence by the officers authorised in this behalf by the Central Government in the presence of the cultivator at the time of delivery by the cultivator.
 - v. Empower the Central Government to fix from time to time the price to be paid to the cultivators for the opium delivered.
 - vi. Provide for the weighment, examination and classification, according to the quality and consistence, of the opium received at the factory and the deductions from or additions (if any) to the standard price to be made in accordance with the result of such examination and the authorities by which the decisions with regard to the weighment, examination, classification, deductions or additions shall be made and the authorities before which appeals against such decisions shall lie.
 - vii. Require that opium delivered by a cultivator, if found as a result of examination in the Central Government factory to be adulterated, may be confiscated by the officers authorised in this behalf.
 - viii. Prescribe the forms and conditions of licenses for the manufacture of manufactured drugs, the authorities by which such licenses may be granted and the fees that may be charged therefore.
 - ix. Prescribe the forms and conditions of licenses or permits for the manufacture, possession, transport, import inter-State, export inter-State, sale, purchase, consumption or use of psychotropic substances, the authorities by which such licenses or permits may be granted and the fees that may be charged therefore.
 - x. Prescribe the ports and other places at which any kind of narcotic drugs or psychotropic substances may be imported into India or exported from India or transhipped; the forms and conditions of certificates, authorizations or permits, as the case may be, for such import, export or transhipment; the authorities by which such certificates, authorizations or permits may be granted and the fees that may be charged therefor.
- C. Power to control and regulate controlled substances:** If the Central Government is of the opinion that, having regard to the use of any controlled substance in the production or manufacture of any narcotic drug or psychotropic substance, it is necessary or expedient so to do in the public interest, it may, by order, provide for regulating or prohibiting the production, manufacture, supply and distribution thereof and trade and commerce therein. An order made thereunder may provide for regulating by licenses, permits or otherwise, the production, manufacture, possession, transport, imports inter-State, export inter-State, sale, purchase, consumption, use, storage, distribution, disposal or acquisition of any controlled substance.
- D. Power of State Government to permit, control and regulate/operations controlled by the State Government:**
- 1. Subject to the provisions of this act, the State Government may, by rules: Permit and regulate:
 - i. The possession, transport, import inter-State, export inter-State, warehousing, sale, purchase, consumption and use of poppy straw.
 - ii. The possession, transport, import inter-State, export inter-State, sale, purchase, consumption and use of opium.

- iii. The cultivation of any cannabis plant, production, manufacture, possession, transport, import inter-State, export inter-State, sale, purchase, consumption or use of cannabis (excluding charas).
- iv. The manufacture of medicinal opium or any preparation containing any manufactured drug from materials which the maker is lawfully entitled to possess.
- v. The possession, transport, purchase, sale, import inter-State, export inter-State, use or consumption of manufactured drugs other than prepared opium and of coca leaf and any preparation containing any manufactured drug.
- vi. The manufacture and possession of prepared opium from opium lawfully possessed by an addict registered with the State Government on medical advice for his personal consumption.

Provided that save in so far as may be expressly provided in the rules shall apply to the import inter-State, export inter-State, transport, possession, purchase, sale, use or consumption of manufactured drugs which are the property and in the possession of the Government. Provided further that such drugs as are referred to in the preceding provision shall not be sold or otherwise delivered to any person who, under the rules made by the State Government under the aforesaid sub-clauses, is not entitled to their possession.

2. In particular and without prejudice to the generality of the foregoing power, such rules may:
 - i. Empower the State Government to declare any place to be a warehouse wherein it shall be the duty of the owners to deposit all such poppy straw as is legally imported inter-State and is intended for export inter-State or export from India; to regulate the safe custody of such poppy straw warehoused and the removal of such poppy straw for sale or export inter-State or export from

- India; to levy fees for such warehousing and to prescribe the manner in which and the period after which the poppy straw warehoused shall be disposed of in default of payment of fees.
- ii. Provide that the limits within which licenses may be given for the cultivation of any cannabis plant shall be fixed from time to time by or under the orders of the State Government.
- iii. Provide that only the cultivators licensed by the prescribed authority of the State Government shall be authorised to engage in cultivation of any cannabis plant.
- iv. Require that all cannabis, the produce of land cultivated with cannabis plant, shall be delivered by the cultivators to the officers of the State Government authorised in this behalf.
- v. Empower the State Government to fix from time to time, the price to be paid to the cultivators for the cannabis delivered.
- vi. Prescribe the forms and conditions of licenses or permits for the purposes specified in this act and the authorities by which such licenses or permits may be granted and the fees that may be charged therefore.

Factories: The manufacture of opium is done by the Central Government at two Government factories at:

1. Neemuch In Madhya Pradesh, near Udaipur.
2. Ghazipur in Uttar Pradesh, near Varanasi.

The State Governments are allowed only to manufacture the damaged or confiscated opium and remodel it.

E. Special provisions relating to coca plant and coca leaves for use in the preparation of flavouring agent: The Central Government may permit, with or without conditions, and on behalf of Government, the cultivation of any coca plant or gathering of any portion thereof or the production, possession, sale, purchase, transport, import inter-State, export inter-State

or import into India of coca leaves for use in the preparation of any flavouring agent which shall not contain any alkaloid and to the extent necessary for such use.

F. Special provision relating to cannabis: The Government may, by general or special order and subject to such conditions as may be specified in such order, allow cultivation of any cannabis plant for industrial purposes only of obtaining fibre or seed or for horticultural purposes.

G. Restrictions over external dealings in narcotic drugs and psychotropic substances: No person shall engage in or control any trade whereby a narcotic drug or psychotropic substance is obtained outside India and supplied to any person outside India save with the previous authorization of the Central Government and subject to such conditions as may be imposed by that Government in this behalf.

OFFENCES AND PENALTIES

The Narcotic Drugs and Psychotropic Substances Act has considerably enhanced the punishment for offences in connection with narcotic drugs and psychotropic substances. On the basis of punishment, the offences can be categorized as follows:

1. Offences punishable with rigorous imprisonment for 10–20 years and a fine of not less than 1,00,000 rupees on first conviction and with rigorous imprisonment for 15–30 years and a fine of not less than 2,00,000 rupees on second and subsequent conviction:

- i. Contravention of provisions of the Act or Rules in relation to poppy straw, coca plant and coca leaves, prepared opium, opium poppy and opium, manufactured drugs and psychotropic substances.
- ii. Embezzlement of opium by cultivator.
- iii. Contravention in relation to cannabis plant and cannabis other than ganja.
- iv. Illegal import into India, export from India or transhipment of narcotic drugs and psychotropic substances.

- v. External dealing in narcotic drugs and psychotropic substances.
- vi. Allowing use of premises, conveyance, etc. for commission of an offence under the act.
- vii. Financing illicit traffic harbouring offenders.

2. Death penalty for certain offences after previous conviction:

- i. If any person who has been convicted of the commission of, or attempt to commit, or abetment of, or criminal conspiracy to commit, any of the offences listed above is subsequently convicted of similar offence relating to:
 - a. Engaging in the production, manufacture, possession, transportation, import into India, export from India or transhipment, of the narcotic drugs or psychotropic substances specified under column (1) of Table 4.1 and involving the quantity which is equal to or more than the quantity indicated against each such drug or substance, as specified in column (2) of the said Table.
 - b. Financing, directly or indirectly, any of the activities specified in clause (a), shall be punishable with death.
- ii. Where any person is convicted by a competent court of criminal jurisdiction outside India under any law in respect of such conviction, shall be dealt with for the purposes of sub-section (i) as if he had been convicted by a court in India."
3. **Offences punishable with rigorous imprisonment up to 5 years and shall also be liable to fine which may extend to fifty thousand rupees (50,000 rupees) on first conviction and with rigorous imprisonment up to 10 years and fine up to one lakh rupees (1,00,000 rupees) on second and subsequent conviction:** Contravention of provisions of the act or rules relates to ganja or the cultivation of cannabis plant.
4. **Offences by licensee and his servant punishable with imprisonment up to 5 years and fine or both:** If the holder of any license permit or

Table 4.1

<i>Particulars of Narcotic Drugs/ Psychotropic Substances</i>	<i>Quantity</i>
(1)	(2)
i. Opium	10 kg.
ii. Morphine	1 kg.
iii. Heroin	1 kg.
iv. Codeine	1 kg.
v. Thebaine	1 kg.
vi. Cocaine	500 gram
vii. Hashish	20 kg.
viii. Any mixture with or without any neutral material of any of the above drugs	1,500 gram
ix. LSD, LSD-25 () - N, N-Diethyllysergamide (d-lysergic acid diethylamide)	500 gram
x. THC (Tetrahydrocannabinols, the following isomers and their stereo chemical variants)	500 gram
xi. Methamphetamine ()-2-amino-1 -Phenyl propane	1,500 gram
xii. Methaqualone (2-Methyl-3-o-tolyl-4-(3H) - quinazolinone)	1,500 gram
xiii. Amphetamine ()-2-amino -1-phenylpropane	1,500 gram
xiv. Salts and preparations of the psychotropic substances mentioned in (ix) to (xiii)	1,500 gram

authorization granted under this Act or any Rule or order made thereunder or any person in his employ and acting on his behalf:

- a. Omits, without any reasonable cause, to maintain accounts or to submit any return in accordance with the provisions of this Act, or any rule made thereunder.
- b. Fails to produce without any reasonable cause such license, permit or authorization on demand of any officer authorised by the Central Government or State Government in this behalf.
- c. Keeps any accounts or makes any statement which is false or which he knows or has reason to believe to be incorrect.
- d. Wilfully and knowingly does any act in breach of any of the conditions of license,

permit or authorization for which a penalty is not prescribed elsewhere in this act.

5. **Offences punishable with imprisonment up to 1 year or fine or both:** Illegal possession in small quantity for personal consumption or consumption of cocaine, morphine, diacetylmorphine or any other narcotic drug or psychotropic substance specified in this behalf.

6. **Offences punishable with imprisonment up to 6 months or fine or both:**

- i. Illegal possession in small quantity for personal consumption or consumption of substances other than those mentioned above.
- ii. Offences for which no penalty is provided separately in the act.

7. Punishment for attempts to commit offences: Whoever attempts to commit any offence punishable under this Act or to cause such offence to be committed and in such attempt does any act towards the commission of the offence shall be punishable with the punishment provided for the offence.

8. Punishment for abetment and criminal conspiracy: Same as that commitment of the offence itself.

9. Punishment for preparation of an offence but where circumstances have prevented the commitment of the offence itself: Half of that for the commitment of the offence itself.

OTHER PROVISIONS RELATED TO THE OFFENCES AND PENALTIES

10. Punishment for offence for which no punishment is provided: Whoever contravenes any provision of this act or any rule or order made, or any condition of any license, permit or authorization issued thereunder for which no punishment is separately provided in this act, shall be punishable with imprisonment for a term which may extend to 6 months, or with fine, or with both.

11. Security for abstaining from commission of offence:

Whenever any person is convicted of an offence punishable under any provision of this act and the court convicting him is of opinion that it is necessary to require such person to execute a bond for abstaining from the commission of any offence under this act, the court may, at the time of passing sentence on such person, order him to execute a bond for a sum proportionate to his means, with or without sureties, for abstaining from commission of any offence under this act during such period not exceeding three years as it thinks fit to fix. An order under this section may also be made by an appellate court or by the High Court or Sessions Judge when exercising the powers of revision.

12. Presumption of culpable mental state: In any prosecution for an offence under this Act which

requires a culpable mental state of the accused, the court shall presume the existence of such mental state but it shall be a defence for the accused to prove the fact that he had no such mental state with respect to the act charged as an offence in that prosecution. For the purpose of this section, a fact is said to be proved only when the court believes it to exist beyond a reasonable doubt and not merely when its existence is established by a preponderance of probability.

13. Constitution of special court: The Government may, for the purpose of providing speedy trial of the offences under this Act, by notification in the Official Gazette, constitute as many Specified in the notification. A Special Court shall consist of a single Judge who shall be appointed by the Government with the concurrence of the Chief Justice of the High Court.

14. Appeal and revision: The High Court may exercise, so far as may be applicable, all the powers on a High Court, as if a Special Court within the local limits of the jurisdiction of the High Court were a Court of Session trying cases within the local limits of the jurisdiction of the High Court.

15. Offences to be cognizable and non-bailable:

- i. Notwithstanding anything contained in the Code of Criminal Procedure, 1973.
- a. Every offence punishable under this Act shall be cognizable.
- b. No person accused of an offence punishable for a term of imprisonment of 5 years or more under this Act shall be released on bail or on his own bond unless:
 - The Public Prosecutor has been given an opportunity to oppose the application for such release. and
 - Where the Public Prosecutor opposes the application the court is satisfied that there are reasonable grounds for believing that he is not guilty of such offence and that he is not likely to commit any offence while on bail.

ii. The limitations on granting of bail are in addition to the limitations under the Code of Criminal Procedure, 1973, or any other law for the time being in force on granting of bail.

16. Offences by companies: Where an offence under this Act has been committed by a company, every person, who, at the time the offence was committed was in-charge of, and was responsible to, the company for the conduct of the business of the company as well as the company, shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly. Provided that nothing contained in this sub-section shall render any such person liable to any punishment if he proves that the offence was committed without his knowledge or that he had exercised all due diligence to prevent the commission of such offence, where any offence under this act has been committed by a company and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of, any director, manager, secretary or other officer of the company, such director, manager, secretary or other officer shall be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

17. Power of court to release certain offenders on probation: When any addict is found guilty of an offence punishable and if the court by which he is found guilty is of the opinion, regard being had to the age, character, antecedents or physical or mental condition of the offender, that it is expedient so to do, then, notwithstanding anything contained in this act or any other law for the time being in force, the court may, instead of sentencing him at once to any imprisonment, with his consent, direct that he be released for undergoing medical treatment for de-toxification or de-addiction from a hospital or an institution maintained or recognised by Government and on his entering into a bond in the form prescribed by the Central Government, with or without sureties, to appear

and furnish before the court within a period not exceeding 1 year, a report regarding the result of his medical treatment and, in the meantime, to abstain from the commission of any offence under this Act.

If it appears to the court, having regard to the report regarding the result of the medical treatment furnished, that it is expedient so to do, the court may direct the release of the offender after due admonition on his entering into a bond in the form prescribed by the Central Government, with or without sureties, for abstaining from the commission of any offence under this act during such period not exceeding 3 years as the court may deem fit to specify or on his failure so to abstain, to appear before the court and receive sentence when called upon during such period.

18. Power of court to publish names, place of business of certain offenders: Where any person is convicted of any of the offences punishable under this Act, it shall be competent for the court convicting the person to cause the name and place of business or residence of such person, nature of the contravention, the fact that the person has been so convicted and such other particulars as the court may consider to be appropriate in the circumstances of the case, to be published at the expense of such person in such newspapers or in such manner as the court may direct.

No publication shall be made until the period for preferring an appeal against the orders of the court has expired without any appeal having been preferred, or such appeal, having been preferred, has been disposed of.

The expenses of any publication shall be recoverable from the convicted person as if it were a fine imposed by the court.

PROCEDURE

1. **Power to issue warrant and authorization:**
 - a. A Metropolitan Magistrate or a Magistrate of the first class or any Magistrate of the second class specially empowered by the State Government in this behalf, may issue

a warrant for the arrest of any person whom he has reason to believe to have committed any offence punishable under this, or for the search, whether by day or by night, of any building, conveyance or place in which he has reason to believe any narcotic drug or psychotropic substance in respect of which an offence punishable under the act has been committed or any document or other article which may furnish evidence of the commission of such offence is kept or concealed.

- b. Any such officer of gazette rank of the departments of central excise, narcotics, customs, revenue intelligence or any other department of the Central Government or of the Border Security Force as is empowered in this behalf by general or special order by the Central Government, or any such officer of the revenue, drugs control, excise, police or any other department of a State Government as is empowered in this behalf by general or special order of the State Government, if he has reason to believe from personal knowledge or information given by any person and taken in writing that any person has committed an offence punishable under this act or that any narcotic drug, or psychotropic substance in respect of which any offence punishable under this act has been committed or any document or other article which may furnish evidence of the commission of such offence has been kept or concealed in any building, conveyance or place, may authorise any officer subordinate to him but superior in rank to a peon, sepoy, or a constable, to arrest such a person or search a building, conveyance or place whether by day or by night or himself arrest a person or search a building, conveyance or place.
- c. The officer to whom a warrant is addressed and the officer who authorised the arrest or search or the officer who is so authorized as above shall have the powers of an officer acting for entry, search, seizure and arrest without warrant or authorization.

2. Power of entry, search, seizure and arrest without warrant or authorization: Any such officer (being an officer superior in rank to a peon, sepoy or constable) of the departments of central excise, narcotics, customs, revenue intelligence or any other department of the Central Government or of the Border Security Force as is empowered in this behalf by general or special order by the Central Government, or any such officer (being an officer superior in rank to a peon, sepoy or constable) of the revenue, drugs control, excise, police or any other department of a State Government as is empowered in this behalf by general or special order of the State Government, if he has reason to believe from personal knowledge or information given by any person and taken down in writing, that any narcotic drug, or psychotropic substance, in respect of which an offence punishable under this act has been committed or any document or other article which may furnish evidence of the commission of such offence is kept or concealed in any building, conveyance or enclosed place, may, between sunrise and sunset:

- i. Enter into and search any such building, conveyance or place.
- ii. In case of resistance, break open any door and remove any obstacle to such entry.
- iii. Seize such drug or substance and all materials used in the manufacture thereof and any other article and any animal or conveyance which he has reason to believe to be liable to confiscation under this act and any document or other article which he has reason to believe may furnish evidence of the commission of any offence punishable under this act relating to such drug or substance.

Where an officer takes down any information in writing or records grounds for his belief under the proviso thereto, he shall forthwith send a copy thereof to his immediate official superior.

3. Power of seizure and arrest in public places: Any officer of any of the departments may:

- a. Seize, in any public place or in transit, any narcotic drug or psychotropic substance in respect of which he has reason to believe an offence punishable under this act has been committed, and, along with such drug or substance, any animal or conveyance or article liable to confiscation under this Act, and any document or other article which he has reason to believe may furnish evidence of the commission of an offence punishable under this act relating to such drug or substance.
- b. Detain and search any person whom he has reason to believe to have committed an offence punishable under this Act, and, if such person has any narcotic drug or psychotropic substance in his possession and such possession appears to him to be unlawful, arrest him and any other person in his company.
4. ***Procedure where seizure of goods liable to confiscation not practicable:*** Where it is not practicable to seize any goods (including standing crop) which are liable to confiscation under this act, any officer duly authorised under Section 42 may serve on the owner or person in possession of the goods, an order that he shall not remove, part with or otherwise deal with the goods except with the previous permission of such officer.
5. ***Duty of land holder to give information of illegal cultivation:*** Every holder of land shall give immediate information to any officer of the police or of any of the departments of all the opium poppy, cannabis plant or coca plant which may be illegally cultivated within his land and every such holder of land who knowingly neglects to give such information, shall be liable to punishment.
6. ***Duty of certain officers to give information of illegal cultivation:*** Every officer of the Government and every panch, sarpanch and other village officer of whatever description shall give immediate information to any officer of the police or of any of the departments when it may come to his knowledge that any land has been illegally cultivated with the opium poppy, cannabis plant or coca plant, and every such officer of the Government, panch, sarpanch and other village officer who neglects to give such information shall be liable to punishment.
7. ***Power of attachment of crop illegally cultivated:*** Any Metropolitan Magistrate, Judicial Magistrate of the first class or any Magistrate specially empowered in this behalf by the State Government or any officer of a gazetted rank empowered may order attachment of any opium poppy, cannabis plant or coca plant which he has reason to believe to have been illegally cultivated and while doing so may pass such order (including an order to destroy the crop) as he thinks fit.
8. ***Power to stop and search conveyance:*** Any officer authorized, may, if he has reason to suspect that any animal or conveyance is, or is about to be, used for the transport of any narcotic drug or psychotropic substance, in respect of which he suspects that any provision of this Act has been, or is being, or is about to be, contravened at any time, stop such animal or conveyance, or, in the case of an aircraft, compel it to land and:
- Rummage and search the conveyance or part thereof.
 - Examine and search any goods on the animal or in the conveyance.
 - If it becomes necessary to stop the animal or the conveyance, he may use all lawful means for stopping it, and where such means fail, the animal or the conveyance may be fired upon.
9. ***Conditions under which search of persons shall be conducted:*** When any officer duly authorised is about to search any person, he shall, if such person so requires, take such person without unnecessary delay to nearest Gazetted Officer of any of the departments or to the nearest Magistrate. If such requisition is made, the officer may detain the person until he can bring him before the Gazetted Officer or the Magistrate. The Gazetted Officer or the Magistrate before whom any such person is

brought shall, if he sees no reasonable ground for search, forthwith discharge the person but otherwise shall direct that search be made. No female shall be searched by anyone excepting a female.

10. Provisions of the Code of Criminal Procedure, 1973 to apply to warrants, arrests, searches and seizures: The provisions of the Code of Criminal Procedure, 1973 shall apply, in so far as they are not inconsistent with the provisions of this act, to all warrants issued and arrests, searches and seizures made under this Act.

11. Disposal of persons arrested and articles seized:

- a. Any officer arresting a person shall, as soon as may be, inform him of the grounds for such arrest.
- b. Every person arrested and article seized under warrant issued shall be forwarded without unnecessary delay to the Magistrate by whom the warrant was issued.
- c. Every person arrested and article seized shall be forwarded without unnecessary delay to:
 - i. The officer-in-charge of the nearest police station.
 - ii. The officer empowered.
- d. The authority or officer to whom any person or article is forwarded shall, with all convenient despatch, take such measures as may be necessary for the disposal according to law of such person or article.

12. Disposal of seized narcotic drugs and psychotropic substances:

- a. The Central Government may, having regard to the hazardous nature of any narcotic drugs or psychotropic substances, their vulnerability to theft, substitution, constraints of proper storage space or any other relevant considerations, by notification published in the Official Gazette, specify such narcotic drugs or psychotropic substances or class of narcotic drugs

or class of psychotropic substances which shall, as soon as may be after their seizure, be disposed of by such officer and in such manner as that Government may, from time, determine after following the procedure hereinafter specified.

- b. Where any narcotic drug or psychotropic substance has been seized and forwarded to the officer-in-charge of the nearest police station or to the officer empowered, the officer shall prepare an inventory of such narcotic drugs or psychotropic substances containing such details relating to their description, quality, quantity, mode of packing, marks, numbers or such other identifying particulars of the narcotic drugs or psychotropic substances or the packing in which they are packed, country of origin and other particulars as the officer may consider relevant to the identity of the narcotic drugs or psychotropic substances in any proceedings under this Act and make an application, to any Magistrate for the purpose of:
 - i. Certifying the correctness of the inventory so prepared.
 - ii. Taking, in the presence of such Magistrate, photographs of such drugs or substances and certifying such photographs as true.
 - iii. Allowing drawing representative samples of such drugs or substances, in the presence of such Magistrate and certifying the correctness of any list of samples so drawn.
- c. The Magistrate shall, as soon as may be, allow the application.
- d. Every court trying an offence under this Act, shall treat the inventory, the photographs of narcotic drugs or psychotropic substances and any list of samples drawn and certified by the Magistrate, as primary evidence in respect of such offence.
- 13. **Power to invest officers of certain departments with powers of an officer-in-charge of a police station:** The Central Government, after

consultation with the State Government, may, by notification published in the Official Gazette, invest any officer of the department of central excise, narcotics, customs, revenue intelligence or Border Security Force or any class of such officers with the powers of an officer-in-charge of a police station for the investigation of the offences under this Act.

The State Government may, by notification published in the Official Gazette, invest any officer of the department of drugs control, revenue or excise or any class of such officers with the powers of an officer-in-charge of a police station for the investigation of offences under this act.

14. Presumption from possession of illicit articles: In trials under this Act, it may be presumed, unless and until the contrary is proved, that the accused has committed an offence under the act in respect of:

- Any narcotic drug or psychotropic substance.
- Any opium poppy, cannabis plant or coca plant growing on any land which he has cultivated.
- Any apparatus specially designed or any group of utensils specially adopted for the manufacture of any narcotic drug or psychotropic substance.
- Any materials which have undergone any process towards the manufacture of a narcotic drug or psychotropic substance, or any residue left of the materials from which any narcotic drug or psychotropic substance has been manufactured, for the possession of which he fails to account satisfactorily.

15. Police to take charge of articles seized and delivered: An officer-in-charge of a police station shall take charge of and keep in safe custody, pending the orders of the Magistrate, all articles seized under this act within the local area of that police station and which may be delivered to him, and shall allow any officer who may accompany such articles to the police station or who may be deputed for the purpose, to affix his seal to such articles or to take samples of

and from them and all samples so taken shall also be sealed with a seal of the officer-in-charge of the police station.

16. Obligation of officers to assist each other: All officers of the several departments mentioned in Section 42 shall, upon notice given or request made, be legally bound to assist each other in carrying out the provisions of this Act.

17. Report of arrest and seizure: Whenever any person makes any arrest or seizure under this Act, he shall, within 48 hours next after such arrest or seizure, make a full report of all the particulars of such arrest or seizure to his immediate official superior.

18. Punishment for vexatious entry, search, seizure or arrest:

- Any duly empowered person who:
 - Without reasonable ground of suspicion enters or searches, or causes to be entered or searched, any building, conveyance or place.
 - Vexatiously and unnecessarily seizes the property of any person on the pretence of seizing or searching for any narcotic drug or psychotropic substance or other article liable to be confiscated under this act, or of seizing any document or other article liable to be seized.
 - Vexatiously and unnecessarily detains, searches or arrests any person, shall be punishable with imprisonment for a term which may extend to 6 months or with fine which may extend to 1,000 rupees, or both.
- Any person wilfully and maliciously giving false information and so causing an arrest or a search being made under this Act shall be punishable with imprisonment for a term which may extend to 2 years or with fine or both.

19. Failure of officer in duty or his connivance at the contravention of the provisions of this Act:

- Any officer, on whom any duty has been imposed by or under this act and who ceases or refuses to perform or withdraws himself

from the duties of his official superior or has other lawful excuse for so doing, be punishable with imprisonment for a term which may extend to one year or with fine or with both.

2. Any officer on whom any duty has been imposed by or under this Act or any person who has been given the custody of any addict; or any other person who has been charged with an offence under this Act, and who wilfully aids in, or connives at, the contravention of any provision of this Act or any Rule or order made thereunder, shall be punishable with rigorous imprisonment for a term which shall not be less than ten years but which may extend to twenty years, and shall also be liable to fine which shall not be less than one lakh rupees but which may extend to two lakh rupees.
3. No court shall take cognizance of any offence under sub-section (1) or sub-section (2) except on a complaint in writing made with the previous sanction of the Central Government, or as the case may be, the State Government.

20. Liability of illicit drugs, substances, plants, articles and conveyances to confiscation: Whenever any offence punishable under the Act has been committed, the narcotic drug, psychotropic substance, the opium poppy, coca plant, cannabis plant, materials, apparatus and utensils in respect of which or by means of which such offence has been committed, shall be liable to confiscation.

Any narcotic drug or psychotropic substance lawfully produced, imported inter-State, exported inter-State, imported into India, transported, manufactured, possessed, used, purchased or sold along with or in addition to any narcotic drug or psychotropic substance which is liable to confiscation and the receptacles, packages and coverings in which any narcotic drug or psychotropic substance, materials, apparatus or utensils liable to confiscation is found, and the other contents, if any, of such receptacles or packages shall likewise be liable to confiscation.

Any animal or conveyance used in carrying any narcotic drug or psychotropic substance, or any article liable to confiscation shall be liable to confiscation, unless the owner of the animal or conveyance proves that it was so used without the knowledge of the owner himself, his agent, if any, and the person-in-charge of the animal or conveyance and that each of them had taken all reasonable precautions against such use.

21. Confiscation of goods used for concealing illicit drugs or substances: Any goods used for concealing any narcotic drug or psychotropic substance which is liable to confiscation under this Act shall also be liable to confiscation.

22. Confiscation of sale proceeds of illicit drugs or substances: Where any narcotic drug or psychotropic substance is sold by a person having knowledge or reason to believe that the drug or substance is liable to confiscation under this Act, the sale proceeds thereof shall also be liable to confiscation.

23. Procedure in making confiscations:

1. In the trial of offences under this Act, whether the accused is convicted or acquitted or discharged, the court shall decide whether any article or thing seized under this Act is liable to confiscation under Section 60 or Section 61 or Section 62 and, if it decides that the article is so liable, it may order confiscation accordingly.
2. Where any article or thing seized under this Act appears to be liable to confiscation under Section 60 or Section 61 or Section 62, but the person who committed the offence in connection therewith is not known or cannot be found, the court may inquire into and decide such liability, and may order confiscation accordingly. Provided that no order of confiscation of an article or thing shall be made until the expiry of one month from the date of seizure, or without hearing any person who may claim any right thereto and the evidence, if any, which he produces in respect of his claim. Provided further that if any such article or thing, other than a

narcotic drug, psychotropic substance, the opium poppy, coca plant or cannabis plant is liable to speedy and natural decay, or if the court is of opinion that its sale would be for the benefit of its owner, it may at any time direct it to be sold; and the provisions of this sub-section shall, as nearly as may be practicable, apply to the net proceeds of the sale.

3. Any person not convicted who claims any right to property which has been confiscated under this Section may appeal to the Court of Session against the order of confiscation.

24. Power to tender immunity from prosecution: The Central Government or the State Government may, if it is of opinion (the reasons for such opinion being recorded in writing) that with a view to obtaining the evidence of any person appearing to have been directly or indirectly concerned in or privy to the contravention of any of provisions of this Act or of any rule or order made thereunder it is necessary or expedient so to do, tender to such person immunity from prosecution for any offence under this Act or under the Indian Penal Code, 1860 or under any other Central Act or State Act, as the case may be, for the time being in force, on condition of his making a full and true disclosure of the whole circumstances relating to such contravention. A tender of immunity made to, and accepted by, the person concerned, shall, to the extent to which the immunity extends, render him immune from prosecution for any offence in respect of which the tender was made. If it appears to the Central Government or, as the case may be, the State Government, that any person to whom immunity has been tendered under this section has not complied with the conditions on which the tender was made or is wilfully concealing anything or is giving false evidence, the Central Government or, as the case may be, the State Government, may record a finding to that effect and thereupon the immunity shall be deemed to have been withdrawn and such person may be tried for the offence in respect of which the

tender of immunity was made or for any other offence of which he appears to have been guilty in connection with the same matter.

25. Immunity from prosecution to addicts volunteering for treatment: Any addict, who is not charged with any offence punishable, who voluntarily seeks to undergo medical treatment for detoxification or de-addiction from a hospital or an institution maintained or recognised by the Government or a local authority and undergoes such treatment shall not be liable to prosecution once in his lifetime. Provided that the said immunity from prosecution may be withdrawn if the addict does not undergo the complete treatment for detoxification or de-addiction."

26. Presumption as to documents in certain cases: Where any document is produced or furnished by any person or has been seized from the custody or control of any person, in either case, under this Act or under any other law, or has been received from any place outside India (duly authenticated by such authority or person and in such manner as may be prescribed by the Central Government) in the course of investigation of any offence under this Act alleged to have been committed by a person, and such document is tendered in any prosecution under this Act in evidence against him, or against him and any other person who is tried jointly with him, the court shall:

- a. Presume, unless the contrary is proved, that the signature and every other part of such document which purports to be in the handwriting of any particular person or which the court may reasonably assume to have been signed by, or to be in the handwriting of, any particular person, is in that persons handwriting; and in the case of a document executed or attested, that it was executed or attested by the person by whom it purports to have been so executed or attested.
- b. Admit the document in evidence, notwithstanding that it is not duly stamped, if such document is otherwise admissible in evidence.

c. Examine any person acquainted with the facts and circumcontrary is proved, the truth of the contents of such document.

27. ***Power to call for information:*** Any officer who is authorised in this behalf by the Central Government or a State Government may, during the course of any enquiry in connection with the contravention of any provision of this Act:

- a. Call for information from any person for the purpose of satisfying himself whether there has been any contravention of the provisions of this Act or any rule or order made thereunder.
- b. Require any person to produce or deliver any document or thing useful or relevant to the enquiry.
- c. Examine any person acquainted with the facts and circumstances of the case.

28. ***Information as to commission of offences:*** No officer acting in exercise of powers vested in him under any provision of this Act or any rule or order made thereunder shall be compelled to say whence he got any information as to the commission of any offence.

FORFEITURE OF PROPERTY DERIVED FROM, OR USED IN, ILLICIT TRAFFIC

A. ***Prohibition of holding illegally acquired property:***

1. As from the commencement of this Chapter, it shall not be lawful for any person to whom this Chapter applies to hold any illegally acquired property either by himself or through any other person on his behalf.
2. Where any person holds any illegally acquired property in contravention of the provisions of sub-section (1), such property shall be liable to be forfeited to the Central Government in accordance with the provisions of this Chapter.

B. ***Competent authority:*** The Central Government may, by order published in the Official Gazette, authorise any Collector of Customs or Collector of Central Excise or Commissioner of Income-tax or any other officer of the Central

Government of equivalent rank to perform the functions of the competent authority under this Chapter. The competent authorities shall perform their functions in respect of such persons or classes of persons as the Central Government may, by order, direct.

C. ***Identifying illegally acquired property:***

1. Every officer empowered and every officer-in-charge of a police station, shall, on receipt of information that any person to whom this Chapter applies has been charged with any offence punishable under this Act, whether committed in India or outside, proceed to take all steps necessary for tracing and identifying any property illegally acquired by such person.
2. The steps referred to in sub-section (1) may include any inquiry, investigation or survey in respect of any person, place, property, assets, documents, books of account in any bank or public financial institution or any other relevant matters.
3. Any inquiry, investigation or survey shall be carried out by an officer in accordance with such directions or guidelines as the competent authority may make or issue in this behalf.

D. ***Seizure or freezing of illegally acquired property:***

1. Where any officer conducting an inquiry or investigation has reason to believe that any property in relation to which such inquiry or investigation is being conducted is an illegally acquired property and such property is likely to be concealed, transferred or dealt with in any manner which will result in frustrating any proceeding relating to forfeiture of such property under this Chapter, he may make an order for seizing such property and where it is not practicable to seize such property, he may make an order that such property shall not be transferred or otherwise dealt with, except with the prior permission of the officer making such order, or of the competent authority and a copy of such

order shall be served on the person concerned.

2. Any order made under sub-section (1) shall have no effect unless the said order is confirmed by an order of the competent authority within a period of thirty days of its being made.
 - a. The creation of a trust in property.
 - b. The grant or creation of any lease, mortgage, charge, easement, license, power, partnership or interest in property.
 - c. The exercise of a power of appointment of property vested in any person, not the owner of the property, to determine its disposition in favour of any person other than the donee of the power.
 - d. Any transaction entered into by any person with intent thereby to diminish directly or indirectly the value of his own property and to increase the value of the property of any other person.

E. Certain officers to assist administrator, competent authority and appellate tribunal: For the purposes of any proceedings under this act, the following officers are hereby empowered and required to assist the Administrator appointed, competent authority and the Appellate Tribunal, namely:

- a. Officers of the Narcotics Control Bureau.
- b. Officers of the Customs Department.
- c. Officers of the Central Excise Department.
- d. Officers of the Income-tax Department.
- e. Officers of enforcement appointed under the Foreign Exchange Regulation Act, 1973
- f. Officers of police.
- g. Officers of the Narcotics Department.
- h. Officers of the Central Economic Intelligence Bureau.
- i. Officers of the Directorate of Revenue Intelligence Bureau.
- j. Such other officers of the Central or State Government as are specified by the Central Government in this behalf by notification in the Official Gazette.

MISCELLANEOUS PROVISIONS RELATED TO THE ACT

A. Protection of action taken in good faith: No suit, prosecution or other legal proceeding shall lie against the Central Government or State Government or any officer of the Central Government or of the State Government or any other person exercising any powers or discharging any functions or performing any duties under this act, for anything in good faith done or intended to be done under this act or any rule or order made thereunder.

B. Central Government and State Government to have regard to international conventions while making Rules: Wherever under this Act the Central Government or the State Government has been empowered to make rules, the Central Government or the State Government, as the case may be, subject to other provisions of this Act, may while making the rules have regard to the provisions of the Single Convention on Narcotic Drugs, 1961, the Protocol of 1972 amending the said Convention and of the Convention on Psychotropic substances, 1971 to which India is a party and to the provisions of any other international convention relating to narcotic drugs or psychotropic substances to which India may become a party.

C. Power of Government to establish centres for identification, treatment, etc. of addicts and for supply of narcotic drug and psychotropic substances: The Government may, in its discretion, establish as many centres as it thinks fit for identification, treatment, education, after-care, rehabilitation, social re-integration of addicts and for supply, subject to such conditions and in such manner as may be prescribed, by the concerned Government of any narcotic drugs and psychotropic substances to the addicts registered with the Government and to others where such supply is a medical necessity.

The Government may make rules consistent with this Act providing for the establishment, appointment, maintenance, management and superintendence of, and for supply of narcotic

drugs and psychotropic substances from, the centres and for the appointment, training, powers, duties and persons employed in such centres.

D. Power of Central Government to give directions: The Central Government may give such directions as it may deem necessary to a State Government regarding the carrying into execution of the provisions of this Act, and the State Government shall comply with such directions.

E. Power of Central Government to make rules: Subject to the other provisions of this Act, the Central Government may, by notification in the Official Gazette, make rules for carrying out the purposes of this Act.

F. Power of State Government to make rules: Subject to the other provisions of this Act, the State Government may, by notification in the official Gazette, make rules for carrying out the purposes of this Act.

G. Application of the Customs Act: All prohibitions and restrictions imposed by or under this Act on the import into India, the export from India and transhipment of narcotic drugs and psychotropic substances shall be deemed to be prohibitions and restrictions imposed by or under the Customs Act, 1962 and the provisions of that Act shall apply accordingly. Provided that, where the doing of anything is an offence punishable under that Act and under this Act, nothing in that Act or in this section shall prevent the offender from being punished under this Act.

H. Application of the Drugs and Cosmetics Act, 1940 not barred: The provisions of this act or the Rules made thereunder shall be in addition to, and not in derogation of, the Drugs and Cosmetics Act, 1940 or the Rules made thereunder.

I. Saving of State and special laws: Nothing in this Act or in the Rules made thereunder shall affect the validity of any Provincial Act or an act of any state legislature for the time being in force, or of any rule made thereunder which imposes any restriction or provides for a punishment not

imposed by or provided for under this act or imposes a restriction or provides for a punishment greater in degree than a corresponding restriction imposed by or a corresponding punishment provided for by or under this act for the cultivation of cannabis plant or consumption of, or traffic in, any narcotic drug or psychotropic substance within India.

J. Power to remove difficulties: If any difficulty arises in giving effect to the provisions of this Act, the Central Government may, publish in the Official Gazette, make such provisions not inconsistent with the provisions of this Act as appear to it to be necessary or expedient for removing the difficulty. Provided that no such order shall be made after the expiry of a period of three years from the date on which this Act receives the assent of the president.

Every order made under this section shall, as soon as may be after it is made, be laid before the houses of parliament.

OPIUM POPPY CULTIVATION AND PRODUCTION OF OPIUM AND POPPY STRAW

A. Opium poppy cultivation and production of opium and poppy straw: The opium poppy for production of opium or poppy straw shall not be cultivated save on account of the Central Government and in the tracts notified by it from time to time and in accordance with the conditions of a license issued by the District Opium Officer. The license of cultivation of opium poppy may be granted by the District Opium Officer on payment of a fee of rupees twenty-five.

Subject to the general conditions relating to grant of license notified by the Central Government, the District Opium Officer may issue license to any person for a crop year of cultivation of the opium poppy for production of opium or poppy straw on receipt of an application made by that person in Form No.2 appended to these rules. The license for cultivation of opium poppy for the production of opium poppy straw shall be issued in Form No.1.

Following Information is to be Furnished in Application

1. Crop year.
2. Name of the cultivator.
3. Father's name.
4. Address of the cultivator.
5. Khasra no. of the plot or land in which poppy is to be cultivated.
6. Whether the plot is in the name of applicant as per the revenue records and if not, in whose name.
7. Whether the plot has irrigation facilities and the kind of such facilities available.
8. Area required for opium poppy cultivation.
9. Whether the applicant cultivated the poppy in the past. If so, the latest year in which he cultivated the poppy.
10. Whether the applicant was ever proscribed from poppy cultivation or was de-licensed for tendering adulterated opium, access cultivation, violation of Departmental Instruction. If so, the year and the reasons for proscription.
11. Signature and thumb-impression of cultivator.
12. Attestations by lambardar.

The License is Subjected to the following Conditions

Conditions of license for production of opium poppy and straw:

1. The licensee shall not transfer this license and cultivate poppy only for production of opium or poppy straw over the area of land and the plot (s) specified in the license.
2. The land in which poppy will be cultivated by the cultivator shall be free from litigation.
3. The licensee shall get his daily collections of opium obtained from the crop weighed by the lambardar and affix his signature/ thumb-impression against each entry made by the lambardar in token of correctness of such entry made by lambardar

and shall submit to preliminary weighment carried out by the staff of the Narcotics Department in the village during which he shall produce the entire quantity collected by him.

4. The licensee shall bring to, and deliver at the place fixed and notified for weighment all opium collected by him from the crop and shall accept for opium so brought by him the price fixed by the Central Government for the crop year.
5. The licensee shall deliver the opium either himself or through any person authorized by him at the time of weighment and his opium shall be weighed under the supervision of the District Opium Officer or any other officer authorized in this behalf by the Narcotics Commissioner.
6. If the licensee does not surrender his entire produce of opium to the Government or retains, embezzles or otherwise illegally dispose of any part of the same he shall liable to be prosecuted as per the provisions of the Narcotic Drugs and Psychotropic Substances Rules, 1985.
7. The licensee shall extract as much opium as is reasonably possible from all implements, pots and cloths used by him in collecting opium and impregnated with opium in consequence of such use.
8. The final payment for opium delivered by the licensee shall be made to him at appropriate time fixed by the District Opium Officer or any other officer authorized in this behalf.
9. If on the final adjustment of accounts any sum is found due from the licensee, he shall pay it to the District Opium Officer or any other officer authorized in this behalf in the manner specified. If the licensee fails to pay the sum due from him it may be recovered from him in the manner prescribed by Section 72 of the Narcotic Drugs and Psychotropic Substances Rules, 1985.
10. The license may be withheld or cancelled at any time if any fact is revealed against

the licensee which makes him ineligible for grant of the license.

11. The licensee shall comply with the provisions of the Narcotic Drugs and Psychotropic Substances Rules, 1985, the Rules framed thereunder and any order issued by the competent authorities of the Narcotics Department from time to time.
12. The licensee shall be punishable under the relevant provisions of the Narcotic Drugs and Psychotropic Substances Rules, 1985 for any breach of the conditions of the license.

B. Withholding or cancellation of license: An officer higher in rank than District Opium Officer may, for sufficient reasons to be recorded in writing, withhold or cancel a license already issued. No order shall be passed unless the cultivator has been given a reasonable opportunity of showing cause against the said order or is heard in person, if he so desires. Where opium poppy has been cultivated under a license which is subsequently withheld, or cancelled, the standing crop, if any, shall be destroyed under the supervision of the proper officer in such manner as may be specified by the Narcotics Commissioner.

C. Procedure: Procedure with regard to measurement of land cultivated with opium poppy. All plots of land cultivated with opium poppy in accordance with the license issued under these rules, shall be measured in meters by the proper officer in the presence of cultivator concerned and lambardar of the village and the concerned cultivator and lambardar of the village shall attest the entries made in the records to be maintained by the lambardar, as may be specified by the narcotics commissioner in this behalf, under their signature/thumb-impression with date, in token having satisfied themselves regarding the correctness of the measurement. The measurement conducted by the proper officer shall be subject to such further checks by such officers as may be specified by the Narcotics Commissioner in this behalf.

Procedure with regard to preliminary weighment: The cultivator shall, during the

course of harvesting, produce daily before the lambardar, each day's collection of opium from his crop of weightment. The lambardar shall make arrangements to weigh such opium and make necessary entries in the records to maintain by him as may be specified by the Narcotics Commissioner in this behalf. The cultivator and the lambardar shall attest the entries made in such records under their signature/thumb-impression with date, showing the quantity of opium weighed on a particular day. The proper officer shall conduct check weighment of the opium collected by the cultivators with reference to the entries in the lambardar record and indicate his finding therein which shall be attested by him and the lambardar under the signature with date. The variations between the quantity of opium produced by the cultivator indicated in the lambardar record and as found by the proper officer during his check, shall be inquired into by the proper officer in order to ascertain the liability of the cultivator for punishment under Section 19 of the Act.

Delivery of opium produced: All opium, the produce of land cultivated with opium poppy, shall be delivered by the cultivators to the District Opium Officer or any other officer duly authorized in this behalf, by the Narcotics Commissioner at a place may be specified by such officer.

Opium to be weighed examined and classified: All opium delivered by the cultivators to the District Opium Officer or any other officer authorized as aforesaid, shall, in the presence of the concerned cultivator or any other persons authorized by him and the lambardar of the village, be weighed, examined and classified according to its quality and consistence and forwarded by the district opium officer to the government opium factory in such manner as may be specified by the Narcotics Commissioner.

Procedure where cultivator is dissatisfied with classification of opium: Any cultivator who may be dissatisfied with the classification

of his opium done by the officer may have it forwarded by such officer to the Government Opium Factory separately, after having it properly sealed in the presence of the cultivator and the concerned lambadar.

Procedure for sending opium suspected to be adulterated: When opium delivered by the cultivator to the District Opium Officer or any other officer to be authorized in this behalf, is suspected of being adulterated with any foreign substance, it shall be forwarded to the Government Opium Factory separately, after it is properly sealed in the presence of the cultivator and the concerned lambadar.

Drawing of samples from opium sent to government opium factory: The sealed opium received separately, shall be opened and sample drawn thereof in the presence of cultivator, if he so desire, to whom, a notice intimating the date and time in this behalf, shall be sent well in advance.

D. Price of opium: Fixation of price of opium: The Central Government shall, from time to time, fix the price of opium, to be paid to the cultivators, in such manner as it may deem fit. Such price shall be fixed per kilogram of opium of a standard consistence.

Provisional payment of price: The District Opium Officer shall, having regard to the weight and consistence of opium delivered by individual cultivators, work out the weight of such opium at the standard consistence and determine provisionally the total price payable to such cultivators. The said officers shall pay to the cultivators, 90% of the price so determined which shall be subject to determined as provided hereinafter.

Determination of final price of opium: The final price of opium payable to the cultivator shall, having regard to the price fixed by the Central Government, be determined by the General Manager on the basis of analysis report of the chemical examiner and communicated to the concerned district opium officer. The price payable in respect of any opium which is delivered to the District Opium Officer or any

other officer authorized in this behalf under Rule 14 and is not initially suspected to be adulterated but found to be adulterated on examination in the Government Opium Factory, shall be subjected to reduction at such rates as may be specified by the Central Government.

E. Weighment: Weighment and examination of the opium at the Government Opium Factory: The opium forwarded by the District Opium Officer shall be received, weighed, examined, and classified in the Government Opium Factory under the supervision of the General Manager in such manner as may be specified by the narcotics commissioner.

Weights and scales: The weights and scales to be used for weighing the opium at the weighment centers and the government opium factory shall be caused to be examined at the appropriate time by the deputy narcotic commissioner or the General Manager, as the case may be.

F. Confiscation: Confiscation of adulterated opium: All such opium received separately, if found to be adulterated on examination by the chemical examiner in the Government Opium Factory may be liable to confiscation by the general manager.

Adjudication of confiscation of adulterated opium: No such confiscation shall be ordered by the general manager unless the concerned cultivator is given a reasonable opportunity of showing cause against the proposed order and is heard in person, if he so desires.

G. Recovery of dues from the cultivators: Adjustment of cultivator's account and recovery of dues from the cultivators: The accounts of the cultivators for a particular crop year shall be adjusted by the District Opium Officer at the time of issuing of license for the subsequent crop year and any balance that may remain due from the cultivators shall be recovered and any amount due to them be paid.

H. Cultivation of opium for exclusive production of poppy straw: The Central Government may, if it considers it expedient so to do, permit cultivation of the opium poppy for the

exclusive production of poppy straw in accordance with a license issued in such tracts and subject to such conditions as may be specified by it, by notification in the official gazette in this behalf. Provided that the poppy straw produced by the cultivators or a result of the cultivation of opium poppy for production of opium, shall be deemed to have been produced under a valid license issued.

I. Appeals: Appeals to the Deputy Narcotics Commissioner. Any person aggrieved by any decision or order made or passed under these rule relating to refusal, withholding or cancellation of a license for opium poppy cultivation by an officer of the Narcotics Department, lower in rank than the Deputy Narcotics Commissioner, may appeal to the Deputy Narcotics Commissioner within thirty days from the date of the communication to him of such decision or order. If the decision or order regarding withholding or cancellation of license for opium poppy cultivation is passed by the Deputy Narcotics Commissioner, such appeal shall lie to the Narcotics Commissioner.

Appeals to the Chief Controller of Factories: Any person aggrieved by any decision or order made or passed by the general manager may appeal to the Chief Controller of Factories within thirty days from the date of the communication to him of such decision or order. Provided that Chief Controller of Factories may, if he is satisfied that the appellant was prevented from submitting his appeal within the said time limit due to reasons beyond his control, allow such appeal to be presented within a further period of thirty days. Every appeal under this rule shall be accompanied by a copy of the decision or order appealed against and shall be in such form and in such manner as may be specified by the Narcotics Commissioner.

Procedure for appeal: The appellate authority shall give an opportunity to appellant to be heard, if he so desires.

The appellate authority may, at hearing an appeal, allow the appellant to go into any ground of appeal not specified in the grounds

of appeal, if the appellate authority is satisfied that omissions of that ground from the grounds of appeal was not willful or unreasonable. The appellate authority may, after making such further inquiry as may be necessary, pass such orders as he thinks fit confirming, modifying or annulling the decision or order appealed against. Provided that any order relating to the quantum of adulterated opium to be confiscated in addition to the opium already confiscated shall not be passed unless the appellant has been given a reasonable opportunity of showing cause against the proposed order. The order of the appellate authority disposing of the appeal under this rule shall be in writing and shall state the points for determination, the decision thereon and the reasons for the decision. On the disposal of the appeal, the appellate authority shall communicate the order passed by him to the appellant and the officer who passed the order or made the decision appealed against. No further appeal or revision shall lie against the order passed by the appellate authority under this rule.

MANUFACTURE, SALE AND EXPORT OF OPIUM

A. Manufacture of opium: The manufacture of opium from the poppy plant is permitted only at two places, government opium factories at Ghazipur in Uttar Pradesh and at Neemuch in Madhya Pradesh. Provided that opium mixtures may be manufactured from opium lawfully possessed by a person authorized under the rules made by the State Government for the said purpose.

B. Export of opium: The export of opium is prohibited save when the export is on behalf of the Central Government.

C. Sale of opium: Sale to State Governments or manufacturing chemists:

1. The Sale of opium to State Governments or, as the case may be, manufacturing chemists shall be only from the Government Opium Factories, Ghazipur.
2. The sale of opium from the Government Opium Factories at Ghazipur to manu-

facturing chemists shall be only under a permit granted by or under the order of the State Governments within whose jurisdiction the chemist resides or has his place of business in the form prescribed by that Government.

3. The permit shall be issued, in quadruplicate and:
 - a. The quadruplicate copy shall be retained by the issuing authority and the remaining copies forwarded to the Government Opium Factories, Ghazipur.
 - b. The said factory shall retain the duplicate copy for record, send the original copy with the consignment of opium and return the triplicate copy to the issuing authority after endorsing thereon the quantity actually supplied and the date of dispatch.

D. Fixation of sakes price of opium: The price to be charged for opium sold under this chapter shall be fixed, from time to time, by the Central Government in such manner as it may deem fit.

MANUFACTURE OF MANUFACTURED DRUGS

A. Manufactured drugs: The manufacture of crude cocaine, ecgonine and its salts and of diacetyl morphine and its salts is prohibited. Provided that nothing contained in this rule shall apply in case the drugs are manufactured by government opium factory or by chemical staff employed under the central board of excise and customs or any person authorized by the Narcotics Commissioner by a special license for purposes mentioned in Chapter VII A. Provided further that the Narcotics Commissioner shall consult the Drugs Controller General of India before issuing a license under this chapter.

B. Manufacture of natural manufactured drugs:

1. The manufacture of cocaine and its salts is prohibited safe the manufacture of cocaine hydrochloride by the chemical staff employed under the central board of excise and customs from confiscated cocaine.
2. The manufacture of morphine, codeine, dionine, thebine, dihydrocodeinone, dihyd-

rocodeine, acetyldihydrocodeine, acetyl-dihydrocodeinone, dihydromorphine, dihydromorphinone, dihydrohydroxy-codeinone, pholcodine and their respective salts is prohibited safe by the government opium factory.

3. The manufacture of medicinal hemp shall be under a license granted by the State Government on payment of such fees and in accordance with such conditions as may be prescribed by that Government in his behalf.

C. Manufacture of synthetic manufactured drugs: The manufacture of manufactured drugs is prohibited safe under and in accordance with the conditions of a license granted by the Narcotics Commissioner or such other officer as may be authorized by the Central Government in this behalf, in Form No.3 appended to these Rules. A fee of ₹ 50 shall be payable in advance to the Central Government for each license issued under this rule for renewal thereof.

Application for license: Every application for a license or for renewal shall be in such form as may be specified by the Narcotics Commissioner.

Conditions for issue of licenses: No license shall be issued unless the applicant therefore has:

- i. Produced to the issuing authority licenses granted to him under.
 - a. The Drugs and Cosmetics Act, 1940 for the manufacture of the drug.
 - b. The Rules framed under Section 10 of the act by the State Government of the State in which he has his place of business, for the possession, sale and distribution of the drugs.
- ii. Made a deposit of rupees five thousand as security in the manner specified by the issuing authority for the due observance of the conditions of the license and has furnished proof to the satisfaction of the issuing authority that he is equipped as to the land, building and other paraphernalia to properly carry on the business prescribed

in the application and is of good financial standing.

Conditions of License for Manufacture of Manufactured Drugs

1. This license is not transferable.
2. This license and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an officer detailed for this purpose by the licensing authority.
3. The licensee shall not manufacture or keep the drug or the materials used for the manufacture of the drug at any other place except his place of business.
4. The licensee shall ensure manufacture of the drug to the standard and specifications laid down by or under the Drugs and Cosmetics Act, 1940.
5. The licensee, if he desires the renewal of his license, shall apply to the licensing authority in the form specified for such renewal, at least thirty days before the expiry of his license.
6. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the license. Where any changes in constitution of the firm take place, the current license shall be deemed to be valid for a maximum period of three months from the date on which the change takes place or the normal expiry of license whichever is earlier unless in the meantime, a fresh license has been taken from the licensing authority in the same, of the firm with the changed constitution.

D. Manufacture only from material lawfully possessed: The licensee shall not manufacture the drug safe from materials which he is lawfully entitled to possess.

E. Limits of manufacture: The issuing authority, while issuing the license, shall take into account all relevant factors for permitting the quantity of the drug to be manufactured by a licensee including the following:

- a. Quantity allotted by the State Government for processing into any preparation in licensee's own manufactory.
- b. Quantity required for supply to other firms within or outside the country.
- c. Quantity required for reasonable inventory.

Provided that the total quantity of the drug manufactured during any one year does not exceed the estimated requirements of this country for the relevant year as furnished to the International Narcotics Control Board.

F. Security arrangements: The licensee shall ensure all necessary security arrangements in the manufacturing premises as may be specified by the issuing authority.

G. Cessation of manufacture: Advance notice for commencement and cessation of manufacture: The licensee shall give at least 15 day's notice in writing to the issuing authority of the date on which he proposes to commence manufacture of the drug and at least one month's notice before he ceases to manufacture the same.

Cessation of manufacture: Where the licensee ceases manufacture in operations for any reasons whatsoever, he shall forthwith inform the issuing authority in this behalf indicating the date on which he proposes to recommence manufacture. Provided that the issuing authority may prohibit all further manufacture in case the period of cessation of manufacture exceed 30 days.

H. Possession, sale and distribution: The licensee shall not possess or sells or distributes the drug otherwise than in accordance with the rules made by the State Government under the Act.

I. Maintenance of accounts and submission of returns: The licensee shall maintain true accounts of all transactions including the accounts of materials used for the manufacture of the drug. The quantities manufactured, sold or otherwise disposed of and furnish returns in such forms and in such manner as may be specified by the Narcotics Commissioner.

J. Inspection of stocks: The stocks of the drug and the materials used for its manufacture and all accounts and records of transactions relating thereto, shall be open to inspection by any officer authorized by the issuing authority. A serially numbered Inspection book shall be maintained by the licensee in good condition for the use of such office.

K. Suspension and revocation of license: Without prejudice to any action that may be taken under the provisions of the act the issuing authority may suspend or cancel a license:

- i. If the license is transferred or sublet without the prior approval of the issuing authority.
- ii. In the event of any breach of any conditions of the license.
- iii. If the licensee is convicted for any offence under the Act or under any other law relating to the narcotic drugs for the time being in force in any State.

L. Appeal: The licensee may file and appeal against the decision or order made or passed under Rule 48 to:

- i. The Narcotics Commissioner where such decision or order was made or passed by any officer subordinate to him.
- ii. The Board, in any other case, within 30 days from the date of communication to him to such decision or order.

Every memorandum of appeal shall be accompanied by a copy of the decision or order appealed against. Every appeal under this rule shall be filed in such form and in such manner as may be specified by the Board.

Procedure for appeal: The appellate authority shall, i.e. an opportunity to the appellant to be heard in person, if he so desires. The appellate authority may, at the hearing of an appeal allow the appellant to go into any ground of appeal not specified in the grounds of appeal, if the appellate authority is satisfied that omission of that ground from the grounds of appeal was not willful or unreasonable. The appellate authority may, after making such further inquiry as may be necessary, pass such orders as it thinks fit,

confirming, modifying or annulling the decision or order appealed against. The order of the appellate authority disposing of the appeal under this rule shall be in writing and shall state the points for determination, the decision thereon and the reason for the decision.

M. Surrender of license: A licensee may, if he so desires, surrender his license, by giving not less than 15 day's notice writing to the issuing authority.

N. Disposal of stocks of drugs on cancellation of license: Such stocks or drugs as may be in the possession of a licensee, on the expiry or cancellation or surrender of his license shall be disposed of in such manner as may be specified by the Narcotic Commissioner in this behalf.

IMPORT, EXPORT AND TRANSSHIPMENT OF NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES

A. Import, export and transshipment of narcotic drugs and psychotropic substances:

General prohibition: Subject to the other provisions to this act, the import into and export out of India of the narcotic drugs and psychotropic substances specified in Schedule I is prohibited. Provided that nothing in this Rule shall apply in case the drug substance specified in Schedule I is prohibited.

No person shall export any of the narcotic drug or psychotropic substance or preparation containing any of such narcotic drug or psychotropic substance specified in Schedule II to the courtiers or to the region of such country specified therein. The Narcotics Commissioner may authorize export of specified quantities of such narcotic drug or psychotropic substance or preparation containing such narcotic drug or psychotropic substance on the basis of special import license issued by the competent authority of the country mentioned in Schedule II which intends such import by way of issuance of special import license. The shipment of the consignment so allowed shall be accompanied by a copy of such special import license duly endorsed by the Narcotics Commissioner.

Import of opium: The import of opium, concentrate of poppy straw, and morphine, codeine, thebaine, and their salt is prohibited safe by the Government opium Factory.

Application for import certificate:

1. No narcotic drug or psychotropic substance specified in the Schedule of the Act shall be imported into India without an import certificate in respect of the consignment issued by the issuing authority, in Form No. 4 appended to these rules.
2. The importer applying for an import certificate under sub-rule (1) in relation to narcotic drug shall submit along with his application the original certified copy of the excise permit issued by the concerned State Government.
3. The application for the import certificate shall state such details as may be specified by the Narcotics Commissioner.

Issue of import certificate:

1. The issuing authority shall prepare seven copies of the import certificate and deal with them in the manner hereunder provided, namely:
 - a. Original and duplicate copies should be supplied to the importer who should transmit the original copy to the exporting country and shall produce the duplicate copy at the customs house, land customs station or airport where the consignment arrives or, in the case of imports by parcel post. At the post office of delivery, in order to obtain delivery of the consignment of narcotic drugs or psychotropic substances. The collector of customs or post master shall state on the copy presented by the importer that the narcotic drugs or the psychotropic substance have actually been imported and return the document of the importer who shall indicate on it that he has received the goods. The importer shall return the duplicate copy of the import certificate incorporating the endorsement from the collector of customs or postmaster and his own endorsement to the issuing authority:
 - i. Where the import certificate relates to narcotic drug, through the excise authorities of the State form which excise permit was produced.
 - ii. Where the import certificate relates to psychotropic substance, through the drug controller of the concerned state.
 - b. Triplicate copy should be supplied to the Collector of Customs concerned who shall return it to the issuing authority along with the copy of the export authority along to be received at the time of receipt of the consignment from the Government of the exporting country, with an endorsement as to actual quantity of narcotic drugs or psychotropic substance cleared.
 - c. Quadruplicate copy of the import certificate in relation to narcotic drug should be supplied to the excise authorities of the State into which the narcotic drug is to be imported, and the said copy of the certificate in relation to psychotropic substance should be supplied to the Drugs Controller of the concerned State for comparison with the copy produced before them, by the importer.
 - d. Quintuplicate copy should be supplied to the Government of the exporting country for comparison with the copy furnished to them by importer.
 - e. Sextuplicate copy should be retained to the Drugs Controller, Government of India.
 - f. Sextuplicate copy should be retained to the issuing authority in his office.
 2. An import certificate issued may allow the importation of the quantity of the concerned drug or the substance in more than one consignment.
- B. **Transit:** No consignment of any narcotic drug, or psychotropic substance specified in



Schedule of the Act, shall be allowed to the transited through India unless such consignment is accompanied by a valid export authorization in this behalf, issued by the Government of the exporting country. Provided that the provisions of this Rule shall not apply to the carriage by any ship or aircraft ,of small quantities of such narcotic drugs and psychotropic substance which are essential for treatment of, or medical aid to, any person on board the ship or aircraft.

C. Export:

Application for export authorization:

1. No narcotic drugs, or psychotropic substance specified in the Schedule II of the Act, shall be exported out of India without an export authorization in respect of the consignment issued by the issuing authority in Form No.5 appended to these Rules.
2. The exporter applying for an export authorization shall submit:
 - a. Where the export authorization relates to narcotic drug, along his application the original or an authenticated copy of the excise permit issued by the concerned State Government.
 - b. The import certificate in original, issued by the Government of the importing country certifying the official approval of the concerned government.
3. The application for the export authorization shall state such details as may be specified by the Narcotics Commissioner.

Issue of export authorization:

1. The issuing authority shall prepare five copies of the export authorization and deal with them in the manner hereunder provided, namely:
 - a. The original should be supplied to the consignor, which shall accompany the consignment.
 - b. The duplicate copy should be forwarded to the collector of customs of the port who will return it to the issuing authority indicating on it the date of export and the quantity exported.

c. The triplicate copy should be forwarded to the Government of the importing country.

d. The quadruplicate copy should be forwarded to the excise authority of the State in which the exporter has his place of business.

e. Quintuplicate copy should be retained by the issuing authority in his office.

2. Where the consignment of narcotic drug or psychotropic substance is to be transshipped or transited through one or more countries, such additional number of copies of export authorization as may be countries.

D. **Transhipment:** No consignment of narcotic drug, or psychotropic substance specified in Schedule II of the Act shall be allowed to the transhipped at any port in India save with the permission of the Collector of Customs.

Procedure for transhipment: The Collector of Customs while allowing any consignment of narcotic drug, or psychotropic substance, specified in schedule of the act, to be transhipped shall, inter alia, satisfy himself that the consignment is accompanied by a valid export authorization issued by the exporting country.

Diversion of consignment: The Collector of Customs shall take all due measures to prevent the diversion of such consignment to a destination other than that named in the aforesaid export authorization.

The Collector of Customs may permit diversion of such a consignment to a country other than that named in the accompanying copy of the export authorisatoin subject to the production of export authorization issued by the issuing authority as if the diversion were an export from India to the country, or territory of new destination. The Collection of Customs shall inform the issuing authority regarding the actual quantity of the narcotic drug or psychotropic substance, the diversion of he consignment of which was allowed whereupon the issuing authority shall, inform the country

from which the export of the consignment originated.

Prohibition of import and export of consignment through a post office box, etc.: The import or export of consignment of any narcotic drug or psychotropic substance though a post office box or through a bank is prohibited.

PSYCHOTROPIC SUBSTANCE

I. General prohibition of psychotropic substance: No person shall manufacture, process, transport, import inter-State, export inter-State, sell, purchase, consume or use any of the psychotropic substances specified in Schedule I.

II. Manufacture of psychotropic substance: The manufacture of any of the psychotropic substance other than those specified in Schedule I shall be in accordance with conditions of a license granted under the Drugs and Cosmetics Rules 1945 Framed under the Drugs and Cosmetics Act, 1940, by an authority in-charge of drugs control in a state appointed by the State Government in this behalf. The authority in-charge of drugs control in a state (hereinafter referred to as the licensing authority) shall consult the Drugs Controller (India) in regard to the assessed annual requirements of each of the psychotropic substance in bulk in the country and taking into account the requirement of such psychotropic substance in the state, the quantity of such substance required for supply to other manufactures outside the state and the quantity of such substance required for reasonable inventory to be held by a manufacturer, shall specify, by order, the limit of the quantity of such substance which may be manufactured by the manufacturer in the state. The quantity of the said psychotropic substance which may be manufactured by a licensee in a year shall be intimated by the licensing authority to the licensee at the time of issuing the license. Provided that nothing contained in this rule shall apply in case the psychotropic substances specified in Schedule I are manufactured, possessed, transported, imported inter-State, exported inter-State, sold purchased, consumed or used

subject to other provisions of this chapter which applies to psychotropic substance which are not included in Schedule I and for the purposes mentioned in Chapter VIIA. Provided further that the authority in-charge of the drug control in a state shall consult the Narcotics Commissioner before issuing a license in respect of psychotropic substance included in Schedule I.

III. Possession of psychotropic substance: No person shall posses any psychotropic substance for any of the purpose covered by the 1945 Rules, unless he is lawfully authorized to posses such substance for any of the said purpose under these rules. any research institution or a hospital or dispensary maintained or supported by Government or local body or by charity or voluntary subscription , which is not authorized to posses any psychotropic substance under the Rules 1945, or any person who is not so authorized under the Rules 1945, may posses a reasonable quantity of such substance as may be necessary for their genuine scientific requirements or genuine medical requirements, or both for such period as is deemed necessary by said research institution or, as the case may be, the said hospital or dispensary or person. Provided that where such psychotropic substance is in possession of an individual for his personal medical use the quantity thereof shall not exceed one hundred dosage units at a time. The research institution, hospital and dispensary shall maintain proper accounts and records in relation to the purchase and consumption of the psychotropic substance in their possession.

IV. Transport of psychotropic substance: No consignment of psychotropic substance shall be transported, imported inter-State or exported inter-State unless such consignment is accompanied by a consignment note in Form 7 appended to these Rules and in the manner as provided hereinafter. The consignment note shall be prepared in triplicate, and the original and duplicate copies of the said note shall be sent along with the consignment of psychotropic substances to the consignee who shall return the duplicate

copy of the note to the consignor for his use after endorsing of the original and duplicate copies the particulars of the receipt of quantity consigned. The consignor shall make necessary entries on the triplicate copy of the said note with reference to the receipt of quantity of the psychotropic substance indicated on that duplicate copy of the note. The consignor and consignee shall keep such consignment note for a period of two years and the said note may be inspected at any time by an officer authorized in this behalf by the Central Government. Special provision regarding manufacture, possession, transport, import-export, purchase and consumption of narcotic drugs and psychotropic substance for medical and scientific purpose.

V. Notwithstanding anything contained in the foregoing provision of these rules:

1. A narcotic drug and psychotropic substance may be used for:
 - i. Scientific requirement including analytical requirements of any Government laboratory or any research institution in India or abroad.
 - ii. Very limited medical requirements of a foreigner by a duly authorized person of a hospital or any other establishment of the Government especially approved by that Government.
 - iii. The purpose of de-addiction of drug addicts by Government or local body or b an approved charity or voluntary organization or by such other institution as may be approved by the Central Government.
2. Persons performing medical or scientific functions shall keep records concerning the acquisition of the substance and the details of their use in Form 7 of these rules and such records are to be preserved for at least two years after their (sic).
3. A narcotic drug and psychotropic substance may be supplied or dispensed for use to a foreigner pursuant to medical prescription only from the authorized

licensed pharmacists or other authorized retail distributors designated by authorities responsible for public health.

VI. Repeal and savings:

1. The Central Opium Rules, 1934 the Dangerous Drugs (import, export and transhipment) Rules, 1957 and the Central Manufactured Drugs Rules, 1962 are hereby repealed.
2. Notwithstanding such repeal, anything done or any action taken or purported to have been done or taken under any of the rules repealed by sub-rule (1) shall, in so far as it is not inconsistent with the provisions of these rules, be deemed to have been done or taken under the corresponding provisions of these rules.

SCHEDULE I

I Narcotic drugs: Substances whose import, export and trans-shipment are prohibited.

1. Coca Leaf, 2. Cannabis (hemp), 3. (a) Acetorphine, (b) Diacetylmorphine (Heroin), (c) Dihydrodesoxymorphine (Desmorphine), (d) Etorphine, (e) Ketobemidone.

And their salts, preparations, admixtures, extracts and other substances containing any of these drugs.

II Psychotropic substances: Substances whose manufacture, possession, transport, imports inter-state, purchase, consumption or use are prohibited.

Methaqualone, amfepramone, benzphetamine, bromazepam, camazepam, cloazeate, clotiazepam, cloxazolam, delorazepam, estazolam, ethinamate, ethylloflazepate, fludiazepam, flunitrazepam, haloxazolam, ketazolam lefetamine spa, loprazolam, lorazepam, mazindol, medazepam, methyprylon, nimezapam, oxazolam, phenidimetrazine, phentermine, pinazepam, pipradrol, prazepam, temazepam, tetrazepam, etryptamine, methcatchinone, zipeprol, aminorex, brotizolam, mesocarb.

Salts and preparations of above.

SCHEDULE II

<i>S. No.</i>	<i>International non-proprietary names</i>	<i>Other non-proprietary names</i>	<i>Chemical name</i>	<i>Country or region to which export is prohibited</i>
1	2	3	4	5
1.	Alprazolam		8-Chloro-1-methyl-6-phenyl-4 H-s-triazolo [4.3 a] [1, 4] benzodiazepine (=)-2-amino-1-pt. enylpropane	Pakistan
2.	Amphetamine			Belize, Japan, Nigeria, Pakistan, Senegal, Thailand, Turkey, Yemen, Venezuela
3.	Barbital		5, 5-diethylbarbituric acid	Pakistan
4.	Cyclobarbital		5-(1-cyclohexene-1-yl)-5-ethylbarbituric acid	Pakistan
5.	Dexamphetamine		(+)-2- amino-1-phenylpropane	Belize, Japan, Nigeria, Pakistan, Senegal Thailand, Turkey, Yemen, Venezuela
6.	Ethchlorvynol		Ethyl-2 chlorovinylethylyn-carbinol	Pakistan
7.	Fenetylline		7 [2-(a-methylphenetyl) amino ethyl theophylline	Belize, Saudi Arabia, Thailand
8.	Flurazepam		7-Chloro-1-[2-(diethylamino) ethyl]-5-(o-fluorophenyl)-1, 3-dihydro-2H-1, 4-benzodiazepine-2-one	Pakistan
9.	Glutethimide		2-ethyl-2-phenylglutarimide	Chile, Pakistan
10.	Halazepam		7-chloro-1, 3-dihydro-5-phenyl-1-(2, 2, 2-trifluoroethyl)-2H-1, 4-benzodiazepine-one	Pakistan
11.	Levamphetamine	Levamphetamine	(-) (R), a-methylphenethylamine	Belize, Japan, Thailand, Venezuela
12.	Levomethamphetamine		(-) N, a-dimethylphenethylamine	Belize, Japan Thailand, Venezuela
13.	Mecloqualone		3-(o-chlorophenyl)-2-methyl-4-(3H)-quinazolinone	Argentina, Belize, Chile, Pakistan, Senegal
14.	Methamphetamine		(+)-2-methylamino-1-phenylpropane	Belize, Japan, Nigeria, Pakistan, Senegal, Thailand, Turkey, Yemen, Venezuela
15.	Methamphetamine racemate	Methamphetamine recemate	(±) N a-dimethylphenethylamine	Belize, Japan, Venezuela,

Contd.

S. No.	International non-proprietary names	Other non-proprietary names	Chemical name	Country or region to which export is prohibited
16.	Methylphenidate		2-phenyl-2 (2-piperidyl) acetic acid, methyl ester	Belize, Japan, Nigeria, Pakistan, Senegal, Thailand, Turkey, Yemen
17	Methylpheno-barbital		5-ethyl-1-methyl-5-phenylbarbituric acid	Pakistan, Senegal, Yemen
18.	Nordazepam		7-Chloro-1,3-dihydro-5-phenyl-(2H)-1,4-benzodiazepine-2-one	Pakistan
19.	Pemoline		2-amino-5-phenyl-2-oxazolin-4-one (=2-amino 5-phenyl-4-oxazolidinone)	Nigeria, Thailand
20.	Phencyclidine	PCP	1-(1-phenylcyclohexyl) piperidine	Belize, Chile, Iceland, Nigeria, Pakistan, Senegal, Yemen
21.	Phenmetrazine		3-methyl-2-phenylmorpholine	Belize, Chile, Nigeria, Pakistan, Senegal, Thailand, Yemen, Venezuela
22.	Secobarbital		5-allyl-5 (1-methylbutyl) barbituric acid	Belize, Nigeria, Pakistan

The Essential Commodities Act, 1955

INTRODUCTION

This Act may be called the Essential Commodities Act, 1955. It extends to the whole of India. The Essential Commodities Act, 1955 is a Central Act. It gives powers to control production, supply, distribution, etc. of essential commodities for maintaining or increasing supplies and for securing their equitable distribution and availability at fair prices. Using the powers under the act, various Ministries/ Departments of the Central Government have issued Control Orders for regulating production/distribution/quality aspects/movement, etc. pertaining to the commodities which are essential and administered by them.

The Essential Commodities Act is being implemented by the State Governments/UT Administrations by availing of the delegated powers under the act. The State Governments/ UT Administrations have issued various control orders to regulate various aspects of trading in Essential Commodities such as food grains, edible oils, pulses kerosene, sugar, etc. The Central Government regularly monitors the action taken by the State Governments/UT administrations to implement the provisions of the essential Commodities Act, 1955.

The items declared as essential commodities under the Essential Commodities Act, 1955 are reviewed from time to time in the light of liberalized economic policies in consultation with the ministries/departments administering the essential commodities.

Effectiveness of the act: Over the three years 2006–2008, State and Union Territory Governments prosecuted 14,541 persons under the provisions of EC Act, 1955 and secured conviction in 2,310 cases. In 2009 as on 31 August, 2533 persons had been prosecuted and 37 convicted. But, doubts have been raised about effectiveness of the Act time and again. Recently, Parliament's estimates committee asked the government to come out expeditiously with a new legislation for controlling the retail prices of essential commodities such as rice, wheat, pulses, edible oils, sugar, milk and vegetables.

Objectives

- The Essential Commodities Act, 1955 was enacted to ensure the easy availability of essential commodities to consumers and to protect them from exploitation by unscrupulous traders.
- Under the Essential Commodities Act, the government has powers to declare a commodity as an essential commodity.
- The essential commodities act gives powers to control production, supply, distribution, etc. of commodities for maintaining or increasing supplies and for securing their equitable distribution and availability at fair prices.

Essential Commodities Act, 1980: In order to prevent unethical trade practices like hoarding and black-marketing, etc. the Prevention of

Black-marketing of Supplies of Essential Commodities, Act, 1980 is being implemented by the State Governments to detain persons whose activities are found to be prejudicial to the maintenance of supplies of commodities essential to the community.

THE ESSENTIAL COMMODITIES ACT, 1955

An act to provide, in the interest of the general public, for the control of the production, supply and distribution of, and trade and commerce, in certain commodities.

DEFINITIONS

- a. Essential commodities is a generic term and has not been defined under the Act.

'Essential Commodity' means any of the following classes of commodities (List of essential commodities):

1. Cattle fodder, including oilcakes and other concentrates.
2. Coal including coke and other derivatives.
3. Component parts and accessories of automobiles.
4. Cotton and woollen textiles.
- 4a. Drugs.
5. Foodstuffs, including edible oilseeds and oils.
6. Iron and steel, including manufactured products of iron and steel.
7. Paper, including newsprint, paperboard and straw board.
8. Petroleum and petroleum products.
9. Raw cotton, whether ginned or unginned, and cotton seed.
10. Raw jute.
11. Any other class of commodity which the Central Government may, by notified order, declare to be an essential commodity for the purposes of this Act.
 - i. Jute textiles.
 - ii. Fertilizer, whether inorganic, organic or mixed.
 - iii. Yarn made wholly from cotton.

- iv. Seeds of food-crops and seeds of fruits and vegetables. Seeds of cattle fodder and jute seeds.
- b. '**Food-crops'** include crops of sugar cane.
- c. '**Notified Order**' means an order notified in the Official Gazette.
- d. '**Order**' includes a direction issued there under.
- e. '**State Government**', in relation to a Union Territory, means the administrator thereof.
- f. '**Sugar**' means:
 - i. Any form of sugar containing more than ninety per cent of sucrose, including sugar candy.
 - ii. Khandsari sugar or bura sugar or crushed sugar or any sugar in crystalline or powdered form.
 - iii. Sugar in process in vacuum pan sugar factory or raw sugar produced therein.
- g. '**Commodity**' means a physical substance, such as food, grains, and metals, which is interchangeable with another product of the same type, and which investors buy or sell, usually through futures contracts. The price of the commodity is subject to supply and demand. Risk is actually the reason exchange trading of the basic agricultural products began. For example, a farmer risks the cost of producing a product ready for market at sometime in the future because he does not know what the selling price will be. More generally, a product which trades on a commodity exchange, this would also include foreign currencies and financial instruments.
- h. '**Collector**' includes an Additional Collector and such other officer, not below the rank of sub-divisional officer, as may be authorised by the collector to perform the functions and exercise the powers of the collector under this act.

CONTROL OF PRODUCTION, SUPPLY AND DISTRIBUTION OF ESSENTIAL COMMODITIES

Powers to control production, supply, distribution of essential commodities under Section 3:

1. If the Central Government may, for maintaining or increasing supplies of any essential commodity or for securing their equitable distribution and availability at fair prices, or for securing any essential commodity for the defence of India or the efficient conduct of military operations, provide for regulating, or prohibiting the production supply and distribution thereof and trade and commerce therein.
2. Without prejudice to the generality of the powers conferred by above sub-section, an order made thereunder may provide:
 - a. For regulating by licenses, permits or otherwise the production or manufacture of any essential commodity.
 - b. For bringing under cultivation any waste or arable land, whether appurtenant to a building or not, for the growing thereon of food-crops generally or of specified food-crops, and for otherwise maintaining or increasing the cultivation of food-crops generally, or of specified food-crops.
 - c. For controlling the price at which essential commodity may be bought or sold.
 - d. For regulating by licenses, permits or otherwise the storage, transport, distribution, disposal, acquisition use or consumption of any essential commodity.
 - e. For prohibiting the withholding from sale of any essential commodity ordinarily kept for sale.
 - f. For requiring any person holding in stock, or engaged in the production, or in the business of buying or selling of any essential commodity:
 - i. To sell the whole or a specified part of the quantity held in stock or produced or received by him.
 - ii. In the case of any such commodity which is likely to be produced or received by him, to sell the whole or a specified part of such commodity when produced or received by him, to the Central Government or the State Government or to an officer or agent of such Government or to a Corporation owned or controlled by such Government or to such other person or class of persons and in such circumstances as may be specified in the order.
 - g. For regulating or prohibiting any class of commercial or financial transactions relating to foodstuffs or cotton textiles which, in the opinion of the authority making the order, are, or, if unregulated, are likely to be, detrimental to the public interest.
 - h. For collecting any information or statistics with a view to regulating or prohibiting any of the aforesaid matters:
 - i. For requiring persons engaged in the production, supply or distribution of or trade and commerce in, any essential commodity to maintain and produce for inspection such books, accounts and records relating to their business and to furnish such information relating thereto, as may be specified in the order.
 - ii. For the grant or issue of licenses, permits or other documents, the charging of fees therefore, the deposit of such sum, if any, as may be specified in the order as security for the due performance of the conditions of any such license, permit or other document, the forfeiture of the sum so deposited or any part thereof for contravention of any such conditions, and the adjudication of such forfeiture by such authority as may be specified in the order.
 - j. For any incidental and supplementary matters, including, in particular, the entry, search or examination of premises, aircraft, vessels, vehicles or other conveyances and animals, and the

- seizure by a person authorised to make such entry, search or examination:
- i. Of any articles in respect of which such person has reason to believe that a contravention of the order has been, is being, or is about to be, committed and any packages, coverings or receptacles in which such articles are found.
 - ii. Of any aircraft, vessel, vehicle or other conveyance or animal used in carrying such article, if such person has reason to believe that such aircraft, vessel, vehicle or other conveyance or animal is liable to be forfeited under the provisions of this Act.
 - iii. Of any books of accounts and documents which in the opinion of such person, may be useful for, or relevant to, any proceeding under this Act and the person from whose custody such books of accounts or documents are seized shall be entitled to make copies thereof or to take extracts therefrom in the presence of an officer having the custody of such books of accounts or documents.
3. **Pricing of essential commodity:** Any person who sells any essential commodity in hole or a specified quantity (held in stock, produced or received by him) to the Central or State Government or to an authorized agency or officer of the Government shall be paid the price thereof as follows:
- i. Where the price can, consistently with the controlled price, if any, fixed under this section, be agreed upon, the agreed price.
 - ii. Where no such agreement can be reached, the price calculated with reference to the controlled price, if any.
 - iii. Where neither clause (i) nor clause (ii) applies, the price calculated at the market rate prevailing in the locality at the date of sale.
- 3A. If the Central Government is of opinion that it is necessary so to do for controlling the rise in prices or preventing the hoarding, of any foodstuff in any locality, it may, by notification in the official gazette, the price at which the foodstuff shall be sold in the locality shall be regulated in accordance with the provisions of this sub-section.
- 3B. Where any person is required, by an order to sell to the Central Government or the State Government or to an officer or agent of such Government or to a Corporation owned or controlled by such Government, any grade or variety of food grains, edible oil seeds or edible oils in relation to which no notification has been issued or such notification having been issued, has ceased to be in force, there shall be paid to the person concerned, notwithstanding anything to the contrary, an amount equal to the procurement price of such food grains, edible oil seeds or edible oils, as the case may be, specified by the State Government, with the previous approval of the Central Government having regard to:
- i. The controlled price, if any, fixed under this section or by or under any other law for the time being in force for such grade or variety of foodgrains, edible oil seeds or edible oils.
 - ii. The general crop prospects.
 - iii. The need for making such grade or variety of foodgrains, edible oil seeds or edible oils available at reasonable prices to the consumers, particularly the vulnerable sections of the consumers. and
 - iv. The recommendations, if any, of the agricultural prices commission with regard to the price of the concerned grade or variety of foodgrains, edible oil seeds or edible oils.
- 3C. Where any producer is required by an order made to sell any kind of sugar (whether to the Central Government or the State

Government or to an officer or agent of such Government or to any other person or class of persons) and either no notification in respect of such sugar has been issued or any such notification, having been issued, has ceased to remain in force by efflux of time, then, notwithstanding any essential commodity in compliance with an order, there shall be paid to that producer an amount therefor which shall be calculated with reference to such price of sugar as the Central Government may, by order, determine, having regard to:

- i. The minimum price, if any, fixed for sugar cane by Central Government under this section.
- ii. The manufacturing cost of sugar.
- iii. The duty or tax, if any, paid or payable thereon.
- iv. The securing of a reasonable return on the capital employed in the business of manufacturing sugar, and different prices may be determined from time to time for different areas or for different factories or for different kinds of sugar.

CONFISCATION OF ESSENTIAL COMMODITY

Confiscation of Essential Commodity

1. Where any essential commodity is seized in pursuance of an order made under Section 3 in relation thereto, a report of such seizure shall, without unreasonable delay, be made to the Collector of the District or the Presidency town in which such essential commodity is seized and whether or not a prosecution is instituted for the contravention of such order, the Collector may, if he thinks it expedient so to do, direct the essential commodity so seized to be produced for inspection before him, and if he is satisfied that there has been a contravention of the order may order confiscation of:
 - a. The essential commodity so seized.

- b. Any package, covering or receptacle in which such essential commodity is found.
- c. Any animal, vehicle, vessel or other conveyance used in carrying such essential commodity.
2. Where the collector on receiving a report of seizure or an inspection of any essential commodity, is of the opinion that the essential commodity is subject to speedy and natural decay or it is otherwise expedient in the public interest so to do, he may:
 - a. Order the same to be sold at the controlled price, if any, fixed for essential commodity under this Act or under any other law for the time being in force.
 - b. Where no such price is fixed, order the same to be sold by public auction.
3. Where any essential commodity is sold, as aforesaid, the sale proceeds thereof, after deduction of the expenses of any such sale or auction or other incidental expenses relating thereto, shall:
 - a. Where no order or confiscation is ultimately passed by the collector.
 - b. Where an order passed on appeal under Section 6 C (appeal) so requires.
 - c. Where in a prosecution instituted for the contravention of the order in respect of which an order of confiscation has been made under this section, the person concerned is acquitted be paid to the owner or the person from whom it is seized.

APPEAL

Any person aggrieved by an order of confiscation may, within one month from the date of the communication to him of such order, appeal to any judicial authority by the State Government concerned and the judicial authority shall, after giving an opportunity to the appellant to be heard, pass such order as it may think fit, confirming, modifying or annulling the order appealed against.

Where an order is modified or annulled by such judicial authority, or where in a prosecution instituted for the contravention of the order in respect of which an order of confiscation has been made under Section 6 A, the person concerned is acquitted, and in either case it is not possible for any reason to return the essential commodity seized, such persons shall be paid the price therefor as if the essential commodity, had been sold to the Government with reasonable interest calculated from the day of the seizure of the essential commodity and such price shall be determined:

- i. In the case of food grains, edible oilseeds or edible oils.
- ii. In the case of sugar.
- iii. In the case of any other essential commodity.

OFFENCES AND PENALTIES

A. Penalties

1. If any person contravenes any order made under this act:
 - a. He shall be punishable:
 - i. With imprisonment for a term which may extend to one year and shall also be liable to fine.
 - ii. In the case of any other order, with imprisonment for a term which shall not be less than 3 months but which may extend to 7 years and shall also be liable to fine. Provided that the court may, for any adequate and special reasons to be mentioned in the judgment, impose a sentence of imprisonment for a term of less than 3 months.
 - b. Any property in respect of which the order has been contravened shall be forfeited to the Government.
 - c. Any package, covering or receptacle in which the property is found and any animal, vehicle, vessel or other conveyance used in carrying the commodity

shall, if the court so orders, be forfeited to the Government.

2. Where a person having been convicted of an offence under sub-section (1) is again convicted of an offence (subsequent offence) under that sub-section for contravention of an order in respect of an essential commodity, the court by which such person is convicted shall, in addition to any penalty which may be imposed on him under that sub-section, by order, direct that that person shall not carry on any business in that essential commodity for such period, not being less than 6 months, as may be specified by the court in the order.
3. If any person to whom a direction is given under the provision of this act fails to comply with the direction, he shall be punishable with imprisonment for a term which shall not be less than 3 months but which may extend to 7 years and shall also be liable to fine.
- 3A. If any person convicted of an offence under this act, if he is again convicted of an offence under the same provision, he shall be punishable with imprisonment for the second and for every subsequent offence for a term which shall not be less than 6 months but which may extend to 7 years and shall also be liable to fine.
- 3B. For the purposes of above sub-sections, the fact that an offence has caused no substantial harm to the general public or to any individual, shall be an adequate and special reason for awarding a sentence of imprisonment for a term of less than 3 months, or 6 months, as the case may be.

B. False Statement

If any person:

- i. Make any statement or furnish any information, which is false in any material particular and which he knows or has reasonable cause to believe to be false, or does not believe to be true.

- ii. Makes any such statement as aforesaid in any book, account, record, declaration, return or other document which he is required by any such order to maintain or furnish, he shall be punishable with imprisonment for a term which may extend to 5 years, or with fine, or both.

C. Offences by Companies

1. If the person contravening an order is a company, every person who, at the time the contravention was committed, was in-charge of, and was responsible to, the company for the conduct of the business of the company as well as the company, shall be deemed to be guilty of the contravention and shall be liable to be proceeded against and punished accordingly.
2. Notwithstanding anything contained in subsection (1), where an offence under this act has been committed by a company and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of any director, manager, secretary or other officer of the company, such director, manager,

secretary or other officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

MISCELLANEOUS

A. *Cognizance of offences:* No court shall take cognizance of any offence punishable under this act except on a report in writing of the facts constituting such offence made by a person who is a public servant as defined in Section 21 of the Indian Penal Code or any person aggrieved or any recognised consumer association, whether such person is a member of that association or not.

B. *Repeals and savings:* The following laws are hereby repealed:

- a. The Essential Commodities Ordinance, 1955.
- b. Any other law in force in any State immediately before the commencement of this act in so far as such law controls or authorizes the control of the production, supply and distribution of, and trade and commerce in, any essential commodity.

CHAPTER

6

New Drug Policy

INTRODUCTION

The New Drug Policy is an encompassing policy framework that is being drafted by an expert committee to provide guidelines to the pharma industry. The basic objectives of Government's policy relating to the drugs and pharmaceutical sector were enumerated in the Drug Policy of 1986. These basic objectives still remain largely valid. However, the drug and pharmaceutical industry in the country today faces new challenges on account of liberalization of the Indian economy, the globalization of the world economy and on account of new obligations undertaken by India under the WTO agreements. These challenges require a change in emphasis in the current pharmaceutical policy and the need for new initiatives beyond those enumerated in the Drug Policy 1986, as modified in 1994, so that policy inputs are directed more towards promoting accelerated growth of the pharmaceutical industry and towards making it more internationally competitive.

The need for radically improving the policy framework for knowledge-based industry has also been acknowledged by the Government. The Prime Minister's advisory council on Trade and Industry has made important recommendations regarding knowledge based industry. The pharmaceutical industry has been identified as one of the most important knowledge based industries in which India has a comparative advantage.

The process of liberalization set in motion in 1991 has considerably reduced the scope of industrial licensing and demolished many non-tariff barriers to imports. Important steps already taken in this regard are:

- Industrial licensing for the manufacture of all drugs and pharmaceuticals has been abolished except for bulk drugs produced by the use of recombinant DNA technology, bulk drugs requiring *in vivo* use of nucleic acids, and specific cell/tissue targeted formulations.
- Reservation of 5 drugs for manufacture by the public sector only was abolished in Feb. 1999, thus opening them up for manufacture by the private sector also.
- Foreign investment through automatic route was raised from 51 to 74% in March, 2000 and the same has been raised to 100%.
- Automatic approval for foreign technology. Agreement is being given in the case of all bulk drugs, their intermediates and formulations except those produced by the use of recombinant DNA technology, for which the procedure prescribed by the Government would be followed.
- Drugs and pharmaceuticals manufacturing units in the public sector are being allowed to face competition including competition from imports. Wherever possible, these units are being privatized.
- Extending the facility of weighted deductions of 150% of the expenditure on in-house

research and development to cover as eligible expenditure, the expenditure on filing patents, obtaining regulatory approvals and clinical trials besides R and D in biotechnology.

- Introduction of the Patents (second amendment) bill in the Parliament. It, inter alia, provides for the extension in the life of a patent to 20 years.

The impact of the policies enunciated, from time to time, by the Government has been salutary. It has enabled the pharmaceutical industry to meet almost entirely the country's demand for formulations and substantially for bulk drugs. In the process the pharmaceutical industry in India has achieved global recognition as a low cost producer and supplier of quality bulk drugs and formulations to the world. In 1999–2000, drugs and pharmaceutical exports were ₹ 6631 crores out of a total production of ₹ 19,737 crores. However, two major issues have surfaced on account of globalization and implementation of our obligations under TRIPs which impact on long-term competitiveness of Indian industry. These have been addressed in the Pharmaceutical Policy, 2002. A reorientation of the objectives of the current policy has also become necessary on account of these issues:

- The essentiality of improving incentives for research and development in the Indian pharmaceutical industry, to enable the industry to achieve sustainable growth particularly in view of anticipated changes in the patent law.
- The need for reducing further the rigours of price control particularly in view of the ongoing process of liberalization.

It is against this backdrop, that Pharmaceutical Policy, 2002 is being enunciated.

The Main Objectives of Pharmaceutical Policy 2002

1. Ensuring abundant availability of medicines at reasonable price and quality for mass consumption.

2. Strengthening the domestic capability for cost effective, quality production and exports of pharmaceuticals by reducing barriers to trade in the pharmaceutical sector.
3. Strengthening the system of quality control over drug and pharmaceutical production and distribution.
4. Encouraging R and D in the pharmaceutical industry in a manner compatible with the country's needs and with particular focus on diseases endemic or relevant to India by creating an conducive environment.
5. Creating an incentive framework for the pharmaceutical and drug industry which promotes new investment into pharmaceutical industry and encourages the introduction of new technologies and new drugs.
6. The process of liberalization set in motion in 1991 has considerably reduced the scope of industrial licensing and demolished many non-tariff barriers to imports. Important steps already taken in this regard are:
 - i. Industrial licensing for the manufacture of all drugs and pharmaceuticals has been abolished except for bulk drugs.
 - ii. Reservation of 5 drugs for manufacture by the public sector only was abolished and opening them up for manufacture by the private sector also.
 - iii. Foreign investment through automatic route was raised from 51 to 74% and further to raised to 100%.
 - iv. Automatic approval for FTA is being given in the case of all bulk drugs, their intermediates and formulations except those produced by the use of recombinant DNA technology.
 - v. Drugs and pharmaceuticals manufacturing units in the public sector are being allowed to face competition including competition from imports.

- Wherever possible, these units are being privatized.
- vi. Extending the facility of weighted deductions of 150% of the expenditure on in-house research and development to cover as eligible expenditure, the expenditure on filing patents, obtaining regulatory approvals and clinical trials besides R and D in biotechnology.
 - vii. Introduction of the Patents (second amendment) Bill in the Parliament provides for the extension in the life of a patent to 20 years.
7. Drug and pharmaceutical industry today meets almost entirely the country's demand. In the process the drug and pharmaceutical industry in India has achieved global recognition as a low cost producer and supplier of quality bulk drugs and formulations to the world. However, two major issues have surfaced on account of globalization and implementation of our obligations under TRIPs. These have been addressed in the Pharmaceutical Policy, 2002. A reorientation of the objectives of the current policy has also become necessary on account of these issues, like:
- i. Improving incentives for R and D in the Indian drug and pharmaceutical industry, to help achieve sustainable growth particularly in view of anticipated changes in the new patent law.
 - ii. The need for reducing bottlenecks of 'price control' particularly in view of the ongoing process of liberalization.

Drug Policy of 1986

Modifications in Drug Policy, 1986

The Drug Policy of 1986, which was titled "measures for rationalisation, quality control and growth of drugs and pharmaceuticals industry in India" was evolved under the dynamic guidance and leadership of late Shri

Rajiv Gandhi. This was done after a detailed examination of the various issues. The main objectives of the Drug Policy, 1986 are as under:

- a. Ensuring abundant availability, at reasonable prices of essential and life saving and prophylactic medicines of good quality.
- b. Strengthening the system of quality control over drug production and promoting the rational use of drugs in the country.
- c. Creating an environment conducive to channelising new investment into the pharmaceutical industry to encouraging cost-effective production with economic sizes and to introducing new technologies and new drugs.
- d. Strengthening the indigenous capability for production of drugs.

For meeting the requirements of medicines for health needs at reasonable prices and strengthening the indigenous base, the Government has, over the years been guided by the above policy. Implementation of the main policy provisions has been through the Industries (D and R) Act on Industrial Licensing aspects and through Drugs (Prices Control) Orders under the Essential Commodities Act in regard to the pricing mechanism. The Drug Policy has also given the policy frame work in regard to quality control and rational use of drugs. Enforcement of quality and standards in medicines is done through the provisions contained in the Drugs and Cosmetics Act, which is administered by the Ministry of Health and Family Welfare, Government of India.

Present Status and Approach of Pharmaceutical Industries

Over the last several years, policy inputs have been directed towards promoting the growth of the industry and in helping it to achieve a broad base in terms of the range of products and technologies needed to produce them from as basic a stage as possible. The results have been very encouraging. As on date, there are about 250 large units and about 8,000 small scale units in operation, which form the core of the industry

(including 5 Central Public Sector Units). These units produce the complete range of formulations, i.e. medicines ready for consumption by patients and about 350 bulk drugs, i.e. chemicals having therapeutic value used for production of formulations. It is estimated that 70% of the indigenous demand for bulk drugs and almost the entire demand for formulations are being met through domestic production.

During the last decade the production of bulk drugs has grown from ₹ 240 crores in 1980–81 to ₹ 1320 crores in 1993–94 and corresponding increase in production of formulations has been from ₹ 1200 crores to ₹ 6900 crores. The export performance of industry has also been commendable. The trade balance has been positive for the last four consecutive years. during 1992–93 the trade balance was ₹ 560 crores (excluding exports of medicinal castor oil).

Since 1986, the drug industry has grown significantly, as mentioned earlier, in terms of production of bulk drugs and formulations. In many cases manufacture of bulk drugs has also been established from the desired basic stage. It is estimated that in case of bulk drug production the contribution of small scale sector is approximately 30% of the total production in the country. It may also be mentioned that the pharmaceutical sector has been able to carve a special niche for itself in the international market as a dependable exporter of bulk drugs.

APPROACH ADOPTED IN THE REVIEW

Review of existing policy: In order to strengthen the pharmaceutical industry's research and development capabilities and to identify the support required by Indian pharmaceutical companies to undertake domestic R and D, a committee was set up in 1999 by this department by the name of Pharmaceutical Research and Development Committee (PRDC) under the chairmanship of director general of CSIR.

To qualify as R and D intensive company in India, the PRDC has suggested following conditions (Gold Standards):

- Invest atleast 5% of its turnover per annum in R and D.
- Invest atleast ₹ 10 crore per annum in innovative research including new drug development, new delivery systems etc. in India.
- Employ atleast 100 research scientists in R and D in India.
- Has been granted atleast 10 patents for research done in India.
- Own and operate manufacturing facilities in India.

The recommendations of the PRDC in so far as they relate to the Pharmaceutical Policy have been taken into account while formulating the proposals on pricing aspects.

The pharmaceutical research and development committee has recommended in its report, submitted inter alia, the setting up of a Drug Development Promotion Foundation (DDPF) and a Pharmaceutical Research and Development Support Fund (PRDSF). Necessary action in this regard has been initiated.

As far as the question of price control is concerned, the span of control has been gradually reduced since 1979. Presently, under DPCO, 1995 there are 74 bulk drugs and their formulations under price control covering approximately 40% of the total market. The functioning of the Drugs (Price Control) Order, 1995, has brought to light some problems in the administration of the price control mechanism for drugs and pharmaceuticals. In order to review the current drug price control mechanism, with the objective, inter alia, of reducing the rigours of price control, where they have become counter-productive, a committee, called the Drugs Price Control Review Committee (DPCRC), under the chairmanship of secretary, Department of Chemicals and Petrochemicals was set up in 1999, which has given its report. The recommendations of DPCRC have been examined and taken into account while formulating the "Pharmaceutical Policy, 2002".

It has emerged that the domestic drugs and pharmaceuticals industry needs reorientation in

order to meet the challenges and harness opportunities arising out of the liberalisation of the economy and the impending advent of the product patent regime. It has been decided that the span of price control over drugs and pharmaceuticals would be reduced substantially. However, keeping in view the interest of the weaker sections of the society, it is proposed that the Government will retain the power to intervene comprehensively in cases where prices behave abnormally.

In view of the steps already taken and in the light of the approach indicated in the foregoing paragraphs, the decisions of the Government are detailed below:

I. Industrial licensing: Industrial licensing for all bulk drugs cleared by Drug Controller General (India), all their intermediates and formulations will be abolished, subject to stipulations laid down from time to time in the Industrial Policy, except in the cases of:

- i. Bulk drugs produced by the use of recombinant DNA technology.
- ii. Bulk drugs requiring *in vivo* use of nucleic acids as the active principles.
- iii. Specific cell/tissue targeted formulations.

II. Foreign investment: Foreign investment up to 100% will be permitted, subject to stipulations laid down from time to time in the Industrial Policy, through the automatic route in the case of all bulk drugs cleared by Drug Controller General (India), all their intermediates and formulations, except those, referred to above under industrial licensing.

III. Foreign technology agreements: Automatic approval for Foreign Technology Agreements will be available in the case of all bulk drugs cleared by Drug Controller General (India), all their intermediates and formulations, except those, referred under industrial licensing, kept under industrial licensing for which a special procedure prescribed by the Government would be followed.

IV. Imports: Imports of drugs and pharmaceuticals will be as per EXIM policy in force. A centralized system of registration will be

introduced under the Drugs and Cosmetics Act and Rules made thereunder. Ministry of Health and Family Welfare will enforce strict regulatory processes for import of bulk drugs and formulations.

V. Encouragement to Research and Development (R and D): In principle approval to the establishment of the Pharmaceutical Research and Development Support Fund (PRDSF) under the administrative control of the Department of Science and Technology, which will also constitute a Drug Development Promotion Board (DDPB) on the lines of the technology development Board to administer the utilization of the PRDSF.

With a view to encouraging generation of intellectual property and facilitating indigenous endeavours in pharma R and D, appropriate fiscal incentives would be provided.

VI. Pricing:

A. Span of price control: The guiding principle for identification of specific bulk drugs for price regulation should continue, as per DPCRC's recommendation, to be:

- a. Mass consumption nature of the drug.
- b. Absence of sufficient competition in such drugs. However, the DPCRC's recommendation regarding the new criteria for ascertaining the mass consumption nature of a bulk drug on the basis of the top selling brand is not acceptable as it gives rise to anomalies.

In this context, it may be noted that there is no tailor made data available for the purpose of ascertaining the mass consumption nature and absence of sufficient competition with reference to a particular bulk drug. There is only one source namely, "retail store audit for pharmaceutical market in India" published by ORG-MARG, which lists out all major brands and their sale estimates on all India basis. This publication contains data for single ingredient as well as multi-ingredient formulations. However, it does not give complete description of all the ingredients of the pharmaceutical product listed therein.

Although ORG-MARG sale estimates available in regard to all single-ingredient formulations of a particular bulk drug would not yield the sale value of that bulk drug in the form of all its formulations, yet it would adequately reflect the mass consumption nature of that bulk drug in the form of single ingredient formulations, which may be used as a practical indicator for formulating the policy.

The Department through NPPA, with the help of NIPER has developed the desired database for single ingredient formulations from the retail store audit data as published by ORG-MARG. On this basis, the department proposes to undertake the exercise of identifying the bulk drugs of mass consumption nature and having absence of sufficient competition according to the following methodology:

- i. The 279 items appearing in the alphabetical list of essential drugs in the National Essential Drug List (1996) of the Ministry of Health and Family Welfare and the 173 items, which are considered important by that ministry from the point of view of their use in various health programmes, in emergency care, etc. with the exclusion, as in the past, therefrom of sera and vaccines, blood products, combinations, etc. should form the total basket out of which selection of bulk drugs be made for price regulation.
- ii. The ORG-MARG data of March 2001 would form the basis for determining the span of price control as suggested by DPCRC.
- iii. The Moving Annual Total (MAT) value for any formulator in respect of any bulk drug will be arrived at by adding the MAT values of all his single-ingredient formulations of that bulk drug, its salts, esters, stereoisomers and derivatives, covering all the strengths, dosage forms and pack sizes listed against that formulator in all groups/categories of the ORG-MARG (March 2001).
- iv. The MAT value for all the formulators, as defined in sub-para (iii) above, in respect of a particular bulk drug will be added to arrive at the total MAT value in the retail trade.
- v. The MAT value for an individual formulator, in respect of any bulk drug, as arrived at in sub-para (iii) above, will be the basis for calculating the percentage share of that formulator in the total MAT value arrived at as in sub-para (iv) above, in respect of that bulk drug.
- vi. Bulk drugs will be kept under price regulation if:
 - a. The total MAT value, arrived at as in sub-para (iv) above, in respect of any particular bulk drug is more than ₹ 2500 lakhs (₹ 25 crore) and the percentage share, as defined in sub-para (v) above, of any of the formulators is 50% or more.
 - b. The total MAT value, arrived at as in sub-para (iv) above, in respect of any particular bulk drug is less than ₹ 2500 lakhs (₹ 25 Crore) but more than ₹ 1000 lakhs (₹ 10 Crore) and the percentage share, as defined in sub-para (v) above, of any of the formulators is 90% or more.
- vii. All formulations containing a bulk drug as identified above, either individually or in combination with other bulk drugs, including those not identified for price control as bulk drug, will be under price control. The Government shall, however, retain the following over-riding power:
In cases of drugs/formulations listed by the Ministry of Health and Family Welfare, mentioned in sub-para (i) above, and those presently under price control, having significant MAT value as per ORG-MARG but not covered under the criteria in sub-para (vi) above, as a result of this proposal, the NPPA would specially monitor intensively their price movement and consumption pattern. If any unusual movement of prices is observed or brought to the notice of the NPPA, the Authority would work out the price in accordance with

the relevant provisions of the price control order.

- B. **Maximum allowable post-manufacturing expenses (MAPE):** Maximum allowable post-manufacturing expenses will be 100% for indigenously manufactured formulations.
- C. **Margin for imported formulations:** For imported formulations, the margin to cover selling and distribution expenses including interest and importer's profit shall not exceed fifty percent of the landed cost.
- D. **Pricing of formulations:**
 - i. For scheduled formulations, prices shall be determined as per the present practice. The time frame for granting price approvals will be two months from the date of the receipt of the complete prescribed information.
 - ii. The present stipulation that a manufacturer, distributor or wholesaler shall sell a formulation to a retailer, unless otherwise permitted under the provisions of Drugs (Prices Control) Order or any other order made thereunder, at a price equal to the retail price, as specified by an order or notified by the Government, (excluding excise duty, if any) minus sixteen percent thereof in case of scheduled drugs, will continue.
 - iii. The present provision of limiting profitability of pharmaceutical companies, as per the Third Schedule of the present Drugs (Prices Control) Order, 1995, would be done away with. However, if necessary so to do in public interest, price of any formulation including a non-scheduled formulation would be fixed or revised by the Government.
- E. **Ceiling prices:** Ceiling prices may be fixed for any formulation, from time to time, and it would be obligatory for all, including small scale units or those

marketing under generic name, to follow the price so fixed.

F. **Exemptions:**

- i. A manufacturer producing a new drug patented under the Indian Patent Act, 1970, and not produced elsewhere, if developed through indigenous R and D, would be eligible for exemption from price control in respect of that drug for a period of 15 years from the date of the commencement of its commercial production in the country.
- ii. A manufacturer producing a drug in the country by a process developed through indigenous R and D and patented under the Indian Patent Act, 1970, would be eligible for exemption from price control in respect of that drug till the expiry of the patent from the date of the commencement of its commercial production in the country by the new patented process.
- iii. A formulation involving a new delivery system developed through indigenous R and D and patented under the Indian Patent Act, 1970, for process patent for formulation involving new delivery system would be eligible for exemption from price control in favour of the patent holder formulator from the date of the commencement of its commercial production in the country till the expiry of the patent.
- iv. The DPCRC has suggested that the low cost drugs measured in terms of "cost per day per medicine" may be taken out of price control. Any formulator can represent to NPPA with proof of per day cost to consumer-patient. NPPA will be authorised to exempt such formulation from price control if its cost to consumer-patient does not exceed ₹ 2/- per day, under intimation to the

Government. All orders passed by the NPPA will be prospective in operation. Whenever the concerned formulator wishes to revise the price, he before effecting any change in price, would be bound to inform NPPA and seek fresh exemption and in case the cost to consumer-patient, on the basis of the proposed revised price, exceeds beyond the limit of ₹ 2/- per day, obtain the necessary price approval.

G. Pricing of scheduled bulk drugs:

- i. For a Scheduled bulk drug, the rate of return in case of basic manufacture would be higher by 4% over the existing 14% on net worth or 22% on capital employed. The time frame for granting price approvals will be 4 months from the date of the receipt of the complete prescribed information.
- ii. The Government shall, however, retain the overriding power of fixing the maximum sale price of any bulk drug, in public interest.

H. Monitoring:

- i. The DPCRC's recommendations to have effective monitoring and enforcement system and to move away from the "controlled regime" to a "monitoring regime" is in the present context an extremely important recommendation as imports will increasingly compete with local drugs and pharmaceuticals in the domestic market. A new system based on solely market prices data is required to be evolved and controls applied selectively only to cases where, either profiteering or monopoly profit seeking is noticed. The National Pharmaceutical Pricing Authority, set up in August, 1997, would need to be revamped and reoriented for this purpose. It will continue to be entrusted with the task

of price fixation/price revision and other related matters, and would be empowered to take final decisions. It would also monitor the prices of decontrolled drugs and formulations and over-see the implementation of the drug prices control orders. The Government would have the power of review of the price fixation and price revision orders, notifications of NPPA.

- ii. Although the prices of some bulk drugs have been steadily decreasing, yet the same do not get reflected in the retail price of non-scheduled formulations. Also, there is need to check high margin/commission offered to the trade by printing high prices on the labels of medicines to the detriment of the consumers. It is, therefore, proposed to strengthen the National Pharmaceutical Pricing Authority by providing appropriate powers under the DPCO which would make it mandatory for the manufacturer to furnish all information as called for by NPPA and also to regulate such prices, wherever, required.
- iii. The other recommendations of DPCRC like giving powers to Drug Control Authorities to dispose of small and petty offences, etc. will require an amendment to the Essential Commodities Act. This suggestion is considered not practicable, monitoring price movement of drugs sold in the country as well as that of imported formulations will require developing appropriate mechanism in the NPPA.
- I. **Drug price equalization account (DPEA):** Provision would be made in the new Drugs (Prices Control) Order (DPCO) to ensure that amounts which have already accrued to the DPEA and

those which are likely to accrue as a result of action in the past, are protected and used for the purpose stipulated in the existing DPCO.

VII. Quality aspects: The Ministry of Health and Family Welfare would:

- i. Progressively benchmark the regulatory standards against the international standards for manufacturing.
- ii. Progressively harmonize standards for clinical testing with international practices.
- iii. Streamline the procedures and steps for quick evaluation and clearance of new drug applications, developed in India through indigenous R and D.
- iv. Set up a world class Central Drug Standard Control Organization (CDSCO) by modernizing, restructuring and reforming the existing system and establish an effective network of drugs standards enforcement

administrations in the States with the CDSCO as a nodal center, to ensure high standards of quality, safety and efficacy of drugs and pharmaceuticals.

VIII. Pharma education and training: The National Institute of Pharmaceutical Education and Research (NIPER) have been set up by the Government of India as an institute of "national importance" to achieve excellence in pharmaceutical sciences and technologies, education and training. Through this institute, Government's endeavor will be to upgrade the standards of pharmacy education and R and D. Besides tackling problems of human resources development for academia and the indigenous pharmaceutical industry, the institute will make efforts to maximize collaborative research with the industry and other technical institutes in the area of drug discovery and pharma technology development.

The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954

INTRODUCTION

This Act may be called the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954. The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 is an Act No. 21 of 1954. It extends to the whole of India except the State of Jammu and Kashmir, and applies also to persons domiciled in the territories to which this Act extends who are outside the said territories. Section 16 of the Act authorizes the Central Government to make rules for carrying out the purpose of the Act. In exercise of the powers conferred by Section 16 of the Act, the Central Government has framed the Drugs and Magic Remedies (Objectionable Advertisements) Rules, 1955.

The **Objectionable Advertisements** tend to cause the ignorant and unwary consumer to resort to self-medication or to resort to quacks who indulge in such advertisements for treatments, which cause great harm. It was therefore found necessary in the public interest to put a stop to such undesirable advertisements. The main object and purpose of the act is to prevent people from self-medicating with regard to various diseases. Self medication in respect of diseases of serious nature mentioned in the Act and the Rules has a deleterious effect on the health of the community and is likely to affect the well-being of the people. Exaggerated and misleading advertisements induce people to resort to self-medication by reasons of elated advertisement,

it was thought necessary in the interest of public health that, the puffing of advertisements is put to a complete check and that, the manufacturers are compelled to route their products through recognized sources so that the products of these manufacturers could be put to valid and proper test and consideration by expert agencies. The Act has been enacted with a view to control the advertisements of drugs in certain cases and to prohibit the advertisements for certain purposes of remedies alleged to possess magic qualities.

The Act defines drugs and registered medical practitioners besides defining magic remedy. According to act the Magic remedy includes a talisman *mantra kavacha*, and any other charm of any kind which is alleged and possess miraculous powers for or in the diagnosis, cure, mitigation treatment or prevention of any disease in human-beings or animals or for affecting or influencing in any way the structure or any organic function of human beings or animals.

Unless prescribed by registered medical Practitioners or after consultation with the Drugs and Cosmetics Act, 1940, no person or company, shall take any part in the publication of any advertisement referring to any drug that is used for:

- a. The miscarriage in woman or prevention of conception in women.
- b. Maintenance or improvement of the capacity of human beings for sexual pleasures.
- c. Correction of menstrual disorder in women.

- d. The diagnosis, cure, mitigation, treatment or prevention of any disease.

No person or company will take part in advertisement which give false impression or makes a false claim for the drug or mislead the people. Whosoever contravenes any of the provision of this Act shall be punishable with imprisonment extended to six months or with fine, or with both for first time conviction. It may extend to one year imprisonment or with fine or with both on subsequent convictions.

Salient Features

Section 3 of the Act prohibits any advertisement promoting drugs for the diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition specified in the Schedule. The Schedule lists a number of diseases, disorders or conditions such as diabetes, cataract, cancer, fevers (in general), obesity, rheumatism, impotence, high or low blood pressure, female diseases, epilepsy, stature of persons, venereal diseases, glaucoma, sterility in women, dropsy, etc.

Section 4 of the act prohibits those advertisements relating to a drug if they contain any matter which directly or indirectly gives a false impression regarding the true character of the drug or makes a false claim for the drug or is otherwise false or misleading.

Section 5 of the act prohibits advertisements of magic remedies for treatment of certain diseases and disorders.

Violation of the law attracts imprisonment for 6 months or fine or both, for first conviction and for subsequent conviction, imprisonment for a year or fine or both. Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 is implemented by food and drug administration through all of their district and divisional offices. There is also a provision available in the Drugs and Cosmetics Act, 1940 which deals with the advertisements of the drugs.

Schedule 'J' of the Drugs and Cosmetic Rules, 1945 too deals with objectionable advertisements. The list of diseases is almost the same

but few more diseases are included in Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954.

There are:

- 54 entries listed in Schedule to DMR Act, 1954.
- 02 entries listed in Schedule to DMR Rules, 1955.
- 51 entries listed in Schedule 'J' to D and C Rules, 1945.

Some entries are similar but some are exclusive to DMR and D and C Schedules.

The Schedules for Diseases Specified Under the Act

Appendicitis, atherosclerosis, blindness, blood poisoning, bright's disease, cancer, cataract, deafness, diabetes, brain diseases or disorder, uterus diseases, disorder of menstrual flow, disorders of nervous system, prostatic gland disorders, dropsy, epilepsy, female disease (in general), fever (in general), fits, forms and structure of the female breast, gallbladder stones, kidney stones, bladder stones, gangrene, glaucoma, goitre, heart diseases, high or low blood pressure, hydrocele, hysteria, infantile paralysis, insanity, leprosy, leucoderma, lock jaw, locomotor ataxia, lupus, nervous debility, obesity, paralysis, plague, pleurisy, pneumonia, rheumatism, ruptures, dexual impotence, smallpox, stature of person, sterility of wome, trachoma, TB, tumours, typhoid fever, ulcers of GI tract, venereal diseases, including syphilis, gonorrhoea, soft chancre venereal granuloma and lymphogranuloma.

The Schedules for Diseases Specified Under the Rules

1. Asthma
2. AIDS

The Drugs and Magic Remedies (Objectionable Advertisements) Act is specifically meant to tackle such false and misleading claims, but it is totally outdated and inadequate to deal with the present day situation, it has no provision to tackle television and internet

advertisements. The Union Health Ministry has said that the law is being amended to curb such advertisements and award stringent punishment to those found guilty of violation.

The Union Ministry of Health has said that the amended law would not only tackle advertisements on the electronic media, but would also provide for severe punishment to those that violate the law. The move is welcome, but it would be far more effective if the laws were to provide for corrective advertisements in fact this is absolutely necessary to ensure that the impression created by a false or misleading advertisement is corrected through a series of advertisements. So in addition to amending the law, the government should provide for an independent mechanism to monitor the implementation of the law and ensure its stringent enforcement. Corrective advertisements are also absolutely essential.

Objectives

- This act is passed to control the advertisement of drugs in certain cases, to prohibit the advertisement for certain purposes of remedies alleged to possess magic qualities and to provide for matters connected therewith.
- This act is passed to control all the advertisements which are objectionable and unethical.
- This act is passed to prevent people from self-medicating with regard to various diseases.
- This act is passed to control and prohibit the advertisements which makes false claim and mislead the public under this act.

The act read as a whole does not merely prohibit advertisements relating to drugs and medicines connected with disease specified under the act but also cover all the advertisements which are objectionable or unethical and are used to promote self-medication or self-treatment.

DEFINITIONS

- a. “Advertisement” includes any notice, circular, label, wrapper, or other document, and any announcement made orally or by any means of producing or transmitting light, sound or smoke.
- b. “Drug” includes:
 - i. A medicine for the internal or external use of human beings or animals.
 - ii. Any substance intended to be used for or in the diagnosis, cure, mitigation, treatment or prevention of disease in human beings or animals.
 - iii. Any article, other than food, intended to affect or influence in any way the structure or any organic function of the body of human beings or animals.
 - iv. Any article intended for use as a component of any medicine, substance or article, referred to in sub-clauses (i), (ii) and (iii) above.

The definition of drug under the act is comprehensive and evens the machine which is an article and covered by the definition. The definition of ‘drug’ in section 2 is very comprehensive and exhaustive. Unlike definition of drug under Drugs and Cosmetics Act, 1940, it brings within its ambit, medicines of all systems including Ayurvedic drugs.

- c. “Magic Remedy” includes a talisman *mantra kavacha*, and any other charm of any kind which is alleged to possess miraculous powers for or in the diagnosis, cure, mitigation treatment or prevention of any disease in human beings or animals or for affecting or influencing in any way the structure or any organic function of the body of human beings or animals.
- d. “Registered Medical Practitioner” means any person:
 - i. Who holds a qualification granted by an authority specified in, or notified under Section 3 of the Indian Medical Degrees Act, 1916 specified in the Schedules to the Indian Medical Council Act, 1956.

- ii. Who is entitled to be registered as a medical practitioner under any law for the time being in force. In any state to which this act extends relating to the registration of medical practitioner.
 - e. "**Taking any Part in the Publication of any Advertisement**" includes:
 - i. The printing of the advertisement.
 - ii. The publication of any advertisement outside the territories to which this act extends by or at the instance of person residing within the said territories.
 - iii. The diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition specified in the Schedule, or any other disease, disorder or condition which may be specified in the rules made under this act.
- Provided that no such rule shall be made except:
- i. In respect of any disease, disorder or condition which requires timely treatment in consultation with a registered medical practitioner or for which there are normally no accepted remedies.
 - ii. After consultation with the drugs technical advisory board constituted under the Drugs and Cosmetics Act, 1940, and, if the Central Government considers necessary, with such other persons having special knowledge or practical experience in respect of Ayurvedic or Unani Systems of medicines as that Government deems fit.

PROHIBIT ADVERTISEMENT

Section 3 to 6 of the act are prohibitory sections.

In view of provisions of Sections 3 and 4, the act seeks to prohibit advertisement not only of drugs for treatment of diseases and disorder but also advertisement of drugs, which are false or misleading. By virtue of Section 5, the persons carrying on or purporting to carry on profession of administering magic remedies are prohibited from taking part in the publication of any advertisement referring to any magic remedy which directly or indirectly claims to be efficacious for any of the purposes specified in Section 3. Section 6 of the Act prohibits import and export of objectionable advertisements. Provisions of Section 3 to 6 are reproduced below for ready reference:

A. Prohibition of advertisement of certain drugs for treatment of certain diseases and disorders (Section 3): Subject to the provisions of this Act, no person shall take any part in the publication of any advertisement referring to any drug in terms which suggest or are calculated to lead to the use of that drug for:

- a. The procurement of miscarriage in women or prevention of conception in women.
- b. The maintenance or improvements of the capacity of human beings for sexual pleasure.
- c. The correction of menstrual disorder in women.

- d. The diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition specified in the Schedule, or any other disease, disorder or condition which may be specified in the rules made under this act.

No person shall also take part in the publication of any advertisement referring to any drug in terms which suggest or are calculated to lead to the use of that drug for the diagnosis, cure, mitigation, treatment or prevention of any disease, disorder, or condition specified in the Schedule for diseases under the Rules. The Schedules for diseases specified under the rules are: 1. Asthma 2. AIDS.

B. Prohibition of misleading advertisements relating to drugs (Section 4): Subject to the provisions of this act, no person shall take any part in the publication of any advertisement relating to a drug if the advertisement contains any matter which:

- i. Directly or indirectly gives a false impression regarding the true character of the drug.
- ii. Makes a false claim for the drug.
- iii. Is otherwise false or misleading in any material particular.

C. Prohibition of advertisement of magic remedies for treatment of certain diseases and disorders (Section 5): No person carrying on or purporting to carry on the profession of

administering magic remedies shall take any part in the publication of any advertisement referring to any magic remedy which directly or indirectly claims to be efficacious for any of the purposes specified in Section 3.

D. Prohibition on import into, and export from India of certain advertisement (Section 6): No person shall import into, or export from, the territories to which this act extends any document containing and advertisement of the nature referred to in Section 3, or Section 4, or Section 5, and any documents containing any such advertisement shall be deemed to be goods of which the import or export has been prohibited under the Sea Customs Act, 1878.

Procedure to be followed in prohibiting import into, and export from India of certain advertisements:

1. If the customs collector has reasons to believe that any consignment contains documents of the nature, he may and if requested by an officer appointed for the purpose by the Central Government, shall detain the consignment and dispose it of in accordance with the provisions of the Sea Customs Act, 1878, and the rules made thereunder, and shall also inform the importer or exporter of the order so passed.
2. If the importer or exporter who has given an undertaking under the first proviso to sub-rule (1) is required by the customs collector to return the consignment or any portion thereof, he shall return the consignment or portion thereof within ten days of the receipt of the notice.

CLASSES OF ADVERTISEMENT EXEMPTED UNDER THE DRUGS AND MAGIC REMEDIES ACT

Classes of exempted advertisement (provision for savings, under the act): Following classes of Advertisement are not prohibited under this act. It means nothing in this act is applicable to these types of advertisements under the provision for saving of this act.

Nothing in this act shall apply to:

- i. Any sign board or notice displayed by a registered medical practitioner on his

premises indicating that treatment for any disease, disorder or condition is undertaken relating to which advertisements otherwise are prohibited.

- ii. Any treatise or book dealing with any of the matter relating to the disease or conditions which are otherwise prohibited to be advertised, provided published from a bona fide scientific or social standpoint.
- iii. Any advertisement relating to any drug sent confidentially in the prescribed manner to a RMP. Advertisement can be sent confidently by posting to a RMP or a wholesaler or retail chemist and bearing at the top, printed in indelible ink in a conspicuous manner, the word 'for the use only of RMP or hospital or a laboratory'.
- iv. Any advertisement relating to a drug printed or published by the Government.
- v. Any advertisement relating to a drug printed or published by any person with the previous sanction of the Government granted prior to the commencement of the Drugs and Magic Remedies (Objectionable Advertisement) Amendment Act, 1963.
- vi. Any advertisement, labels or sets of instructions which are permitted under the Drug and Cosmetic Act and Rules thereunder.

The Government may, for reasons to be recorded in writing withdraw the sanction after giving the person an opportunity of showing cause against such withdrawal.

Power to exempt from application of Act: If in the opinion of the Central Government public interest requires that the advertisement of any specified drug or class of drugs or any specified class of advertisement relating to drugs should be permitted, it may by notification in the official gazette, direct that the provisions of Sections 3 to 6 or any one of such provision shall not apply subject to the advertisement of any such drug or class of drugs or any such class of advertisement relating to drugs.

The Central Government though a notification issued in 1967 has further exempted from the provisions of the act the following classes of the advertisements with the conditions against them:

it may furnish evidence of the commission of an offence punishable under this act.

2. The provisions of the Code of Criminal Procedure, 1898, shall, so far as may be,

<i>Class of advertisement</i>	<i>Conditions</i>
1. Leaflets or literature accompanying packaging of drugs.	1. The advertisement contains only such information as is required for the guidance of RMP in respect of matters relating to. a. Therapeutic indications of the drug. b. Its administration. c. Its dosage. d. Its side effects.
2. Advertisement of drug in medical, pharmaceutical, scientific and technical journals.	2. The precautions to be observed in treatment with the drug. It shall be the responsibility of the advertiser to prove that any claim made in the advertisement with respect of the drug is not false, exaggerated or misleading.
3. Price lists or therapeutic indexes published by manufacturers, importers or distributors of drugs.	3. Same as above.
4. Medical literature distributed by medical representatives appointed by manufacturers, importers or distributors of drugs duly licensed under the Drugs and Cosmetics Act, 1940 and rules thereunder.	4. The distribution of such literature is confined only to the RMP, hospitals, dispensaries, medical and research institutions and chemists and druggist or pharmacies duly licensed under the provisions of the D and C Rules.

ENTRY, SEARCH AND SEIZURE

1. Subject to the provisions of any rules made in this behalf, any gazetted officer authorised by the State Government may, within the local limits of the area for which he is so authorized:
 - a. Enter and search at all reasonable times, with such assistants, if any, as he considers necessary, any place in which he has reason to believe that an offence under this act has been or is being committed.
 - b. Seize any advertisement which he has reason to believe contravenes any of the provisions of this act. Provided that the

power of seizure under this clause may be exercised in respect of any document, article or thing which contains any such advertisement, including the contents, if any, of such document, article or thing, if the advertisement cannot be separated by reason of its being embossed or otherwise, from such document, article or thing without affecting the integrity utility or saleable value thereof.

- c. Examine any record, register, document or any other material object found in any place mentioned in clause (a) and seize the same if he has reason to believe that

apply to any search or seizure under this act as they apply to any search or seizure made under the authority of a warrant issued under Section 98 of the said code. Where any person seizes anything, he may be informing a Magistrate and takes his orders as to the custody thereof.

OFFENCES AND PENALTIES

A. Offences

I. Offences by companies:

1. If the person contravening any of the provisions of this act is a company, every person who at the time the offence was committed, was in-charge of and was responsible to the company for the conduct of the business of the company as well as the company shall be deemed to be guilty of the contravention and shall be liable to be proceeded against and punished accordingly.
2. Notwithstanding anything contained in above sub-section where an offence under this act has been committed by a company and it is proved that the offence was committed with the consent or connivance of or is attributable to any neglect on the part of any director or manager secretary or other officer of the company such Director, Manager, Secretary or other officer of the company shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

II. Offences to be cognizable: Notwithstanding anything contained in the Code of Criminal Procedure, 1898 an offence punishable under this act shall be cognizable.

III. Jurisdiction to try offences: No Court inferior to that of a presidency Magistrate or a magistrate of the first class shall try any offence punishable under this act.

B. Penalties

- i. Whoever contravenes any of the provisions of this act or the rules made thereunder shall, on conviction, be punishable.

- ii. In the case of a first conviction, with imprisonment which may extend to 6 months, or with fine, or both.
- iii. In the case of a subsequent conviction, with imprisonment which may extend to one year, or with fine, or both.

MISCELLANEOUS

A. Manner in which advertisements may be sent confidentially: All documents containing advertisements relating to drugs shall be sent by post to a registered medical practitioner by name or to a wholesale or retail chemist, the address of such registered medical practitioner or wholesale or retail chemist being given. Such document shall bear at the top, printed in indelible ink in a conspicuous manner, the words. "For the use only of registered medical practitioners or a hospital or a laboratory".

B. Scrutiny of misleading advertisements relating to drugs: Any person authorized by the State Government in this behalf may, if satisfied, that an advertisement relating to a drug contravenes the provisions of the act, may require the manufacturer, packer, distributor or seller of the drug to furnish, within such time as may be specified in the order or such further time as may be allowed in this behalf by the person so authorized information regarding the composition of the drug or the ingredients thereof or any other information in regard to that drug as he deems necessary for holding the scrutiny of the advertisement and where any such order is made, it shall be the duty of the manufacturer, packer, distributor or seller of the drug to which the advertisement relates to comply with the order. Any failure to comply with such order shall, for the purposes of the provision related to the penalty under the act, be deemed to be a contravention of the provisions related to the prohibition of misleading advertisements relating to drugs. Provided that no publisher or advertising agency of any medium for the dissemination of any advertisement relating to a drug shall be deemed to have made any contravention merely

by reason of the dissemination by him or if any such advertisement, unless such publisher or advertising agency has failed to comply with any discretion made by the authorized person in this behalf calling upon him or it to furnish the name and address of the manufacturer, packer, distributor, seller or advertising agency, as the case may be, who or which caused such advertisement to be disseminated.

C. Forfeiture: Where a person has been convicted by any court for contravening any provision of this act or any rule made there under, the court may direct that any document (including all copies thereof), article or thing, in respect of which the contravention is made,

including the contents thereof where such contents are seized under this act, shall be forfeited to the Government.

D. Indemnity: No suit, prosecution or other legal proceeding shall lie against any person for anything which is in good faith done or intended to be done under this act.

E. Other laws not affected: The provision of this Act is in addition to, and not in derogation of the provisions of any other law for the time being in force.

F. Power to make rules: The Centre Government may, by notification in the official gazette, make rules for carrying out the purposes of this Act.

CHAPTER 8

The Poisons Act, 1919

INTRODUCTION

Special provisions are needed to deal with the substances that are poisonous. Earlier the Schedule E to the Drug and Cosmetic Rules, 1945 enlisted the poisons but the same has been dropped in the 1982 amendment to the said rules. The Poison Act was passed on 3rd September 1919 to control the import, possession and sale of poisons. This act replaced the Poison Act, 1904 possessing the limiting boundary. This act may be called the Poisons Act, 1919. It extends to the whole of India. Provided that it shall not apply to the State of Jammu and Kashmir except to the extent to which the provisions of this act relate to the importation into India of any specified poison. Under this act the Central Government has been authorised to regulate the import the poisons across any of the defined frontiers, while the various State Governments have been authorized to make rules regarding the possession and sale of poisons within their respective territories. For the purpose of the act, all substances, specified as poisons in notifications issued under the act, are to be deemed as poisons.

Salient Features

- Poison Act has been divided into 10 sections.
- The State Government has power to regulate possession for sale and sale of any poison under this Act.

- The State Government has power to grant of licenses to possess any specified poison for sale, wholesale or retail, and fixing of the fee (if any) to be charged for such licenses, and inspection and examination of any such poison when possessed for sale by any such vendor.
- The State Government has power to regulate possession of any poison in certain areas.
- The Central Government has power to prohibit importation into India of any poison except under license.
- Penalty for unlawful importation, possession for sale and sale for any poison: imprisonment for a term which may extend to 3 months, or with fine which may extend to 500 rupees, or both.
- The District Magistrate, the Sub-Divisional-Magistrate and, in a Presidency-town, the Commissioner of Police, has power to issue a warrant for the search under Section 7 of the Act.

Objectives

An act to consolidate and amend the law regulating the importation, possession and sale of poisons. It is expedient to consolidate and amend the law regulating the importation, possession and sale of poison.

DEFINITIONS

Poison: Any substance specified as a poison in a rule made or notification issued under this act shall be deemed to be a poison for the purposes of this act.

The substances deemed to be poisonous are categorized in this act as:

List A: Aconite, Arsenic, Atropine, Belladonna, Cantharides, Chloral hydrates, Coca, Corrosive sublimate, Potassium cyanide, Dimorphine (Heroin) diethyl barbituric acid, Digitalis, Ecgonine, Ergot of Rye, Lead, Nux vomica, Strachnine, Morphine, Pectrotoxine, Prussic acid, Savin and its oils, Stramonillan, Stropanthus, Stropanthin tarter emetic, Tetra ethyl lead.

List B: Essential oil of Almonds (unless deprived of prussic acid) Antimonial wine, all salts of barbiun, except Barbium sulphate, Tinchure of conthrides, Carbolic acid, Chloroform, Mercuric sulphocynide, Oxalic acid, Poppies, all oxides of mercury, Sulphonial, Zinc chloride.

Exemption from certain provisions of the Act is made for the provisions substances of list B.

IMPORT OF POISON

The import of poisons is permitted only under the authority of a license granted for the purpose by the Central Government. Persons licensed to import poisons, should import them across one of the defined customs frontiers and in accordance with the conditions of the license.

POSSESSION AND SALE OF POISON

A. Power of the State Government to regulate possession for sale and sale of any poison:

1. The State Government may make rules to regulate the possession for sale and the sale, whether wholesale or retail, of any specified poison within the whole or any part of the territories under its administration.

2. In particular, and without prejudice to the generality of the foregoing power, such rules may provide for:

- a. The grant of licenses to possess any specified poison for sale, wholesale or retail, and fixing of the fee (if any) to be charged for such licenses.
- b. The classes of persons to whom alone such licenses may be granted.
- c. The classes of persons to whom alone any such poison may be sold.
- d. The maximum quantity of any such poison which may be sold to any person.
- e. The maintenance by vendors of any such poison of registers of sales, the particulars to be entered in such registers, and the inspection of the same.
- f. The safe custody of such poisons and the labelling of the vessels, packages or coverings in which any such poison is sold or possessed for sale.
- g. The inspection and examination of any such poison when possessed for sale by any such vendor.

B. Power to regulate possession of any poison in certain areas: The State Government may by rule regulate the possession of any specified poison in any local area in which the use of such poison for the purpose of committing murder or mischief by poisoning cattle appears to it to be of such frequent occurrence as to render restrictions on the possession thereof desirable. The State Government may direct that any breach thereof shall be punishable with imprisonment for a term which may extend to one year, or with fine which may extend to one thousand rupees (1,000 rupees), or with both, together with confiscation of the poison in respect of which the breach has been committed, and of the vessels, packages or coverings in which the same is found.

C. Power to prohibit importation into India of any poison except under license: The Central Government may, by notification in the official gazette, prohibit, except under and in

accordance with the conditions of a license, the importation into India across any customs frontier defined by the Central Government of any specified poison, and may by rule regulate the grant of licenses.

PENALTIES

Penalty for unlawful importation, possession for sale and sale for any poison:

1. Whoever:
 - a. Imports or possesses or sells any poisons except as provided under the act, shall be liable to punishment with imprisonment.
 - b. Imports without a license into India across a customs frontier defined by the Central Government any poison the importation of which is for the time being restricted.
 - c. Breaks any condition of a license for the importation of any poison granted to him, shall be punishable.
 - i. On a first conviction, with imprisonment for a term which may extend to 3 months, or with fine which may extend to 500 rupees, or with both.
 - ii. On a second or subsequent conviction, with imprisonment for a term which may extend to 6 months, or with fine which may extend to 1,000 rupees, or both.
2. Any poison in respect of which an offence has been committed under this section, together with the vessels, packages or coverings in which the same is found, shall be liable to confiscation.

WARRANTS

Power to issue search warrants: The District Magistrate, the Sub-divisional Magistrate and, in a Presidency-Town, the Commissioner of Police, may issue a warrant for the search of any place in which he has reason to believe or the suspect that any poison is possessed or sold in

contravention of this suspect that any poison is possessed or sold in contravention of this Act or any rule thereunder, or that any poison liable to confiscation under this act is kept or concealed. The person to whom the warrant is directed may enter and search the place in accordance therewith, and the provisions of The Code of Criminal Procedure, 1898, relating to search warrants shall, as far as may be, deemed to apply to the execution of the warrant.

RULES

Power of Government to make the rules: In addition to any other power to make rules herein before conferred the State Government may make rules generally to carry out the purposes and objects of this act except Section 3 (power to prohibit importation into India of any poison except underlicense). Every power to make rules conferred by this Act shall be subject to the condition of the rules being made after previous publication. All rules made by the Central Government or by the State Government under this Act shall be published in the official gazette and on such publication shall have effect as if enacted in this Act. Every rule made by the Central Government under this act shall be laid, as soon as may be after it is made, before each house of parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule. Every rule made by the State Government under this act shall be laid, as soon as may be after it is made, before the State Legislature.

SAVINGS

Nothing in this act or in any license granted or rule made thereunder shall extend to, or interfere with, anything done in good faith in the exercise of his profession as such by a medical or veterinary practitioner. The State Government may by general or special order declare that all or any of the provisions of this act except Section 3 (power to prohibit importation into India of any poison except underlicense).

The authority on which any power to make Rules under this Act is conferred may, by general or special order, either wholly or partially:

- a. Exempt from the operation of any such rules.
- b. Exclude from the scope of the exemption, any person or class of persons either generally or in respect of any poisons specified in the order.

The Medical Termination of Pregnancy Act, 1971

INTRODUCTION

During the last thirty years many countries have liberalized their abortion laws. The worldwide process of liberalization continued after 1980. Today only 8% of the world's population lives in countries where the law prevents abortion. Although the majority of countries have very restricted Abortion Laws, 41% of women live in countries where abortion is available on request of women. In India, Shantilal Shah Committee (1964) recommended liberalization of Abortion Law in 1966 to reduce maternal morbidity and mortality associated with illegal abortion. On these bases, in 1969 Medical Termination of Pregnancy Bill was introduced in Rajya Sabha and Lok Sabha and passed by Indian Parliament in Aug. 1971. This act may be called the Medical Termination of Pregnancy Act, 1971. It extends to the whole of India except the State of Jammu and Kashmir. It came on the Statute Book as the "The MTP Act, 1971". This law guarantees the right of women in India to terminate an unintended pregnancy by a registered medical practitioner in a hospital established or maintained by the Government or a place being approved for the purpose of this act by the Government. Medical termination of Pregnancy Act, 1971 (MTP Act) was implemented from April 1972. Implemented rules and regulations were again revised in 1975 to eliminate time consuming procedures for the approval of the place and to make services more readily available. The MTP Act, 1971 preamble

states" an act to provide for the termination of certain pregnancies by registered medical practitioners and for matters connected therewith or incidental thereto.

Salient Features

- The MTP Act, 1971 has been divided into 8 Sections.
- This act provides the termination of pregnancy by a RMP for bona fide medical reasons under Section 3 of MTP Act, 1971.
- The pregnancy may be terminated only at a hospital established or maintained by the Government or a place approved by it for the purpose.
- The Central Government has power to make rules.
- The State Government has power to make regulations.

Objectives

This act was passed to provide for the termination of certain pregnancies by registered medical practitioners and for matters connected therewith or incidental thereto.

The declared objects and reasons of the act state that pregnancy can be terminated:

- As a health measure when there is a danger to the life or risk to physical or mental health of the women.
- On humanitarian grounds—such as when pregnancy arises from a sex crime like rape or intercourse with a lunatic woman, etc.

- Eugenic grounds—where there is a substantial risk that the child, if born, would suffer from deformities and diseases.

DEFINITIONS

- a. **"Guardian"** means a person having the care of the person of a minor or a lunatic.
- b. **"Lunatic"** has the meaning assigned to it in Section 3 of the Indian Lunacy Act, 1912.
- c. **"Minor"** means a person who, under the provisions of the Indian Majority Act, 1875, is to be deemed not to have attained his majority.
- d. **"Registered Medical Practitioner"** means a medical practitioner who possesses any recognised medical qualification as defined in the Indian Medical Council Act, 1956, whose name has been entered in a state medical register and who has such experience of training in gynecology and obstetrics as may be prescribed by rules made under this Act.
- e. **"Chief Medical Officer of the District"** means the Chief Medical Officer of a District, by whatever name called.
- f. **"Chief Medical Officer of the State"** means the Chief Medical Officer of the State, by whatever name called.
- g. **"Owner"** in relation to a place, means any person who is the administrative head or otherwise responsible for the working or maintenance of such hospital or clinic, by whatever name called.
- h. **"Place"** means such building, tent, vehicle, or vessel, or part thereof, as is used for the establishment or maintenance therein of a hospital or clinic which is used, or intended to be used, for the termination of any pregnancy.
- i. **"Approved Place"** means a place approved under Rule 4 of MTP Rules.
- j. **"Hospital"** means a hospital established or maintained by the Central Government or, the Government of Union territory.

- k. **"Admission Register"** means a register maintain as per Regulation-5 of the MTP Act, 1971.

Pregnancy: Pregnancy is the carrying of one or more offspring, known as a fetus or embryo, inside the womb of a female. Child birth usually occurs about 38 weeks after conception, i.e. approximately 40 weeks from the last normal menstrual period (LNMP) in humans. The World Health Organization defines normal term for delivery as between 37 weeks and 42 weeks.

Abortion: An abortion is the removal or expulsion of an embryo or fetus from the uterus, resulting in or caused by, its death.

This can occur spontaneously as a miscarriage, or be artificially induced through chemical, surgical or other means. Commonly, "abortion" refers to an induced procedure at any point in the pregnancy, medically, it is defined as a miscarriage or induced termination before twenty weeks gestation, which is considered nonviable.

Abortion may be classified into various categories depending upon the nature and circumstances under which it occurs. For instance, it may be either:

- i. Natural.
- ii. Accidental.
- iii. Spontaneous.
- iv. Artificial or induced abortion.

Abortions falling under the first three categories are not punishable, while induced abortion is criminal unless exempted under the law. Natural abortions is a very common phenomena and may occur due to many reasons, such as bad health, defect in generative organs of the mother, shocks, fear, joy, etc. Accidental abortion very often takes place because of pathological reasons where pregnancy cannot be completed and the uterus empties before the maturity of fetus. Induced abortions are denied in law as an untimely delivery voluntarily procured with intent to destroy the foetus. It may be procured at any time before the natural birth of the child.

TERMINATION OF PREGNANCY

A. Conditions for termination of pregnancy according to the Act:

1. Not notwithstanding anything contained in the Indian Penal Code, 1980, a registered medical practitioner shall not be guilty of any offence under that code or under any other law for the time being in force, if any pregnancy is terminated by him in accordance with the provisions of this Act.
2. **A pregnancy may be terminated by a registered medical practitioner:**
 - a. Where the length of the pregnancy does not exceed 12 weeks.
 - b. Where the length of the pregnancy exceeds 12 weeks but does not exceed 20 weeks, if not less than two registered medical practitioners are of opinion, formed in good faith, that:
 - i. The continuance of the pregnancy would involve a risk to the life of the pregnancy woman or of grave injury to her physical or mental health.
 - ii. There is a substantial risk that if the child were born, it would suffer from such physical or mental abnormalities as to be seriously handicapped.

Explanation:

- I. Where any pregnancy is alleged by the pregnant woman to have been caused by rape, the anguish caused by such pregnancy shall be presumed to constitute a grave injury to the mental health of the pregnant woman.
- II. Where any pregnancy occurs as a result of failure of any device or method used by any married woman or her husband for the purpose of limiting the number of children, the anguish caused by such unwanted pregnancy may be presumed to constitute a grave injury to the mental health of the pregnant woman.
3. In determining whether the continuance of pregnancy would involve such risk of injury to the health and account may be

taken of the pregnant woman's actual or reasonable for foreseeable environment.

4. Consent for abortion:

- a. No pregnancy of a woman, who has not attained the age of 18 years, or, who, having attained the age of 18 years, is a lunatic, shall be terminated except with the consent in writing of her guardian.
- b. No pregnancy shall be terminated except with the consent of the pregnant woman.

B. Place where pregnancy may be terminated: Termination of pregnancy shall not be made at any place other than:

- a. A hospital established or maintained by Government.
- b. A place for the time being approved for the purpose of this act by Government.

PREGNANCIES MAY NOT BE TERMINATED

The provisions related to the length of the pregnancy and the opinion of not less than two registered medical practitioners, shall not apply to the termination of a pregnancy by a registered medical practitioner in a case where he is of opinion, formed in good faith, that the termination of such pregnancy is immediately necessary to save the life of the pregnant woman. Notwithstanding anything contained in the Indian Penal Code, the termination of pregnancy by a person who is not a registered medical practitioner shall be an offence punishable under that code, and that code shall, to this extent, stand modified.

Protection of action taken in good faith: No suit or other legal proceeding shall lie against any registered medical practitioner for any damage caused or likely to be caused by anything which is in good faith done or intended to be done under this Act.

QUALIFICATION OF DOCTORS

According to the Act, 'a medical practitioner who possess any recognized medical qualification as defined in clause (h) of Sec. 2 of the

Indian Medical Council Act, 1956 whose name has been entered in a State medical register and who has such experience or training in gynaecology or obstetrics as may be prescribed by rules made under this act is permitted to conduct the termination of pregnancy'. Allopathic doctors who are duly registered with the State Medical Council are authorized to do abortion. Other like Homeopathic, Ayurvedic, Unani doctors and unqualified doctors like RMP, quacks, et al. are not entitled to perform abortion. Even among allopathic doctors, only those who satisfy one or the other of the following qualifications are eligible to do MTP. Once a doctor satisfies the required qualifications, he automatically becomes eligible to do abortions. He need not apply for eligibility to any authority. A doctor cannot refuse to do abortions on religious grounds. If he does so, his name is liable to be erased from the Medical Council. If he is a Govt. doctor, he is liable for departmental action.

EXPERIENCE OR TRAINING

Requirement of experience or training for an RMP to terminate pregnancy: For the purpose of the act, a registered medical practitioner shall have one or more of the following experience or training in gynaecology and obstetrics, namely:

- a. In the case of a medical practitioner who was registered in a state medical register immediately before the commencement of the act, experience in the practice of gynaecology and obstetrics for a period of not less than three years.
- b. In case of a medical practitioner who was registered in a State Medical Register on or after the date of commencement of the act:
 - i. If he has completed six months of house surgery in gynaecology and obstetrics.
 - ii. Unless the following facilities are provided therein, if he had experience at any hospital for a period of not less

than one year in the practice of obstetrics and gynaecology.

- iii. If he has assisted a registered medical practitioner in the performance of 25 cases of medical termination of pregnancy in a hospital established or maintained, or a training institute approved for this purpose, by the Government.
- c. In the case of medical practitioner who has been registered in a state medical register and who holds a postgraduate Degree or Diploma in gynaecology and obstetrics, the experience or training gained during the course of such Degree or Diploma.

APPROVAL OF A PLACE

Requirements of places approved for termination of pregnancy: Medical termination of pregnancy can be done by a RMP only at an approved place. The application for the approval of a place should be addressed of the district who shall verify or inspect such place with a view to ascertain himself that the following conditions are satisfied:

1. No place shall be approved.
 - a. Unless the Government is satisfied that termination of pregnancies may be done therein under safe and hygienic conditions.
 - b. Unless the following facilities are provided therein namely:
 - i. An operation table and instruments for performing abdominal or gynaecological surgery.
 - ii. Unaesthetic equipment, resuscitation equipment and sterilization equipment.
 - iii. Drugs and parenteral fluids for emergency use.
2. Every application for the approval of a place shall be in a Form A and shall be addressed to the Chief Medical Officer of the District.
3. The Chief Medical Officer of the District shall verify or enquiry any information

contained in any such application or inspect any such place with a view to satisfying himself that the facilities are provided therein, and that termination of pregnancies may be made therein under safe and hygienic conditions.

4. Every owner of the place which is inspected by the Chief Medical Officer of the District shall afford all reasonable facilities for the inspection of the place.
5. The Chief Medical Officer of the District may, if he is satisfied after such verification, enquiry or inspection, as may be considered necessary, that termination of pregnancies may be done under safe and hygienic conditions, at the place, recommend the approval of such place to the Government.
6. The Government may after considering the application and the recommendations of the Chief Medical Officer of the District approve such place and issue a certificate of approval in Form B.
7. The certificate of approval issued by the Government shall be conspicuously displayed at the place to be easily visible to persons visiting the place.

INSPECTION OF A PLACE

1. A place approved by the Government may be inspected by the Chief Medical Officer of the District, as often as may be necessary with a view to verify whether termination of pregnancies is being done therein under safe and hygienic conditions.
2. If the Chief Medical Officer has reason to believe that there has been death of, or injury to, a pregnant woman at the place or that termination of pregnancies is not being done at the place under safe and hygienic conditions, he may call for any information or may seize any article, medicine, ampule, admission register or other document, maintained, kept or found at the place.
3. The provisions of the Code of Criminal Procedure, 1973, relating to seizure shall, so far as may be, apply to seizure.

CANCELLATION OR SUSPENSION OF CERTIFICATE OF APPROVAL

1. If, after inspection of any place approved by Government under rule approval of a place, the Chief Medical Officer of the District is satisfied that the facilities are not being properly maintained therein and the termination of pregnancy at such place cannot be made under safe and hygienic conditions, he shall make a report of the fact to the Government giving the detail of the deficiencies or defects found at the place. On receipt of such report the Government may, after giving the owner of the place a reasonable opportunity of being heard, either cancel the certificate of approval or suspend the same for such period as it may think fit.
2. Where a certificate issued under Rule 4 is cancelled or suspended, the owner of the place may make such additions or improvements in the place as he may think fit and thereafter, he may make an application to the Government for the issue to him of a fresh certificate or approval under Rule 4 or, as the case may be, for the revival of the certificate which was suspended under sub-rule (1).
3. The provisions of Rule 4 shall, as far as may, apply to an application for the issue of a fresh certificate of approval in relation to a place, or as the case may be for the revival of a suspended as they apply to an application for the issue of a certificate of approval under that rule.
4. In the event of suspension of a certificate, of approval, the place shall not be deemed to be an approved place for the purposes of termination of pregnancy from the date of communication of the order of such suspension.

CUSTODY OF FORMS

The consent given by a pregnant woman for the termination of her pregnancy, together with the certified opinion recorded, as the case may be and the intimation of termination of pregnancy

shall be placed in an envelope which shall be scaled by the registered medical practitioner or practitioners by whom such termination of pregnancy was performed and until that envelope is sent to the head of the hospital or owner of the approved place of the chief medical officer of the State, it shall be kept in the safe custody of the concerned registered medical practitioner or practitioners, as the case may be. On every envelope, pertaining to the termination of pregnancy, there shall be noted the serial number assigned to the pregnant woman in the admission register and the name of the registered medical practitioner or practitioners by whom the pregnancy was terminated and such envelope shall be marked "Secret". Every envelope shall be sent immediately after the termination of the pregnancy to the head of the hospital or owner of the approved place where the pregnancy was terminated. On receipt of the envelope, the head of the hospital or owner of the approved place shall arrange to keep the same in safe custody. Every head of the hospital or owner of the approved place shall send to the Chief Medical Officer of the State a weekly statement of cases where medical termination of pregnancy has been done in Form II. On every, pertaining to a termination of pregnancy, shall be noted the name and address of the registered medical practitioner by whom the pregnancy was terminated and the date on which the pregnancy was terminated and such envelopes shall be marked "Secret". Where the pregnancy is not terminated in an approved place or hospital, every envelope shall be sent by registered post to the Chief Medical Officer of the State on the same day on which the pregnancy was terminated or on the working day next following the day on which the pregnancy was terminated.

MAINTENANCE OF RECORDS/ADMISSION REGISTER

A. Maintenance of admission register: Every head of the hospital or owner of the approved place shall maintain a register in Form III for

recording therein the admissions or woman for the termination of their pregnancies. The entries in the admission register shall be made serially and a fresh serial shall be started at the commencement of each calendar year and the serial number of the particular year shall be distinguished from the serial number of other years by mentioning the year against the serial number, for example, serial number 5 of 1972 and serial number 5 of 1973 shall be mentioned as 5/1972 and 5/1973. The admission register shall be a secret document and the information contained therein as to the name and other particulars of the pregnant woman shall not be disclosed to any person.

B. Admission register not to be open to inspection:

The admission register shall be kept in the safe custody of the head of the hospital or owner of the approved place, or by any person authorised by such head or owner shall not be open to inspection by any person except under the authority of:

- i. In the case of a departmental or other enquiry, the Chief Secretary to the Government of a Union Territory.
- ii. In the case of an investigation into an offence a Magistrate of the first class within the local limits or whose jurisdiction the hospital or approved place is situated.
- iii. In the case of suit or other action for damages, the District Judge, within the local limits of whose jurisdiction the hospital or approved place is situated.

Provided that the registered medical practitioner shall, on the application of an employed woman whose pregnancy has been terminated, grant a certificate for the purpose of enabling her to obtain leave from her employer.

C. Entries in registers maintained in hospital or approved place: No entry shall be made in any case-sheet, operation theatre register, follow-up card or any other document or register (except the admission register) maintained at any hospital or approved place indicating therein the name of the pregnant woman and reference to

the pregnant woman shall be made therein by the serial number assigned to such woman in the admission register.

D. Destruction of admission register and other papers: Save as otherwise directed by the chief secretary to the union territory administration or for in relation to any proceeding pending before him, as directed by a District Judge or a Magistrate of the first class, every admission Register shall be destroyed on the expiry of a period of five years from the date of the last entry in that register and other papers on the expiry of a period of three years from the date of termination of the pregnancy concerned "Secret".

OFFENCES AND PENALTIES

The termination of a pregnancy by a person who is not a registered medical practitioner is a punishable offence under the Indian Penal Code. Anyone who fails to comply with rules made under the act or contravenes them may be fined up to 1,000 rupees.

In 2002, under the Medical Termination of Pregnancy Amendment Act, the penalties for performing an illegal abortion were increased. Abortions performed by a non-medical practitioner carry a penalty of 2 to 7 years in prison. The same penalty applies to those who perform abortions outside of hospitals or other approved locations. In addition, the owner of the non-approved facility will also be faced with 2 to 7 years in prison.

MISCELLANEOUS

A. MTP in nonrecognised centers: MTP law lays down precise requirement and procedures for recognition of place for MTP. In recent survey carried out by an NGO, it was found that only 22% of eligible centers are registered under MTP act. There are many reasons including 'red tapism'. But that hardly protects one in the court of law.

B. Repeal and saving: The Medical Termination of Pregnancy Rules, 1972 are hereby repealed

except as respects things done or omitted to be done before such repeal.

C. Power to make rules: The Central Government may, by notification in the official gazette, make rules to carry out the provisions of this Act.

In particular, and without prejudice to the generality of the foregoing power, such rules may provide for all or any of the following matters, namely:

- The experience or training, or both, which a registered medical practitioner shall have if he intends to terminate any pregnancy under this Act.
- Such other matters as are required to be or may be, provided by rules made under this Act.

Every rule made by the Central Government under this Act shall be laid, as soon as may be after it is made, before each House of Parliament while it is in session for a total period of 30 days which may be comprised in one session or in two successive sessions, and if, before the expiry of the session in which it is so laid or the session immediately following, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be. So, however that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rules.

D. Power to make regulations: The State Government may, by regulations:

- Require any such opinion as to be certified by a registered medical practitioner or practitioners concerned, in such form and at such time as may be specified in such regulations, and the preservation or disposal of such certificates.
- Require any registered medical practitioner, who terminates a pregnancy, to give intimation of such termination and such other information relating to the termination as may be specified in such regulations.

c. Prohibit the disclosure, except to such persons and for such purposes as may be specified in such regulations, of intimations given or information furnished in pursuance of such regulations.

The intimation given and the information furnished in pursuance of regulations shall be given or furnished, as the case may be, to the chief medical officer of the state. Any person who willfully contravenes or willfully fails to comply with the requirements of any regulation shall be liable to be punished with fine which may extend to 1,000 rupees.

E. Amendment: The MTP Act, 1971 was amended by the MTP (Amendment) Act, 2002. The **main objective** of the recent amendment to the MTP Act aimed at reducing the rate of unsafe abortions by making legal abortion more widely accessible. Lack of access to MTP services at the primary healthcare level is an important reason for the high rate of unsafe and illegal abortions. The amendment is aiming at decentralization of authority for approval and registration of MTP centres from the State to the district level. The current system for approving such centres is extremely cumbersome and slow. At the same time, however, efforts at decentralization need to be closely monitored to ensure that a speedier approval process does not compromise quality of care, and that adequate resources for both training and technology are made available. There is an increase in punishment in violations of the Act.

Medical abortion is one that is brought about by taking medication that will end a pregnancy. The alternative is surgical abortion as dealt with by the MTP Act, 1971, which ends a pregnancy by emptying the uterus with its associated complications and infection. Medical abortions can be performed as early as pregnancy can be confirmed. Infact, the shorter the time that a woman has been pregnant, better will the medication work. Medication can be taken under proper supervision and appropriate counseling. It requires almost no infrastructure and no surgery. Though medical abortions are safer, easier and more effective, surgical abortions continue to be the most common method, as the majority of the population in the rural and urban areas is still ignorant about the availability and technique of medical abortion.

A suitable and specific amendment in the MTP Act, 1971 is urgently required. Keeping in tune with the changed times and techniques, effort should be made to push for relevant amendment of the MTP act so that a medical practitioner would legally terminate a pregnancy by using the drugs for medical abortion without contravention of the medical termination of pregnancy act or the Indian Penal Code or any other act for the time being in force. Such an amendment can also lay down the procedure of medical abortion and issue such guidelines and rules so as to restrict its misuse.

CHAPTER 10

The Prevention of Cruelty to Animals Act, 1960

INTRODUCTION

Animals have been used throughout the history of scientific research. It has been estimated that approximately 15 million animals are used to test drugs. The animal testing is based on the grounds of morality, the necessity of the procedure, whether such tests are actually needed and whether such tests practically provide any useful information to the scientific society. Animals are highly useful and kept as pets, beasts of burden or as tools for scientific experimentations, etc. use of animals in experiments for establishing the therapeutic efficacy and safety of drugs is generally unavoidable but causing them unnecessary pain or for unethical and inhuman. In almost all the progressive countries there are laws to safeguard animals from infliction of unnecessary pain and suffering or in other words to prevent the man from behaving cruelly towards them. In India also, there is an act which aims at the same objective. This act may be called the Prevention of Cruelty to Animals Act, 1960. It extends to the whole of India except the State of Jammu and Kashmir. It shall come into force on such date as the Central Government may, by notification in the official gazette, appoint, and different dates may be appointed for different States and for the different provisions in this act. This act has been passed to prevent the infliction of unnecessary pain or suffering on animals and for that purpose to amend the law relating to the prevention of cruelty to animals. The term

cruelty means inflicting of unnecessary pain or suffering to animals.

SALIENT FEATURES

- Central act-in force throughout the territory of India.
- Rules under the act-in force throughout India unless specified otherwise.
- Applies only to "captive" and "domestic" animals.
- This act enumerates the various forms of cruelty on animals which are prohibited.
- The provision of this act which relate to "experimentation of animals" is of pharmaceutical interests.
- Experimentation on animals-CPCSEA-to regulate experimentation-general objectives laid down-non-cognizable offences.
- Performing animals-registration mandatory-procedure laid down in S. 23-S. 26 offence and punishment-non-cognizable offence.

Aims and Objectives

- The prevention of Cruelty to Animals Act, 1960 is an act to prevent the infliction of unnecessary pain or suffering on animals and for that purpose to amend the law relating to the prevention of cruelty to animals.
- Earlier to the enactment of this act, local acts were there in some parts of our

country, which were confined to roads or streets of towns and to actions caused obstruction or inconvenience to residents and passengers by the animals.

- Social organizations like SPCA (Society for Prevention of Cruelty To Animals) were doing in the protection of animals. Now a voluntary organization called "blue cross" is also doing good service in taking care of the health of unprotected and stray animals.
- The act provides for the constitution of Animal Welfare Board of India and a committee to control and supervision of experiments on animals, giving the constitution and functions of these.
- Similarly cruelty to animals and performing animals are also dealt in the act, with penalty for offences.

DEFINITIONS

- a. "**Animal**" means any living creature other than a human being.
- b. "**Board**" means the board established under Section 4 (Constitution of the board) and as reconstituted from time to time under Section 5 A (Re-Constitution of the board).
- c. "**Captive Animal**" means any animal (not being a domestic animal) which is in capacity or confinement, whether permanent or temporary, or which is subjected to any appliance of contrivance for the purpose of hindering or preventing its escape from captivity or confinement or which is pinioned or which is or appears to be maimed.
- d. "**Domestic Animal**" means any animal which is tamed or which has been or is being sufficiently tamed to serve some purpose for the use of man or which, although it neither has been nor is intended to be so tamed, is or has become in fact wholly or partly tamed.
- e. "**Local Authority**" means a municipal committee, district board or other autho-
- rity for the time being invested by law with the control and administration of any matters within a specified local area.
- f. "**Owner**", used with reference to an animal, includes not only the owner but also any other person for the time being in possession or custody of the animal, whether with or without the consent of the owner.
- g. "**Phooka**" or "**Doom Dev**" includes any process of introducing air or any substance into the female organ of a milch animal with the object of drawing off from the animal any secretion of milk.
- h. "**Street**" includes any way, road, lane, square, court, alley, passage or open space, whether a thoroughfare or not to which the public have access.
- i. "**Breeder**" means a person including an institution, which breeds animals for the purpose of transfer to other authorised institution for performing experiments.
- j. "**Establishment**" means any individual, company, firm, corporation, institution other than schools upto higher secondary level, which performs experiments on animals.
- k. "**Experiment**" means any programme, project involving experiments on an animal/animals for the purpose of advancement by new discovery of physiological knowledge which will be useful for saving or prolonging life or alleviating suffering or for combating any disease whether on human beings or animals.
- l. "**Institutional Animals Ethics Committee**" means a body comprising of a group of persons recognised and registered by the Committee for the purpose of control and supervision of experiments on animal performed in an establishment which is constituted and operated in accordance with procedures specified for the purpose by the committee.
- m. "**Contract Research**" means any research undertaken by an individual, company,

firm, corporation or institution on behalf of a foreign individual, company, firm, corporation or institution for any consideration.

- n. "**Collaborative Research**" means any research undertaken between two or more research institutions on an equal footing which does not involve any financial or monetary considerations and is undertaken solely for the purpose of advancement of scientific research and human welfare.
- o. "**Specified Format**" means the form specified for the purpose by the committee from time to time.

It shall be the duty of every person having the care or charge of any animal to take all reasonable measures to ensure the well-being of such animal and to prevent the infliction upon such animal of unnecessary pain or suffering.

Duties of Persons Having Charge of Animals

It shall be the duty of every person having the care or charge of any animal to take all reasonable measures to ensure the well-being of such animal and to prevent the infliction upon such animal of unnecessary pain or suffering.

CRUELTY TO ANIMALS GENERALLY

Under the Act "Treating Animals Cruelly" Generally Includes

- 1. If any person:
 - a. Beats, kicks, overrides, over-drives, over-loads, tortures or otherwise treats any animal so as to subject it to unnecessary pain or suffering.
 - b. Employing any unfit animal for work or labour.
 - c. Wilfully and unreasonably administering any injurious drug or injurious substance to domestic or captive animal.
 - d. Conveys or carries, whether in or upon any vehicle or not, any animal in such a manner or position as to subject it to unnecessary pain or suffering.
- e. Keeps or confines any animal in any cage or other receptacle which does not measure sufficiently in height, length and breadth to permit the animal a reasonable opportunity for movement.
- f. Keeps for an unreasonable time any animal chained or tethered upon an unreasonably short or unreasonably heavy chain or cord.
- g. Being the owner, neglects to exercise or cause to be exercised reasonably any dog habitually chained up or kept in close confinement.
- h. Being the owner of any animal fails to provide such animal with sufficient food, drink or shelter.
- i. Without reasonable cause, abandons any animal in circumstances which render it likely that it will suffer pain by reason of starvation thirst.
- j. Wilfully permits any animal, of which he is the owner, to go at large in any street, while the animal is affected with contagious or infectious disease or, without reasonable excuse permits any diseased or disabled animal, of which he is the owner, to die in any street.
- k. Offers for sale or without reasonable cause, has in his possession any animal which is suffering pain by reason of mutilation, starvation, thirst, over-crowding or other ill-treatment.
- l. Mutilates any animal or kills any animal including stray dogs by using the method of strychnine injections, in the heart or in any other unnecessarily cruel manner.
- m. Solely with a view to providing entertainment.
- n. Confines or causes to be confined any animal including tying of an animal as a bait in a tiger or other sanctuary so as to make it an object or prey for any other animal.

- o. Organises, keeps uses or acts in the management or, any place for animal fighting or for the purpose of baiting any animal or used for any such purposes.
- p. Promotes or takes part in any shooting match or competition wherein animals are released from captivity for the purpose of such shooting:

Treating animals cruelly is an **offence punishable** in the case of a first offence, with fine which shall not be less than 10 rupees but which may extend to 50 rupees and in the case of a second or subsequent offence committed within 3 years of the previous offence, with fine which shall not be less than 25 rupees but which may extend, to 100 rupees or with imprisonment for a term which may extend, to 3 months, or with both.

2. An owner shall be deemed to have committed an offence if he has failed to exercise reasonable care and supervision with a view to the prevention of such offence.
3. Nothing in this section shall apply to:
 - a. The dehorning of cattle, or the castration or branding or nose roping of any animal in the prescribed manner.
 - b. The destruction of stray dogs in lethal chambers by such other methods as may be prescribed.
 - c. The extermination or destruction of any animal under the authority of any law for the time being in force.
 - d. Any matter dealt within this part of the Act.
 - e. The commission of any act in the course of the destruction or the preparation for destruction of any animal as food for mankind unless such destruction or preparation was accompanied by the infliction of unnecessary pain or suffering.

ANIMAL WELFARE BOARD

After the enactment of this act, the animal board of India was formed for the promotion of animal welfare.

A. Establishment of animal welfare board of India: Animal welfareboard of India was established by Central Government under Section 4 of the Act.

For the promotion of animal welfare generally and for the purpose of protecting animals from being subjected to unnecessary pain or suffering, in particular, there shall be established by the Central Government, as soon as may be after the commencement of this Act, a Board to be called the Animal Board of India. The Board shall be a body corporate having perpetual succession and a common seal with power, subject to the provisions of this act, to acquire, hold and dispose of property and may by its name sue and is sued.

I. Constitution of the board: Animal Welfare Board of India was constituted by Central Government under Section 5 of the Act:

1. The board shall consist of the following persons, namely:
 - a. The Inspector General of Forests, Government of India, *ex-officio*.
 - b. The Animal Husbandry Commissioner to the Government of India, *ex-officio*.
 - c. Two persons to represent respectively the ministries of the Central Government dealing with home affairs and education, to be **appointed** by the Central Government.
 - d. One person to represent the Indian Board for wild life, to be **appointed** by the Central Government.
 - e. Two persons who, in the opinion of the Central Government, are or have been actively engaged in animal welfare work and are well-known humanitarians, to be **nominated** by the Central Government.
 - f. Two persons to represent practitioners of modern and indigenous systems of medicine, to be **nominated** by the Central Government.
 - g. One person to represent such association of veterinary practitioners as in the opinion of the Central Government ought to be represented on the Board,

to be **elected** by that association in the prescribed manner.

- h. One person to represent each of such two municipal corporations as in the opinion of the Central Government ought to be represented on the board, to be **elected** by each of the said corporations in the prescribed manner.
- i. Six members of parliament, four to be **elected** by the House of the people (Lok Sabha) and two by the Council of States (Rajya Sabha).
- j. One person to represent each of such three organizations actively interested in animal welfare as in the opinion of the Central Government ought to be **represented** on the board, to be chosen by each of the said organizations in the prescribed manner.
- k. One person to represent each of such three societies dealing with prevention of cruelty to animal as in the opinion of the Central Government ought to be **represented** on the board, to be chosen, in the prescribed manner.
- 2. Any of the persons may depute any other person to attend any of the meetings of the board.
- 3. The Central Government shall nominate one of the members of the board to be its **Chairman** and another member of the Board to be its **Vice-Chairman**.

II. Reconstitution of the board: In order that the Chairman and other members of the board hold office till the same date and that their terms of office come to an end on the same date, the Central Government may, by notification in the official gazette, reconstitute, as soon as may be after the Prevention of Cruelty to Animals (amendment) Act, 1982 comes into force. The board shall be reconstituted from time to time on the expiration of every third year, from the date of its reconstitution. There shall be included amongst the members of the board reconstituted, all persons who immediately before the date on which such reconstitution is to take

effect, are members of the board but such persons shall hold office only for the unexpired portion of the term for which they would have held office if such reconstitution had not been made and the vacancies arising as a result of their ceasing to be members of the board shall be filled up as casual vacancies for the remaining period of the term of the board as so reconstituted.

III. Secretary and other employees of the board: The Central Government shall appoint the secretary of the board. Subject to such rules as may be made by the Central Government in this behalf, the board may appoint such number of other officers and employees as may be necessary for the exercise of its powers and the discharge of its functions and may determine the terms and conditions of service of such officers and other employees by regulations made by it with the previous approval of the Central Government.

B. Funds of the board: The funds of the board shall consist of grants made to it from time to board time by the Government and of contributions, subscriptions, bequests, gifts and the like made to it by any local authority or by any other person.

C. Functions of the board: The functions of the board shall be:

- a. To keep the law in force in India for the prevention of cruelty to animals under constant study and advise the Government on the amendments to be undertaken in any such law from time to time.
- b. To advise the Central Government on the making of rules under this act with a view to prevent unnecessary pain or suffering to animals generally, and more particularly when they are being transported from one place to another or when they are used as performing animals or when they are kept in captivity or confinement.
- c. To advise the Government or any local authority or other person on improvements in the design of vehicles so as to lessen the burden on draught animals.

- d. To take all such steps as the Board may think fit for amelioration of animals by encouraging or providing for, the construction of sheds, water-troughs and the like and by providing for veterinary assistance to animals.
 - e. To advise the Government or any local authority or other person in the design of slaughter-houses or the maintenance of slaughter houses or in connection with slaughter of animals so that unnecessary pain or suffering, whether physical or mental, is eliminated in the pre-slaughter stages as far as possible, and animals are killed wherever necessary, in as humane a manner as possible.
 - f. To take all such steps as the board may think fit to ensure that unwanted animals are destroyed by local authorities, whenever it is necessary to do so, either instantaneously or after being rendered insensible to pain or suffering.
 - g. To encourage by the grant of financial assistance or otherwise (the formation or establishment of pinjrapoles, rescue homes, animal shelters, sanctuaries and the like), where animals and birds may find a shelter when they have become old and useless when they need protection.
 - h. To co-operate with and co-ordinate the work of, associations or bodies established for the purpose of preventing unnecessary pain or suffering to animals or for the protection of animals and birds.
 - i. To give financial and other assistance to animal welfare organizations functioning in any local area or to encourage the formation of animal welfare organizations in any local area which shall work under the general supervision and guidance of the board.
 - j. To advise the Government on matters relating to the medical care and attention which may be provided in animal hospital, and to give financial and other assistance to animal hospitals whenever the board thinks it necessary to do so.
 - k. To impart education in relation to the humane treatment of animals and to encourage the formation of public opinion against the infliction of unnecessary pain or suffering to animals and for the promotion of animal welfare by means of lectures, books, posters, cinematographic exhibitions and the like.
 - l. To advise the Government on any matter connected with animal welfare or the prevention of infliction of unnecessary pain or suffering on animals.
- D. **Power of Board to make regulations:** The board may, subject to the previous approval of the Central Government, make such regulations as it may think fit for the administration of its affairs and for carrying out its functions.

EXPERIMENTATION ON ANIMALS

A. **Experiments on animals:** Nothing contained in this Act shall render unlawful performance of experiments (including experiments involving operations) on animals for the purpose of advancement by new discovery of physiological knowledge or of knowledge which will be useful for saving or for prolonging life or alleviating suffering or for combating any disease, whether of human beings, animals or plants.

B. **CPCSEA:** The Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA).

The Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) has been constituted under this act. It gives the guidelines for the conduct of animal experiments. CPCSEA has been in existence for the past 50 years and its role of is not to cause any hindrance to scientific research involving experiments on animals but to ensure that:

- i. Animals are maintained in a proper and healthy manner.
- ii. Animals are not subjected to unnecessary pain or suffering before, during and after performance of experiments on them.

- iii. There is no unnecessary sacrifice of animals for the sake of science. There should be no duplication of research.
- iv. Animals are kept in disease free condition to ensure proper data collection.
- v. Animals are procured from registered breeders.
- vi. Experiments on large animals are to be avoided whenever it is possible to achieve the same results by experiments on small laboratory animals.

For effective implementation of these rules and guidelines, the Institutional Animals Ethics Committees (IAEC) has been constituted in institutions conducting experiments on animals. This is a scientific body nominated by the Head of the Institution. The IAEC is required to examine proposals for conducting experiments on small animals, which would chiefly examine the necessity of performing the experiment, and ensure that experiments are not performed in a routine manner. All decisions are to be taken with the approval of the committee.

I. Constitution of CPCSEA: Constitution of the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA):

1. If at any time, on the advice of the Board, the Central Government is of opinion that it is necessary so to do for the purpose of controlling and supervising experiments on animals it may be notification in the official gazette constitute a committee consisting of such number of officials and non-officials, as it may think fit to appoint thereto.
2. The Central Government shall nominate one of the members of the committee to be its Chairman.
3. The committee shall have power to regulate its own procedure in relation to the performance of its duties.
4. The funds of the committee shall consist of grants made to it from time to time by the Government and of contributions, donations, subscriptions, bequests, gifts and the like made to it by any person.

II. Sub-committee of the CPCSEA: The committee may constitute as many sub-committees as it thinks fit for exercising any power or discharging any duty of the committee or for inquiring into or reporting and advising on any matter which the committee may refer. A sub-committee shall consist exclusively of the members of the committee.

III. Staff of the committee: Subject to the control of the Central Government, the committee may appoint such number of officers and other employees as may be necessary to enable it to exercise its powers and perform its duties and may determine the remuneration and other terms and conditions of service of such officers and other employees.

C. Duties and power of the committee: Duties of the Committee and power of the committee to make rules relating to experiments on animals.

1. It shall be the duty of the committee to take all such measures as may be necessary to ensure that animals are not subjected to unnecessary pain or suffering before, during or after the performance of experiments on them, and for the purpose it may, by notification in the gazette of India and subject to the condition of previous publication, make such rules as it may think fit in animals relation to the conduct of such experiments.
- 1A. In particular, and without prejudice to the generality to the foregoing power, such rules may provide for the following matters namely:
 - a. The registration of persons or institutions carrying experiments on animals.
 - b. The reports and other information which shall be forwarded to the committee by persons and institutions carrying experiments on animals.
2. In particular, and without prejudice to the generality of the foregoing power, rules made by the committee shall be designed to secure the following objects, namely:

- a. That in cases where experiments are performed in any institution, the responsibility therefore is placed on the person in-charge of the institution and that, in cases where experiments are performed outside an institution by individuals, the individuals, are qualified in that behalf and the experiments are performed on their full responsibility.
 - b. That experiments are performed with due care and humanity and that as far as possible experiments involving operations are performed under the influence of some anaesthetic of sufficient power to prevent the animals feeling pain.
 - c. That animals which, in the course of experiments under the influence of anaesthetics, are so injured that their recovery would involve serious suffering, are ordinarily destroyed while still insensible.
 - d. That experiments on animals are avoided wherever it is possible to do so as for example; in medical schools, hospitals, colleges and the like, if other teaching devices such as books, models, films and the like, may equally suffice.
 - e. That experiments on larger animals are avoided when it is possible to achieve the same results by experiments upon small laboratory animals like guinea-pigs, rabbits, frogs and rats.
 - f. That, as far as possible, experiments are not performed merely for the purpose of acquiring manual skill.
 - g. That animals intended for the performance of experiments are properly looked after both before and after experiments.
 - h. That suitable records are maintained with respect to experiments performed on animals.
 - 3. In making any rules under this section, the Committee shall be guided by such directions as the Central Government (consistently with the objects for which the Committee is set up) may give to it, and the Central Government is hereby authorised to give such direction.
 - 4. All rules made by the committee shall be binding on all individuals performing experiments outside institutions and on persons-in-charge of institutions in which experiments are performed.
- D. Power of entry and inspection:** For the purpose of ensuring that the rules made by it are being complied and with the committee may authorise any of its officers or any other person in writing to inspect any institution or place where experiments are being carried on and report to it as a result of such inspection, and any officer or person so authorised may enter at any time considered reasonable by him and inspect any institution or place in which experiments on animals are being carried on; and require any person to produce any record kept by him with respect to experiments on animals.
- E. Power to prohibit experiments on animals:** If the committee is satisfied on the report of any officer or other person made to it as a result of any inspection or otherwise that the rules made by it are not being followed the committee may, after giving an opportunity to the person or institution carrying on experiments on animals. The committee may, after giving an opportunity to the person or institution of being heard in the matter, by order, prohibit the person or institution from carrying on any such experiments either for a specified period or indefinitely, or may allow the person or institution to carry on such experiments subject to such special conditions as the committee may think fit to impose.

INSTITUTIONAL ANIMAL ETHICS COMMITTEE (IAEC)

- A. Composition of IAEC:** IAECs shall be multi-disciplinary and multisectorial in composition.

The committee will be nominated by the Dean and will be approved by the academic board. The composition of the committee will be as follows, and will fulfil the CPCSEA norms vide gazette Rule 13 of breeding of and experiments on Animals (Control and Supervision) Rules 1998.

The composition may be as follows:

1. Chairperson, 2. Dean, 3. Two faculty members of the institute preferably involved in animal experiments, out of two, one from the non-clinical discipline, 4. One veterinarian of involved in the care of animals, 5. In-charge animal House, 6. A scientist from outside the institute, 7. One nonscientific socially aware person, 8. One representative or nominee of CPCSEA, 9. One specialist may be co-opted while reviewing special projects using hazardous agents such as radioactive substance and deadly microorganisms, 10. Member-Secretary.

The Chairperson of the Committee shall be from outside the institution. The member secretary, drawn from college itself, shall conduct the business of the committee. Other members will be a mix of medical and non-medical, scientific and non-scientific persons to reflect differed viewpoints.

B. Functions of IAEC: IAEC should provide independent, competent and timely review of the ethics of a proposed study before the commencement of the same and regularly monitor the ongoing studies. IAEC will review and approve all research proposals involving animal experiments with a view to assure quality maintenance and welfare of animals used in laboratory studies while conducting research. For experiments on higher animals, the IAEC will forward its recommendation to the CPCSEA, New Delhi, for its approval. IAEC will review the proposals before the start of the study, as well as monitor the research throughout the study and after completion of the study (through six monthly reports, final report). IAEC will visit the laboratory/animal house where the experiments are conducted. The committee will

also ensure compliance with all regulatory requirements, applicable guidelines and laws.

IAEC will also:

- i. Monitor and inspect the housing of animals of breeders/establishments to ensure that it is as per specified standards.
- ii. Grant permission for conducting experiments on animals.
- iii. Regulate experiments on animals as per stipulated conditions and standards.
- iv. Ensure that animals which in course of the experiments are so injured that their recovery would involve serious sufferings are euthanized as per specified norms.
- v. Ensure that experiments on animals are avoided whenever it is possible and propagate the principles of 3 rupees (reduce, refine and replace the use of animals in experiments).
- vi. Ensure that experiments on larger animals are avoided when it is possible to achieve the same results by experiments upon small animals.
- vii. Ensure that required records are maintained with respect to experiments performed on animals.
- viii. Ensure that as far as possible experiments are not performed merely for the purpose of acquiring manual skill.
- ix. Ensure that animals intended for the performance of experiments are properly looked after both before and after experiments.

C. Membership duration and responsibilities: The duration of membership will be 3 years. There will be no bar on the members serving for more than one term but it is desirable to have around one third fresh members. A member can be replaced in the event of long-term non-availability (three consecutive meetings). Authority to replace the member shall be with the director. members should maintain confidentiality of all discussions during the meeting and sign a confidentiality form at the start of their term. Each member of the committee will submit a declaration to maintain the confidentiality of the

documents submitted to them during their membership period.

PERFORMING ANIMALS

A. **"Exhibit" and "train" defined:** In this part, "exhibit" means exhibit or any entertainment to which the public are admitted through sale of tickets, and "train" means train for the purpose of any such exhibition, and the expressions "exhibitor" and "trainer" have respectively the corresponding meanings.

B. **Restriction on exhibition and training of performing animals:** No person shall exhibit or train:

- i. Any performing animal unless he is registered in accordance with the provisions of this act.
- ii. As a performing animal, any animal which the Central Government may, by notification in the official gazette, specify as an animal which shall not be exhibited or trained as a performing animal.

C. Procedure for registration:

1. Every person desirous of exhibiting or training any performing animal shall, on making an application in the prescribed form to the prescribed authority and on payment of the prescribed fee, be registered under this act unless he is a person who, by reason of an order made by the court under this chapter, is not entitled to be so registered.
2. An application for registration under this part of the act shall contain such particulars as to the animals and as to the general nature of the performances in which the animals are to be exhibited or for which they are to be trained as may be prescribed, and the particulars so given shall be entered in the register maintained by the prescribed authority.
3. The prescribed authority shall be given to every person whose name appears on the register kept by them, a certificate of

registration in the prescribed form containing the particulars entered in the register.

4. Every register kept under this part of the act shall at all reasonable times be open for inspection on payment of the prescribed fee, and any person shall, on payment of the prescribed fee, be entitled to obtain copies thereof or make extracts therefrom.
5. Any person whose name is entered in the register shall, subject to the provisions of any order made under this act by any court, be entitled, on making an application for the purpose, to have the particulars entered in the register with respect to him varied, and where any such particulars are so varied, the existing certificate shall be cancelled and a new certificate issued.

D. Power of court to prohibit or restrict exhibition and training of performing animals:

1. Where it is proved to the satisfaction of any Magistrate on a complaint made by a police officer or an officer authorised in writing by the prescribed authority, that the training or exhibition of any performing animals has been accompanied by unnecessary pain or suffering and should be prohibited or allowed only subject to conditions, the court may make an order against the person in respect of whom the complaint is made, prohibiting the training or exhibition or imposing such conditions in relation thereto, as may be specified by the order.
2. Any court by which an order is made under this section, shall cause a copy of the order to be sent, as soon as may be after the order is made, to the prescribed authority by which the person against whom the order is made is registered, and shall cause the particulars of the order to be endorsed upon the certificate field by the person, and that person shall produce his certificate on being so required by the court for the purposes of endorsement, and the prescribed authority to which a copy of an order is sent under "his section shall enter the particulars of the order in that register".

PERFORMANCE OF EXPERIMENTS

A. Performance of Experiments

1. Experiments shall be performed under supervision of a qualified person (veterinarian/postgraduates in life sciences/trained laboratory technician) and under the responsibility of the person performing the experiment.
2. Experiment shall be performed with due care and humanity.
3. Animals intended for the performance of experiments shall be properly looked after both before and after experiments.
4. Personnel using experimental animals shall be responsible for the welfare of animals during their use in experiments.
5. Investigators shall be responsible for the aftercare and rehabilitation of animals after experimentation, and shall not euthanize animals except in situations as defined.
6. The following parameters shall be adopted for application of euthanasia, namely:
 - a. When the animal is paralyzed and is not able to perform its natural functions or it becomes incapable of independent locomotion or it can no longer perceive the environment in an intelligible manner.
 - b. If during the course of anaesthesia/experimental procedure the animal has been left with a recurring pain wherein the animal exhibits obvious signs of pain and suffering.
 - c. Where the non-termination of the life of the experimental animal will be life threatening to human beings or other animals.
7. Rehabilitation treatment of an animal after experimentation shall extend till the point the animal is able to resume a normal existence. It is mandatory that the cost of after care and rehabilitation should be met from the contingency of the project.
8. Experiments involving operative procedures shall be performed under anaes-

thesia to be administered by a veterinary surgeon/scientist/technician so trained for the purpose.

9. Experiments shall not be performed by way of an illustration/as a public demonstration.
10. No experiment the result of which is already conclusively known shall be repeated without justification.

B. Laboratory animal ethics: All scientists working with laboratory animals must have a deep ethical consideration for the animals they are dealing with. From the ethical point of view it is important that such considerations are taken care of at the individual level, institutional level and finally at the national level.

C. Record keeping and archiving: All of the following documents must be stored for a period of five years.

1. Curriculum Vitae (CV) of all members of IAEC.
2. Minutes of all meetings duly signed by the Chairperson and CPCSEA nominee, copy of all correspondence with members, researchers and other regulatory bodies.
3. Copy of existing relevant national and international guidelines on research ethics and laws along with amendments.
4. All study related documents (study projects with enclosed documents) should be archived for minimum of five years after the completion of study. A copy of filled proforma related to the projects shall remain with the principal Investigator for minimum of 5 years.

BREEDING AND STOCKING OF ANIMALS

Whereas the Draft Breeding of and Experimentation on Animals (Control and Supervision) Rules, 1998 were published, under the Prevention of Cruelty to Animals Act, 1960 under the notification of the government of India. Under the Prevention of Cruelty to Animals Act, 1960, the committee for control and supervision of experiments on animals hereby makes the following rules, namely:

Breeding of animals: No establishment shall carry on the business of breeding of animals or trade of animals for the purpose of experiments unless it is registered. Every breeder/establishment carrying on the business of breeding animals or trade of animals for the purpose of experiments, shall apply for registration within 60 days from the date of commencement of these rules and stop breeding of animals if registration is subsequently refused to it by the committee.

Registration of establishments: No establishment shall perform any experiment on animals unless it is registered. Every establishment performing experiments on animals, shall apply for registration within 60 days from the date of commencement of these rules and, stop performing experiments on animals if registration is subsequently refused to it by the committee.

Application for registration: The application for registration shall be made in the specified format to the member-secretary or any other officer authorised in this regard by the committee. The member-secretary or the authorised officer of the committee, may for deciding the issue of registration, ask for information relating to premises where the experiments are to be conducted, animal housing facilities, details of breeding of animals and its trade, other infrastructure including availability of manpower trained in handling animals and for verification of facts mentioned in the application for registration, and if satisfied, shall register such establishment or the breeder. A breeder or the establishment on registration for the purpose of performing experiments on animals shall comply with the conditions as may be specified, at the time of registration, by the member-secretary of the committee or any officer authorised in this regard by the committee.

Details of the experiments conducted: Every registered establishment shall maintain a register as per the specified format and keep complete particulars about the kind of animal to be used for conducting any experiment, the

health of the animal, the nature of experiment to be performed, and the reasons necessitating the performance of such an experiment on particular species. The member-secretary or the officer authorised by the committee in this behalf may examine the register so maintained, and if, he is not satisfied irrespective of the opportunity given for improvement, he may bring the same to the notice of the committee seeking directions in this regard.

Stocking of animals: The animals shall be stocked by the breeder and the establishment in the following manner:

- a. Animal houses shall be located in a quiet atmosphere undisturbed by traffic, and the premises should be kept tidy, hygienic and the animals should be protected from drought and extremes of weather.
- b. Animal cages for small animals and stables for large animals shall be such that animals can live in comfort and overcrowding is avoided.
- c. Where standards have been laid down by the Indian standards institution, the cages, the stable, as the case may be, shall conform to those standards.
- d. Animals attendants must be suitably trained and experienced in the duties allotted to them.
- e. Animals shall be looked after, before and after the experiments by a trained and experienced attendant.
- f. There shall be satisfactory arrangement for looking after the animals during off hours and on holidays.

Permission of the committee required for conducting experiments: Every registered establishment before acquiring an animal or conducting any experiment on an animal/animals shall apply for permission of the committee or the Institutional Animals Ethics Committee recognised for the purpose by the committee along with the details contained in the specified format to the member secretary of the committee or the Institutional Animals Ethics Committee, as the case may be. The member secretary of the

Committee or the Institutional Animals Ethics Committee, shall cause the application for permission to be brought before the committee/institutional animals ethics committee as the case may be, and the committee/Institutional Animals Ethics Committee after scrutiny of the application, if satisfied, may grant permission to the establishment stating the name of the species and the number of animals that can be acquired for carrying out the experiments. The committee or Institutional Animals Ethics Committee, as the case may be, may, while granting permission for conducting experiments on animals, put conditions as it may deem fit to ensure that animals are not subjected to unnecessary pain or suffering before, during or after the performance of experiments on them. The committee may require the establishments and Institutional Animals Ethics Committees and persons carrying on experiments on animals to forward to the committee such information as it may require, on completion of experiments for which the permission has been granted.

Performance of experiments: In conducting experiments on animals, regard shall be had to the following conditions, namely:

- a. Experiments shall be performed in every case by or under the supervision of a person duly qualified in that behalf, that is, Degree or Diploma holders in veterinary science or medicine or laboratory animal science of a University or an Institution recognised by the Government for the purpose and under the responsibility of the person performing the experiment.
- b. Experiments shall be performed with due care and humanity.
- c. Animals intended for the performance of experiments are properly looked both before and after experiments.
- d. Experiments involving operative procedure more severe than simple inoculation or superficial venesection shall be performed under the influence of anaesthetic to prevent the animal feeling pain and it shall remain so throughout the experiment. Anesthesia shall be admini-

stered by a veterinary surgeon trained in methods of anesthesia or a scientist/technician so trained for this purpose and who shall remain present near the animal till the completion of the experiment.

- e. Animals which in the course of experiments under the influence of anaesthetic are so injured that their recovery would involve pain or suffering shall be destroyed humanely while still under the influence of anesthesia.
- f. When there is reason to believe that an animal is suffering abnormal or severe pain at any stage of a continuing experiment, it shall be painlessly destroyed at that stage without proceeding with the experiment.
- g. The experiment shall not be performed for the purpose of attaining or retaining manual skill except in schools, colleges and recognised training institutions.
- h. Experiments shall not be performed by way of an illustration.
- i. Experiments shall not be performed as a public demonstration.
- j. The substance known as urari or curari or any such paralysan shall not be used or administered for the purpose of any experiment except in conjunction with anaesthetic of sufficient depth to produce loss of consciousness.
- k. No experiment the result of which is already conclusively known shall be repeated without previous justification.
- l. There shall not be applied to the eye of an animal by way of experiment any chemical substance for the purpose of absorption through the conjunctival membrane or through the cornea calculated to only give pain.
- m. Dogs held for experimental purposes shall not be debarked.
- n. Where experiments are performed in any institution, the responsibility therefor is placed on the person in charge of the institution and in cases where experiments are performed outside an institution by an individual qualified in that behalf, the

experiments, are performed on his responsibility.

Transfer and acquisition of animals for experiment: A breeder shall not transfer any animal by sale or otherwise to an establishment which is not registered under these' rules. An establishment shall not acquire any animal by sale or otherwise except from a registered breeder/establishment. Similarly every establishment after acquisition of a animal or animals shall not transfer such animal or animals by sale or otherwise to any other establishment or person except to a registered breeder/establishment. The animals used for experimentation in a production/breed improvement programme may be given out by the breeder' institution for domestic use. No animal shall be imported by a breeder or an establishment which is available in the country. A breeder or establishment shall comply, with the directions given by the committee for the purpose of controlling and supervising experiments on animals.

Records: Every, establishment/institutional animals ethics committee shall maintain a record of the animals under its control and custody in the specified format. Every establishment/institutional animals ethics committee shall furnish such information, as the committee may from time to time require in the specified format. All laboratories shall inform the exact number/species of animals to the member secretary or any officer authorised in this regard by the committee as per the specified format.

Contract animal experiments: No establishment shall contract or undertake to perform contract research or experiments on contract basis on behalf of any other establishment or research or Educational Institution, This shall not apply to collaborative research between academic institutions.

Composition of institutional animals ethics committee: Every Institutional Animals Ethics Committee shall include a biological scientist, two scientists from different biological disciplines, a veterinarian involved in the care of animal, the scientist in charge of animals facility of the establishment concerned, a scientist from,

outside the institute, a non scientific socially aware member and a representative or nominee of the specialist may be co-opted while reviewing special project using hazardous agents such as radio-active substance and deadly microorganisms.

Power to suspend or revoke registration: If the committee is satisfied, on the report of the member-secretary of the authorised officer of the committee made to it as a result of any inspection or information received otherwise that the rules made by it are not being complied with by any establishment or breeder or an Institutional Animals Ethics Committee, the committee may, after giving a reasonable opportunity to the establishment or breeder or Institutional Animals Ethics Committee of being heard in the matter, revoke the registration of such establishment or breeder or Institutional Animals Ethics Committee either for a specified period or indefinitely, or may allow the establishment of breeder or Institutional Animals Ethics Committee to carry on subject to such special conditions as the committee may impose. The committee may, pending the final determination, if, it is of the opinion that an establishment or breeder has *prima facie* failed to comply with the provisions of these Rules, suspend the registration of such establishment or the breeder. The committee may in the event of revocation or suspension of registration of an establishment or breeder, issue such directions as it, deems fit for the care and protection of the animals which are under the custody or control of such establishment or the breeder. That in the event of suspension or revocation of a license, such establishment or breeder shall forthwith on the communication of the order cease to perform any experiment on, any animal or acquire or transfer any animal.

EXEMPTIONS

Nothing contained in this chapter shall apply to:

- The training of animals for bonafide military or police purpose or the exhibition of any animals so trained.

- b. Any animals kept in any zoological garden or by any society or association which has for its principal object the exhibition of animals for educational or scientific purposes.

OFFENCES AND PENALTY

Offences

If any person:

- a. Not being registered under this chapter, exhibits or trains any performing animal.
- b. Being registered under the act, exhibits or trains any performing animal with respect to which or in a manner with respect to which, he is not registered.
- c. Exhibits or trains as a performing animal, any animal which is not to be used for the purpose.
- d. Obstructs or wilfully delays any person or police officer in the exercise of powers under this Act as to entry and inspection.
- e. Conceals any animal with a view to avoid such inspection.
- f. Being a person registered under the act, on being duly required in pursuance of this act to produce his certificate under this act, fails without reasonable excuse so to do.
- g. Applies to be registered under this act when not entitled to be so registered.

He shall be punishable on conviction with fine which may extend to 500 rupees or with imprisonment which may extend to 3 months, or both.

Penalties

- I. *Penalty for practicing phooka or doom dev:*
 If any persons upon any cow or other milch animal the operation called practising phooka or doom dev or any other operation (including injection of any or doom dev substance) to improve lactation which is injurious to health of the animal or permits such operation being performed upon any such animal in his pos-

session or under his control, he shall be punishable with fine which may extend to 1,000 rupees, or with imprisonment for a term which may extend to 2 years, or with both, and the animal on which the operation was performed shall be forfeited to the Government.

II. '*Destruction of suffering animals*:

1. Where the owner of an animal is convicted of an offence, it shall be lawful for the court, if the court is satisfied that it would be cruel to keep the animal alive, to direct that the animal be destroyed and to assign the animals to any suitable person for that purpose, and the person to whom such animal is so assigned shall as soon as possible, destroy such animal or cause such animal to be destroyed in his presence without unnecessary suffering: and any reasonable expense incurred in destroying the animal may be ordered by the court, if the court is satisfied that it would be cruel to keep the animal alive, to direct that the animal be destroyed and to assign the animal to any reasonable expense incurred in destroying the animal mal be ordered by the court to be recovered from the owner as if it were a fine.
2. When any Magistrate, Commissioner of police or District Superintendent of police has reason to believe that an offence has been committed in respect of any animal, he may direct the immediate destruction of the animal, if in his opinion it would be cruel to keep the animal alive.
3. Any police officer above the rank of a constable or any person authorised by the State Government in this behalf who finds any animal so diseased or so severely injured or in such a physical condition that in his opinion it cannot be removed without cruelty, may, if the owner is absent or refuses his consent to the destruction of the animal, forth with summon the veterinary officer in charge of the area in which the animal is found, and if the veterinary officer certifies

that the animal is mortally injured or so severely injured or in such a physical condition that it would be cruel to keep it alive, the police officer or the person authorised, as the case may be, may, after obtaining orders from a Magistrate, destroy the animal injured or cause it to be destroyed.

4. No appeal shall lie from any order of a Magistrate for the destruction of an animal.

III. If any person contravene any order made by or committing a breach of any condition imposed by the Committee is punishable with fine which may extend to 200 rupees. When the contravention or breach of condition has taken place in any institution the person incharge of the institution shall be deemed to be guilty of the offence and shall be punishable accordingly.

IV. If any person/institution contravenes any order made by CPCSEA/commits a breach of any conditions imposed by committee punishable accordingly: He/She may be punishable with fine which may be extended to ₹ 3,000/- and when the breach of conditions has taken place in any institution, the person-in-charge of

the Institution shall be deemed to be guilty of the offence and shall be punishable accordingly.

MISCELLANEOUS

A. Saving as respects manner of killing prescribed by religion: Nothing contained in this act shall render it an offence to kill any animal in a manner required by the religion of any community.

B. Power of court to deprive person convicted of ownership of animal: If the owner of any animal is found guilty of any offence under this act. the court upon his conviction thereof, may, if it thinks fit, in addition to any other punishment make an order that the animal with respect to which the offence was committed shall be forfeited to Government and may, further, make such order as to the disposal of the animal as it thinks fit under the circumstances.

C. Power to make rules: The Central Government may, by notification in the official gazette and subject to the condition of previous publication, make rules to carry out the purposes of this Act.

The Shops and Establishment Act, 1954

INTRODUCTION

The Shops and Establishment Act is a State Legislation Act and each state has framed its own rules for the act. Many States in India have laws, which provide certain provision for the person employed in shops and other commercial establishments. The acts, in various states differ in matters to detail but their main provision and objects are the same. The acts are one of the numerous social acts passed with a view to ensure fair deals by the employers to their employees. The Shops and Establishment Act in various States of India are enacted to regulate the working conditions, etc. of employees, in absence of which there is always a possibility of the employees being exploited by their employers. This act makes provisions for the work Schedules, environmental conditions, wages, leave, etc. for persons employed in shops and other commercial establishments like hotels, theaters, etc.

Objectives

- The object of this act is to provide statutory obligation and rights to employees and employers in the unauthorized sector of employment, i.e. shops and establishments.
- This act is applicable to all persons employed in an establishment with or without wages, except the members of the employers' family.

Scope and Coverage

- i. A State Legislation; each state has framed its own rules for the Act.
- ii. Applicable to all persons employed in an establishment with or without wages, except the members of the employer's family.
- iii. State Government can exempt, either permanently or for a specified period, any establishments from all or any provisions of this Act.

Main Provisions

- i. Compulsory registration of shop/establishment within 30 days of commencement of work.
- ii. Communications of closure of the establishment within 15 days from the closing of the establishment.
- iii. Lays down the hours of work per day and week.
- iv. Lays down guidelines for spread-over, rest interval, opening and closing hours, closed days, national and religious holidays, and overtime work.
- v. Rules for employment of children, young persons and women.
- vi. Rules for annual leave, maternity leave, sickness and casual leave, etc.
- vii. Rules for employment and termination of service.

- viii. Maintenance of registers and records and display of notices.
- ix. Obligations of employers.

Consult and refer: At the time of start of an enterprise.

The rules in the Shops and Establishment Act:

This act lays down the following rules:

- i. Working hours per day and week.
- ii. Guidelines for spread-over, rest interval, opening and closing hours, closed days, national and religious holidays, overtime work.
- iii. Employment of children, young persons and women.
- iv. Rules for annual leave, maternity leave, sickness and casual leave, etc.
- v. Rules for employment and termination of service.

Registration of Shop

- i. Under this act, registration of shop / establishment is necessary within 30 days of commencement of work.
- ii. 15 days of notice is required to be served before the closing of the establishment State Government can exempt, either permanently or for specified period, any establishments from all or any provisions of this Act.

THE DELHI SHOPS AND ESTABLISHMENTS ACT

This act may be called the Delhi Shops and Establishments Act, 1954. It shall apply in the first instance only to the municipal areas, notified areas and cantonment limits of Delhi, New Delhi, Shahdara, Civil lines, Mehrauli, Red Fort and Delhi cantonment but government may (by notification in the official gazette), direct that it shall come into force in any other local area or areas or shall apply to such shops or establishments or class of shops and establishments in such other areas as may be specified in the notification.

The object of Delhi Shops and Establishments Act, 1954, is to give some minimum benefits and relief to the vast unorganized sector of

employees, employed in shops and establishments. Industrial Dispute Act, 1947 and Delhi Shops and Establishments Act, 1954 are supplemental to each other.

DEFINITIONS

- a. "**Adult**" means a person who has completed his eighteenth year of age.
- aa. "**Apprentice**" means a person, who is employed, whether on payment of wages or not, for the purpose of being trained in any trade, craft or employment in any establishment.
- b. "**Child**" means a person who has not completed his twelfth year of age.
- c. "**Child day**" means the day of the week on which a shop or commercial establishment remains closed.
- d. "**Closing hours**" means the hour at which a shop or commercial establishment closes.
- e. "**Commercial establishment**" means any premises wherein any trade, business or profession or any work in connection with, or incidental or ancillary thereto, is carried on and includes a society registered under the Societies Registration Act, 1860 and charitable or other trust, whether registered or not, which carries on any business, trade or profession or work in connection with or incidental or ancillary thereto, journalistic and printing establishments, contractors and auditors establishments quarries, and mines not governed by the Mines Act, 1952, educational or other institution run for private gain and premises in which business of banking, insurance, stocks and shares, brokerage or produce exchange is carried on, but does not include a shop or a factory registered under the Factories Act, 1948, or theatres, cinemas, restaurants, eating houses, residential hotels, clubs or other places of public amusement or entertainment.
- f. "**Day**" means a period of twenty-four hours beginning at mid-night.

Provided that in the case of an employee whose hours of work extend beyond midnight, day means the period of twenty-four hours beginning when such employment commences irrespective of midnight:

- g. "**Employee**" means a person wholly or principally employed, whether directly or otherwise, and whether for wages, (payable on permanent, periodical, contract, piece-rate or commission basis) or other consideration, about the business of an establishment and includes an apprentice and any person employed in a factory but not governed by the Factories Act, 1948, and for the purpose of any matter regulated by this act, also includes a person discharged or dismissed whose claims have not been settled in accordance with this Act.
- h. "**Employer**" means the owner of any establishment about the business of which persons are employed, and where the business of such establishment is not directly managed by the owner, means the manager, agent, or representative of such owner in the said business.
- i. "**Establishment**" means a shop, a commercial establishment, residential hotel, restaurant, eating house, theatre or other places of public amusement or entertainment to which this act applies and includes such other establishments as Government may, by notification in the official gazette, declare to be an establishment for the purposes of this Act.
- j. "**Family**" means the husband, wife, son, daughter, father, mother, brother, sister or grand-son of an employer, living with and wholly dependent on such employer.
- k. "**Holiday**" means a day on which an establishment shall remain closed, or on which an employee shall be given a holiday under the provisions of the Act.
- l. "**Hours of work**" or "**working hours**" mean the time during which the persons employed are at the disposal of the employer exclusive of any interval allowed for rest and meals and "hours worked" has a corresponding meaning.
- m. "**Leave**" means leave as provided for under this Act.
- n. "**Occupier**" means a person owning or having charge or control of the establishment and includes the manager, agent or representative of such occupier.
- o. "**Opening hour**" means the hour at which (a shop or commercial establishment) opens for the service of a customer.
- p. "**Register of establishments**" means a register maintained for the registration of establishment under this Act.
- q. "**Registration certificate**" means a certificate showing the registration of an establishment.
- r. "**Religious festival**" means any festival which the Government may by notification in the official gazette declare to be a religious festival for the purposes of this Act.
- s. "**Retail trade or business**" includes the business of a barber or hair-dresser, the sale of refreshment of intoxicating liquors, and retail sales by auction.
- t. "**Shop**" means any premises where goods are sold, either by retail or wholesale or where services are rendered to customers, and includes an office, a store-room, godown, warehouse or workhouse or work place, whether in the same premises or otherwise, used in or in connection with such trade or business but does not include a factory or commercial establishment.
- u. "**Spread over**" means the period between the commencement and the termination of the work of an employee on any day.
- v. "**Summer**" means the period covering the months of April, May, June, July, August and September.
- w. "**Wages**" means wages as defined in Section 2 of the Minimum Wages Act, 1948.
- x. "**Week**" means a period of seven days beginning at midnight on Saturday.

- y. "Winter" means the period covering the months of October, November, December, January, February and March.
- z. "Year" means the Calendar year.
- zz. "Young person" means a person who is not a child and has not completed his eighteenth year of age.

REGISTRATION OF ESTABLISHMENTS

Within 30 days from the date of establishment commences its work, the employers of every shop or establishment are required to send a statement in a prescribed form together with the prescribed fee to the inspector of local area, for registration of the shop or establishment. The certificate of registration remains valid upto the end of the year in which it is granted and should be renewed from time to time. Application for the renewal of a registration certificate should be made to the Inspector in the prescribed form together with the prescribed fee not later than 15 days before the date of its expiry.

The statement should contain:

- a. The name of the employer and the manager, if any.
- b. The postal address of the establishment.
- c. The name, if any, of the establishment.
- d. The category of the establishment, i.e. whether it is a shop, commercial establishment, residential hotel, restaurant eating house, theatre or other place of public amusement or entertainment.
- e. The number of employees working about the business of the establishment.
- f. Such other particulars as may be prescribed.

On receipt of the statement and the fees, the Chief Inspector shall, on being satisfied about the correctness of the statement, register the establishment in the register of establishments in such manner as may be prescribed and shall issue, in a prescribed form, a registration certificate to the occupier. The registration certificate shall be prominently displayed at the establishment and shall be renewed at such intervals as may be prescribed in this respect. In the event of any doubt or difference of

opinion between an occupier and the chief inspector as to the category to which shall after such enquiry, as it may think proper, decide the category of each establishment and the decision thereto shall be final for the purpose of this Act. Within 90 days from the date mentioned in column 2 below in respect of the establishment mentioned in column 1, the statement together with fees shall be sent to the chief inspector (Table 11.1).

WORK IN ESTABLISHMENT/ HOURS AND TIMING OF WORKS

A. Working Hours

I. *Employment of adults (18 years and above), hours of work:* No adult shall be employed or allowed to work about the business of an establishment for more than nine hours on any day or 48 hours in any week and the occupier shall fix the daily periods of work accordingly. Any adult employee may be allowed or required to work for more than the hours fixed in this section, but not exceeding 54 hours in any week subject to the conditions that the aggregate hours so worked shall not exceed 150 hours in a year. The Chief Inspector and that any person employed on overtime shall be entitled to remuneration for such overtime work at twice the rate of his normal remuneration calculated by the hour.

II. *Employment of young persons (12–18 years)-hours of work:* No young person shall be required or allowed to work about the business of an establishment for more than 6 hours a day. No young person shall be employed continuously for more than 3 and a half hours without an interval of at least half an hour for rest or meals and the spread over shall not exceed 8 hours on any day.

III. *Young persons and women to work during day time:* No young person or woman shall be allowed or required to work, whether as an employee or otherwise, in any establishment between 9 P.M. and 7 AM. during the summer season and between 8 PM and 8 AM during the winter season.

Table 11.1: Registration of establishments

<i>Establishments</i>	<i>Date from which the period of 90 days is to commence</i>
1	2
i. Establishments existing in municipal areas, notified areas, and cantonment limits of Delhi, New Delhi, Shahdara, Civil Lines, Mehrauli, Red Fort and Delhi cantonment.	The date on which this act comes into force.
ii. Establishments existing in local areas in which this act is brought into force by notification.	The date on which this act comes into force in the local areas concerned.
iii. New establishments in areas mentioned in clauses (i) and (ii) of this sub-section.	The date on which the establishment commences the work.

IV. Opening and closing hours of shops and commercial establishment: No shop or commercial establishment on any day, be opened earlier than such hour or closed later than such hour, or closed later than such hour, as may be fixed by the Government by general or special order made in that behalf. Any customer who was being served or was waiting to be served in any shop or commercial establishment at the closing hour so fixed may be served during the period of 15 minutes immediately following such hour. The Government may fix different opening hours and different closing hours for different classes of shops or commercial establishments or for different areas or for different times of the year.

V. Opening and closing hours: The opening and closing hours of all shops, within the urban, semi-urban and rural areas of the Union Territory of Delhi, whether comprised in the Municipal Corporation of Delhi, the New Delhi Municipal Committee or the Delhi Cantonment Board, are 9 am and 7 pm respectively, while in respect of commercial establishments within such territory, the opening and closing hours are 8 am and 6 pm respectively.

B. Close Day

Every shop and commercial establishment shall remain closed on a close day. In addition to the close day every shop and commercial establishment shall remain closed on 3 of the National

holidays each year as the Government may specify.

The Government may specify a close day for the purposes of this section and different days may be specified for different classes of shops or commercial establishments or for different areas. The occupier of any shop or a commercial establishment may, open his shop or commercial establishment on a close day, if such a day happens to coincide with a religious festival, or "the Mahurat day", the day of the commencement of the financial year of the establishment concerned, provided a notice to this effect has been given to the Chief Inspector at least 24 hours before the close day and that in lieu thereof the shop or the commercial establishment is closed on either of the two days immediately preceding or following that close day.

I. Restriction on double employment: No person shall work about the business of an establishment or two or more establishment and a factory in excess of the period during which he may be lawfully employed under this Act.

II. Interval for rest and meals: The period of work of an adult employee in an establishment each day shall be so fixed that no period of continuous work shall exceed 5 hours and that no employee shall be required or allowed to work for more than 5 hours before he has had an interval for rest and meals of at least half an hour. The time for such interval shall be fixed by the employer and intimated to the Chief Inspector a week

before such fixation and shall remain operative for a period of not less than 3 months.

III. Period of rest (weekly holiday): Every employee shall be allowed atleast twenty-four consecutive hours of rest (weekly holiday) in every week, which shall, in the case of shops and commercial establishments required by this act to observe a close day, be on the close day.

IV. Overtime working: Other purposes for which overtime may be worked. An employer may require an adult employee to work overtime subject to the conditions laid down in section 8 (employment of adults, hours of work), for any of the following additional purposes:

- a. Seasonal pressure of work.
- b. Work in pursuance of any custom or usage observed in the establishment.
- c. Temporary increase in work due to absence of any other employee or any other emergency.
- d. Treating of material liable of deterioration, if not treated immediately.
- e. Work necessitated as a result of any order from Court or any Government authority.

Advance intimation in respect of requiring adult employees to work overtime in an establishment under the 1st provision to section 8 (Employment of adults, hours of work) shall contain the following information:

- a. The purpose of overtime.
- b. Date or dates and the probable time or period for which overtime is proposed to be worked.
- c. Number of the employees required to work overtime.

V. Spread over: The periods of work on any day of an adult person shall be so arranged that inclusive of his interval for rest or meals, they shall not spread over more than 10 and a half hours in any commercial establishment or for more than 12 hours in any shop.

HEALTH AND SAFETY

I. Cleanliness: In every establishment, all the inside walls of the rooms and all the ceiling tops

of such rooms (whether such walls, ceilings and tops be plastered or not) and all the passages and stair-cases shall be lime-washed or colour-washed at least once in tow years dating from the time when they were last lime-washed or colour-washed, and shall be maintained in a clean state. All beams, rafters, doors, window-frames and other wood-work with the exception of floors shall be painted at least once in four years dating from the period when last painted and shall be kept in a clean state. No rubbish, filth, debris shall be allowed to accumulate or to remain in any premises in an establishment in such position that effluvia therefrom can arise within the establishment. All filth and other decomposing matter shall be kept in covered receptacles. The area around the place where drinking water is distributed to the employee shall be kept clean and properly drained.

II. Lighting and ventilation: The premises of every establishment shall be kept sufficiently lighted and ventilated during all working hours. Suitable arrangements shall be made for supply of drinking water to the employees.

III. Precautions against fire: No persons shall smoke or use a naked light or cause or permit any light to be used in the immediate vicinity of any inflammable material in any establishment.

IV. Prohibition of employment of children: No child shall be required or allowed to work whether as an employee or otherwise in any establishment not with standing that such child is a member of the family of the employer.

SERVICE CONDITIONS

A. Employment and Dismissals

I. Employer to furnish letters of appointment to employees: The employer shall furnish every employee with a letter of appointment. Such letters of appointment shall contain the following and such other particulars as may be prescribed, namely:

- a. The name of employer.
- b. The name, if any, and the postal address of the establishment.

- c. The name, father's name and the age of the employee.
- d. The hours of work.
- e. Date of appointment.

The **letters of appointment** to employee shall also contain the following further particulars:

- i. The rate of wages or salary.
- ii. Designation or nature of work for which employed (whether employed for clerical, supervisory, managerial, manual work, etc.).
- iii. Other concessions or benefits, if any, that may be special to his appointment.

II. Notice of dismissal: No employer shall dispense with the services of an employee who has been in his continuous employment for not less than three months, without giving such person at least one months' notice in writing or wages in lieu of such notice. No employee who has put in 3 months' continuous service shall terminate his employment unless he has given to his employer a notice, of at least one month, in writing. In case he fails to give one month's notice he will be released from his employment on payment of an amount equal to one month's pay.

If a Magistrate is satisfied that an employee had been dismissed without any reasonable cause or discharged without proper notice or pay in lieu of notice, the magistrate may, for reason to be recorded in writing, award, in addition to one month's salary, compensation to the employee as follows:

- a. When immediately before his discharge or dismissal, the employee was in receipt of a salary not exceeding ₹ 100 per month, such amount of compensation not exceeding his month's salary, as the Magistrate may direct.
- b. When immediately before his dismissal or discharge, the employee was in receipt of a salary exceeding 100 rupees per month, such amount of compensation not exceeding 100 rupees, as the Magistrate may direct.

The amount payable as compensation under this section shall be in addition to any fine

payable under Section 40 (penalties). No person who has been awarded compensation under this section shall be at liberty to bring a civil suit in respect of the same claim.

B. Wages

I. Wages for the holiday: No deduction shall be made from the wages of any employee on account of the close day or a holiday granted under this act. If an employee is employed on a daily wage, he shall nonetheless be paid his daily wage for the holiday and where an employee is paid on piece rates, he shall receive the average of the wages received during the week.

II. Time and conditions of payment of wages: Every employer or his agent or the manager of any establishment shall fix periods in respect of which wages to the employee shall be payable and such person shall be responsible for the payment to persons employed by him of all wages required to be paid under this act. No wage period, so fixed, shall exceed one month. The wages of every employee in any shop or establishment shall be paid on a working day before the expiry of the seventh day of the last day of the wage period in respect of which the wages are payable. All wages shall be paid in cash. Where the employment of any person is terminated by or on behalf of the employer, the wages earned by him shall be paid before the expiry of the second working day after the day on which his employment is terminated.

III. Deductions which may be made from wages:

1. Deductions from the wages of an employee shall be of one or more of the following kinds, namely:
 - i. Fines.
 - ii. Deductions for absence from duty.
 - iii. Deductions for damage to or loss of goods expressly entrusted to the employed person for custody, or for loss of money for which he is required to account, where such damage or loss is directly attributable to his neglect or default.

- iv. Deductions for house accommodation supplied by the employer.
 - v. Deductions for such amenities and services supplied by the employer as the Government may by general or special order authorize.
 - vi. Deductions for the recovery of advances or for adjustment of over-payments of wages, provided that such advances do not exceed an amount equal to wages for 2 Calendar months of the employed person and; in no case, shall the monthly instalment of deduction exceed one-fourth of the wages earned in that month.
 - vii. Deductions of income tax payable by the employed person.
 - viii. Deductions required to be made by order of a court or other competent authority.
 - ix. Deductions for subscription to, and for repayment of advances from, any provident fund.
 - x. Deductions for payment to cooperative societies or to a scheme of insurance approved by the Government.
2. Any employer desiring to impose a fine on an employed person or to make a deduction for damage or loss caused by him shall explain to him personally and also in writing the act or omission or the damage or loss, in respect of which the fine or deduction is proposed to be imposed or made, and give him an opportunity to offer any explanation in the presence of another person. The amount of the said fine or deduction shall also be intimated to him.

IV. Wages during leave: Every employee shall be paid for the period of his leave at a rate equivalent to the daily average of his wages for the days on which he actually worked during the preceding three months, exclusive of any earnings in respect of overtime but inclusive of dearness allowance.

C. Leave

Every person employed in an establishment shall be entitled:

- a. After every 12 months', continuous employment, to privilege leave for a total period of not less than 15 days.
- b. In every year, to sickness or casual leave for a total period of not less than 12 days.

I. Privilege, sickness or casual: Every employee who has become entitled to privilege leave may apply in writing to the employer indicating in advance the date from and the period for which he would like to avail of this leave during the ensuing 12 months, and no such leave would ordinarily be refused by the employer except for valid cause. In all other cases, the employee shall apply in writing ordinarily 15 days in advance and the employer shall pass his orders thereon not later than 7 days from the receipt of the application.

II. Casual and sick leave: Ordinarily, the previous permission of the employer for casual leave shall be obtained by the employee, but when this is not possible, the employer shall be informed in writing as soon as practicable for the grant of such leave. The employer shall record his order on all such applications and shall retain them till the 31st March of the following year. An employer, however, may refuse an application for casual leave from an employee on grounds of exceptional pressure of work requiring his attendance on the day or days in respect of which casual leave has been asked for. Where an application for casual leave is refused by the employer under clause (ii) above, the employer shall record his reasons for refusal on the application, and shall grant equivalent leave on demand by the employee in the same calendar year.

No application from an employer for sickness leaves shall be refused, but if in any case, the employer is not satisfied about the correctness if the assertion set out therein, the employer may either require the employee to submit medical certificate in respect thereof from a registered medical practitioner, or get the employee or the wife or the child of the employee, as the employee, as the case may be, examined at his (employer's) own expense by

a registered medical practitioner (lady doctor in case of females) for the purpose of verifying the facts mentioned in the leave application and may grant or reject the application in the basis of the certificate of such medical practitioner. Every such medical certificate shall be retained by the employer till 31st March of the following year.

INSPECTION OF ESTABLISHMENTS

A. Inspectors

I. *Appointment of inspectors:* The Government shall appoint a Chief Inspector and such inspectors as may be necessary for the purpose of carrying out the provision act the Chief Inspector and the inspectors so appointed shall carry identity cards.

II. *Powers and duties of the inspector:* Subject to any Rules made by the Government in this behalf the Chief Inspector or an Inspector may.

- a. Enter at all reasonable times with such assistance as may be necessary any place which is, or which is being used as an establishment.
- b. Make such examination of the premises and of any prescribed registers, records and notices and take on the spot or otherwise evidence of any person as he may deem necessary for carrying out the purpose of this act.
- c. Make copies of or take extracts from any book, registers or other document maintained for the purpose of this act.
- d. Exercise such other powers as may be necessary for carrying out the purpose of this act.

B. Records

I. *Maintenance of records (Section 33):* The occupier of every shop or commercial establishment shall, in the prescribed form and in the prescribed manner, keep exhibited in the shop or establishment a notice setting forth the close day. The occupier of any shop or establishment, about the business of which persons

are employed, shall in the prescribed form and in the prescribed manner keep a record of the hours worked and the amount of leave taken by, and of the intervals allowed for rest and meals to, every person employed about the business of the shop or establishment, and particulars of all employment overtime shall be separately entered in the record. The occupier of any shop or establishment, about the business of which persons are employed, shall in the prescribed form and in the prescribed manner keep exhibited in the shop or establishment notices setting forth number of hours in the week during which persons may in accordance with the provision of this Act be employed about the business of a shop or establishment and such other particulars as may be prescribed. The occupier of every shop or establishment shall for the purpose of this act maintain such other records and registers and display such other notices as may be prescribed.

II. *Inspection of registers and calling for information:* It shall be the duty of every occupier of a shop or establishment to produce for inspection of an Inspector, all accounts or records required to be kept for the purpose of this act, and to give any other information in connection therewith as may be required.

OFFENCES AND PENALTIES

I. Penalties for offences under the Act:

1. Any person, who contravention of any provisions of this Act, or any rule or order made thereunder except Sections 33, 41 and 42 shall on conviction, be liable to punishment with fine which shall not be less than 25 rupees and which may extend to 250 rupees.

2. *Failure to maintain records:* If any person failing to maintain proper records under the Act, he shall be liable, on conviction, to a fine of ₹ 5 for everyday on which the contravention occurs or continues.

II. *Wilfully making false entries (Section 41):* If any person with intent to deceive makes or causes or allows to be made in any record,

register, or notice prescribed an entry which is to his knowledge false in any material particular, or wilfully omits or causes or allows to be omitted from any such record, register or notice an entry required to be made therein, he shall be liable on conviction to an imprisonment for a term not exceeding 3 months or to a fine which shall not be less than 50 rupees and which may extend to 250 rupees or both.

III. Penalty for obstructing inspector (Section 42): Whoever wilfully obstructs an Inspector in the exercise of any power or conceals any employee in an establishment from appearing before or being examined by an Inspector shall, on conviction, be punished with fine which shall not be less than 50 rupees and which may extend to 250 rupees.

IV. Cognisance of offence: No prosecution under this act or the rules or orders made thereunder shall be instituted except by or with the previous sanction of the chief inspector appointed under the act. No court inferior to that magistrate of the first class shall try any offence under this act or any rule or order made thereunder.

MISCELLANEOUS

A. Exemption: Exemption of occupier from liability in certain cases.

Where the occupier of a shop or commercial establishment is charged with an offence against this act or the rules or orders made thereunder, he shall be entitled, upon complaint duly made by him, to have his agent or servant whom he charges as the actual offender brought before the court at the time appointed for hearing the charge.

B. Savings: Nothing in this act shall apply to:

- a. Any office of or under the Central Government, or Delhi Administration.
- b. Any office of any local authority, any Railway Administration, the Reserve Bank of India, the Delhi Development Authority, the Delhi Water Supply and Sewage Disposal Undertaking, the Delhi Electric Supply Undertaking and the Delhi Transport Undertaking of the Municipal Corporation of Delhi (now Delhi Transport Corporation), the Delhi University or Airlines Corporation.
- c. Any telegraph, telephone or postal service.

C. Power to make rules: The Government may after, previous publication make, by notification in the official gazette, rules to carry out the purposes of this Act.

CHAPTER 12

The Insecticides Act, 1968

INTRODUCTION

The use of insecticides has revolutionised agriculture production as the crops which used to be generally destroyed by insects, etc. can now be protected. However, the increasing use of insecticides has also highlighted the problems associated with their use. Some insecticides such as DDT have a light stability and they pass on from crops to living beings. Also rivers, soils get polluted due to indiscriminate use of insecticides. Since insecticides are highly toxic chemical compounds, their unsafe handling during manufacture, transportation, distribution, use can also result in toxicity.

The Insecticides Act, 1968 has been passed. It extends to the whole of India. It shall come into force on such date as the Central Government may, by notification in the official gazette, appoint and different dates may be appointed for different states and for different provisions of this act. The Insecticides Act, 1968 and Insecticides Rules, 1971 regulate the import, registration process, manufacture, sale, transport, distribution and use of insecticides with a view to prevent risk to human beings or animals and for all connected matters, throughout India.

Objectives

- To regulate the import, manufacture, sale, transport, distribution and use of insecticides with a view to prevent risk to human

beings or animals, and for matters connected therewith.

- To make available safe, effective and quality pesticide to farmers/users.

SALIENT FEATURES

The Salient features of the act are described below:

1. Establishment of Central Insecticide Board and the setting up of a committee called the Registration Committee for the purpose of granting certificates of registration to persons desiring to import manufacture insecticides.
2. Licencing of persons desiring to manufacture, sell or exhibit for sell or distribution of any insecticides.
3. Establishment of Central Laboratory for carrying out certain functions under the act.
4. Prohibition of imports, manufacture, sale, etc. of insecticides in contraventions of the provisions of the act.
5. Regulation of transport and storage of insecticides soon as to prevent cases of accidental contamination of food with insecticides.
6. Provision for taking immediate action by way of prohibition of sale, distribution or use of any insecticide where it is found that the sale, distribution or use of any insecticide is being done in such a way as to involve

risk to human beings or vertebrate animals and where immediate action is necessary.

DEFINITIONS

- a. "**Animals**" means animals useful to human beings and include fish and fowl, and such kinds of wild life as the Central Government may, by notification in the official gazette, specify, being kinds which in its opinion, it is desirable to protect or preserve.
- b. "**Central Insecticides Laboratory**" means the Central Insecticides Laboratory established, or as the case may be, the institution specified under Section 16.
- c. "**Import**" means bringing into any place within the territories to which this act extends from a place outside those territories.
- d. "**Insecticide**" means:
 - i. Any substance specified in the Schedule.
 - ii. Such other substance (including fungicides and insecticides) as the Central Government may, after consultation with the board, by notification in the official gazette, include in the schedule from time to time.
 - iii. Any preparation containing any one or more of such substances.
- e. "**Insecticide Analyst**" means an insecticide analyst appointed under Section 19 (insecticide analysts).
- f. "**Label**" means any written, printed or graphic matter on the immediate package and on every other covering in which the package is placed or packed and includes any written, printed or graphic matter accompanying the insecticide.
- g. "**Manufacture**" in relation to any insecticide, includes:
 - i. Any process or part of a process for making, altering, finishing, packing, labelling, breaking up or otherwise treating or adopting any insecticide with
- a view to its sale, distribution or use but does not include the packing or breaking up of any insecticide in the ordinary course of retail business.
- ii. Any process by which preparation containing an insecticide is formulated.
- h. "**Misbranded**"—an insecticide shall be deemed to be misbranded:
 - i. If its label contains any statement, design or graphic representation relating thereto which is false or misleading in any material particular, or if its package is otherwise deceptive in respect of its contents.
 - ii. If it is an imitation of, or is also under the name of, another insecticide.
 - iii. If its label does not contain a warning or caution which may be necessary and sufficient, if compiled with to prevent risk to human beings or animals.
 - iv. If any word, statement or other information required by or under this act to appear on the label is not displayed thereon in such conspicuous manner as the other words, statements, designs or graphic matter have been displayed on the label and in such terms as to render it likely to be read and understood by any ordinary individual under customary conditions of purchase and use. or
 - v. If it is not packed or labelled as required by or under this Act.
 - vi. If it is not registered in the manner required by or under this act.
 - vii. If the label contains any reference to registration other than the registration number.
 - viii. If the insecticide has a toxicity which is higher than the level prescribed or is mixed or packed with any substance so as to alter its nature or quality or contains any substance which is not included in the registration.
- i. "**Package**" means a box, bottle, casket, tin, barrel, case, receptacle, sack, bag, wrapper,

or other thing in which an insecticide is placed or packed.

- j. "**Premises**" means any land, shop, stall or place, where any insecticide is sold or manufactured or stored or used, and includes any vehicle carrying insecticides.
- k. **Pesticide:** The suffix "-cide" means an act related to killing (from the Latin caedere: "to cut, kill, hack (at), strike"). When attached to a word indicating an animal or plant considered to be pestilent, the combined word is frequently used to indicate a substance used to eliminate the pest.

A "**Pesticide**", means the killing of a pest or the substance used to perform this function—the target can be an insect (insecticide), rodent (rodenticide), fungus (fungicide), acarid (acaricide), bird (avicide), weed or herb (weedicide or herbicide), bacteria (bactericide), germs (germicide), virus (viricide), microbes (microbicide), and so on. Thus, all insecticides are pesticides, but all pesticides are not necessarily insecticides. Sometimes, insecticides are referred to or grouped according to their use against specific insects (e.g. termiticides against termites) or stages of their growth (e.g. larvicides against larvae and adulticides against adult stages of mosquitoes).

ADMINISTRATIVE AGENCIES

Under the act following agencies are required to be established:

- Central Insecticides Board
- Registration Committee
- Central Insecticides Laboratory
- Insecticides Inspectors.

A. THE CENTRAL INSECTICIDES BOARD

The Central Insecticides Board is constituted by Central Government under Section 4 of the Act.

I. Constitution

1. The Central Government shall constitute a Board to be called the Central Insecticides

Board to advise the Central Government and State Governments on technical matters arising out of administration of this act and to carry out the other functions assigned to the board by or under this act.

2. The matters on which the board may advise shall advise the Central and State Government include matter relating to:
 - i. The risk to human beings or animals involved in the use of insecticides and the safety measures necessary to prevent such risk.
 - ii. The manufacture, sale, storage, transport and distribution of insecticides with a view to ensure safety to human beings or animals.

Members of the Board

3. The Board shall consist of the following members, namely:

Ex-officio Members

- i. The Director-General of Health Services, who shall be Chairman.
- ii. The Drugs Controller, India.
- iii. The Plant Protection Adviser to the Government of India.
- iv. The Director of Storage and Inspection, Ministry of Food, Agriculture, Community Development and Co-operation (Department of food).
- v. The Chief Adviser of Factories.
- vi. The Director-General, National Institute of Communicable Diseases.
- vii. The Director-General, Indian Council of Agricultural Research.
- viii. The Director-General, Indian Council of Medical Research.
- ix. The Director, Zoological Survey of India.
- x. The Director-General, Indian Standards Institution.
- xi. The Director-General of Shipping, Ministry of Transport and Shipping.
- xii. The Joint Director, Traffic (General), Ministry of Railways (Railway board).

- xiii. The Secretary, Central Committee for Food Standards.
- xiii-a. The Animal Husbandry Commissioner, Department of Agriculture.
- xiii-b. The Joint Commissioner (Fisheries), Department of Agriculture.
- xiii-c. The Deputy Inspector-General of Forests (wild life), Department of Agriculture.

Nominated Members—Nominees of the Central Government

- xiv. One person to represent the Ministry of Petroleum and Chemicals, to be nominated by the Central Government.
- xv. One pharmacologist to be nominated by the Central Government.
- xvi. One medical toxicologist to be nominated by the Central Government.
- xvii. One person who shall be incharge in industrial health and occupational hazards, to be nominated by the Central Government.
- xviii. Two persons who shall be incharge of Agriculture in States, to be nominated by the Central Government.
- xix. Four persons, one of who shall be an expert in industrial health and occupational hazards, to be nominated by the Central Government.
- xx. One person to represent the Council of Scientific and Industrial Research, to be nominated by the Central Government.
- xxi. One ecologist to be nominated by the Central Government
- 4. The persons nominated shall, unless their seats become vacant earlier by registration, death or otherwise, hold office for three years from the date of their nomination but shall be eligible for re-nomination.
- 5. No act or proceeding of the board, the Registration Committee or any other committee appointed shall be called in question on the ground merely of the existence of any vacancy in, or any defect in the constitution of the board, the

Registration Committee or such committee, as the case may be.

II. Procedure for Board

The Board may, subject to the previous approval of the Central Government, make bye-laws for the purpose of regulating its own procedure and the procedure of any committee thereof and the conduct of all business to be transacted by it or such committee.

B. REGISTRATION COMMITTEE

Registration committee is constituted by Central Government under Section 5 of the Act.

1. The Central Government shall constitute a Registration Committee consisting of a Chairman, and not more than five persons who shall be members of the board (including the Drugs Controller, India and the plant protection adviser to the Government of India):
 - i. To register insecticides after scrutinising their formulae and verifying claims made by the importer or the manufacturer, as the case may be, as regards their efficacy and safety to human beings and animals.
 - ii. To perform such other functions as are assigned to it by or under this act.
2. Where the Chairman is not a member of the Board, his term of office and other conditions of service shall be such as may be determined by the Central Government.
3. A member of the registration committee shall hold office for so long as he is a member of the board.
4. The committee may also co-opt such number of experts and for such purpose or period as it may deem fit, by any expert so co-opted shall have no right to vote.
5. Registration committee shall regulate its own procedure and the conduct of the business to be transacted by it.

Other committees: The board may appoint such committees as it deems fit and may appoint to them, persons who are not members of the

board to exercise such powers and perform such duties as may, subject to such conditions, if any, as the board may impose, be delegated to them by the board.

Secretary and other officers of board and Registration Committee: Secretary and other officers of board and Registration Committee are appointed by Central Government under Section 8 of the Act.

The Central Government shall:

- i. Appoint a person to be the secretary of the board who shall also function as Secretary to the Registration Committee.
- ii. Provide the board and the Registration Committee with such technical and other staff as the Central Government considers necessary.

C. CENTRAL INSECTICIDES LABORATORY

The Central Government may establish a Central Insecticide Laboratory under the control of director to be appointed by the Central Government to carry out the functions entrusted to it by or under this act. The Central Government or State Government may also appoint persons possessing technical and other qualifications, as insecticide analyst for such areas and in respect of such insecticides as may be notified in the official gazette. No person having any financial interest in the manufacture, import or sale of any insecticides can be appointed as insecticide analyst. The insecticides analysts are required to analyse and test samples of insecticides sent to them by insecticide inspectors and submit report of analysis to the inspectors within 60 days.

The functions of the Central Insecticides Laboratory shall, to such extent as may be specified in the notification, be carried out at any such institution as may be specified therein and thereupon the functions of the director of the Central Insecticides Laboratory shall to the extent so specified, be exercised by the head of the institution.

Functions

- i. To analysis samples received from Central/State Govt.

- ii. Analysis of samples of material for pesticide residue.
- iii. Verification of condition of registration.
- iv. Efficacy and toxicity testing.

D. INSECTICIDE INSPECTORS

Insecticide inspectors are appointed by the Central Government or the State Government under Section 20 of the Act.

The Central Government or the State Government may, by notification in the official gazette, appoint persons in such number as it thinks fit and possessing such technical and other qualifications as may be prescribed to be Insecticide Inspectors for such areas as may be specified in the notification. Provided further that no person who has any financial interest in the manufacture, import or sale of any insecticide shall be so appointed. Every Insecticide Inspector shall be deemed to be a public servant within the meaning of Section 21 of the Indian Penal Code, 1860 and shall be officially subordinate to such authority as the Government appointing him may specify in this behalf.

Powers and duties of insecticide inspectors: An insecticide inspector shall have power:

- a. To enter and search, at all reasonable times, and any premises in which he has reason to believe that an offence under this Act made thereunder has been or is being to be committed, or the conditions of any certificate of registration/license issued thereunder are being complied with.
- b. To inspect, examine, and he can take extracts from, registers, records or other documents kept by a manufacturer, distributor, carrier, dealer. Inspector have power to inspect and examine any other person in pursuance of the provisions of this act or the rules made thereunder and seize the same, if he has reason to believe that all or any of them, may furnish evidence of the commission of an offence punishable under this act or the rules made thereunder.
- c. To make such examination and inquiry as he thinks fit in order to ascertain whether

the provisions of this act or the rules made thereunder are being complied with and for that purpose stop any vehicle.

- d. To stop the distribution, sale or use of an insecticide which he has reason to believe is being distributed, sold or used in contravention of the provisions of this act or the rules made thereunder, for a specified period not exceeding twenty days, or unless the alleged contravention is such that the defect may be removed by the possessor of the insecticide, seize the stock of such insecticide.
- e. To take samples of any insecticide and send such samples for analysis to the Insecticide Analyst for test in the prescribed manner.
- f. To exercise such other powers as may be necessary for carrying out the purposes of this act or the rules made thereunder.

The provisions of the Code of Criminal Procedure, 1973 shall, as far as may be, apply to any search or seizure under this Act as they apply to any search or seizure made under the authority of a warrant issued under Section 94 of the said Code. An Insecticide Inspector may exercise the powers of a police officer under Section 42 of the Code of Criminal Procedure, 1973, for the purpose of ascertaining the true name and residence of the person from whom a sample is taken or an insecticide is seized.

REGISTRATION OF INSECTICIDES

A. Registration: Any person desiring to import or manufacture any insecticide may apply to the Registration Committee for the registration of such insecticide and there shall be separate application for each such insecticide. Any person engaged in the business of import or manufacture of any insecticide immediately before the commencement of this section shall make an application to the registration committee within a period of seventeen months from the date of such commencement for the registration of any insecticide which he has been importing or manufacturing before the date. Any person

referred into the preceding provision fails to make an application under that proviso within the period specified therein; he may make such application at any time thereafter on payment of a penalty of one hundred rupees for every month or part thereof after expiry of such period for the registration of each such insecticide. Every application under above sub-section shall be made in such form and contain such particulars as may be prescribed. On receipt of any such application for the registration of an insecticide, the committee may, after such enquiry as it deems fit and after satisfying itself that the insecticide to which the application relates conforms to the claims made by the importer or by the manufacturer, as the case may be, as regards the efficacy of the insecticide and its safety to human beings and animals, register on such conditions as may be specified by it and on payment of such fee as may be prescribed, the insecticide, allot a registration number thereto and issue a certificate of registration on token thereof within a period of twelve months from the date of receipt of the application. In the case of applications received by it prior to the 31st March, 1975, notwithstanding the expiry of the period for disposal of such applications, it shall be lawful and shall be deemed always to have been lawful for the Registration Committee to dispose of such applications at any time after such expiry but within a period of one year from the commencement of the Insecticides (Amendment) Act, 1977. Where the Registration Committee is of opinion that the insecticide is being introduced for the first time in India, it may be pending any enquiry register it provisionally for a period of two years on such conditions as may be specified by it. The Registration Committee may, having regard to the efficacy of the insecticide and its safety to human beings and animals, vary of conditions subject to which a certificate of registration has been granted and may for that purpose require the certificate-holder by notice in writing to deliver up the certificate to it within such time as may be specified in the notice.

Notwithstanding anything contained in the section, where an insecticide has been registered on the application of any person, any other person desiring to import or manufacture the insecticide or engaged in the business of, import or manufacture thereof, shall on application and on payment of prescribed fee be allotted a registration number and granted a certificate of registration in respect thereof on the same conditions on which the insecticide was originally registered.

B. Cancellation of registration: Notification of cancellation of registration.

A refusal to register any insecticide or a cancellation of a certificate of registration of any insecticides shall be notified in official gazette and in such other manner as may be prescribed.

GRANT OF LICENSE TO SALE, STOCK OR DISTRIBUTE INSECTICIDE

The State Government may, by notification in the official gazette, appoint such persons as it thinks fit to be licensing officers for the purposes of this act and define the areas in respect of which they shall exercise jurisdiction.

A. Grant of license:

1. Any person desiring to manufacture or to sell, stock or exhibit for sale or distribute any insecticide or to undertake commercial pest control operations with the use of any insecticide may make an application to the licensing officer for the grant of a license.
2. Every application under above sub-section shall be made in such form and shall contain such particulars as may be prescribed.
3. On receipt of any such application for the grant of a license, the licensing officer may grant a license in such form, on such conditions and on payment of such fee as may be prescribed.
4. A license granted under the section shall be valid for the period specified therein and may be renewed from time to time for such period and on payment of such fee as may be prescribed.

5. In prescribing fees the grant of renewal of licenses under this section, different fees may be prescribed for the sale or distribution of insecticides for purposes of domestic use and for other purposes.

B. Revocation of licenses: Revocation, suspension and amendment of licenses:

1. If the licensing officer is satisfied, either on a reference made to him in this behalf or otherwise, that:
 - a. The license granted has been granted because of misrepresentation as to an essential fact.
 - b. The holder of a license has failed to comply with the conditions subject to which the license was granted or has contravened any of the provisions of this act or the rules made thereunder, then, without prejudice to any other penalty to which the holder of the license may be liable under this act, the licensing officer may, after giving the holder of the license an opportunity of showing cause, revoke or suspend the license.
2. Subject to any rules that may be made in this behalf, the licensing officer may also vary or amend a license granted.

C. Appeal: Appeal against non-registration or cancellation: Any person aggrieved by a decision of the Registration may, within a period of 30 days from the date on which the decision is communicated to him, appeal in the prescribed manner and on payment of the prescribed fee to the Central government whose decision thereon shall be final.

Appeal against the decision of a licensing officer: Any person aggrieved by a decision of a licensing officer may, within a period of 30 days from the date on which the decision is communicated to him, appeal to such authority in such manner and on payment of such fee as may be prescribed. Provided that the appellate authority may entertain an appeal after the expiry of the said period if it is satisfied that the appellant was prevented by sufficient cause

from filing the appeal in time. On receipt of an appeal under above sub-section, the appellate authority shall, after giving the appellant an opportunity of showing cause, dispose of the appeal ordinarily within a period of 6 months and the decision of the appellate authority shall be final.

IMPORT, MANUFACTURE AND SALE OF CERTAIN INSECTICIDES

A person wishing to manufacture or to sale, stock or exhibit for sale insecticides has to obtain a license for the purpose from the Licensing Officers appointed on this behalf by the State Governments. No license is, however, needed for the import of a registered insecticide.

PROHIBITION OF IMPORT, MANUFACTURE AND SALE OF CERTAIN INSECTICIDES

A. Prohibition of Import and Manufacture of Certain Insecticides

1. No person shall, himself or by any person on his behalf, import or manufacture:
 - a. Any misbranded insecticides.
 - b. Any insecticide the sale, distribution or use of which is for the time being prohibited.
 - c. Any insecticide except in accordance with the condition on which it was registered.
 - d. Any insecticide in contravention of any other provision of this act or of any rule made thereunder.
2. No person shall, himself or by any person on his behalf, manufactaure any Insecticides except under, and in accordance with the conditions of a license issued for such purpose under this Act.

B. Prohibition of Sale of Certain Insecticides

1. No person shall, himself or by any person on his behalf, sell, stock or exhibit for sale, distribute, transport, use, or cause to be used by any worker:
 - a. Any insecticide which is not registered under this Act.

- b. Any insecticide, the sale, distribution or use of which is for the time being prohibited.
- c. Any insecticide in contravention of any other provision of this act or of any rule made thereunder.
2. No person shall, himself or by any person on his behalf, sell, stock or exhibit for sale or distribute or use for commercial pest control operations any insecticide except under and in accordance with the conditions of, a license issued for such purpose under this Act.

C. Prohibition of Sale of Insecticides for Reasons of Public Safety

The Central Government or the State Government is of opinion, for reasons to be recorded in writing, that the use of any insecticide or any specific batch thereof is likely to involve such risk to human beings or animals as to render it expedient or necessary to take immediate action then that Government may, by notification in the official gazette, prohibit the sale, distribution or use of the insecticide or batch in such area, to such extent and for such period (not exceeding sixty days) as may be specified in the notification pending investigation into the matte. If, as a result of its own investigation or on receipt of the report from the State Government, and after consultation with the Registration Committee, the Central Government, is satisfied that the use of the said insecticide or batch is likely to cause any such risk, it may pass such order (including an order refusing to register the insecticide or cancelling the certificate of registration, if any, granted in respect thereof), as it deems fit, depending on the circumstances of the case.

The license issued for manufacture or sale may be cancelled or suspended by the Licensing Officers under the provision related to the revocation of license. Any person aggrieved by a decision of a licensing officer may, within a period of 30 days of the suspension or cancellation order. The decision of the appellate authority shall be final.

OFFENCES AND PUNISHMENT

A. Offences and Punishment

1. Whoever:

- a. Imports, manufactures, sells, stocks or exhibits for sale or distributes any insecticide deemed to be misbranded, or
- b. Imports or manufactures any insecticide without a certificate of registration, or
- c. Manufactures, sells, stocks or exhibits for sale or distributes an insecticide without a license,
- d. Sells or distributes an insecticide prohibited for reasons of public safety,
- e. Causes an insecticide, the use of which has been prohibited for reasons of public safety, to be used by any worker,
- f. obstructs an Insecticide Inspector in the exercise of his powers or discharge of his duties under this Act or the rules made thereunder.

Shall be Punishable

- i. For the first offence, with imprisonment for a term which may extend to 2 years, or with fine which may extend to 2,000 rupees or both.
- ii. For the second and a subsequent offence, with imprisonment for a term which may extend to 3 years, or with fine, or both.
- 2. Whoever uses an insecticide in contravention of any provision of this act or any rule made thereunder shall be punishable with fine which may extend to 500 rupees.
- 3. Whoever contravenes any of the other provisions of this act or any rule made thereunder or any condition of a certificate of registration or license granted thereunder.

Shall be Punishable

- i. For the first offence, with imprisonment for a term which may extend to 6 months, or with fine, or with both.
- ii. For the second and a subsequent offence, with imprisonment for a term

which may extend to one year, or with fine, or both.

- 4. If any person convicted of an offence under this act commits a like offence afterwards it shall be lawful for the court before which the second or subsequent conviction takes place to cause the offender's name and place of residence, the offence and the penalty imposed to be published in such newspapers or in such other manner as the Court may direct.

B. Cognizance and Trial of Offences

No prosecution for an offence under this Act shall be instituted except by, or with the written consent of the State Government or a person authorised in this behalf by the State Government. No Court inferior to that of a (Metropolitan Magistrate or a Judicial Magistrate of the First Class) shall try any offence under this act.

C. Offences by Companies

- 1. Whenever an offence under this Act has been committed by a company, every person who at the time the offence was committed was in charge of, or was responsible to the company for the conduct of the business of the company, as well as the company, shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly.
- 2. Where an offence under this Act has been committed by a company and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect, on the part, of, any director, manager, secretary or other officer of the company, such director, manager, secretary or other officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

D. Protection of Action Taken in Good Faith

No prosecution, suit or other proceeding shall lie against the Government, or any officer of the Government, or the board, the Registration

Committee or any committee of the Board, for anything in good faith done or intended to be done under this Act.

EXEMPTION

Nothing in this act shall apply to the use of any insecticide by any person for his own household purposes or for garden or in respect of any land under his cultivation. Nothing in this act applies to any substance specified or included in the Schedule or any preparation containing any one or more such substances, if such substance or preparation is intended for purposes other than preventing, destroying, repelling or mitigating any insects, rodents, fungi, weeds and other forms of plant or animal life not useful to human beings. The Central Government may exempt from all or any of the provisions of this act or the rules made thereunder, any educational, scientific or research organization engaged in carrying out experiments, with insecticides.

MISCELLANEOUS

A. Persons bound to disclose place where insecticides are manufactured or kept: Every person for the time being in-charge of any premises where any insecticide is being manufactured or is kept for sale or distribution shall, on being required by an insecticide inspector so to do, be legally bound to disclose to the insecticide Inspector the place where the insecticide is being manufactured or is kept, as the case may be.

B. Confiscation: Where any person has been convicted under this act for contravening any of the provisions of this act or of the rules made thereunder, the stock of the insecticide in respect of which the contravention has been made shall be liable to confiscation. Where the court is satisfied on the application of an Insecticide Inspector or otherwise and after such inquiry as may be necessary, that the insecticide is

misbranded insecticide, such insecticide shall be liable to confiscation.

C. Notification of poisoning: The State Government, may, by notification in the official gazette, require any person or class of persons specified therein to report all occurrences of poisoning (through the use or handling of any insecticide) coming within his or their cognizance to such officer as may be specified in the said notification.

D. Power of revision of Central Government: The Central Government may at any time, call for the record relating to any case in which the Registration Committee has given a decision under Section 9 for the purpose of satisfying itself as to the legality or propriety of any such decision and may pass any such order in relation thereto as it thinks fit. Provided that no such order shall be passed after the expiry of one year from the date of the decision. Provided further that the Central Government shall not pass any order prejudicial to any person unless that person has had a reasonable opportunity of showing cause against the proposed order.

E. Power of the Central Government to give directions: The Central Government may give such directions to any State Government as may appear to the Central Government to be necessary for carrying into execution in the State any of the provisions of this Act or of any rule or order made thereunder.

F. Power of the Central Government to make rules: The Central Government may, after consultation with the Board and subject to the condition of previous publication, by notification in the official gazette, make rules for the purpose of giving effect to the provisions of this Act.

G. Power of the State Government to make rules: The State Government may, after consultation with the Board and subject to the condition of previous publication, by notification in the official gazette, make rules for the purpose of giving effect to the provisions of this act and not inconsistent with the rules, if any, made by the Central Government.

The All India Council for Technical Education Act, 1987

INTRODUCTION

Technical Education in India contributes a major share to the overall education system and plays a vital role in the social and economic development of our nation. In India, technical education is imparted at various levels such as craftsmanship, diploma, degree, post-graduate and research in specialized fields, catering to various aspects of technological development and economic progress.

The beginning of formal Technical Education in India can be dated back to the mid 19th Century. The major policy initiatives in the pre-independence period included appointment of the Indian Universities Commission in 1902, issue of the Indian Education Policy Resolution in 1904 and the Governor General's Policy Statement of 1913 stressing the importance of technical education, the establishment of IISc in Bangalore, Institute for Sugar, Textile and Leather technology in Kanpur, N.C.E. in Bengal in 1905 and Industrial schools in several provinces. Significant developments include:

- Constitution of the Technical Education Committee of the Central Advisory Board of Education (CABE) of 1943.
- Preparation of the Sergeant Report of 1944.
- Formation of the All India Council for Technical Education (AICTE) in 1945 by the Government of India.

About AICTE

The AICTE was constituted in 1945 as an advisory body in all matters relating to technical education. Even though it had no statutory powers, it played a very important role in the development of technical education in the country. It had four regional committees with offices at Chennai, Mumbai, Kanpur and Kolkata. All the new schemes and proposals for starting new institutions/programmes were approved by the corresponding Regional Committee and subsequently vetted by the Council.

There was large-scale expansion of technical education in the late fifties and early sixties and again in the eighties. While the expansion in the fifties was done with the approval of the AICTE and the Government of India, the expansion in the eighties was localised mostly in the four states of Karnataka, Maharashtra, Tamil Nadu and Andhra Pradesh and was primarily in the self-financing sector without the approval of the AICTE and Government of India. It was in this period that the National Policy on Education, 1986 made a specific mention of the need to make AICTE a statutory body and stated.

Even earlier, the Education Commission of 1964, popularly known as Kothari Commission after the name of its Chairman, made the following recommendation for the proper administration of technical education.

"To ensure the pursuit of the highest standards at the first degree and postgraduate levels, and to provide on adequate machinery with the national and professional concern with the future development at these levels, we have recommended the setting up of a UGC-type organization, industry and concerned ministries. This body should have a full-time chairman, and funds should be allotted to it on a block basis."

In view of the above, AICTE became a statutory body through an Act of Parliament 52, in 1987. The Council, i.e. AICTE was established with a view to the proper planning and coordinated development of the technical education system throughout the country, the promotion of qualitative improvement of such education in relation to planned quantitative growth and the regulation and proper maintenance of norms and standards in the technical education system for matters connected therewith. Technical Education was defined as programmes of education, research and training in engineering, technology, architecture, town planning, management, pharmacy and applied arts and crafts and such other programmes or areas as the Central Government may, in consultation with the Council, by notification in the Official Gazette, declare. The Act also laid down the powers, functions and structure of the AICTE.

Having vested with Statutory powers, AICTE has initiated necessary steps for planning, formulation and maintenance of norms and standards, accreditation, funding of priority areas, monitoring and evaluation of courses/programmes in the field of technical education to ensure coordinated and integrated development of technical education in the Country. In order to achieve the planned growth and to nurture quality in technical education system, AICTE has spared no effort to inculcate competitiveness to face the globalization and in generating competence and quality in technically qualified human resources to make it globally acceptable.

ALL INDIA COUNCIL FOR TECHNICAL EDUCATION

The All India Council for Technical Education (AICTE) is the statutory body and a National-level council for technical education, under Department of Higher Education, Ministry of Human Resource Development. Established in November, 1945 first as an advisory body and later on in 1987 given statutory status by an Act of Parliament, AICTE is responsible for proper planning and coordinated development of the Technical Education and Management Education system in India. The AICTE accredits postgraduate and graduate programs under specific categories at Indian institutions as per its Charter.

The AICTE has its Headquarters in Indira Gandhi Sports Complex, Indraprastha Estate, New Delhi, which has the offices of the Chairman, Vice-Chairman and the Member Secretary, plus it has regional offices located at Kolkata, Chennai, Kanpur, Mumbai, Chandigarh, Guwahati, Bhopal and Bengaluru, Hyderabad and Gurgaon.

In 2009, the Union Minister of Education formally communicated his intentions of closing down AICTE and related body, the University Grants Commission due to corruption and inefficiency charges against the bodies in favour of a larger regulatory body. The AICTE will be superseded by the National Board of Accreditation (NBA). The NBA which currently operates under the wing of AICTE will be converted into an independent body.

All India Council for Technical Education

Abbreviation	AICTE
Formation	November, 1945
Headquarters	New Delhi
Location	Kolkata, Chennai, Kanpur, Mumbai, Chandigarh, Guwahati, Bhopal, Bengaluru, Hyderabad, Gurgaon
Main organ	Council
Affiliations	Department of Higher Education, Ministry of Human Resource Development

Salient Features of the Act

I. The statutory bodies of AICTE as prescribed by the act are:

- Council
- Executive Committee
- Regional Committees
- All India Board of Studies.

II. The council is a 51 member body and has Chairman, Vice-Chairman and Member-Secretary who have full time tenure appointments and includes amongst others, representatives of various Departments of the Government of India, the Lok Sabha and the Rajya Sabha, Governments of States and Union Territories, representatives from the Statutory Boards and committees of the council, professional bodies and organizations in the concerned areas of technical education and research and representatives from industry, commerce, etc. The Council performs its functions in consultation with State Governments, Universities, State Boards of Technical Education, Professional bodies and experts. The prime duty of the Council is to take all such steps as it may think fit for ensuring coordinated and integrated development of technical and management education and maintenance of standards.

III. The Executive Committee is a 21-member body constituted by the Council and discharges such functions as may be assigned to it by the Council. The Executive Committee is chaired by the Chairman of the Council and includes Vice-Chairman of the Council, Education Secretary to the Government of India, two Chairman of the Regional Committees, three Chairman of the All India Boards of Studies, one member of the Council representing the Ministry of Finance of the Central Government; four members of the Council representing States/UTs, four members with expertise and distinction in areas relevant to technical education, Chairman of the University Grants Commission; Director of the Institute of Applied Manpower Research, Director General of Indian Council of Agriculture Research. The Member-Secretary of the

Council is the Member-Secretary of the Executive Committee.

IV. The AICTE Act provided for the establishment of five boards of studies. However, the Council was empowered by the Act to establish such other Boards of Studies as it may think fit. It is assisted by 10 Statutory Boards of Studies, namely, UG Studies in Eng. and Tech., PG and Research in Eng. and Tech. These are:

1. All India Board of Vocational Education
2. All India Board of Technician Education
3. All India Board of Undergraduate Studies in Engineering and Technology
4. All India Board of Postgraduate Education and Research in Engineering and Technology
5. All India Board of Management Studies
6. All India Board of Pharmaceutical Education
7. All India Board of Hotel Management and Catering Technology
8. All India Board of Information Technology
9. All India Board of Town Planning
10. All India Board of Architecture

Each Board of Studies has about 15 members and is headed by subject experts of eminence. These Boards advise the Executive Committee on academic matters falling in their areas of concern including norms, standards, model curricula, model facilities and structure of courses and all other areas of academic development in their respective fields.

V. The AICTE Act provided for the establishment of four Regional Committees. However, the Council was empowered by the Act to establish such other Regional Committee as it may think fit. Each Regional Committee has 15-20 members and is headed by a person of eminence. These Committees advise and assist the Council in all aspects of planning, promoting and regulating technical education within their respective regions.

VI. AICTE has also established regional offices situated in Bhopal, Bengaluru, Chandigarh, Chennai, Kanpur, Kolkata, Hyderabad and Mumbai, for the efficient discharge of the

Council's functions within their respective regions. These offices act as secretariats of the Regional Committees and coordinate with the Headquarters and the State Technical Education Departments.

AICTE Bureaus

The AICTE comprises 9 Bureaus, namely:

- Faculty Development (*FD*) Bureau
- Undergraduate Education (*UG*) Bureau
- Postgraduate Education and Research (*PGER*) Bureau
- Quality Assurance (*QA*) Bureau
- Planning and Coordination (*PC*) Bureau
- Research and Institutional Development (*RID*) Bureau
- Administration (*Admin*) Bureau
- Finance (*Fin*) Bureau.
- Academic (*Acad*) Bureau.

For each Bureau, Adviser is the Bureau Head who is assisted by technical officers and other supporting staff. The multidiscipline technical officer and staff of the Council are on deputation or on contract from various Government Departments, University Grants Commission, academic institutions, etc.

Objectives of the AICTE Act of 1987

AICTE is vested with statutory authority for planning, formulation and maintenance of norms and standards, quality assurance through school accreditation, funding in priority areas, monitoring and evaluation, maintaining parity of certification and awards and ensuring coordinated and integrated development and management of technical education in the country as part of the AICTE Act No. 52 of 1987. To provide for establishment of an All India council for Technical Education with a view to the proper planning and coordinated development of the technical education system throughout the country, the promotion of qualitative improvement of such education in relation to planned quantitative growth and the regulation and proper maintenance of norms and standards in the technical education system and for matters connected therewith.

Current Objectives

In order to improve upon the present technical education system, the current objectives is to modify the engineering curriculum as follows:

1. Greater emphasis on design oriented teaching, teaching of design methodologies, problem solving approach.
2. Greater exposure to industrial and manufacturing processes.
3. Exclusion of outmoded technologies and inclusion of the new appropriate and emerging technologies.
4. Greater input of management education and professional communication skills.

Mission of the AICTE

- A true facilitator and an objective regulator.
- Transparent governance and accountable approach towards the society.
- Planned and coordinated development of technical education in the country by ensuring world-class standards of institutions through accreditation.
- Facilitating world-class Technical Education through:
 - Emphasis on developing high quality institutions, academic excellence and innovative research and development programmes.
 - Networking of institutions for optimum resource utilization.
 - Dissemination of knowledge.
 - Technology forecasting and global manpower planning.
 - Promoting industry-institution interaction for developing new products, services, patents.
 - Inculcating entrepreneurship.
 - Encouraging indigenous technology.
 - Focusing on nonformal education.
 - Providing affordable education to all.
 - Making Indian Technical Education globally acceptable.

- To be a forward-looking organization that has an efficient, flexible and empowered manpower, sensitive to stakeholders' expectations.

DEFINITIONS

- a. "**Commission**" means the university grants commission established under Section 4 of the University Grants Commission Act, 1956.
- b. "**Council**" means the All India Council for Technical Education established under Section 3 (Establishment of the Council).
- c. "**Fund**" means the Fund of the Council constituted under Section 16.
- d. "**Member**" means a member of the Council and includes the Chairman and Vice-Chairman.
- e. "**Regulations**" means regulations made under this Act.
- f. "**Technical education**" means programmes of education, research and training in engineering technology, architecture, town planning, management, pharmacy and applied arts and crafts and such other programme or areas as the Central Government may, in consultation with the Council, by notification in the official gazette, declare.
- g. "**Technical institution**" means an institution, not being a University, which offers courses or programmes of technical education and shall include such other institutions as the Central Government may, in consultation with the council, by notification in the official gazette, declare as technical institutions.
- h. "**Bureau BOS**" means the Bureau of Board of Studies of the Council.
- i. "**Bureau MPCD**" means the Bureau of Manpower Planning and Career Development of the Council.
- j. "**Bureau RA**" means the Bureau of recognition and Accreditation of the Council.
- k. "**Bureau RC**" means the Bureau of regional committees of the Council.

- l. "**University**" means a University defined under the University Grants Commission Act, 1956 and includes an institution deemed to be a University under Section 3 of that Act.
- m. "**Deemed university**" means any institution of higher education other than University, declared as such under Section 3 of the UGC Act, 1956.
- n. "**University technical department**" means the department of the concerned University conducting 'technical education' courses or programmes.

ESTABLISHMENT OF THE COUNCIL

A. The Council

I. *Establishment of the council and composition of the council:* The council established by the Central Government.

1. With effect from such date as the Central Government may appoint, there shall be established a council by the name of the all India Council for Technical Education. The Council shall be a body corporate by the name AICTE, having perpetual succession and a common seal, with power to contract. The head office of the Council shall be at Delhi.
2. The Council shall consist of the following members, namely:
 - a. A Chairman to be appointed by the Central Government.
 - b. A Vice-Chairman to be appointed by the Central Government.
 - c. The Secretary to the Government of India in the Ministry of the Central Government dealing with education, *ex-officio* member.
 - d. The Educational Adviser (general) to the Government of India, *ex-officio* member.
 - e. The Chairmen of the 4 Regional Committees, *ex-officio* member.
 - f. The Chairmen of:
 - i. The All India Board of Vocational Education, *ex-officio* member.

- ii. The All India Board of Technician Education, *ex-officio* member.
 - iii. The All India Board of Under-graduate studies in Engineering and Technology, *ex-officio* member.
 - iv. The all India board of post graduate education and research in engineering and technology, *ex-officio* member.
 - v. The All India Board of Management Studies, *ex-officio* member.
 - g. One member to be appointed by the Central Government to represent the Ministry of Finance of the Central Government.
 - h. One member to be appointed by the Central Government to represent the Ministry of Science and Technology of the Central Government.
 - i. Four members to be appointed by the Central Government by rotation to represent the Ministries and the Departments of the Central Government, other than those specified in clauses (g) and (h).
 - j. Two members of Parliament of whom one shall be elected by the House of the People and one by the Council of States.
 - k. Eight members to be appointed by the Central Government by rotation in the alphabetical order to represent the States and the Union territories.
 - l. Four members to be appointed by the Central Government to represent the organizations in the field of industry and commerce.
 - m. Seven members to be appointed by the Central Government to represent:
 - i. The Central Advisory Board of Education.
 - ii. The Association of Indian Universities.
 - iii. The Indian Society for Technical Education.
 - iv. The Council of the Indian Institutes of Technology.
 - v. The Pharmacy Council of India.
 - vi. The Council of Architecture.
 - vii. The National Productivity Council.
 - n. Four members to be appointed by the Central Government to represent the professional bodies in the field of technical and management education.
 - o. Not more than 2 members to be appointed by the Central Government to represent such interests not covered by the foregoing clauses as the Central Government may deem fit.
 - p. The Chairman, University Grants Commission, *ex-officio* member.
 - q. The Director, Institute of Applied Manpower Research, New Delhi, *ex-officio* member.
 - r. The Director General, Indian Council of Agricultural Research, *ex-officio* member.
 - s. The Director General, Council of Scientific and Industrial Research, *ex-officio* member.
 - t. Member Secretary to be appointed by the Central Government.
3. Notwithstanding anything contained in sub-section (2):
- a. The first Chairman shall be the Minister of Human Resource Development of the Central Government.
 - b. The first Vice-Chairman of the Council shall be the Minister of State for Education of the Central Government.
 - c. The first Member-Secretary of the Council shall be the Educational Adviser (Technical) of the Central Government.
- II. Term of office of members:**
1. The term of office of a member, other than an *ex-officio* member, on the first constitution of the Council shall be 5 years and thereafter 3 years.
 2. If a casual vacancy occurs in the office of the Chairman, whether by reason of his death, resignation or inability to discharge his functions owing to illness or other incapacity, the Vice-Chairman holding office as such for the time being shall Act as

the Chairman and shall, unless any other person is appointed earlier as the Chairman, hold office of the chairman for the remainder of the term of office of the person in whose place he is to so Act.

3. If a casual vacancy occurs in the office of the Vice-Chairman or any other member, whether by reason of his death, resignation or inability to discharge his functions owing to illness or other incapacity, such vacancy shall be filled by the Central Government by making a fresh appointment and the member so appointed shall hold office for the remainder of the term of office of the person in whose place he is so appointed.
4. The Vice-Chairman shall perform such functions as may be assigned to him by the Chairman from time to time.
5. The procedure to be followed by the members in the discharge of their functions shall be such as may be prescribed.

III. Meetings of the council: The Council shall meet at such time and places, and shall observe such rules of procedure in regard to the transaction of business at its meetings (including the quorum at such meetings) as may be provided by regulations. The Chairman and in his absence the Vice-Chairman shall preside at the meetings of the Council. If for any reason the Chairman or the Vice-Chairman is unable to attend any meeting of the Council, any other member chosen by the members present at the meeting shall preside at the meeting. All questions which come up before any meeting of the Council shall be decided by a majority of the votes of the members present and voting, and in the event of an equality of votes, the Chairman, or in his absence, the person presiding, shall have and exercise a second or casting vote.

IV. Vacancies not to invalidate proceedings of the council: No act or proceeding of the council shall be invalid merely by reason or:

1. Any vacancy in, or any defect in the constitution of, the council.
2. Any defect in the appointment of a person acting as a member of the council.

3. Any irregularity in the procedure of the council not affecting the merits of the case.

V. Temporary association of persons with the council for particular purposes: The council may associate with itself, in such manner and for such purposes as may be determined by regulations, any person whose assistance or advice it may desire in carrying out any of the provisions of this Act. A person associated with it by the council for any purpose shall have a right to take part in the discussions relevant to that purpose, but shall not have a right to vote at a meeting of the Council, and shall not be a member for any other purpose.

VI. Appointment of officers and other employees of the council: For the purpose of enabling it efficiently to discharge its functions under this act, the council shall, subject to such regulations as may be made in this behalf appoint (whether on deputation or otherwise) such number of officers and other employees. Every officer or other employee appointed by the council shall be subject to such conditions of service and shall be entitled to such remuneration as may be determined by regulations.

VII. Authentication of orders and other instruments of the council: All orders and decisions of the Council shall be authenticated by the signature of the Chairman or any other member authorised by the council in this behalf, and all other instruments issued by the council shall be authenticated by the signature of the Member-Secretary or any other officer of the Council authorised in like manner in this behalf.

B. Powers and Functions of the Council

I. Functions of the council: It shall be the duty of the council to take all such steps as it may think fit for ensuring coordinated and integrated development of technical education and maintenance of standards and for the purposes for performing its functions under this Act, the council may:

- a. Undertake survey in the various fields of technical education, collect data on all related matters and make forecast of the needed growth and development in technical education.

- b. Coordinate the development of technical education in the country at all levels.
- c. Allocate and disburse out of the fund of the council such grants on such terms and conditions as it may think fit to:
 - i. Technical institutions.
 - ii. Universities imparting technical education in coordination with the commission.
- d. Promote innovations, research and development in established and new technologies, generation, adoption and adaptation of new technologies to meet developmental requirements and for overall improvement of educational processes.
- e. Formulate schemes for promoting technical education for women, handicapped and weaker sections of the society.
- f. Promote an effective link between technical education system and other relevant systems including research and development organizations, industry and the community.
- g. Evolve suitable performance appraisal systems for technical institutions and universities imparting technical education, incorporating norms and mechanisms for enforcing accountability.
- h. Formulate schemes for the initial and in-service training of teachers and identify institution or centres and set up new centres for offering staff development programmes including continuing education of teachers.
- i. Lay down norms and standards for courses, curricula, physical and instructional facilities, staff pattern, staff qualifications, quality instructions, assessment and examinations.
- j. Fix norms and guidelines for charging tuition and other fees.
- k. Grant approval for starting new technical institutions and for introduction of new courses or programmes in consultation with the agencies concerned.
- l. Advise the Central Government in respect of grant of charter to any professional body or institution in the field of technical education conferring powers, rights and privileges on it for the promotion of such profession in its field including conduct of examinations and awarding of membership certificates.
- m. Lay down norms for granting autonomy to technical institutions.
- n. Take all necessary steps to prevent commercialisation of technical education.
- o. Provide guidelines for admission of students to technical institutions and universities imparting technical education.
- p. Inspect or cause to inspect any technical institution.
- q. Withhold or discontinue grants in respect of courses, programmes to such technical institutions which fail to comply with the directions given by the Council within the stipulated period of time and take such other steps as may be necessary for ensuring compliance of the directions of the Council.
- r. Take steps to strengthen the existing organizations, and to set up new organizations to ensure effective discharge of the Council's responsibilities and to create positions of professional, technical and supporting staff based on requirements.
- s. Declare technical institutions at various levels and types offering courses in technical education fit to receive grants.
- t. Advise the commission for declaring any institution imparting technical education as a deemed university.
- u. Set up a National Board of Accreditation to periodically conduct evaluation of technical institutions or programmes on the basis of guidelines, norms and standards specified by it and to make recommendation to it, or to the Council, or to the commission or to other bodies, regarding recognition or de-recognition of the institution or the programme.

- v. Perform such other functions as may be prescribed.

II. Inspection: For the purposes of ascertaining the financial needs of technical institution or a university or its standards of teaching, examination and research the council may cause an inspection of any department or departments of such technical institution or University to be made in such manner as may be prescribed and by such person or person as it may direct. The council shall communicate to the technical institution or University the date on which any inspection under is to be made and the technical institution or University shall be entitled to be associated with the inspection in such manner as may be prescribed. The council shall communicate to the technical institution or the University, its views in regard to the results of any such inspection and may, after ascertaining the opinion of that technical institution or university, recommend to that institution or university the action to be taken as a result of such inspection. All communications to a technical institution or university under this section shall be made to the executive authority thereof and the executive authority of the technical institution or university shall report to the council the action, if any, which is proposed to be taken for the purposes of implementing.

BODIES OF THE COUNCIL

I. Executive Committee of the Council:

1. The council shall constitute a Committee, called the Executive Committee for discharging such functions as may be assigned to it by the council.
2. The Executive Committee shall consist of the following members, namely:
 - a. The Chairman of the Council.
 - b. The Vice-Chairman of the Council.
 - c. Secretary to the Government of India in the Ministry of the Central Government dealing with Education, *ex-officio*.
 - d. 2 Chairmen of the Regional Committees.
 - e. 3 Chairmen of the Boards of Studies.

- f. A member of the Council representing the Ministry of Finance of the Central Government, *ex-officio* member.
 - g. 4 out of eight members of the Council representing the States and Union territories.
 - h. 4 members with expertise and distinction in areas relevant to Technical Education to be **ominated** by the Chairman of the Council.
 - i. The Chairman of the University Grants Commission, *ex-officio* member.
 - j. The Director, Institute of Applied Manpower Research, New Delhi, *ex-officio* member.
 - k. The Director General, Indian Council of Agricultural Research, *ex-officio* member.
 - l. The Member-Secretary of the Council.
 3. The Chairman and the Member-Secretary of the Council shall, respectively, function as the Chairman and the Member-Secretary of the Executive Committee.
 4. The Chairman or in his absence, the Vice-Chairman of the Council shall preside at the meetings of the Executive Committee and in the absence of both the Chairman and the Vice-Chairman. Any other member chosen by the members present at the meeting shall preside at the meeting.
 5. The Executive Committee shall meet at such time and places, and shall observe such rules of procedure in regard to the transaction of business at its meetings (including the quorum at such meetings) as the Council may provide by regulations.
- II. Boards of studies:**
1. The Council shall establish the following Boards of Studies, namely:
 - i. All India Board of Vocational Education.
 - ii. All India Board of Technician Education.
 - iii. All India Board of Undergraduate Studies in Engineering and Technology.
 - iv. All India Board of Postgraduate Education and Research in Engineering and Technology.

- v. All India board of Management Studies.
- 2. The Council may, if it considers necessary, establish such other Boards of Studies as it may think fit.
- 3. Every Board of Studies shall advise the Executive Committee on academic matters falling in its area of concern including norms standards, model curricula, model facilities and structure of courses.
- 4. The area of concern, powers, the constitution and functions of the Boards of Studies shall be such as the Council may provide by regulations.

III. Regional Committees:

- 1. The Council shall establish the following Regional Committees, namely:
 - i. The Northern Regional Committee with its office at Kanpur.
 - ii. The Southern Regional Committee with its office at Madras.
 - iii. The Western Regional Committee with its office at Mumbai.
 - iv. The Eastern Regional Committee with its office at Kolkata.
- 2. The Council may, if it considers necessary, establish such other Regional Committees as it may think fit.
- 3. The Regional Committee shall advise and assist the Council to look into all aspects of planning, promoting and regulating technical education within the region.
- 4. The region for which the Regional Committees may be established and the constitution and functions of such committees shall be prescribed by regulations.

IV. National Board of Accreditation:

Accreditation: Literally accreditation means recognition and guarantee of minimum quality. For the NBA it means.

A process of quality assurance, giving credit where it is due for some clearly visible and demonstrable strategies of academic activities and objectives of the institutions, known to be honestly pursued and efficiently achieved by the resources currently available with a potential for

continuous improvement in quality for effective growth.

National Board of Accreditation (NBA): The National Board of Accreditation (NBA) was established by All India Council of Technical Education (AICTE) as an Autonomous body under Section 10(u) of the AICTE act 1987 to conduct periodical evaluation of the technical institutions and programmes on a periodical basis according to specified norms and standards as recommended by AICTE council. It has the full authority to recognize or derecognize any technical institute/faculty or programmes offered by it. Many different Diploma, Degree and Post-graduate technical programmes and institutes offering such programmes come under the purview of National Board of Accreditation (NBA). The NBA approval of technical institutions is a process of quality assurance and it makes sure that an institute providing technical education is giving its students the quality of education for that it makes commitment. It strives to provide the quality benchmarks targeted at global and national levels in all fields of technical education.

The goals of NBA: To develop a quality Conscious systems of Technical Education where excellence, relevance to market needs and participation by all stake holders are prime the major determinants. NBA is dedicated to building a technical education system, as vendors of human resources that will match the national goals of growth by competence, contributions to economy through competitiveness and compatibility to societal development. NBA will provide the Quality benchmarks targeted at Global and National Stockpile of human capital in all fields of technical education.

FINANCE, ACCOUNTS AND AUDIT

A. Finance

I. Payment to the council: The Central Government may, after due appropriation made by Parliament by law in this behalf, pay to the Council in each financial year such sums may

be considered necessary for the performance of functions of the council under this Act.

II. Fund of the council: The Council shall have its own fund and all sums which may, from time to time be paid to it by the Central Government and all the receipts of the Council (including any sum which any State Government or any other authority or person may hand over to the Council) shall be credited to the Fund and all payments by the Council shall be made therefrom. All moneys belonging to the Fund shall be deposited in such banks or invested in such manner as may, subject to the approval of the Central Government, be decided by the Council. The Council may spend such sums as it thinks fit for performing its functions under this act, and such sums shall be treated as expenditure payable out of the Fund of the Council.

III. Budget: The Council shall prepare, in such form and at such time each year as may be prescribed a budget in respect of the financial year next ensuing showing the estimated receipts and expenditure, and copies thereof shall be forwarded to the Central Government.

IV. Annual report: The Council shall prepare once every year, in such form and at such time as may be prescribed, an annual report giving a true and full account of its activities during the previous year and copies thereof shall be forwarded to the Central Government and that Government shall cause the same to be laid before both Houses of Parliament.

B. Accounts and Audit

The Council shall cause to be maintained such books of account and other books in relation to its accounts in such form and in such manner as may, in consultation with the Comptroller and Auditor-General of India, be prescribed. The Council shall, as soon as may be, after closing its annual accounts prepare a statement of accounts in such form, and forward the same

to the Comptroller and Auditor-General of India by such date, as the Central Government may, in consultation with the Comptroller and Auditor-General determine. The accounts of the Council shall be audited by the Comptroller and Auditor-General of India at such times and in such manner as he thinks fit. The accounts of the Council as certified by the Comptroller and Auditor-General of India or any other person appointed by him in this behalf together with the audit report thereon shall be forwarded annually to the Central Government and that Government shall cause the same to be laid before both Houses of Parliament.

MISCELLANEOUS

A. Directions by the Central Government: The Council shall, in the discharge of its functions and duties under this Act, be bound by such directions on questions of policy as the Central Government may give in writing to it from time to time. The decision of the Central Government as to whether a question is one of policy or not shall be final.

B. Power to supersede the council: If the Central Government is of the opinion that the Council is unable to perform, or has persistently made default in the performance of, the duty imposed on its by or under this Act or has exceeded or abused its powers, or has wilfully or without sufficient cause, failed to comply with any direction issued by the Central Government, the Central Government may supersede the Council for such period as may be specified in the notification.

C. Power to make rules: The Central Government may, by notification in the official gazette, make rules to carry out the purposes of this Act.

D. Power to make regulations: The Council may, by notification in the official gazette, make regulations not inconsistent with the provisions of this Act, and the rules generally to carry out the purposes of this Act.

CHAPTER

14

The Factories Act, 1948

INTRODUCTION

A factory or manufacturing plant is an industrial building where laborers manufacture goods or supervise machines processing one product into another. Most modern factories have large warehouses or warehouse-like facilities that contain heavy equipment used for assembly line production. Typically, factories gather and concentrate resources: laborers, capital and plant.

The law relating to the regulation of labour employed in factories in India was embodied in the Factories Act, 1934. It was amended several times but its general framework remained unchanged. Application of this act revealed a number of defects and weaknesses which hampered effective administration. In the meanwhile industrial activities in the country grew to a very large extent and it became essential to overhaul the Factories Law. To achieve this objective the Factories Bill was introduced in the legislature.

Factories Act, 1948

An Act to consolidate and amend the law regulating labour in factories. This act may be called the Factories Act, 1948. It extends to the whole of India. The act comes into force on the 1st day of April, 1949. Factories Act, 1948 is a social legislation which has been enacted for occupational safety, health and welfare of workers at work places and being enforced by

technical officers, i.e. Inspectors of factories, Dy. Chief Inspectors of factories who work under the control of the chief Inspector of factories and overall control of the Labour Commissioner, Government of National Capital Territory of Delhi.

Objectives

- To ensure adequate safety measures and to promote the health and welfare of the workers employed in factories.
- To prevent haphazard growth of factories through the provisions related to the approval of plans before the creation of a factory.
- To provide for the prevention of accidents on machines and other equipments.
- To regulate and control its working by appointment of inspectors by the State Governments.

SALIENT FEATURES

- Approval of factory Building Plans before construction/extension, under the Delhi Factories Rules, 1950.
- Grant of Licenses under the Delhi Factories Rules, 1950, and to take action against factories running without obtaining License.
- Renewal of Licenses granted under the Delhi Factories Rules, 1950, by the Dy. Chief Inspectors of Factories

- Inspections of factories by District Inspectors of factories, for investigation of complaints, serious/fatal accidents as well as suo moto inspections to check compliance of provisions of this act related to: Health, safety, welfare facilities, working hours, employment of young persons and annual leave with wages, etc.

Applicability: The industries in which ten or more than ten workers are employed on any day of the preceding twelve months-engaged in manufacturing process being carried out with the aid of power or twenty or more than twenty workers employed in manufacturing process being carried out without the aid of power.

Scope and Coverage

1. Regulates working condition in factories.
2. Basic minimum requirements for ensuring safety, health and welfare of workers.
3. Applicable to all workers.
4. Applicable to all factories using power and employing 10 or more workers, and if not using power, employing 20 or more workers on any day of the preceding 12 months.

Main Provisions

1. Compulsory approval, licensing and registration of factories.
2. Health measures.
3. Safety measures.
4. Welfare measures.
5. Working hours.
6. Employment of women and young persons.
7. Annual leave provision.
8. Accident and occupational diseases.
9. Dangerous operations.
10. Penalties.
11. Obligations and rights of employees.

Consult and Refer

- i. On starting a factory.
- ii. Throughout the life of the factory.

DEFINITIONS

- a. "**Adult**" means a person who has completed his eighteenth year of age.
- b. "**Adolescent**" means a person who has completed his fifteen year of age but has not completed his eighteenth year.
- bb. "**Calendar year**" means the period of twelve months beginning with the first day of January in any year.
- c. "**Child**" means a person who has not completed his fifteenth year of age.
- ca. "**Competent person**", in relation to any provision of this act, means a person or an institution recognised as such by the Chief Inspector for the purposes of carrying out tests, examinations and inspections required to be done in a factory under the provisions of this act having regard to:
 - i. The qualifications and experience of the person and facilities available at his disposal.
 - ii. The qualifications and experience of the persons employed in such institution and facilities available therein, with regard to the conduct of such test, examinations and inspections, and more than one person or institution can be recognised as a competent person in relation to a factory.
- cb. "**Hazardous process**" means any process or activity in relation to an industry specified to the first Schedule where, unless special care is taken, raw materials used therein or the intermediate or finished products, bye-products, wastes or effluents thereof would:
 - i. Cause material impairment to the health of the persons engaged in or connected therewith.
 - ii. Result in the pollution of the general environment.
- d. "**Young person**" means a person who is either a child or an adolescent.
- e. "**Day**" means a period of twenty-four hours beginning at midnight.

- f. "**Week**" means a period of seven days beginning at midnight on Saturday night or such other night as may be approved in writing for a particular area by the Chief Inspector of factories.
- g. "**Power**" means electrical energy, or any other form of energy which is mechanically transmitted and is not generated by human or animal agency.
- h. "**Prime mover**" means any engine, motor or other appliance which generates or otherwise provides power.
- i. "**Transmission machinery**" means any shaft, wheel drum, pulley, system of pulleys, coupling, clutch, driving belt or other appliance or device by which the motion of a prime mover is transmitted to or received by any machinery or appliance.
- j. "**Machinery**" includes prime movers, transmission machinery and all other appliances whereby power is generated, transformed, transmitted or applied.
- k. "**Manufacturing process**" means any process for:
 - i. Making, altering, repairing, ornamenting, finishing, packing, oiling, washing, cleaning, breaking up, demolishing, or otherwise treating or adapting any article or substance with a view to its use, sale, transport, delivery or disposal.
 - ii. Pumping oil, water, sewage or any other substance.
 - iii. Generating, transforming or transmitting power.
 - iv. Composing types for printing, printing by letter press, lithography, photogravure or other similar process or book binding.
 - v. Constructing, reconstructing, repairing, refitting, finishing or breaking up ships or vessels.
 - vi. Preserving or storing any article in cold storage.
- l. "**Worker**" means a person employed, directly or by or through any agency (including a contractor) with or without the knowledge of the principal employer, whether for remuneration or not, in any manufacturing process, or in cleaning any part of the machinery or premises used for a manufacturing process, or in any other kind of work incidental to, or connected with, the manufacturing process, or the subject of the manufacturing process but does not include any member of the armed forces of the union.
- m. "**Factory**" means any premises including the precincts thereof:
 - i. Whereon ten or more workers are working, or were working on any day of the preceding twelve months, and in any part of which a manufacturing process is being carried on with the aid of power, or is ordinarily so carried on.
 - ii. Whereon twenty or more workers are working, or were working on any day of the preceding twelve months, and in any part of which a manufacturing process is being carried on without the aid of power, or is ordinarily so carried on, but does not include a mine subject to the operation of the Mines Act, 1952 (35 of 1952), or a mobile unit belonging to the armed forces of the union, a railway running shed or a hotel, restaurant or eating place.
 - n. "**Occupier**" of a factory means the person who has ultimate control over the affairs of the factory.
 - o. Where work of the same kind is carried out by two or more sets of workers working during different periods of the day, each of such sets is called a "**group**" or "**relay**" and each of such periods is called a "**shift**".

REFERENCES TO TIME OF DAY

In this act references to time of day are references to Indian standard time, being five and a half hours ahead of Greenwich Mean Time. Any area in which Indian standard time is not ordinarily observed the State Government may make rules:

- a. Specifying the area.
- b. Defining the local mean time ordinarily observed therein.
- c. Permitting such time to be observed in all or any of the factories situated in the area.

APPROVAL, LICENSING AND REGISTRATION OF FACTORIES

The State Government may make rules:

- a. Requiring, for the purposes of this act, the submission of plans of any class or description of factories to the Chief Inspector or the State Government.
- aa. Requiring, the previous permission in writing of the State Government or the Chief Inspector to be obtained for the site on which the factory is to be situated and for the construction or extension of any factory or class or description of factories.
- b. Requiring for the purpose of considering applications for such permission the submission of plans and specifications.
- c. Prescribing the nature of such plans and specifications and by whom they shall be certified.
- d. Requiring the registration and licensing of factories or any class or description of factories, and prescribing the fees payable for such registration and licensing and for the renewal of licenses.
- e. Requiring that no license shall be granted or renewed unless the notice specified in Section 7 (notice by occupier) has been given.

The State Government or Chief Inspector by registered post, no order is communicated to the applicant within 3 months from the date on which it is so sent, the permission applied for in the said application shall be deemed to have been granted. Where a State Government or a Chief Inspector refuses to grant permission to the site, construction or extension of a factory or to the registration and licensing of a factory, the applicant may within 30 days of the date of such refusal appeal to the Central Government if the decision appealed from was of the State

Government and to the State Government in any other case.

NOTICE BY OCCUPIER

The occupier shall, at least 15 days before he begins to occupy or use any premises as a factory, send to the Chief Inspector a written notice containing:

- a. The name and situation of the factory.
 - b. The name and address of the occupier.
 - bb. The name and address of the owner of the premises or building (including the precincts thereof).
 - c. The address to which communication relating to the factory may be sent.
 - d. The nature of the manufacturing process carried on in the factory during the last twelve months in the case of factories in existence on the date of the commencement of this Act, and to be carried on in the factory during the next twelve months in the case of all factories.
 - e. The total rated horse power installed or to be installed in the factory, which shall not include the rated horse power of any separate stand-by plant.
 - f. The name of the manager of the factory for the purposes of this Act.
 - g. The number of workers likely to be employed in the factory.
 - h. The average number of workers per day employed during the last twelve months in the case of a factory in existence on the date of the commencement of this Act.
 - i. Such other particulars as may be prescribed.
- In respect of all establishments which come within the scope of the act for the first time, the occupier shall send a written notice to the chief inspector within thirty days, from the date of the commencement of this Act. Before a factory engaged in a manufacturing process which is ordinarily carried on for less than one hundred and eighty working days in the year resumes working, the occupier shall send a written notice to the Chief Inspector at least thirty days before the date of the commencement of work.

Whenever a new manager is appointed, the occupier shall send the Inspector a written notice and to the Chief Inspector a copy thereof within seven days from the date on which such person takes over charge. During any period for which no person has been designated as manager of a factory or during which the person designated does not manage the factory, any person found acting as manager, or if no such person is found, the occupier himself, shall be deemed to be the manager of the factory for the purposes of this Act.

GENERAL DUTIES OF THE OCCUPIER

1. Every occupier shall ensure, so far as is reasonably practicable, the health, safety and welfare of all workers while they are at work in the factory.
2. The matters to which such duty extends, shall include:
 - a. The provision and maintenance of plant and systems of work in the factory that are safe and without risks to health.
 - b. The arrangements in the factory for ensuring safety and absence of risks to health in connection with the use, handling, storage and transport of articles and substances.
 - c. The provision of such information, instruction, training and supervision as are necessary to ensure the health and safety of all workers at work.
 - d. The maintenance of all places of work in the factory in a condition that is safe and without risks to health and the provision and maintenance of such means of access to, and access from, such places as are safe and without such risks.
 - e. The provision, maintenance or monitoring of such working environment in the factory for the workers that is safe, without risks to health and adequate as regards facilities and arrangements for their welfare at work.
3. Except in such cases as may be prescribed, every occupier shall prepare, and, as often

as may be appropriate, revise, a written statement of his general policy with respect to the health and safety of the workers at work and the organization and arrangements for the time being in force for carrying out that policy, and to bring the statement and any revision thereof to the notice of all the workers in such manner as may be prescribed.

THE INSPECTING STAFF

A. Inspectors

1. The State Government may appoint such persons as possess the prescribed qualification to be Inspectors for the purposes of this act and may assign to them such local limits as it may think fit.
2. Appoint any person to be a Chief Inspector who shall, in addition to the powers conferred on a Chief Inspector under this act, exercise the powers of an inspector throughout the State.
- 2A. Appoint as many Additional Chief Inspectors, Joint Chief Inspectors and Deputy Chief Inspectors and as many other officers as it thinks fit to assist the Chief Inspector and to exercise such of the powers of the Chief Inspector as may be specified in such notification.
- 2B. Every Additional Chief Inspector, Joint Chief Inspector, Deputy Chief Inspector and every other officer appointed shall in addition to the powers of a Chief Inspector specified in the notification by which he is appointed, exercise the powers of an Inspector throughout the State.
3. No person shall be appointed or having been so appointed, shall continue to hold office, who is or becomes directly or indirectly interested in a factory or in any process or business carried on therein or in any patent or machinery connected therewith.
4. Every District Magistrate shall be an Inspector for his district.

5. The State Government may also, by notification as aforesaid, appoint such public officers as it thinks fit to be additional Inspectors for all or any of the purposes of this Act, within such local limits as it may assign to them respectively.
6. In any area where there are more Inspectors than one the State Government may, by notification as aforesaid, declare the powers, which such Inspectors shall respectively exercise and the Inspector to whom the prescribed notices are to be sent.
7. Every Chief Inspector, Additional Chief Inspector, Joint Chief Inspector, Deputy Chief Inspector, Inspector and every other officer appointed under this section shall be deemed to be a public servant within the meaning of the Indian Penal Code 1860, and shall be officially subordinate to such authority as the State Government may specify in this behalf.

B. Powers of Inspectors

Subject to any rules made in this behalf, an Inspector may, within the local limits for which he is appointed:

- a. Enter, with such assistants being persons in the service of the Government, or any local or other public authority, or with an expert as he thinks fit, any place which is used, or which he has reason to believe is used, as a factory.
- b. Make examination of the premises, plant, machinery, article or substance.
- c. Inquire into any accident or dangerous occurrence, whether resulting in bodily injury, disability or not, and take on the spot or otherwise statements of any person which he may consider necessary for such inquiry.
- d. Require the production of any prescribed register or any other document relating to the factory.
- e. Seize, or take copies of, any register, record or other document or any portion thereof, as he may consider necessary in respect of

- any offence under this Act, which he has reason to believe, has been committed.
- f. Direct the occupier that any premises or any part thereof, or anything lying therein, shall be left undisturbed for so long as is necessary for the purpose of any examination.
- g. Take measurements and photographs and make such recordings as he considers necessary for the purpose of any examination, taking with him any necessary instrument or equipment.
- h. In case of any article or substance found in any premises, being an article or substance which appears to him as having caused or is likely to cause danger to the health or safety of the workers, direct it to be dismantled or subject it to any process or test (but not so as to damage or destroy it unless the same is, in the circumstances necessary, for carrying out the purposes of this Act), and take possession of any such article of substance or a part thereof, and detain it for so long as is necessary for such examination.

CERTIFYING SURGEONS

1. The State Government may appoint qualified medical practitioners to be certifying surgeons for the purposes of this Act within such local limits or for such factory or class or description of factories as it may assign to them respectively.
2. A certifying surgeon may, with the approval of the State Government, authorize any qualified medical practitioner to exercise any of his powers under this Act for such period as the certifying surgeon may specify and subject to such conditions as the State Government may think fit to impose, and references in this Act to a certifying surgeon shall be deemed to include references to any qualified medical practitioner when so authorized.
3. No person shall be appointed to be, or authorized to exercise the powers of, a

certifying surgeon, or having been so appointed or authorized, continue to exercise such powers, who is, or becomes the occupier of a factory or is or becomes directly or indirectly interested therein or in any process or business carried on therein or in any patent or machinery connected therewith or is otherwise in the employ of the factory.

4. The certifying surgeon shall carry out such duties as may be prescribed in connection with:
 - a. The examination and certification of young persons under this Act.
 - b. The examination of persons engaged in factories in such dangerous occupations or processes as may be prescribed.
 - c. The exercising of such medical supervision as may be prescribed for any factory or class or description of factories where:
 - i. Cases of illness have occurred which it is reasonable to believe are due to the nature of the manufacturing process carried on, or other conditions of work prevailing, therein.
 - ii. By reason of any change in the manufacturing process carried on or in the substances used therein or by reason of the adoption of any new manufacturing process or of any new substance for use in a manufacturing process, there is a likelihood of injury to the health of workers employed in that manufacturing process.
 - iii. Young persons are, or are about to be, employed in any work which is likely to cause injury to their health.

CONSTITUTION OF SITE APPRAISAL COMMITTEES

Site Appraisal Committees appointed by the State Government under Section 41 A:

1. The State Government may, for purposes of advising it to consider applications for grant of permission for the initial location of a factory involving a hazardous process

or for the expansion of any such factory, appoint a Site Appraisal Committee consisting of:

- a. The Chief Inspector of the State who shall be its Chairman.
- b. A representative of the Central Board for the Prevention and Control of Water Pollution appointed by the Central Government under Section 3 of the Water (Prevention and Control of Pollution) Act, 1974.
- c. A representative of the Central Board for the Prevention and Control of Air Pollution referred into Section 3 of the Air (Prevention and Control of Pollution) Act, 1981.
- d. A representative of the State Board appointed under Section 4 of the Water (Prevention and Control of Pollution) Act, 1974.
- e. A representative of the State Board for the Prevention and Control of Air Pollution referred into Section 5 of the Air (Prevention and Control of Pollution) Act, 1981.
- f. A representative of the Department of Environment in the State.
- g. A representative of the Meteorological Department of the Government of India.
- h. An expert in the field of occupational health.
- i. A representative of the Town Planning Department of the State Government, and not more than five other members who may be co-opted by the State Government who shall be:
 - i. A scientist having specialised knowledge of the hazardous process which will be involved in the factory.
 - ii. A representative of the local authority within whose jurisdiction the factory is to be established.
 - iii. Not more than three other persons as deemed fit by the State Government.
2. The Site Appraisal Committee shall examine an application for the establishment of a

factory involving hazardous process and make its recommendation to the State Government within a period of ninety days of the receipt of such applications in the prescribed form.

3. Where any process relates to a factory owned or controlled by the Central Government or to a corporation or a company owned or controlled by the Central Government, the State Government shall co-opt in the site appraisal committee a representative nominated by the Central Government as a member of that committee.
4. The site appraisal committee shall have power to call for any information from the person making an application for the establishment or expansion of a factory involving a hazardous process.
5. Where the State Government has granted approval to an application for the establishment or expansion of a factory involving hazardous process, it shall not be necessary for an applicant to obtain a further approval from the Central Board or the state board established under the Water (Prevention and Control of Pollution) Act 1974 and the Air (Prevention and Control of Pollution) Act, 1981.

HEALTH OF THE WORKERS

A. Cleanliness:

1. Every factory shall be kept clean and free from effluvia arising from any drain, privy or other, nuisance, and in particular:
 - a. Accumulations of dirt and refuse shall be removed daily by sweeping or by any other effective method from the floors and benches of workrooms and from staircases and passages, and disposed of in a suitable manner.
 - b. The floor of every workroom shall be cleaned at least once in every week by washing, using disinfectant, where necessary, or by some other effective method.

- c. Where a floor is liable to become wet in the course of any manufacturing process to such extent as is capable of being drained, effective means of drainage shall be provided and maintained.
- d. All inside walls and partitions, all ceilings or tops of rooms and all walls, sides and tops of passages and staircases shall:
 - i. Where they are painted otherwise than with washable water-paint or varnished, be repainted or revarnished least once in every period of 5 years.
 - ia. Where they are painted with washable water paint, be repainted with at least one coat of such paint at least once in every period of three years and washed at least once in every period of 6 months.
 - ii. Where they are painted or varnished or where they have smooth impervious surfaces, be cleaned at least once in every period of fourteen months by such method as may be prescribed.
 - iii. In any other case, be kept whitewashed or colourwashed, and the whitewashing or colourwashing shall be carried out at least once in every period of 14 months.
- dd. All doors and window frames and other wooden or metallic frame work and shutters shall be kept painted or varnished and the painting or varnishing shall be carried out at least once in every period of 5 years.
- e. The dates on which the processes required are carried out shall be entered in the prescribed register.
2. If, in view of the nature of the operations carried on in a factory or class or description of factories or any part of a factory or class or description of factories, it is not possible for the occupier to comply with all or any of the provisions of subsection (1), the State Government may by

order exempt such factory or class or description of factories or part from any of the provisions of that sub-section and specify alternative methods for keeping the factory in a clean state.

B. Disposal of wastes and effluents: Effective arrangements shall be made in every factory for the treatment of wastes and effluents due to the manufacturing process carried on therein, so as to render them innocuous, and for their disposal.

C. Ventilation and temperature: Effective and suitable provision shall be made in every factory for securing and maintaining in every workroom, adequate ventilation by the circulation of fresh air, and such a temperature as will secure to workers therein reasonable conditions of comfort and prevent injury to health, and in particular walls and roofs shall be of such material and so designed that such temperature shall not be exceeded but kept as low as practicable. Where the nature of the work carried on in the factory involves, or is likely to involve, the production of excessively high temperatures such adequate measures as are practicable shall be taken to protect the workers therefrom, by separating the process which produces such temperatures from the workroom, by insulating the hot parts or by other effective means. The State Government may prescribe a standard of adequate ventilation and reasonable temperature for any factory or class or description of.

D. Dust and fume: In every factory in which, by reason of the manufacturing process carried on, there is given off any dust or fume or other impurity of such a nature and to such an extent as is likely to be injurious or offensive to the workers employed therein, or any dust in substantial quantities, effective measures shall be taken to prevent its inhalation and accumulation in any workroom, and if any exhaust appliance is necessary for this purpose, it shall be applied as near as possible to the point of origin of the dust, fume or other impurity, and such point shall be enclosed so far as possible.

E. Artificial humidification:

1. In respect of all factories in which the humidity of the air is artificially increased, the State Government may make rules:
 - a. Prescribing standards of humidification.
 - b. Regulating the methods used for artificially increasing the humidity of the air.
 - c. Directing prescribed tests for determining the humidity of the air to be correctly carried out and recorded.
 - d. Prescribing methods to be adopted for securing adequate ventilation and cooling of the air in the workrooms.
2. In any factory in which the humidity of the air is artificially increased, the water used for the purpose shall be taken from a public supply, or other source of drinking water, or shall be effectively purified before it is so used.
3. If it appears to an Inspector that the water used in a factory for increasing humidity which is required to be effectively purified is not effectively purified he may serve on the manager of the factory an order in writing, specifying the measures which in his opinion should be adopted, and requiring them to be carried out before specified date.

F. Overcrowding: No room in any factory shall be overcrowded to an extent injurious to the health of the workers employed therein. There shall be in every workroom of a factory in existence on the date of the commencement of this act at least 9.9 cubic metres and of a factory built after the commencement of this Act at least 14.2 cubic metres or space for every worker employed therein, and for the purposes of this sub-section no account shall be taken of any space which is more than 4.2 metres above the level of the floor of the room.

G. Lighting, drinking water: In every part of a factory where workers are working or passing there shall be provided and maintained sufficient and suitable lighting, natural or artificial, or both.

In every factory effective arrangements shall be made to provide and maintain at suitable points conveniently situated for all workers employed therein a sufficient supply of wholesome drinking water.

H. Latrines, urinals and spittoons: In every factory sufficient latrine and urinal accommodation of prescribed types shall be provided conveniently situated and accessible to workers at all times while they are at the factory. Separate enclosed accommodation shall be provided for male and female workers. In every factory there shall be provided a sufficient number of spittoons in convenient places and they shall be maintained in a clean and hygienic condition.

SAFETY OF WORKERS

A. Fencing of machinery: In every factory the following, namely:

- a. Every moving part of a prime mover and every flywheel connected to a prime mover, whether the prime mover or flywheel is in the engine house or not.
- b. The headrace and tailrace of every water-wheel and water turbine.
- c. Any part of a stock-bar which projects beyond the head stock of a lathe.
- d. Unless they are in such position or of such construction as to be safe to every person employed in the factory as they would be if they were securely fenced, the following, namely:
 - i. Every part of an electric generator, a motor or rotary converter.
 - ii. Every part of transmission machinery.
 - iii. Every dangerous part of any other machinery, shall be securely fenced by safeguards of substantial construction which shall be constantly maintained and kept in position while the parts of machinery they are fencing are in motion or in use.

The State Government may by rules prescribe such further precautions as it may consider necessary in respect of any particular machinery

or part thereof, or exempt, subject to such condition as may be prescribed, for securing the safety of the workers, any particular machinery or part thereof from the provisions of this section.

B. Work on or near machinery in motion: Where in any factory it becomes necessary to examine any part of machinery while the machinery is in motion, or, as a result of such examination, to carry out:

- 1. Lubrication or other adjusting operation.
- 2. Any mounting or shipping of belts or lubrication or other adjusting operation, while the machinery is in motion such examination or operation shall be made or carried out only by a specially trained adult male worker wearing tight fitting clothing (which shall be supplied by the occupier) whose name has been recorded in the register prescribed in this behalf and who has been furnished with a certificate of his appointment, and while he is so engaged:
 - a. Such worker shall not handle a belt at a moving pulley unless:
 - i. The belt is not more than fifteen centimeters in width.
 - ii. The pulley is normally for the purpose of drive and not merely a flywheel or balance wheel (in which case a belt is not permissible).
 - iii. The belt joint is either laced or flush with the belt.
 - iv. The belt, including the joint and the pulley rim, are in good repair.
 - v. There is reasonable clearance between the pulley and any fixed plant or structure.
 - vi. Secure foothold and, where necessary, secure handhold, are provided for the operator.
 - vii. Any ladder in use for carrying out any examination or operation aforesaid is securely fixed or lashed or is firmly held by a second person.

- b. Without prejudice to any other provision of this act relating to the fencing of machinery, every set screw, bolt and key on any revolving shaft, spindle, wheel or pinion, and all spur, worm and other toothed or friction gearing in motion with which such worker would otherwise be liable to come into contact, shall be securely fenced to prevent such contact.

No woman or young person shall be allowed to clean, lubricate or adjust any part of a prime mover or of any transmission machinery while the prime mover or transmission machinery is in motion, or to clean, lubricate or adjust any part of any machine if the cleaning, lubrication or adjustment thereof would expose the woman or young person to risk of injury from any moving part either of that machine or of any adjacent machinery.

The State Government may prohibit, in any specified factory or class or description of factories, the cleaning, lubricating or adjusting by any person of specified parts of machinery when those parts are in motion.

C. Employment of young persons on dangerous machines: No young person shall be required or allowed to work at any machine to which this section applies, unless he has been fully instructed as to the dangers arising in connection with the machine and the precautions to be observed and has received sufficient training in work at the machine, or the State Government, being machines which in its opinion are of such a dangerous character that young persons ought not to work at them unless the foregoing requirements are complied with.

D. Self-acting machines: No traversing part of a self-acting machine in any factory and no material carried thereon shall, if the space over which it runs is a space over which any person is liable to pass, whether in the course of his employment or otherwise, be allowed to run on its outward or inward traverse within a distance of 45 centimeters from any fixed structure which is not part of the machine. The Chief Inspector may permit the continued use of a machine

installed before the commencement of this act which does not comply with the requirements of this section on such conditions for ensuring safety as he may think fit to impose.

E. Prohibition of employment of women and children near cotton-openers: No woman or child shall be employed in any part of a factory for pressing cotton in which a cotton-opener is at work. If the feed-end of a cotton-opener is in a room separated from the delivery end by a partition extending to the roof or to such height as the Inspector may in any particular case specify in writing, women and children may be employed on the side of the partition where the feed-end is situated.

F. Revolving machinery: In every factory in which the process of grinding is carried on there shall be permanently affixed to or placed near each machine in use a notice indicating the maximum safe working peripheral speed of every grindstone or abrasive wheel, the speed of the shaft or spindle upon which the wheel is mounted, and the diameter of the pulley upon such shaft or spindle necessary to secure such safe working peripheral speed. The speeds indicated in notices under above sub-section shall not be exceeded. Effective measures shall be taken in every factory to ensure that the safe working peripheral speed of every revolving vessel, cage, basket, flywheel, pulley, disc or similar appliance driven by power is not exceeded.

G. Pressure plant: If in any factory, any plant or machinery or any part thereof is operated at a pressure above atmospheric pressure, effective measures shall be taken to ensure that the safe working pressure of such plant or machinery or part is not exceeded. The State Government may make rules providing for the examination and testing of any plant or machinery such as is referred to in above sub-section and prescribing such other safety measures in relation thereto as may in its opinion be necessary in any factory or class or description of factories. The State Government may, by rules, exempt, subject to such conditions as may be specified therein.

H. Protection of eyes: In respect of any such manufacturing process carried on in any factory as may be prescribed, being a process which involves risk of injury to the eyes from particles or fragments thrown off in the course of the process, or risk to the eyes by reason of exposure to excessive light, the State Government may by rules require that effective screens or suitable goggles shall be provided for the protection of persons employed on, or in the immediate vicinity of, the process.

I. Precautions against dangerous fumes and gases: No person shall be required or allowed to enter any chamber, tank, vat, pit, pipe, flue or other confined space in any factory in which any gas, fume, vapour or dust is likely to be present to such an extent as to involve risk to persons being overcome thereby, unless it is provided with a manhole of adequate size or other effective means of egress.

J. Precautions regarding the use of portable electric light: In any factory no portable electric light or any other electric appliance of voltage exceeding twenty-four volts shall be permitted for use inside any chamber, tank, vat, pit, pipe, flue or other confined space unless adequate safety devices are provided and if any inflammable gas, fume or dust is likely to be present in such chamber, tank, vat, pit, pipe, flue or other confined space, no lamp or light other than that of flame-proof construction shall be permitted to be used therein.

K. Explosive or inflammable dust and gas:

1. Where in any factory any manufacturing process produces dust, gas, fume or vapour of such character and to such extent as to be likely to explode to ignition, all practicable measures shall be taken to prevent any such explosion by:
 - a. Effective enclosure of the plant or machinery used in the process.
 - b. Removal or prevention of the accumulation of such dust, gas, fume or vapour.
 - c. Exclusion or effective enclosure of all possible sources of ignition.

2. The State Government may by rules exempt, subject to such conditions as may be prescribed, any factory or class or description of factories from compliance with all or any of the provisions of this section.

L. Precautions in case of fire:

1. In every factory, all practicable measures shall be taken to prevent outbreak of fire and its spread, both internally and externally, and to provide and maintain:
 - a. Safe means of escape for all persons in the event of a fire.
 - b. The necessary equipment and facilities for extinguishing fire.
2. Effective measures shall be taken to ensure that in every factory all the workers are familiar with the means of escape in case of fire and have been adequately trained in the routine to be followed in such cases.
3. The State Government may make rules, in respect of any factory or class or description of factories.
4. The Chief Inspector, having regard to the nature of the work carried on in any factory, the construction of such factory, special risk to life or safety, or any other circumstances, is of the opinion that the measures provided in the factory.

M. Safety of buildings and machinery: If it appears to the Inspector that any building or part of a building or any part of the ways, machinery or plant in a factory is in such a condition that it is dangerous to human life or safety, he may serve on the occupier or manager or both of the factory an order in writing specifying the measures which in his opinion should be adopted, and requiring them to be carried out before a specified date. If it appears to the Inspector that the use of any building or part of a building or any part of the ways, machinery or plant in a factory involves imminent danger to human life or safety, he may serve on the occupier or manager or both of the factory an order in writing prohibiting its use until it has been properly repaired or altered.

N. Maintenance of Buildings: If it appears to the Inspector that any building or part of a building in a factory is in such a state of disrepair as is likely to lead to conditions detrimental to the health and welfare of the workers, he may serve on the occupier or manager or both of the factory an order in writing specifying the measures which in his opinion should be taken and requiring the same to be carried out before such date as is specified in the order.

O. Safety officers: In every factory,—wherein one thousand or more workers are ordinarily employed, or wherein, in the opinion of the State Government, any manufacturing process or operation is carried on, which process or operation involves any risk of bodily injury, poisoning or disease, or any other hazard to health, to the persons employed in the factory, the occupier shall, if so required by the State Government by notification in the official Gazette, employ such number of Safety officers as may be specified in that notification.

The duties, qualifications and conditions of service of safety officers shall be such as may be prescribed by the State Government.

WELFARE

Washing facilities: In every factory adequate and suitable facilities for washing shall be provided and maintained for the use of the workers. Separate and adequately screened facilities shall be provided for the use of male and female workers.

Facilities for storing and drying clothing: The State Government may, in respect of any factory or class or description of factories, make rules requiring the provision therein of suitable places for keeping clothing not worn during working hours and for the drying of wet clothing.

Facilities for sitting: In every factory suitable arrangements for sitting shall be provided and maintained for all workers obliged to work in a standing position, in order that they may take advantage of any opportunities for rest which may occur in the course of their work.

First aid appliances: There shall in every factory be provided and maintained so as to be

readily accessible during all working hours first-aid boxes or cupboards equipped with the prescribed contents, and the number of such boxes or cupboards to be provided and maintained shall not be less than one for every one hundred and fifty workers ordinarily employed at any one time in the factory.

Canteens: The State Government may make rules requiring that in any specified factory wherein more than two hundred and fifty workers are ordinarily employed, a canteen or canteens shall be provided and maintained by the occupier for the use of the workers.

Shelters, rest rooms and lunch rooms: In every factory wherein more than one hundred and fifty workers are ordinarily employed, adequate and suitable shelters or rest rooms and a suitable lunch room, with provision for drinking water, where workers can eat meals brought by them, shall be provided and maintained for the use of the workers: Provided that any canteen maintained in accordance with the provisions of Section 46 shall be regarded as part of the requirements of this sub-section : Provided further that where a lunch room exists no workers shall eat any food in the work room.

Welfare officers: In every factory wherein five hundred or more workers are ordinarily employed the occupier shall employ in the factory such number of Welfare officers as may be prescribed. The State Government may prescribe the duties, qualifications and conditions of service of officers employed under above sub-section.

HOLIDAYS AND WORKING HOURS OF ADULTS

A. Weekly holidays: No adult worker shall be required or allowed to work in a factory on the first day of the week (hereinafter referred to as the said day), unless:

- He has or will have a holiday for a whole day on one of the three days immediately before or after the said day.
- The manager of the factory has, before the said day or the substituted day under clause (a), whichever is earlier:

- i. Delivered a notice at the office of the Inspector of his intention to require the worker to work on the said day and of the day which is to be substituted.
- ii. Displayed a notice to that effect in the factory.

Notices given may be cancelled by a notice delivered at the office of the Inspector and a notice displayed in the factory not later than the day before the said day or the holiday to be cancelled, whichever is earlier. Any worker works on the said day and has had a holiday on one of the three days immediately before it that said day shall, for the purpose of calculating his weekly hours of work, be included in the preceding week.

B. Compensatory holidays: Where, as a result of the passing of an order or the making of a rule under the provisions of this act exempting a factory or the workers therein, he shall be allowed, within the month in which the holidays were due to him or within the two months immediately following that month, compensatory holidays of equal number to the holidays so lost. The State Government may prescribe the manner in which the holidays for which provision is made in above sub-section shall be allowed.

C. Weekly hours: No adult workers shall be required or allowed to work in a factory for more than forty-eight hours in any week.

D. Daily hours: No adult worker shall be required or allowed to work in a factory for more than nine hours in any day. Subject to the previous approval of the Chief Inspector, the daily maximum hours specified in this section may be exceeded in order to facilitate the change of shifts.

E. Intervals for rest: The periods of work of adult workers in a factory each day shall be so fixed that no period shall exceed 5 hours and that no worker shall work for more than five hours before he has had an interval for rest of atleast half an hour.

F. Night shifts: Where a worker in a factory works on a shift which extends beyond midnight:

- a. A holiday for a whole day shall mean in his case a period of twenty-four consecutive hours beginning when his shift ends.
- b. The following day for him shall be deemed to be the period of twenty-four hours beginning when such shift ends, and the hours he has worked after midnight shall be counted in the previous day.

G. Prohibition of overlapping shifts: Work shall not be carried on in any factory by means of a system of shifts so arranged that more than one relay of workers is engaged, in work of the same kind at the same time.

H. Restriction on double employment: No adult worker shall be required or allowed to work in any factory on any day on which he has already been working in any other factory, save in such circumstances as may be prescribed.

REGISTER

A. Register of adult workers:

1. The manager of every factory shall maintain a register of adult workers, to be available to the Inspector at all times during working hours, or when any work is being carried on in the factory, showing:
 - a. The name of each adult worker in the factory.
 - b. The nature of his work.
 - c. The group, if any, in which he is included.
 - d. Where his group works on shifts, the relay to which he is allotted.
 - e. Such other particulars as may be prescribed.

No adult worker shall be required or allowed to work in any factory unless his name and other particulars have been entered in the register of adult workers.

2. The State Government may prescribe the form of the register of adult workers, the manner in which it shall be maintained and the period for which it shall be preserved.

B. Register of child workers:

1. The manager of every factory in which children are employed shall maintain a

register of child workers, to be available to the Inspector at all times during working hours or when any work is being carried on in a factory, showing:

- a. The name of each child worker in the factory.
- b. The nature of his work.
- c. The group, if any, in which he is included.
- d. Where his group works in shifts, the relay to which he is allotted.
- e. The number of his certificate of fitness granted under Section 69.

No child worker shall be required or allowed to work in any factory unless his name and other particulars have been entered in the register of child workers.

2. The State Government may prescribe the form of the register of child workers, the manner in which it shall be maintained and the period for which it shall be preserved.

PROHIBITION OF EMPLOYMENT OF YOUNG CHILDREN

No child who has not completed his 14th year shall be required or allowed to work in any factory.

A. Certificate of fitness: A certifying surgeon shall, on the application of any young person or his parent or guardian accompanied by a document signed by the manager of a factory that such person will be employed therein if certified to be fit for work in a factory, or on the application of the manager of the factory in which any young person wishes to work, examine such person and ascertain his fitness for work in a factory.

B. Working hours for children: No child shall be employed or permitted to work, in any factory:

- a. For more than four and a half hours in any day.
- b. During the night; (for the purposes of this sub-section "night" shall mean a period of at least twelve consecutive hours which shall include the interval between 10 P.M. and 6 A.M.).

The period of work of all children employed in a factory shall be limited to two shifts which shall not overlap or spread over more than five hours each; and each child shall be employed in only one of the relays which shall not, except with the previous permission in writing of the Chief Inspector, be changed more frequently than once in a period of thirty days. The provisions of Section 52 (weekly holidays) shall apply also to child workers and no exemption from the provisions of that section may be granted in respect of any child.

No child shall be required or allowed to work in any factory on any day on which he has already been working in another factory. No female child shall be required or allowed to work in any factory except between 8 A.M. and 7 P.M.

WAGES

A. Annual leave with wages:

1. Every worker who has worked for a period of 240 days or more in a factory during a calendar year shall be allowed during the subsequent calendar year, leave with wages for a number of days calculated at the rate of:
 - a. If an adult, one day for every 20 days of work performed by him during the previous calendar year.
 - b. If a child, one day for every 15 days of work formed by him during the previous calendar year.
 - c. In the case of a female worker, maternity leave for any number of days not exceeding 12 weeks.
 - d. The leave earned in the year prior to that in which the leave is enjoyed shall be deemed to be days on which the worker has worked in a factory for the purpose of computation of the period of 240 days or more, but he shall not earn leave for these days.
2. A worker whose service commences otherwise than on the first day of January

shall be entitled to leave with wages if he has worked for two-thirds of the total number of days in the remainder of the calendar year.

3. If a worker is discharged or dismissed from service or quits his employment or is superannuated or dies while in service, during the course of the calendar year, he or his heir or nominee, as the case may be, shall be entitled to wages in lieu of the quantum of leave to which he was entitled immediately before his discharge, dismissal, quitting of employment, superannuation or death calculated at the rates, even if he had not worked for the entire period, making him eligible to avail of such leave, and such payment shall be made:
 - a. Where the worker is discharged or dismissed or quits employment, before the expiry of the second working day from the date of such discharge, dismissal or quitting.
 - b. Where the worker is superannuated or dies while in service, before the expiry of 2 months from the date of such superannuation or death.
4. In calculating leave under this section, fraction of leave of half a day or more shall be treated as one full day's leave, and fraction of less than half a day shall be omitted.
5. If a worker does not in any one calendar year take the whole of leaves allowed to him, as the case may be, any leave not taken by him shall be added to the leave to be allowed to him in the succeeding calendar year.
6. A worker may at any time apply in writing to the manager of a factory not less than 15 days before the date on which he wishes his leave to begin, to take all the leave or any portion thereof allowable to him during the calendar year.
7. If a worker wants to avail himself of the leave with wages due to him to cover a period of illness, he shall be granted such leave even if the application for leave is not

made within the time and in such a case wages as admissible under Section 81 shall be paid not later than 15 days, or in the case of a public utility service not later than thirty days from the date of the application for leave.

8. For the purpose of ensuring the continuity of work, the occupier or manager of the factory, in agreement with the works committee of the factory constituted under Section 3 of the Industrial Disputes Act, 1947, or a similar committee constituted under any other act or if there is no such Works Committee or a similar committee in the factory, in agreement with the representatives of the workers therein chosen in the prescribed manner, may lodge with the chief Inspector a scheme in writing whereby the grant of leave allowable under this section may be regulated.

B. Wages during leave period: For the leave allowed to him a worker shall be entitled to wages at a rate equal to the daily average of his total full time earnings for the days on which he actually worked during the month immediately preceding his leave, exclusive of any overtime and bonus but inclusive of dearness allowance and the cash equivalent of the advantage accruing through the concessional sale to the worker of foodgrains and other articles. The cash equivalent of the advantage accruing through the concessional sale to the worker of foodgrains and other articles shall be computed as often as may be prescribed, on the basis of the maximum quantity of foodgrains and other articles admissible to a standard family.

The State Government may make rules prescribing:

- a. The manner in which the cash equivalent of the advantage accruing through the concessional sale to a worker of foodgrains and other articles shall be computed.
- b. The registers that shall be maintained in a factory for the purpose of securing compliance with the provisions of this section.

C. Payment in advance in certain cases: A worker who has been allowed leave for not less than four days, in the case of an adult, and 5 days, in the case of a child, shall, before his leave begins, be paid the wages due for the period of the leave allowed.

D. Extra wages for overtime:

1. Where a worker works in a factory for more than nine hours in any day or for more than forty-eight hours in any week, he shall, in respect of overtime work, be entitled to wages at the rate of twice his ordinary rate of wages.
2. "Ordinary rate of wages" means the basic wages plus such allowances, including the cash equivalent of the advantage accruing through the concessional sale to workers of foodgrains and other articles, as the worker is for the time being entitled to, but does not include a bonus and wages for overtime work.
3. Where any workers in a factory are paid on a piece-rate basis, the time rate shall be deemed to be equivalent to the daily average of their full-time earnings for the days on which they actually worked on the same or identical job during the month immediately preceding the calendar month during which the overtime work was done, and such time rates shall be deemed to be the ordinary rates of wages of those workers.
4. The cash equivalent of the advantage accruing through the concessional sale to a worker of foodgrains and other articles shall be computed as often as may be prescribed on the basis of the maximum quantity of foodgrains and other articles admissible to a standard family.
5. The State Government may make rules prescribing:
 - a. The manner in which the cash equivalent of the advantage accruing through the concessional sale to a worker of foodgrains and other articles shall be computed.

- b. The registers that shall be maintained in a factory for the purpose of securing compliance with the provisions of this section.

SPECIAL PROVISION

A. Power to apply the Act to certain premises:

1. The State Government may, by notification in the Official Gazette, declare that all or any of the provisions of this Act shall apply to any place wherein a manufacturing process is carried on with or without the aid of power or is so ordinarily carried on, notwithstanding that:
 - i. The number of persons employed therein is less than 10, if working with the aid of power and less than 20 if working without the aid of power.
 - ii. The persons working therein are not employed by the owner thereof but are working with the permission of, or under agreement with, such owner.
2. After a place is so declared, it shall be deemed to be a factory for the purposes of this Act, and the owner shall be deemed to be the occupier, and any person working therein, a worker.

B. Power to exempt public institutions: The State Government may exempt, subject to such conditions as it may consider necessary, any workshop or workplace where a manufacturing process is carried on and which is attached to a public institution, maintained for the purposes of education, training, research or reformation, from all or any of the provisions of this Act.

C. Dangerous operations: Under Section 87 where the State Government is of opinion that any manufacturing process or operation carried on in a factory exposes any persons employed in it to a serious risk of bodily injury, poisoning or diseases, it may make rules applicable to any factory or class or description of factories in, which the manufacturing process or operation is carried on:

- a. Specifying the manufacturing process or operation and declaring it to be dangerous.

- b. Prohibiting or restricting the employment of women, adolescents or children in the manufacturing process or operation.
- c. Providing for the periodical medical examination of persons employed, or seeking to be employed, in the manufacturing process or operation, and prohibiting the employment of persons not certified as fit for such employment and requiring the payment by the occupier of the factory of fees for such medical examination.
- d. Providing for the protection of all persons employed in the manufacturing process or operation or in the vicinity of the places where it is carried on.
- e. Prohibiting, restricting or controlling the use of any specified materials or processes in connection with the manufacturing process or operation.
- f. Requiring the provision of additional welfare amenities and sanitary facilities and the supply of protective equipment and clothing, and laying down the standards thereof, having regard to the dangerous nature of the manufacturing process or operation.

D. Power to prohibit employment on account of serious hazard: Where it appears to the Inspector that conditions in a factory or part thereof are such that they may cause serious hazard by way of injury or death to the persons employed therein or to the general public in the vicinity, he may, by order in writing to the occupier of the factory, state the particulars in respect of which he considers the factory or part thereof to be the cause of such serious hazard and prohibit such occupier from employing any person in the factory or any part thereof other than the minimum number of persons necessary to attend to the minimum tasks till the hazard is removed.

E. Notice of certain accidents: Where in any factory an accident occurs which causes death, or which causes any body injury by reason of which the person injured is prevented from working for a period of forty-eight hours or

more immediately following the accident, or which is of such nature as may be prescribed in this behalf, the manager of the factory shall send notice thereof to such authorities, and in such form and within such time, as may be prescribed. Where a notice given under above sub-section relates to an accident causing death, the authority to whom the notice is sent shall make an inquiry into the occurrence within one month of the receipt of the notice or, if such authority is not the Inspector, cause the Inspector to make an inquiry within the said period. The State Government may make rules for regulating the procedure at inquiries under this section.

F. Notice of certain dangerous occurrences: Where in a factory any dangerous occurrence of such nature as may be prescribed, occurs, whether causing any bodily injury or disability or not, the manager of the factory shall send notice thereof to such authorities, and in such form and within such time, as may be prescribed.

G. Notice of certain diseases:

1. Where any worker in a factory contracts any disease specified in the Third Schedule, the manager of the factory shall send notice thereof to such authorities, and in such form and within such time as may be prescribed.
2. If any medical practitioner attends on a person who is or has been employed in a factory, and who is, or is believed by the medical practitioner to be, suffering from any disease, specified in the Third Schedule the medical practitioner shall without delay send a report in writing to the office of the Chief Inspector stating:
 - a. The name and full postal address of the patient.
 - b. The disease from which he believes the patient to be suffering.
 - c. The name and address of the factory in which the patient is, or was last, employed.
3. Where the report under sub-section (2) is confirmed to the satisfaction of the Chief

Inspector, by the certificate of a certifying surgeon or otherwise, that the person is suffering from a disease specified in the Third Schedule, he shall pay to the medical practitioner such fee as may be prescribed, and the fee so paid shall be recoverable as an arrear of land revenue from the occupier of the factory in which the person contracted the disease.

4. If any medical practitioner fails to comply with the provisions of sub-section (2), he shall be punishable with fine which may extend to 1,000 rupees.
5. The Central Government may add to or alter the Third Schedule and any such addition or alteration shall have effect as if it had been made by this Act.

H. Power to direct enquiry into cases of accident or disease: The State Government may, if it considers it expedient so to do, appoint a competent person to inquire into the causes of any accident occurring in a factory or into any case where a disease specified in the Third Schedule has been, or is suspected to have been, contracted in a factory, and may also appoint one or more persons possessing legal or special knowledge to act as assessors in such inquiry. The person appointed to hold an inquiry under this section shall have all the powers of a civil court under the Code of Civil Procedure, 1908, for the purposes of enforcing the attendance of witnesses and compelling the production of documents and material objects, and may also, so far as may be necessary for the purposes of the inquiry, exercise any of the powers of an Inspector under this act; and every person required by the person making the inquiry to furnish any information shall be deemed to be legally bound so to do within the meaning of Section 176 of the Indian Penal Code, 1860. The person holding an inquiry under this section shall make a report to the State Government stating the causes of the accident, or as the case may be, disease, and any attendant circumstances, and adding any observations which he or any of the assessors may think fit to make.

The State Government may, if it thinks fit, cause to be published any report made under this section or any extracts therefrom. The State Government may make rules for regulating the procedure as Inquiries under this section.

I. Power to take samples:

1. An Inspector may at any time during the normal working hours of a factory, after informing the occupier or manager of the factory or other person for the time being purporting to be in charge of the factory, take in the manner hereinafter provided a sufficient sample of any substance used or intended to be used in the factory, such use being:
 - a. In the belief of the Inspector in contravention of any of the provisions of this act or the rules made thereunder.
 - b. In the opinion of the Inspector likely to cause bodily injury to, or injury to the health of, workers in the factory.
2. Where the Inspector takes a sample under sub-section (1), he shall, in the presence of the person informed under that sub-section unless such person wilfully absents himself, divide the sample into three portions and effectively seal and suitably mark them, and shall permit such person to add his own seal and mark thereto.
3. The person informed as aforesaid shall, if the Inspector so requires, provide the appliances for dividing, sealing and marking the sample taken under this section.
4. The Inspector shall:
 - a. Give one portion of the sample to the person informed under sub-section (1).
 - b. Send the second portion to a Government Analyst for analysis and report thereon.
 - c. Retain the third portion for production to the Court before which proceedings, if any, are instituted in respect of the substance.
5. Any document purporting to be a report under the hand of any Government Analyst upon any substance submitted to him for

analysis and report under this section, may be used as evidence in any proceedings instituted in respect of the substance.

OFFENCES AND PENALTY

A. General penalty for offences: If any factory there is any contravention of any of the provisions of this Act or of any rules made thereunder or of any order in writing given thereunder, the occupier and manager of the factory shall each be guilty of an offence and punishable with imprisonment for a term which may extend to 2 years or with fine which may extend to one lakh rupees or with both, and if the contravention is continued after conviction, with a further fine which may extend to 1,000 rupees for each day on which the contravention is so continued. Any rule made thereunder or under Section 87 (dangerous operations) has resulted in an accident causing death or serious bodily injury, the fine shall not be less than 25,000 rupees in the case of an accident causing death, and 5,000 rupees in the case of an accident causing serious bodily injury.

B. Enhanced penalty after previous conviction: If any person who has been convicted of any offence punishable under Section 92 (general penalty for offences) is again guilty of an offence involving a contravention of the same provision, he shall be punishable on a subsequent conviction with imprisonment for a term which may extend to 3 years or with fine which shall not less than 10,000 rupees but which may extend to two lakh rupees or with both. No cognizance shall be taken of any conviction made more than 2 years before the commission of the offence for which the person is subsequently being convicted.

C. Penalty for obstructing inspector: Under Section 95 whoever wilfully obstructs an Inspector in the exercise of any power conferred on him by or under this act, or fails to produce on demand by an Inspector any registers or other documents in his custody kept in pursuance of this act or of any rules made thereunder, or conceals or prevents any worker

in a factory from appearing before, or being examined by, an Inspector, shall be punishable with imprisonment for a term which may extend to 6 months or with fine which may extend to 10,000 rupees or with both.

D. Penalty for wrongfully disclosing results of analysis under Section 91 (power to take samples): Section 96 provides whoever, except in so far as it may be necessary for the purposes of a prosecution for any offence punishable under this act, publishes or discloses to any person the results of an analysis made under Section 91, shall be punishable with imprisonment for a term which may extend to 6 months or with fine which may extend to 10,000 rupees or both.

E. Offences by workers: Under Section 97 if any worker employed in a factory contravenes any provision of this act or any rules or orders made thereunder, imposing any duty or liability on workers, he shall be punishable with fine which may extend to 500 rupees.

Where a worker is convicted of an offence punishable, the occupier or manager of the factory shall not be deemed to be guilty of an offence in respect of that contravention, unless it is proved that he failed to take all reasonable measures for its prevention.

F. Penalty for using false certificate of fitness: Section 98 provides that whoever knowingly uses or attempts to use, as a certificate of fitness granted to himself under Section 70 (effect of certificate of fitness granted to adolescent), a certificate granted to another person under that section, or who, having procured such a certificate, knowingly allows it to be used, or an attempt to use to be made, by another person, shall be punishable with imprisonment for a term which may extend to 2 months or with fine which may extend to 1,000 rupees or both.

G. Penalty for permitting double employment of child: Under Section 99 if a child works in a factory on any day on which he has already been working in another factory, the parent or guardian of the child or the person having

custody of or control over him or obtaining any direct benefit from his wages, shall be punishable with fine which may extend to 1,000 rupees unless it appears to the court that the child so worked without the consent or connivance of such parent, guardian or person.

COGNIZANCE OF OFFENCES

Under Section 105: No Court shall take cognizance of any offence under this Act except on complaint by, or with the previous sanction in writing of, an Inspector. No Court below that of a Presidency Magistrate or of a Magistrate of the first class shall try any offence punishable under this Act.

Limitation of prosecutions: No Court shall take cognizance of any offence punishable under this Act unless complaint thereof is made within 3 months of the date on which the alleged commission of the offence came to the knowledge of an Inspector.

APPEALS

The manager of a factory on whom an order in writing by an Inspector has been served under the provisions of this Act or the occupier of the factory may, within thirty days of the service of the order, appeal against it to the prescribed authority, and such authority may, subject to rules made in this behalf by the State Government, confirm, modify or reverse the order.

OBLIGATIONS AND RIGHT OF WORKERS

A. Obligations of workers:

1. No worker in a factory:
 - a. Shall wilfully interfere with or misuse any appliance, convenience or other thing provided in a factory for the purposes of securing the health, safety or welfare of the workers therein.
 - b. Shall wilfully and without reasonable cause do anything likely to endanger himself or others.
 - c. Shall wilfully neglect to make use of any appliance or other thing provided in the

factory for the purposes of securing the health or safety of the workers therein.

2. If any worker employed in a factory contravenes any of the provisions of this section or of any rule or order made thereunder, he shall be punishable with imprisonment for a term which may extend to three months, or with fine which may extend to one hundred rupees, or both.

B. Right of workers: Every worker shall have the right to:

- i. Obtain from the occupier, information relating to workers' health and safety at work.
- ii. Get trained within the factory wherever possible, or, to get himself sponsored by the occupier for getting trained at a training centre or institute, duly approved by the Chief Inspector, where training is imparted for workers' health and safety at work.
- iii. Represent to the Inspector directly or through his representative in the matter of inadequate provision for protection of his health or safety in the factory.

MISCELLANEOUS

A. Application of Act to government factories: Unless otherwise provided this act shall apply to factories belonging to the Central or any State Government.

B. Repeal and savings: The enactments set out in the Table appended to this section are hereby repealed. Provided that anything done under the said enactments which could have been done under this Act if it had then been in force shall be deemed to have been done under this Act.

C. Powers to exempt factories: Where the State Government is satisfied that the leave rules applicable to workers in a factory provide benefits which in its opinion are not less favorable than those for which this act makes provision it may, by written order, exempt the factory from all or any of the provisions of this

act subject to such conditions as may be specified in the order.

D. General power to make rules: The State Government may make rules providing for any matter which, under any of the provisions of this act, is to be or may be prescribed or which may be considered expedient in order to give effect to the purposes of this act. The State Government may make rules directing

managers of factories to keep registers containing such particulars as may be prescribed and requiring the registers to be made available for examination by Inspectors. The State Government may make rules requiring the provision in any factory or in any class or description of factories of such further devices and measures for securing the safety of persons employed therein as it may deem necessary.

CHAPTER

15

The Minimum Wages Act, 1948

INTRODUCTION

The need for a country of having minimum wage-fixing machinery was stressed by the International Labour Organization long back in 1928. Twenty years later our country passed the Minimum Wages Act, 1948. A tripartite committee viz., "The Committee on fair wage" was set up in 1948 to provide guidelines for wage structures in the country. The report of this committee was a major landmark in the history of formulation of wage policy in India. Its recommendations set out the key concepts of the 'living wage', "minimum wages" and "fair wage" besides setting out guidelines for wage fixation. This act may be called the Minimum Wages Act, 1948. It extends to the whole of India.

The Minimum Wages Act empowers the Government to fix minimum wages for employees working in specified employments. It provides for review and revision of minimum wages already fixed after suitable intervals not exceeding five years. Central Government is the appropriate agency in relation to any scheduled employment carried on by or under its authority or in railway administration or in relation to mines, oilfields or major ports or any corporation established under the Central Act. State Governments are the appropriate agencies in relation to other scheduled employment. The Central Government is concerned to a limited extent with building and construction activities

mostly carried on by central public works department, Ministry of Defence, etc. and agricultural farms under the Ministries of defence and agriculture. Bulk of such employment fall in the state spheres and state governments are required to fix/revise wages and ensure their implementation in respect of scheduled employment within their spheres.

Enforcement of minimum wages in Central Sphere is secured through the Central Industrial Relations Machinery (CIRM). The Central Government has fixed Minimum Wages under the Minimum Wages Act, 1948 for 40 Scheduled employments under the Central Sphere.

The State shall, in particular, direct its policy towards securing that the citizen, men and women equally shall have the right to an adequate livelihood and there is equal pay for equal work for both men and women. The State shall endeavor, by suitable legislation or economic organization or in any other way, to give all workers, agricultural, industrial or otherwise, work, a living wage, conditions of work ensuring a decent standard of life and full enjoyment of leisure, and social and cultural opportunities.

Minimum wages in India: In India, 422.6 million workers out of the total workforce of 467 million belong to the unorganised/informal sector. These workers contribute to more than 60% to India's GDP growth. Among other sectors, these workers work as farm labourers, landless labourers, factory workers and

construction workers. Currently the number of Scheduled employments in the Central Government is 45, whereas in the state sphere the number is 1596. The Minimum Wage Act, 1948 provides for fixation and enforcement of minimum wages in respect of schedule employments to prevent sweating or exploitation of labour through payment of low wages. The objective of the Act is to ensure a minimum subsistence wage for workers.

Applicability: Minimum wages act applies to all persons engaged in scheduled employments in respect of which minimum rates of wages have been fixed under this Act.

Objectives

- For fixing minimum rates of wages in certain employments which are included in the schedule.
- To determine the minimum wages in industry and trade where labour organizations are nonexistent or ineffective.
- To revise the minimum rates of wages at intervals not exceeding five years.

Scope and Coverage

- i. Applicable to all employees engaged to do any work, skilled, unskilled manual or clerical, in a scheduled employment, including out-workers.
- ii. Fixation of minimum wages.

Main Provisions

- i. Fixation of minimum wage of employees.
- ii. Procedure for fixing and revising minimum wages.
- iii. Obligation of employees.
- iv. Rights of workers.

Consult and refer: At the time of fixation of salary of new/existing employees.

Salient Features of Minimum Wages Act

1. A Minimum Wages Bill was introduced in the Central Legislative Assembly on 11.4.48 to provide for fixation of minimum wages in certain employments. It was

passed in 1948 and came into force with effect from 15.3.48.

2. Under the Act, Central and State Governments are appropriate Governments to:
 - a. Notify scheduled employment.
 - b. Fix/revise minimum wages.
3. The act contains list of all these employments for which minimum wages are to be fixed by the appropriate Governments.
4. There are two parts of the Schedule. Part I has non-agricultural employments whereas Part-II has employment in agriculture.
5. The appropriate Government fixes the minimum wage in respect of only those scheduled employments where the number of employees is 1,000 or more.
6. The norms include those, which were recommended by the Indian labour conference in its session held in 1957 at Nainital:
 - i. Three consumption units for one earner.
 - ii. Minimum food requirements of 2,700 calories per average Indian adult.
 - iii. Clothing requirements of 72 yards per annum per family.
 - iv. Rent corresponding to the minimum area provided for under Government's Industrial Housing Scheme.
 - v. Fuel, lighting and other miscellaneous items of expenditure to constitute 20% of the total Minimum Wages.
 - vi. "Children education, medical requirement, minimum recreation including festivals/ceremonies and provision for old age, marriage etc. should further constitute 25% of the total minimum wage." This judgment was delivered by the Supreme Court of India in 1991 in the case of Reptakos Brett and Co.Vs. its workmen.
7. Section 3 empowers appropriate Government to fix the minimum rates of wages in the schedule employments.
8. It was recommended in the Labour Ministers' Conference held in 1988, to evolve a mechanism to protect wages

- against inflation by linking it to rise in the Consumer Price Index. The Variable Dearness Allowance came into being in the year 1991. The allowance is revised twice a year, once on 1st April and then on 1st October. In the State Sphere, 22 States/Union Territories have provisions for Variable Dearness Allowance, at present.
9. The enforcement of the provisions of the Minimum Wages Act in the Central Sphere, is secured through the officers of Central Industrial Relations Machinery In so far as State Governments/Union Territories are concerned, the enforcement is the responsibility of the respective State Government/Union Territory.
 10. The Central Government introduced national floor level wage in 1996 at ₹ 35/- based on the recommendations of the National Commission on Labour in 1991 and subsequent rise in the price level. The floor level wage was last revised to ₹ 45/- in November, 1999 on the basis of increase in the Consumer Price Index. The Central Government has been writing to all the State Governments through letters from Honourable Prime Minister and Union Labour Minister to ensure that in none of the scheduled employments under their respective jurisdictions, the minimum wages are below the national floor level wage.

DEFINITIONS

- a. "**Adolescent**" means a person who has completed his fourteenth year of age but has not completed his eighteenth year.
- b. "**Adult**" means a person who has completed his eighteenth year of age
- c. "**Appropriate Government**" means:
 - i. In relation to any scheduled employment carried on by or under the authority of the Central Government, or a railway administration, or in relation to a mine, oilfield or major port, or any corporation established by a Central Act, the Central Government.
 - ii. In relation to any other scheduled employment, the State Government.
- d. "**Child**" means a person who has not completed his fourteenth year of age.
- e. "**Competent authority**" means the authority appointed by the appropriate Government by notification in its official gazette to ascertain from time to time the cost of living index number applicable to the employees employed in the scheduled employments specified in such notification.
- f. "**Cost of living index number**", in relation to employees in any scheduled employment in respect of which minimum rates of wages have been fixed, means the index number ascertained and declared by the competent authority by notification in the Official Gazette to be the cost of living index number applicable to employees in such employment.
- g. "**Employer**" means any person who employs, whether directly or through another person, or whether on behalf of himself or any other person, one or more employees in any scheduled employment in respect of which minimum rates of wages have been fixed under this Act.
 - i. In a factory where there is carried on any scheduled employment in respect of which minimum rates of wages have been fixed under this Act, any person named under clause (f) of sub-section (1) of section 7 (Notice by occupier) of the Factories Act, 1948, as manager of the factory.
 - ii. In any scheduled employment under the control of any Government in India in respect of which minimum rates of wages have been fixed under this act, the person or authority appointed by such Government for the supervision and control of employees or where no person or authority is so appointed, the head of the department.
 - iii. In any scheduled employment under any local authority in respect of which

- minimum rates of wages have been fixed under this act, the person appointed by such authority for the supervision and control of employees or where no person is so appointed, the Chief Executive Officer of the local authority.
- iv. In any other case where there is carried on any scheduled employment in respect of which minimum rates of wages have been fixed under this Act, any person responsible to the owner for the supervision and control of the employees or for the payment of wages.
 - h. "**Scheduled employment**" means an employment specified in the Schedule, or any process or branch of work forming part of such employment.
 - i. "**Wages**" means all remuneration, capable of being expressed in terms of money, which would, if the terms of the contract of employment, express or implied, were fulfilled, be payable to a person employed in respect of his employment or of work done in such employment, and includes house rent allowance but does not include:
 - i. The value of:
 - a. Any house-accommodation, supply of light, water, medical attendance.
 - b. Any other amenity or any service excluded by general or special order of the appropriate Government.
 - ii. Any contribution paid by the employer to any Pension Fund or Provident Fund or under any scheme of social insurance.
 - iii. Any traveling allowance or the value of any traveling concession.
 - iv. Any sum paid to the person employed to defray special expenses entailed on him by the nature of his employment.
 - v. Any gratuity payable on discharge.
 - i. "**Employee**" means any person who is employed for hire or reward to do any work, skilled or unskilled, manual or clerical, in a scheduled employment in respect of which minimum rates of wages have been fixed, and includes an out-worker to whom any articles or materials are given out by another person to be made up, cleaned, washed, altered, ornamented, finished, repaired, adapted or otherwise processed for sale for the purposes of the trade or business of that other person where the process is to be carried out either in the home of the out-worker or in some other premises not being premises under the control and management of that other person and also includes an employee declared to be an employee by the appropriate Government, but does not include any member of the Armed Forces of the Union.

PROVISIONS FOR FIXING MINIMUM RATES OF WAGES

The appropriate Government shall fix the minimum rates of wages payable to employees employed in a scheduled employment. Review at such intervals not exceeding 5 years, the minimum rates of wages so fixed and revise the minimum rates if necessary. The minimum rates of wages may be fixed as a minimum time rate or a minimum piece rate or as a guaranteed time rate.

A. *Fixing of minimum rates of wages:* Fixing of minimum rates of wages under Section 3 of the Act.

1. The appropriate Government (Central Government or State Government as the case may be) has been empowered under the Act to:
 - a. Fix the minimum rates of wages payable to employees employed in an employment specified in Part I or Part II of the Schedule.
 - b. Review at such intervals as it may think fit, such intervals not exceeding 5 years, the minimum rates of wages so fixed and revise the minimum rates, if necessary.
- 1A. The appropriate Government may refrain from fixing minimum rates of wages in

respect of any scheduled employment in which there are in the whole State less than one thousand employees engaged in such employment.

2. The appropriate Government may fix:
 - a. A minimum rate of wages for time work (hereinafter referred to as "a minimum time rate").
 - b. A minimum rate of wages for piece work (hereinafter referred to as "a minimum piece rate").
 - c. A minimum rate of remuneration to apply in the case of employees employed on piece work for the purpose of securing to such employees a minimum rate of wages on a time work basis (hereinafter referred to as "a guaranteed time rate").
 - d. A minimum rate (whether a time rate or a piece rate) to apply in substitution for the minimum rate which would otherwise be applicable, in respect of overtime work done by employees (hereinafter referred to as "overtime rate").
3. In fixing or revising minimum rates of wages under this section:
 - a. Different minimum rates of wages may be fixed for:
 - i. Different scheduled employments.
 - ii. Different classes of work in the same scheduled employment.
 - iii. Adults, adolescents, children and apprentices.
 - iv. Different localities.
 - b. Minimum rates of wages may be fixed by any one or more of the following wage periods, namely:
 - i. By the hour.
 - ii. By the day.
 - iii. By the month.
 - iv. By such other larger wage period as may be prescribed, and where such rates are fixed by the day or by the month the manner of calculating wages for a month or for a day, as the case may be, may be indicated.

B. *Minimum rate of wages:*

1. Any minimum rate of wages fixed or revised by the appropriate Government in respect of scheduled employments under shall consist of:
 - i. A basic rate of wages and a special allowance at a rate to be adjusted, at such intervals and in such manner as the appropriate Government may direct, to accord as nearly as practicable with the variation in the cost of living index number applicable to such workers (referred to as the "cost of living allowance").
 - ii. A basic rate of wages with or without the cost of living allowance, and the cash value of the concessions in respect of supplies of essential commodities at concessional rates, where so authorized.
 - iii. An all inclusive rate allowing for the basic rate, the cost of living allowance and the cash value of the concessions, if any.
2. The cost of living allowance and the cash value of the concessions in respect of supplies of essential commodities at concessional rates shall be computed by the competent authority at such intervals and in accordance with such directions as may be specified or given by the appropriate Government.

C. *Procedure for fixing and revising minimum wages:*

1. In fixing minimum rates of wages in respect of any scheduled employment for the first time under this act or in revising minimum rates of wages so fixed, the appropriate Government shall either:
 - a. Appoint as many committees and sub-committees as it considers necessary to hold enquiries and advise it in respect of such fixation or revision, as the case may be.
 - b. By notification in the official gazette, publish its proposals for the information

of persons likely to be affected thereby and specify a date, not less than two months from the date of the notification, on which the proposals will be taken into consideration.

2. After considering the advice of the committee all representations received by it before the date specified in the notification the appropriate Government shall fix, or revise the minimum rates of wages in respect of each schedule employment, and it shall come into force on the expiry of 3 months from the date of its issue.

D. Wages in kind: Minimum wages payable under this Act shall be paid in cash. Where it has been the custom to pay wages wholly or partly in kind, the appropriate Government may authorise the payment of minimum wages either wholly or partly in kind. If the appropriate Government is of the opinion that provision should be made for the supply of essential commodities at concession rates, the appropriate Government may authorize the provision of such supplies at concession rates. The cash value of wages in kind and of concession in respect of supplies of essential commodities at concession rates authorized shall be estimated in the prescribed manner.

E. Payment of minimum rates of wages: Where a minimum rates of wages has been fixed by the Government in respect of any scheduled employment, the employer shall pay to every employee engaged in a scheduled employment under him wages at a rate not less than the minimum rate of wages fixed by such notification for that class of employees in that employment without any deductions except as may be authorized within such time and subject to such conditions as may be prescribed.

BOARDS AND COMMITTEES

A. Advisory Board: For the purpose of coordinating the work of committees and sub committees appointed and advising the appropriate Government generally in the matter of fixing and revising minimum rates of wages the

appropriate Government shall appoint an advisory board.

B. Central Advisory Board: For the purpose of advising the Central and State Governments in the matters of the fixation and revision of minimum rates of wages and other matters under this Act and for coordinating the work of the Advisory Boards, the Central Government shall appoint a Central Advisory Board. The Central advisory Board shall consist of persons to be nominated by the Central Government representing employers and employees in the scheduled employments, who shall be equal in number, and independent persons not exceeding one-third of its total number of members, one of such independent persons shall be appointed the Chairman of the Board by the Central Government.

C. Composition of Committees: Each of the committees, sub-committees and the Advisory Board shall consist of persons to be nominated by the appropriate Government representing employers and employees in the scheduled employments, who shall be equal in number, and independent persons not exceeding one-third of its total number of members, one of such independent persons shall be appointed the Chairman by the appropriate Government.

PROVISION OF FIXING HOURS OF WORK

The act also provides for regulation of working hours, overtime, weekly holidays and overtime wages. Period and payment of wages, and deductions from wages are also regulated.

A. Fixing hours for a normal working day:

1. In regard to any scheduled employment minimum rates of wages in respect of which have been fixed under this act, the appropriate Government may:
 - a. Fix the number of hours of work which shall constitute a normal working day. inclusive of one or more specified intervals.
 - b. Provide for a day of rest in every period of 7 days which shall be allowed to all employees or to any specified class of

- employees and for the payment of remuneration in respect of such day of rest.
- c. Provide for payment for work on a day of rest at a rate not less than the overtime rate.
 2. The provisions of sub-section (1) shall, in relation to the following classes of employees, apply only to such extent and subject to such conditions as may be prescribed:
 - a. Employees engaged on urgent work, or in any emergency which could not have been foreseen or prevented.
 - b. Employees engaged in work in the nature of preparatory or complementary work which must necessarily be carried on outside the limits laid down for the general working in the employment concerned.
 - c. Employees whose employment is essentially intermittent.
 - d. Employees engaged in any work which for technical reasons has to be completed before the duty is over.
 - e. Employees engaged in a work which could not be carried on except at times dependent on the irregular action of natural forces.
 3. Employment of an employee is essentially intermittent when it is declared to be so by the appropriate Government on the ground that the daily hours of duty of the employee, or if there be no daily hours of duty as such for the employee, the hours of duty, normally include periods of inaction during which the employee may be on duty but is not called upon to display either physical activity or sustained attention.

B. Wages of worker who works for less than normal working day: If an employee whose minimum rate of wages has been fixed under this Act by the day works on any day on which he was employed for a period less than the requisite number of hours constituting a normal working day, he shall be entitled to receive

wages in respect of work done by him on that day as if he had worked for a full normal working day: He shall not be entitled to receive wages for a full normal working day:

- i. In any case where his failure to work is caused by his unwillingness to work and not by the omission of the employer to provide him with work.
- ii. In such other cases and circumstances as may be prescribed.

C. Wages for two or more classes of work: Where an employee does two or more classes of work to each of which a different minimum rate of wages is applicable, the employer shall pay to such employee in respect of the time respectively occupied in each such class of work, wages at not less than the minimum rate in-force in respect of each such class.

D. Overtime: To be fixed by the hour, by the day or by such a longer wage-period works on any day in excess of the number of hours constituting normal working day. Payment for every hour or for part of an hour so worked in excess at the overtime rate double of the ordinary rate.

E. Minimum time rate wages for piecework: Not less than minimum rates wages as fixed. Where an employee is employed on piece of work for which minimum time rate and not a minimum price rate has been fixed under this Act, the employer shall pay to such employee wages at not less than the minimum time rate.

REGISTER-MAINTENANCE OF REGISTERS AND RECORDS BY EMPLOYER

Maintenance of registers and records: Every employer shall maintain such registers and records giving such particulars of employees employed by him, the work performed by them, the wages paid to them, the receipts given by them and such other particulars and in such form as may be prescribed. Every employer shall keep-exhibited, in such manner as may be prescribed, in the factory, workshop or place where the employees in the scheduled employment may be employed; or in the case of out-workers, in such factory, workshop or place as

may be used for giving out-work to them notices in the prescribed form containing prescribed particulars. The appropriate Government may, by rules made under this Act, provide for the issue of wage books or wage slips to employees employed in any scheduled employment in respect of which minimum rates of wages have been fixed and prescribe the manner in which entries shall be made and authenticated in such wage books or wage slips by the employer or his agent.

- Register of fines—Form I Rule 21(4).
- Annual returns—Form III Rule 21(4-A).
- Register for overtime—Form IV Rule 25.
- Register of wages—Form X, Wages slip—Form XI, muster roll—Form V Rule 26.
- Representation of register—for 3 years Rule 26-A {Section 18}.

Preservation of registers: All the registers shall be preserved for a period of 3 years after the date of last entry made therein.

CLAIMS

A. Claims under the Act: This section makes provisions to appoint authorities to hear and decide all claims arising out of payment less than the minimum rates of wages or any other monetary payments due under the Act. The Presiding Officers of the Labour Court and Deputy Labour Commissioners are the authorities appointed.

B. Who can file a claim petition:

- i. The Employee
- ii. Any legal practitioner or any official of a regd. Trade Union authorised in writing to act on his behalf
- iii. Any Inspector
- iv. Any person acting with the permission of the authority under Section 20 (I) Powers and duties of Inspectors.

C. Claims by employees: To be filled by before authority constituted under the Act within 6 months.

Compensation up to 10 times on under or non-payment of wages {Section 16}.

INSPECTORS

Appointment, power and duties of inspectors:

1. The appropriate Government may appoint such persons as he thinks fit to be Inspector for the purposes of this act, and define the local limits within which they shall exercise their functions.
2. An Inspector may, within the local limits for which he is appointed:
 - a. Enter, at all reasonable hours, with such assistants, being persons in the service of the Government or any local or other public authority, as he thinks fit, any premises or place where employees are employed or work is given out to out-workers in any scheduled employment irrespective of which minimum rates of wages have been fixed under this act, for the purpose of examining any register, record of wages or notices required to be kept or exhibited by or under this act or rules and require the inspection.
 - b. Examine any person or place or an employee whom he finds in any such premises.
 - c. Require any person giving out-work and any out-workers, to give any information, which is in his power to give, with respect to the names and addresses of the persons to, for and from whom the work is given out or received, and with respect to the payments to be made for the work.
 - d. Seize or take copies of such register, record of wages or notices or portions thereof as he may consider relevant in respect of an offence under this act which he has reason to believe has been committed by an employer.
 - e. Exercise such other powers as may be prescribed.
3. Every Inspector shall be deemed to be a public servant within the meaning of the Indian Penal Code.
4. Any person required to produce any document or thing or to give any information by an Inspector shall be deemed to be legally bound to do so within the

meaning of Section 175 and Section 176 of the Indian Penal Code.

OFFENCES AND PENALTIES

I. Penalties: Any employer who contravenes any of the provisions of this Act other than those relating to Sections 12 and 13 of any rule or any order made thereunder shall be punishable with fine, which may extend to ₹ 500. Any employer who contravenes the provision relating to the payment of minimum rates of wages fixed (Section 12), hours of work stipulated for constituting a normal working day as per Section 13 shall be punishable with imprisonment for a term which may extend to 6 months or with fine which may extend to ₹ 500/- or both.

II. Penalties for certain offences: Any employer who:

- a. Pays to any employee less than the minimum rates of wages fixed for that employee's class of work, or less than the amount due to him under the provisions of this Act.
- b. Contravenes any rule or order made under Section 13 (fixing hours for a normal working day), shall be punishable with imprisonment for a term which may extend to 6 months, or with fine which may extend to 500 rupees, or both.

III. Penalty for obstructing inspector: Whoever wilfully obstructs an Inspector in the exercise of any power conferred on him by or under this Act, or fails to produce on demand by an Inspector any registers, records or other documents in his custody kept in pursuance of this Act, and which he is required to produce by or under this Act shall, on conviction, be punished with fine which may extend to 500 rupees.

IV. General provision for punishment of other offences: Any employer who contravenes any provision of this Act or of any rule or order made thereunder shall, if no other penalty is provided for such contravention by this Act, be punishable with fine which may extend to 500 rupees.

V. Offences by companies:

1. If the person committing any offence under this act is a company, every person who at

the time the offence was committed, was in charge of, and was responsible to, the company for the conduct of the business of the company as well as the company shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly.

2. Where an offence under this act has been committed by a company and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of, any, director, manager, secretary or other officer of the company, such director, manager, secretary or other officer of the company shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

MISCELLANEOUS

A. Single application in respect of a number of employees: A single application may be presented on behalf or in respect of any number of employees employed in the scheduled employment in respect of which minimum rates of wages have been fixed and in such cases the maximum compensation which may be awarded under shall not exceed ten times the aggregate amount of such excess or 10 rupees per head as the case may be. The Authority may deal with any number of separate pending applications presented under Section 20 in respect of employees in the scheduled employments in respect of which minimum rates of wages have been fixed, as a single application presented of this section and the provisions of that sub-section shall apply accordingly.

B. Power of the central Government to make rules: The Central Government may, subject to the condition of previous publication, by notification in the official gazette, make rules prescribing the term of office of the members, the procedure to be followed in the conduct of business, the method of voting, the manner of filling up casual-vacancies in membership and the quorum necessary for the transaction of business of the Central Advisory Board.

CHAPTER

16

Intellectual Property Rights

INTRODUCTION

Intellectual Property Rights (IPR) is a general term covering patents, copyright, trademark, industrial designs, geographical indications, protection of layout design of integrated circuits and protection of undisclosed information (trade secrets).

Intellectual Property: Property (as an idea, invention, or process) that derives from the work of the mind or intellect: an application, right, or registration relating to this. The intellectual property rights definition gives the creator or holder exclusive rights to the intellectual property for varying lengths of time, depending upon the type of Intellectual Property.

Intellectual Property (IP) refers to creations of the mind, inventions, literary and artistic works, and symbols, names, images, and designs used in commerce. IP is divided into two categories: Industrial Property, which includes inventions (patents), trademarks, industrial designs, and geographic indications of source; and copyright, which includes literary and artistic works such as novels, poems and plays, films, musical works, artistic works such as drawings, paintings, photographs and sculptures, and architectural designs. Rights related to copyright include those of performing artists in their performances, producers of phonograms in their recordings, and those of broadcasters in their radio and television programs. Although many of the legal principles governing intellectual property have

evolved over centuries, it was not until the 19th century that the term *intellectual property* began to be used, and not until the late 20th century that it became commonplace in the United States.

Objectives

Financial incentive: These exclusive rights allow owners of intellectual property to reap monopoly profits. These monopoly profits provide a financial incentive for the creation of intellectual property, and pay associated research and development costs. Some commentators, such as David Levine and Michele Boldrin, dispute this justification.

Economic growth: The legal monopoly granted by IP laws are credited with significant contributions toward economic growth. Economists estimate that two-thirds of the value of large businesses in the U.S. can be traced to intangible assets. "IP-intensive industries" are estimated to produce 72% more value added per employee than "non-IP-intensive industries".

Economics: Intellectual property rights are temporary state-enforced monopolies regarding use and expression of ideas and information.

INTRODUCTION OF INTELLECTUAL PROPERTY RIGHTS

The right to possess or control the use of intellectual property, such as trademarks,

copyrights, patents and trade secrets. Or Intellectual property rights are the rights given to persons over the creations of their minds. They usually give the creator an exclusive right over the use of his/her creation for a certain period of time.

Intellectual property rights are usually limited to non-rival goods, that is, goods which can be used or enjoyed by many people simultaneously—the use by one person does not exclude use by another. This is compared to rival goods, such as clothing, which may only be used by one person at a time. For example, any number of people may make use of a mathematical formula simultaneously. Some objections to the term intellectual property are based on the argument that property can only properly be applied to rival goods (or that one cannot "own" property of this sort).

Since a non-rival good may be simultaneously used (copied, for example) by many people (produced with minimal marginal cost), monopolies over distribution and use of works are meant to give producers incentive to create further works. The establishment of intellectual property rights, therefore, represents a trade-off, to balance the interest of society in the creation of non-rival goods (by encouraging their production) with the problems of monopoly power. Since the trade-off and the relevant benefits and costs to society will depend on many factors that may be specific to each product and society, the optimum period of time during which the temporary monopoly rights should exist is unclear.

Administration of Intellectual Property Rights in the Country: Patents, designs, trademarks and geographical indications are administered by the Controller General of Patents, designs and trademarks which is under the control of the department of Industrial policy and promotion, Ministry of Commerce and Industry. Copyright is under the charge of the ministry of human resource development. The act on layout design of integrated circuits. Will be implemented by the ministry of communication and Information technology.

Nature of Intellectual Property Rights: IPR are largely territorial rights except copyright, which is global in nature in the sense that it is immediately available in all the members of the berne convention. These rights are awarded by the State and are monopoly rights implying that no one can use these rights without the consent of the right holder. It is important to know that these rights have to be renewed from time to time for keeping them in force except in case of copyright and trade secrets. IPR have fixed term except trademark and geographical indications, which can have indefinite life provided these are renewed after a stipulated time specified in the law by paying official fees. Trade secrets also have an infinite life but they do not have to be renewed. IPR can be assigned, gifted, sold and licensed like any other property. Unlike other moveable and immovable properties, these rights can be simultaneously held in many countries at the same time. IPR can be held only by legal entities, i.e. who have the right to sell and purchase property. In other words an institution, which is not autonomous may not in a position to own an intellectual property. These rights especially, patents, copyrights, industrial designs, IC layout design and trade secrets are associated with something new or original and therefore, what is known in public domain cannot be protected through the rights mentioned above. Improvements and modifications made over known things can be protected. It would however, be possible to utilize geographical indications for protecting some agriculture and traditional products.

INTELLECTUAL PROPERTY RIGHTS (IPR)

Intellectual Property Rights as a collective term includes the following independent IP rights which can be collectively used for protecting different aspects of an inventive work for multiple protection:

1. Patents.
2. Copyrights.
3. Trademarks.
4. Registered (industrial) design.
5. Protection of IC layout design.

6. Geographical indications.
7. Protection of undisclosed information (trade secrets).

PATENTS

Patents are one of the oldest forms of intellectual property protection. The aim of patent system is to encourage economic and technological development by rewarding by intellectual creativity. A patent is an exclusive right granted by a country to the owner of an invention to make, use, manufacture and market the invention, provided the invention satisfies certain conditions stipulated in the law. Exclusive right implies that no one else can make, use, manufacture or market the invention without the consent of the patent holder. This right is available for a limited period of time. In spite of the ownership of the rights, the use or exploitation of the rights by the owner of the patent may not be possible due to other laws of the country which has awarded the patent. These laws may relate to health, safety, food, security, etc. further, existing patents in similar area may also come in the way. A patent in the law is a property right and hence, can be gifted, inherited, assigned, sold or licensed. As the right is conferred by the State, it can be revoked by the State under very special circumstances even if the patent has been sold or licensed or manufactured or marketed in the meantime. The patent right is territorial in nature and inventors/their assignees will have to file separate patent applications in countries of their interest, along with necessary fees, for obtaining patents in those countries. A new chemical process or a drug molecule or an electronic circuit or a new surgical instrument or a vaccine is a patentable subject matter provided all the stipulations of the law are satisfied.

Types of Patent

Following types of patents are granted under the Act:

1. An ordinary patent.
2. A patent of addition for improvement in or modification of an invention for which a

patent has already been applied for or granted.

3. A patent granted in respect of a convention application filled under Section 135 of the Act.
4. A product patent for a medicine or drug as provided by the Patents (amendment) Act, 1999.

Purpose of a Patent

- To provide a form of protection for technological advances.
- Provide reward not only for the creation of an invention, but also for the development of an invention to the point at which it is technologically feasible and marketable.
- It promotes additional creativity.
- It encourages companies to continue their development.

Short of Things can be Patented

- Patents are available for any inventions:
 - Process
 - Products
 - Utilities
- Things that already exist in nature, with very few exceptions, cannot be patented.
 - Human genes
- A perpetual motion machine, which goes against the laws of nature, cannot be patented unless someone can show it working.

Patent Protection

- The term of patent is typically 20 years from the date on which the application is filed.
- When the patent rights expire, the technology becomes public property, and the public is free to use it for their own goods.
- There is no one patent that covers every country in the world, or even a large number of the countries of the world.
- If you have patents in 10 countries, you have to pay the maintenance fees in each countries, otherwise your patent would lapse and you would lose your patent.

THE PATENTS ACT, 1970

Patent Right varies from country to country. In India the Law which govern patent right is "Indian Patent Act, 1970". Indian Patent Act, 1970 grants exclusive right to the inventor for his invention for limited period of time. Generally 20 years time has been granted to the patent holder but in case of inventions relating to manufacturing of food or drugs or medicine it is for seven years from the date of patent. There is certain legal procedure which needs to be followed in order to register. There are several attorney helping inventor in patent registration by providing them best well informed knowledge. In India patent registration can be filed individually or jointly. In case of deceased inventor this can be done his legal representative on behalf of him. All the required documents need to be filed along with the application form. Only after verification registration certificate is provided to the applicant.

Patents Act, 1970 is designed to protect inventions in respect of manufacture, machine or process of manufacture. On the other hand, the Copyright Act, 1957 is to protect rights of artists, authors, producers of films, computer software owners, etc. Patent is an exclusive right granted to the patent holder, for a limited period, as a reward for creative work based on his private initiative. 'Creativity' is accorded the status of 'property' which can be bought, sold, licensed or hired like any other commodity. The principle behind patent protection is that creativity will not get encouragement if it cannot be protected from pirating or copying. Major changes have been made by **Patents (Amendment) Act, 2002**, which was passed on 25th June 2002 aligning it to TRIPS in many aspects.

Patents Act, 1970 and TRIPS agreement: The Indian Patents Act, 1970 provides patent protection in India. The same is in accordance with the provisions of the TRIPS agreement (trade-related aspects of intellectual property Rights). The recent conferment of 'product patent' along with the 'process patent' is an example of such compatibility. The protection

to plant varieties has been excluded from the realm of patent law and a separate Act has been made for that purpose. Further, the provisions of 'international patent application' and 'compulsory licenses' are also in conformity with TRIPS Agreement and Doha Declaration respectively. Thus, the interest of the public at large has also been taken care of by the Indian Patents Act, 1970 and there is no need of being panicked from product patent of medicines. However, there is no need of a 'further protection' to pharmaceuticals in the form of 'Data Exclusivity' as the protection under the Patents Act, 1970 is not only sufficient but also in conformity with the TRIPS Agreement. The protection in the form of 'Data Exclusivity' is a 'TRIPS plus' provision to which India does not owe any obligation.

Patents in India/Indian Patent System 1970: The first Indian patent laws were first promulgated in 1856. These were modified from time to time. New patent laws were made after the independence in the form of the Indian Patent Act, 1970. The act has now been radically amended to become fully compliant with the provisions of TRIPS. The most recent amendment was made in 2005 which were preceded by the amendments in 2000 and 2003. While the process of bringing out amendments was going on, India became a member of the Paris Convention, Patent Cooperation Treaty and Budapest Treaty. The salient and important features of the amended Act are explained here.

The word patent originated from the Latin Word "Patene" which means 'to open'. If a person makes, what he thinks is an invention, or if he works for an entity, that entity can ask the Government, by filing an application with the Patent office to give him a certificate in which it is stated what the invention is and that he is the owner of it. Such a right conferred upon the inventor is called 'Patent' by which the inventor, more properly called as the Patentee, can make exclusive use of his invention.

Thus a patent is a monopoly right granted to a person who has invented a new and useful

article or a new process of making an article. In India the Law relating to Patents is governed by the Patents Act, 1970 along with the recent Amendment in 1999.

The Indian Patents Act Defines an Invention as Follows

Invention means any new and useful:

- i. Art, process, method or manner of manufacture.
- ii. Machine, apparatus or other article.
- iii. Substance produced by manufacture and includes any new and useful improvement of any of them and an alleged invention.

Therefore, in order to be Patentable, an Invention Must Possess the Following Characteristics

- a. It should relate to a manner of manufacture.
- b. The manner of manufacture should be novel.
- c. It should be the outcome of inventive activity.
- d. It should have utility.
- e. It should not be contrary to law and morality.

Salient Features of Indian Patent Law

The Patent law of India has the following salient features that decide whether a patent will be granted or not:

- a. ***The object:*** The object of patent law is to encourage scientific research, new technology and industrial progress. The price of the grant of the monopoly is the disclosure of the invention at the Patent Office, which, after the expiry of the fixed period of the monopoly, passes into the public domain.
- b. ***Inventive step:*** The fundamental principle of Patent law is that a patent is granted only for an invention which must have novelty and utility. It is essential for the validity of a patent that it must be the inventor's own discovery as opposed to

mere verification of what was, already known before the date of the patent.

- c. ***Useful:*** The previous Act, i.e. Act of 1911, does not specify the requirement of being useful, in the definition of invention, but courts have always taken the view that a patentable invention, apart from being a new manufacture, must also be useful.
- d. ***Improvement:*** In order to be patentable, an improvement on something known before or a combination of different matters already known, should be something more than a mere workshop improvement, and must independently satisfy the test of invention or an inventive step. It must produce a new result, or a new article or a better or cheaper article than before. The new subject matter must involve "invention" over what is old. Mere collection of more than one, integers or things, not involving the exercise of any inventive faculty does not qualify for the grant of a patent.
- e. ***The guiding tests:*** To decide whether an alleged invention involves novelty and an inventive step, certain broad criteria can be indicated. Firstly if the "manner of manufacture" patented, was publicly known, used or practised in the country before or at the date of the patent, it will negative novelty or 'subject matter'. Prior public knowledge of the alleged invention can be by word of mouth or by publication through books or other media. Secondly, the alleged discovery must not be the obvious or natural suggestion of what was previously known.

In short the invention must involve an inventive step and the same must be capable of industrial application. It must be supplemented by the concept of non-obviousness.

DEFINITIONS

- a. "**Assignee**" includes the legal representative of a deceased assignee and references to the assignee of the legal representative or assignee of that person.

- b. "**Controller**" means the Controller General of Patents, Designs and Trade Marks referred into Section 73 (Controller and other officers).
- c. "**Convention application**" means an application for a patent made by virtue of Section 135 (Convention applications).
- d. "**Convention country**" means a country notified as such under sub-section (1) of Section 133 (notification as to convention countries).
- e. "**District Court**" has the meaning assigned to that expression by the Code of Civil Procedure, 1908.
- f. "**Exclusive license**" means a license from a patentee which confers on the licensee, or on the licensee and persons authorised by him, to the exclusion of all other persons (including the patentee), any right in respect of the patented invention, and "exclusive licensee" shall be construed accordingly.
- g. "**Food**" means any article of nourishment and includes any substance intended for the use of babies, invalids or convalescents as an article of food or drink.
- h. "**Government undertaking**" means any industrial undertaking carried on:
 - i. By a department of the Government, or
 - ii. By a corporation established by a Central, Provincial or State Act, which is owned or controlled by the Government.
 - iii. By a Government company as defined in Section 617 of the Companies Act, 1956, and includes the Council of Scientific and Industrial Research and any other institution which is financed wholly or for the major part by the said Council.
- i. "**Invention**" means any new and useful:
 - i. Art, process, method or manner of manufacture.
 - ii. Machine, apparatus or other article.
 - iii. Substance produced by manufacture, and includes any new and useful improvement of any of them, and an alleged invention.
- j. "**Legal representative**" means a person who in law represents the estate of a deceased person.
- k. "**Medicine or drug**" includes:
 - i. All medicines for internal or external use of human beings or animals.
 - ii. All substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of diseases in human beings or animals.
 - iii. All substances intended to be used or in the maintenance of public health, or the prevention or control of any epidemic disease among human beings or animals.
 - iv. Insecticides, germicides, fungicides, pecticides and all other substances intended to be used for the protection or preservation of plants.
 - v. All chemical substances which are ordinarily used as intermediates in the preparation or manufacture of any of the medicines or substances above referred to.
- l. "**Patent**" means a patent granted under this Act.
- m. "**Patent agent**" means a person for the time being registered under this Act as a patent agent.
- n. "**Patented article**" and "**patented process**" mean respectively an article or process in respect of which a patent is in force.
- o. "**Patentee**" means the person for the time being entered on the register as the grantee or proprietor of the patent.

PATENTABLE INVENTION

An invention to be patentable should be technical in nature and should meet the following criteria:

- i. **Novelty:** The matter disclosed in the specification is not published in India or elsewhere before the date of filling of the patent application in India.

- ii. **Inventive step:** The invention is not obvious to a person skilled in the light of the prior publication/knowledge/document.
- iii. **Industrially applicable:** Invention should possess utility so that it can be made or used in the industry.

INVENTIONS NOT PATENTABLE

The following are not inventions within the meaning of this Act:

- i. An invention which is frivolous or which claims anything obvious contrary to well established natural laws, e.g. different types of perpetual motion machines.
- ii. An invention the primary or intended use of which would be contrary to law or morality or injurious to public health, e.g. a process for making brown sugar will not be patented.
- iii. The mere discovery of a scientific principle or the formulation of an abstract theory, e.g. Raman effect and theory of relativity cannot be patented.
- iv. The mere discovery of any new property of new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. For the purposes of this clause, salts, esters, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance unless they differ significantly in properties with regard to efficacy.
- v. A substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance.
- vi. The mere arrangement or re-arrangement or duplication of known devices each functioning independently of one another in a known way. If you put torch bulbs around an umbrella and operate them by

- a battery so that people could see you walking in rain when it is dark, then this arrangement is patentable as bulbs and the umbrella perform their functions independently.
- vii. A method or process of testing applicable during the process of manufacture for rendering the machine, apparatus or other equipment more efficient or for the improvement or restoration of the existing machine, apparatus or other equipment or for the improvement or control of manufacture.
- viii. A method of agriculture or horticulture.
- ix. Any process for the medicinal, surgical, curative, prophylactic or other treatment of human beings or any process for a similar treatment of animals or plants to render them free of disease or to increase their economic value or that of their products.

Computer program as such has not been defined in the act but would generally tend to mean that a computer program without any utility would not be patentable. Protection of seeds and new plant varieties is covered under a different act, which provides a protection for a period of 10 years. Similarly, topography of integrated circuits is protected through yet a different Act.

Inventions relating to atomic energy not patentable: No patent shall be granted in respect of an invention relating to atomic energy falling under Section 20 of the Atomic Energy Act, 1962.

INVENTIONS WHERE ONLY METHODS OR PROCESSES OF MANUFACTURE PATENTABLE

In the case of inventions:

- a. Claiming substances intended for use, or capable of being used, as food or as medicine or drug.
- b. Relating to substances prepared or produced by chemical processes (including alloys, optical glass, semiconductors and inter-metallic compounds).

No patent shall be granted in respect of claims for the substances themselves, but claims for the methods or processes of manufacture shall be patentable.

TERM OF THE PATENT

Term of the patent will be 20 years from the date of filing for all types of inventions.

PROCEDURE FOR OBTAINING PATENT/ APPLICATIONS FOR PATENTS

A. Application: In respect of patent applications filed, following aspects will have to be kept in mind:

- a. Claim or claims can now relate to single invention or group of inventions linked so as to form a single inventive concept.
- b. Patent application will be published 18 months after the date of filing.
- c. Applicant has to request for examination 12 months within publication or 48 months from date of application, whichever is later.
- d. No person resident in India shall, except under the authority of a written permit sought in the manner prescribed and granted by or on behalf of the Controller, make or cause to be made any application outside India for the grant of a patent for an invention unless:
 - i. An application for a patent for the same invention has been made in India, not less than 6 weeks before the application outside India.
 - ii. Either no direction has been given under the secrecy clause of the act or all such directions have been revoked.

B. Persons entitled to apply for patents:

1. An application for a patent for an invention may be made by any of the following persons, that is to say:
 - a. By any person claiming to be the true and first inventor of the invention.
 - b. By any person being the assignee of the person claiming to be the true and first

inventor in respect of the right to make such an application.

- c. By the legal representative of any deceased person who immediately before his death was entitled to make such an application.
2. An application may be made by any of the persons preferred to therein either alone or jointly with any other person.

C. Form of application:

1. Every application for a patent shall be for one invention only and shall be made in the prescribed form and filed in the patent office.
2. Where the application is made by virtue of an assignment of the right to apply for a patent for the invention, there shall be furnished with the application, or within such period as may be prescribed after the filing of the application, proof of the right to make the application.
3. Every application under this Section shall state that the applicant is in possession of the invention and shall name the owner claiming to be the true and first inventor; and where the person so claiming is not the applicant or one of the applicants, the application shall contain a declaration that the applicant believes the person so named to be the true and first inventor.
4. Every such application (not being a convention application) shall be accompanied by a provisional or a complete specification.

D. Information and undertaking regarding foreign applications:

1. Where an applicant for a patent under this Act is prosecuting either alone or jointly with any other person an application for a patent in any country outside India in respect of the same or substantially the same invention, or where to his knowledge such an application is being prosecuted by some person through whom he claims or by some person deriving title from him, he shall file along with his application:

- a. A statement setting out the name of the country where the application is being prosecuted, the serial number and date of filing of the application and such other particulars as may be prescribed.
 - b. An undertaking that is up to the date of the acceptance of his complete specification filed in India, he would keep the Controller informed in writing, from time to time, of details of the nature in respect of every other application relating to the same or substantially the same invention, if any, filed in any country outside India subsequently to the filing of the statement referred to in the aforesaid clause, within the prescribed time.
2. The Controller may also require the applicant to furnish, as far as may be available to the applicant, details relating to the objections, if any, taken to any such application as is referred to in sub-section (1) on the ground that the invention is lacking in novelty or patentability, the amendments effected in the specifications, the claims allowed in respect thereof and such other particulars as he may require.

E. Timing for filing a patent application: Filing of an application for a patent should be completed at the earliest possible date and should not be delayed. An application filed with provisional specification, disclosing the essence of the nature of the invention helps to register the priority by the applicant. Delay in filing an application may entail some risks like (i) other inventors might forestall the first inventor by applying for a patent for the said invention and (ii) there may be either an inadvertent publication of the invention by the inventor himself/herself or by others independently of him/her. Publication of an invention in any form by the inventor before filing of a patent application would disqualify the invention to be patentable. Hence, inventors should not disclose their inventions before filing the patent application. The invention should be considered for publication after a patent application has

been filed. Thus, it can be seen that there is no contradiction between publishing an inventive work and filing of patent application in respect of the invention.

SPECIFICATION

A. Provisional specification: A provisional specification is usually filed to establish priority of the invention in case the disclosed invention is only at a conceptual stage and a delay is expected in submitting full and specific description of the invention. Although, a patent application accompanied with provisional specification does not confer any legal patent rights to the applicants, it is, however, a very important document to establish the earliest ownership of an invention. The provisional specification is a permanent and independent scientific cum legal document and no amendment is allowed in this. No patent is granted on the basis of a provisional specification. It has to be followed by a complete specification for obtaining a patent for the said invention. Complete specification must be submitted within 12 months of filing the provisional specification. This period can be extended by 3 months. It is not necessary to file an application with provisional specification before the complete specification. An application with complete specification can be filed right at the first instance.

B. Complete specification: It may be noted that a patent document is a technolegal document and it has to be finalized in consultation with an attorney. Submission of complete specification is necessary to obtain a patent. Contents of a complete specification would include the following:

1. Title of the invention.
2. Field to which the invention belongs.
3. Background of the invention including prior art giving drawbacks of the known inventions and practices.
4. Complete description of the invention along with experimental results.
5. Drawings, etc. essential for understanding the invention.

6. Claims, which are statements, related to the invention on which legal proprietorship is being sought. Therefore the claims have to be drafted very carefully.

C. Examination of application:

1. When the complete specification has been led in respect of an application for a patent, the application and the specification relating thereto shall be referred by the controller to an examiner for making a report to him in respect of the following matters, namely:
 - a. Whether the application and the specification relating thereto are in accordance with the requirements of this act and of any rules made thereunder.
 - b. Whether there is any lawful ground of objection to the grant of the patent under this act in pursuance of the application.
 - c. The result of investigations made under Section 13 (search for anticipation by previous publication and by prior claim).
 - d. Any other matter which may be prescribed.
2. The examiner to whom the application and the specification relating thereto are referred under sub-section (1) shall ordinarily make the report to the controller within a period of eighteen months from the date of such reference.

D. Search for anticipation by previous publication and by prior claim:

1. The examiner to whom an application for a patent shall make investigation for the purpose of ascertaining whether the invention so far as claimed in any claim of the complete specification:
 - a. Has been anticipated by publication before the date of filing of the applicant's complete specification in any specification filed in pursuance of an application for a patent made in India and dated on or after the 1st day of January, 1912.
 - b. Is claimed in any claim of any other complete specification published on or after the date of filing of the applicant's

complete specification, being a specification filed in pursuance of an application for a patent made in India and dated before or claiming the priority date earlier than that date.

2. The examiner shall, in addition, make such investigation as the Controller may direct for the purpose of ascertaining whether the invention, so far as claimed in any claim of the complete specification, has been anticipated by publication in India or elsewhere in any document other than those mentioned in sub-section (1) before the date of filing of the applicant's complete specification.
3. Where a complete specification is amended under the provisions of this Act before it has been accepted, the amended specification shall be examined and investigated in like manner as the original specification.
4. The examination and investigations required under Section 12 and this section shall not be deemed in any way to warrant the validity of any patent, and no liability shall be incurred by the Central Government or any officer thereof by reason of, or in connection with, any such examination or investigation or any report or other proceedings consequent thereon.

E. Power of Controller in cases of anticipation:

1. The Controller may refuse to accept the complete specification unless the applicant:
 - a. Shows to the satisfaction of the Controller that the priority date of the claim of his complete specification is not later than the date on which the relevant document was published.
 - b. Amends his complete specification to the satisfaction of the Controller.
2. The Controller may, subject to the provisions hereinafter contained, direct that a reference to that other specification shall be inserted by way of notice to the public in the applicant's complete specification unless within such time as may be prescribed:
 - a. The applicant shows to the satisfaction of the Controller that the priority date of his

- claim is not later than the priority date of the claim of the said other specification.
- b. The complete specification is amended to the satisfaction of the Controller.
 3. The Controller that the priority date of the applicant's claim is not later than the priority date of the claim of that specification shall apply thereto in the same manner as they apply to a specification published on or after the date of filing of the applicant's complete specification.

F. Advertisement of acceptance of complete specification: On the acceptance of a complete specification, the Controller shall give notice thereof to the applicant and shall advertise in the official gazette the fact that the specification has been accepted, and thereupon the application and the specification with the drawings (if any) filed in pursuance thereof shall be open to public inspection.

EXCLUSIVE MARKETING RIGHTS (EMR)

A. Application for grant of exclusive rights (under section 24 A):

1. Anything contained in examination of application, the Controller shall not refer an application in respect of a claim for a patent covered under inventions where only methods or processes of manufacture patentable to an examiner for making a report till the 31st day of December, 2004 and shall, where an application for grant of exclusive right to sell or distribute the article or substance in India has been made in the prescribed form and manner and on payment of prescribed fee, refer the application for patent, to an examiner for making a report to him as to whether the invention is not an invention within the meaning of this act or the invention is an invention for which no patent can be granted in terms of Section 4 (inventions relating to atomic energy not patentable).
2. Where the controller, on receipt of a report under above sub-section and after such

other investigation as he may deem necessary, is satisfied that the invention is not an invention within the meaning of this act or the invention is an invention for which no patent can be granted, he shall reject the application for exclusive right to sell or distribute the article or substance.

3. In a case where an application for exclusive right to sell or distribute an article or a substance is not rejected by the controller on receipt of a report and after such other investigation, if any, made by him, he may proceed to grant exclusive right to sell or distribute the article or substance in the manner provided under grant of exclusive of rights.

B. Grant of exclusive rights:

1. TRIPS requires that member countries of the WTO not having provision in their laws for granting product patents in respect of drugs and agrochemical, must introduce exclusive marketing rights (EMR) for such products. Where a claim for patent covered under Inventions where only methods or processes of manufacture patentable has been made and the applicant has:

- a. Where an invention has been made whether in India or a country other than India and before filing search a claim, filed an application for the same invention claiming identical article or substance in a convention country on or after the 1st day of January, 1995 and the patent and the approval to sell or distribute the article or substance on the basis of appropriate tests conducted on or after the first day of January, 1995 in that country has been granted or after the date of making claim for patent.
- b. Where an invention has been made in India and before filing search a claim, made a claim for patent on or after the first day of January, 1995 for method or a process of manufacture for that invention relating to identical article or substance and has been granted in India the patent

- therefor on or after the making the claim for patent covered, and has been received the approval to sell or distribute the article or substance from the authority specify in this behalf by the Central Government, then, we shall have the exclusive right by himself, his agents or licensee to sell or distribute in India the article or the substance on or from the date of approval granted by the controller in this behalf till a period of five years or till the date of grant of patent or the date of rejection of application for the grant of patent, whichever is earlier.
2. Where, the specifications of an invention relatable to an article or a substance have been recorded in a document or the invention has been tried or used, or, the article or the substance has been sold, by a person, before a claim for a patent of that invention is made in India or in a convention country, then, the sale or distribution of the article or substance by such person, after the claim referred to above is made shall not be deemed to be an infringement of exclusive right to sell or distribute.

OPPOSITION TO GRANT OF PATENT

Opposition to grant of patent:

1. At any time within 4 months from the date of advertisement of the acceptance of a complete specification under this act any person interested may give notice to the Controller of opposition to the grant of the patent on any of the following grounds, namely:
 - a. That the applicant for the patent or the person under or through whom he claims, wrongfully obtained the invention or any part thereof from him or from a person under or through whom he claims.
 - b. That the invention so far as claimed in any claim of the complete specification has been published before the priority date of the claim:
 - i. In any specification filed in pursuance of an application for a patent made in India on or after the 1st day of January, 1912.
 - ii. In India or elsewhere, in any other document.
 - c. That the invention so far as claimed in any claim of the complete specification is obvious and clearly does not involve any inventive step, having regard to the matter published as mentioned in clause (b) or having regard to what was used in India before the priority date of the applicant's claim.
 - d. That the subject of any claim of the complete specification is not an invention within the meaning of this act, or is not patentable under this Act.
 - e. That the complete specification does not sufficiently and clearly describe the invention or the method by which it is to be performed.
 - f. That the applicant has failed to disclose to the controller the information required by Section 8 or has furnished the information which in any material particular was false to his knowledge.
 - g. That in the case of a convention application, the application was not made within 12 months from the date of the first application for protection for the invention made in a convention country by the applicant or a person from whom he derives title.
2. Where any such notice of opposition is duly given, the Controller shall notify the applicant and shall give to the applicant and the opponent an opportunity to be heard before deciding the case.
 3. The grant of a patent shall not be refused on the ground stated if no patent has been granted in pursuance of the application mentioned in that clause, and for the purpose of any inquiry, no account shall be taken of any secret use.

GRANT AND SEALING OF PATENTS AND RIGHTS CONFERRED THEREBY

A. Grant and sealing of patents:

1. Where a complete specification in pursuance of an application for a patent has been accepted and either:
 - a. The application has not been opposed under Section 25 (opposition to grant of patent) and the time for the filing of the opposition has expired.
 - b. The application has been opposed and the opposition has been finally decided in favour of the applicant.
 - c. The application has not been refused by the controller by virtue of any power vested in him by this act.

The patent shall, on request made by the applicant in the prescribed form, be granted to the applicant or, in the case of a joint application, to the applicants jointly, and the Controller shall cause the patent to be sealed with the seal of the patent office and the date on which the patent is sealed shall be entered in the register.

2. The sealing of a patent shall be made not later than the expiration of a period of six months from the date of advertisement of the acceptance of the complete specification.
3. The period within which a request for the sealing of a patent may be made, may, from time to time, be extended by the Controller to such longer period as may be specified in an application made to him in that behalf, if the application is made and the prescribed fee paid within that longer period.

B. Date of patent: Subject to the other provisions contained in this act, every patent shall be dated as of the date on which the complete specification was filed. The date of every patent shall be entered in the register.

C. Form, extent and effect of patent: Every patent shall be in the prescribed form and shall have effect throughout India. A patent shall be granted for one invention only it shall not be competent for any person in a suit or other proceeding to take any objection to a patent on

the ground that it has been granted for more than one invention.

CONDITIONS

The grant of a patent under this act shall be subject to the condition that:

1. Any machine, apparatus or other article in respect of which the patent is granted or any article made by using a process in respect of which the patent is granted, may be imported or made by or on behalf of the Government for the purpose merely of its own use.
2. Any process in respect of which the patent is granted may be used by or on behalf of the Government for the purpose merely of its own use.
3. Any machine, apparatus or other article in respect of which the patent is granted or any article made by the use of the process in respect of which the patent is granted, may be made or used, and any process in respect of which the patent is granted may be used, by any person, for the purpose merely of experiment or research including the imparting of instructions to pupils.
4. In the case of a patent in respect of any medicine or drug, the medicine or drug may be imported by the Government for the purpose merely of its own use or for distribution in any dispensary, hospital or other medical institution maintained by or on behalf of the Government or any other dispensary, hospital or other medical institution which the Central Government may, having regard to the public service that such dispensary, hospital or medical institution renders, specify in this behalf by notification in the official gazette.

RIGHTS

A. Rights of patentees:

1. Subject to the other provisions contained in this act, a patent granted before the commencement of this act, shall confer on the

- patentee the exclusive right by himself, his agents or licensees to make, use, exercise, sell or distribute the invention in India.
2. A patent granted after the commencement of this act shall confer upon the patentee:
 - a. Where the patent is for an article or substance, the exclusive right by himself, his agents or licensees to make, use, exercise, sell or distribute such article or substance in India.
 - b. Where a patent is for a method or process of manufacturing an article or substance, the exclusive right by himself, his agents or licensees to use or exercise the method or process in India.
 3. Any agreement for the time being in force, where two or more persons are registered as grantee or proprietor of a patent, then a license under the patent shall not be granted and a share in the patent shall not be assigned by one of such persons except with the consent of the other person or persons.
 4. Where a patented article is sold by one or two or more persons registered as grantee or proprietor of a patent, the purchaser and any person claiming through him shall be entitled to deal with the article in the same manner as if the article had been sold by a sole patentee.

B. Rights of co-owners of patents:

1. Where a patent is granted to two or more persons, each of those persons shall, unless an agreement to the contrary is in force, be entitled to an equal undivided share in the patent.
2. Where two or more persons are registered as grantee or proprietor of a patent, then, unless an agreement to the contrary is in force, each of those persons shall be entitled, by himself or his agents, to make, use, exercise and sell the patented invention for his own benefit without accounting to the other person or persons.
3. Any agreement for the time being in force, where two or more persons are registered as grantee or proprietor of a patent, then, a

license under the patent shall not be granted and a share in the patent shall not be assigned by one of such persons except with the consent of the other person or persons.

4. Where a patented article is sold by one or two or more persons registered as grantee or proprietor of a patent, the purchaser and any person claiming through him shall be entitled to deal with the article in the same manner as if the article had been sold by a sole patentee.
5. Subject to the provisions contained in this section, the rules of law applicable to the ownership and devolution of movable property generally shall apply in relation to patents shall affect the mutual rights or obligations of trustees or of the representatives of a deceased person or their rights or obligations as such.

TERM OF PATENT

1. Subject to the provisions of this act, the term of every patent granted under this act shall:
 - a. In respect of an invention claiming the method or process of manufacture of a substance, where the substance is intended for use, or is capable of being used, as food or as a medicine or drug, be five years from the date of sealing of the patent, or seven years from the date of the patent whichever period is shorter.
 - b. In respect of any other invention, be fourteen years from the date of the patent.
2. A patent shall cease to have effect notwithstanding anything therein or in this act on the expiration of the period prescribed for the payment of any renewal fee, if that fee is not paid within the prescribed period or within that period as extended under this section.
3. The period prescribed for the payment of any renewal fee shall be extended to such period, not being more than six months longer than the prescribed period, as may be specified in a request made to the controller if the request is made and the

renewal fee and the prescribed additional fee paid before the expiration of the period so specified.

PATENTS OF ADDITION

A. *Patents of addition:*

1. Where an application is made for a patent in respect of any improvement in or modification of an invention described or disclosed in the complete specification filed therefor (in this act referred to as the "main invention") and the applicant also applies or has applied for a patent for that invention or is the patentee in respect thereof, the Controller may, if the applicant so requests, grant the patent for the improvement or modification as a patent of addition.
2. Where an invention, being an improvement in or modification of another invention, is the subject of an independent patent and the patentee in respect of that patent is also the patentee in respect of the patent for the main invention, the Controller may, if the patentee so requests, by order, revoke the patent for the improvement or modification and grant to the patentee a patent of addition in respect thereof, bearing the same date as the date of the patent so revoked.
3. A patent shall not be granted as a patent of addition unless the date of filing of the complete specification was the same as or later than the date of filing of the complete specification in respect of the main invention.
4. A patent of addition shall not be sealed before the sealing of the patent for the main invention; and if the period within which, but for the provisions of this sub-section, a request for the sealing of a patent of addition could be made expires before the period within which a request for the sealing of the patent for the main invention may be so made, the request for the sealing of the patent of addition may be made at any time within the last mentioned period.

B. *Term of patents of addition:*

1. A patent of addition shall be granted for a term equal to that of the patent for the main invention, or so much thereof as has not expired, and shall remain in force during that term or until the previous cesser of the patent for the main invention and no longer.
2. No renewal fee shall be payable in respect of a patent of addition, but, if any such patent becomes an independent patent, the same fee shall thereafter be payable, upon the same dates, as if the patent had been originally granted as an independent patent.

RESTORATION OF LAPSED PATENTS

A. *Applications for restorations of lapsed patents:*

Where a patent has ceased to have effect by reason of failure to pay any renewal fee within the prescribed period, the patentee or his legal representative, and where the patent was held by two or more persons jointly, then, with the leave of the Controller, one or more of them without joining the others, may, within one year from the date on which the patent ceased to have effect, make an application for the restoration of the patent. An application under this section shall contain a statement, verified in the prescribed manner, fully setting out the circumstances which led to the failure to pay the prescribed fee, and the Controller may require from the applicant such further evidence as he may think necessary.

B. *Procedure for disposal of applications for restoration of lapsed patents:*

1. If, after hearing the applicant in cases where the applicant so desires or the controller thinks fit, the Controller is *prima facie* satisfied that the failure to pay the renewal fee was unintentional and that there has been no undue delay in the making of the application, he shall advertise the application in the prescribed manner; and within the prescribed period any person interested may give notice to the Controller of opposition thereto on either or both of the following grounds, that is to say:

- a. That the failure to pay the renewal fee was not unintentional.
- b. That there has been undue delay in the making of the application.
- 2. If notice of opposition is given within the period aforesaid, the Controller shall notify the applicant, and shall give him and to the opponent an opportunity to be heard before he decides the case.
- 3. If no notice of opposition is given within the period aforesaid or if in the case of opposition, the decision of the Controller is in favour of the applicant, the controller shall, upon payment of any unpaid renewal fee and such additional fee as may be prescribed, restore the patent and any patent of addition specified in the application which has ceased to have effect on the cesser of that patent.
- 4. The Controller may, if he thinks fit as a condition of restoring the patent, require that an entry shall be made in the register of any document or matter which, under the provisions of this act, has to be entered in the register but which has not been so entered.

SURRENDER AND REVOCATION OF PATENTS

A. Surrender of patents:

- 1. A patentee may, at any time by giving notice in the prescribed manner to the controller, offer to surrender his patent.
- 2. Where such an offer is made, the Controller shall advertise the offer in the prescribed manner, and also notify every person other than the patentee whose names appears in the register as having an interest in the patent.
- 3. Any person interested may, within the prescribed period after such advertisement, give notice to the Controller of opposition to the surrender, and where any such notice is given the Controller shall notify the patentee.
- 4. If the controller is satisfied after hearing the patentee and any opponent, if desirous of being heard, that the patent may properly

be surrendered, he may accept the offer and, by order, revoke the patent.

B. Revocation of patents:

- 1. A patent, whether granted before or after the commencement of this act, may, on the petition of any person interested or of the Central Government or on a counter-claim in a suit for infringement of the patent, be revoked by the High Court on any of the following grounds, that is to say:
 - a. That the invention, so far as claimed in any claim of the complete specification, was claimed in a valid claim of earlier priority date contained in the complete specification of another patent granted in India.
 - b. That the patent was granted on the application of a person not entitled under the provisions of this Act to apply therefore:
 - c. That the patent was obtained wrongfully in contravention of the rights of the petitioner or any person under or through whom he claims.
 - d. That the subject of any claim of the complete specification is not an invention within the meaning of this Act.
 - e. That the invention so far as claimed in any claim of the complete specification is not new, having regard to what was publicly known or publicly used in India before the priority date of the claim or to what was published in India or elsewhere in any of the documents referred to in Section 13 (search for anticipation by previous publication and by prior claim).
 - f. That the invention so far as claimed in any claim of the complete specification is obvious or does not involve any inventive step, having regard to what was publicly known or publicly used in India or what was published in India or elsewhere before the priority date of the claim:

- g. That the invention, so far as claimed in any claim of the complete specification, is not useful.
 - h. That the complete specification does not sufficiently and fairly describe the invention and the method by which it is to be performed, that is to say, that the description of the method or the instructions for the working of the invention as contained in the complete specification are not by themselves sufficient to enable a person in India possessing average skill in, and average knowledge of, the art to which the invention relates, to work the invention, or that it does not disclose the best method of performing it which was known to the applicant for the patent and for which he was entitled to claim protection.
 - i. That the scope of any claim of the complete specification is not sufficiently and clearly defined or that any claim of the complete specification is not fairly based on the matter disclosed in the specification.
 - j. That the patent was obtained on a false suggestion or representation.
 - k. That the subject of any claim of the complete specification is not patentable under this Act.
 - l. That the invention so far as claimed in any claim of the complete specification was secretly used in India.
 - m. That the applicant for the patent has failed to disclose to the controller the information required by Section 8 or has furnished information which in any material particular was false to his knowledge.
 - n. That the applicant contravened any direction for secrecy passed under Section 35 or made or caused to be made an application for the grant of a patent outside India in contravention of Section 39.
 - o. That leave to amend the complete specification under Section 57 or Section 58 was obtained by fraud.
- 2. For the purposes of clauses (e) and (f) of sub-section (1):
 - a. No account shall be taken of secret use.
 - b. Where the patent is for a process or for a product as made by a process described or claimed, the importation into India of the product made abroad by that process shall constitute knowledge or use in India of the invention on the date of the importation, except where such importation has been for the purpose of reasonable trial or experiment only.
 - 3. For the purpose of clause (l) of sub-section (1), no account shall be taken of any use of the invention:
 - a. For the purpose of reasonable trial or experiment only.
 - b. By the Government or by any person authorised by the Government or by a Government undertaking, in consequence of the applicant for the patent or any person from whom he derives title having communicated or disclosed the invention directly or indirectly to the Government or person authorised as aforesaid or to the Government undertaking.
 - c. By any other person, in consequence of the applicant for the patent or any person from whom he derives title having communicated or disclosed the invention, and without the consent or acquiescence of the applicant or of any person from whom he derives title.
 - 4. A patent may be revoked by the High Court on the petition of the Central Government, if the High Court is satisfied that the patentee has without reasonable cause failed to comply with the request of the Central Government to make, use or

exercise the patented invention for the purposes of Government.

5. A notice of any petition for revocation of a patent under this section shall be served on all persons appearing from the register to be proprietors of that patent or to have shares or interests therein and it shall not be necessary to serve a notice on any other person.

C. Revocation of patent or amendment of complete specification on directions from Government in cases relating to atomic energy:

Where at any time after acceptance of a complete specification, the Central Government is satisfied that an application for a patent is for an invention relating to atomic energy for which no patent can be granted under the Atomic Energy Act, 1962. The Controller may allow the applicant for the patent or the patentee to amend the complete specification in such manner as he considers necessary instead of refusing to proceed with the application or revoking the patent.

D. Revocation of patent in public interest: Where the Central Government is of opinion that a patent or the mode in which it is exercised is mischievous to the State or generally prejudicial to the public, it may, after giving the patentee an opportunity to be heard, make a declaration to that effect in the official gazette and thereupon the patent shall be deemed to be revoked.

REGISTER OF PATENTS

A. Register of patents and particulars to be entered therein:

1. There shall be kept at the patent office a register of patents, wherein shall be entered:
 - a. The names and addresses of grantees of patents.
 - b. Notifications of assignments, extensions, and revocations of patents.
 - c. Particulars of such other matters affecting the validity or proprietorship of patents as may be prescribed.

2. No notice of any trust, whether express, implied or constructive, shall be entered in the register, and the Controller shall not be affected by any such notice.
3. Subject to the superintendence and directions of the Central Government, the register shall be kept under the control and management of the controller.
4. For the removal of doubts, it is hereby declared that the register of patents existing at the commencement of this act shall be incorporated in, and form part of, the register under this Act.

B. Register to be open for inspection: The register shall at all convenient times be open to inspection by the public and certified copies, sealed with the seal of the patent office, and of any entry in the register shall be given to any person requiring them on payment of the prescribed fee. The register shall be *prima facie* evidence of any matters required or authorised by or under this Act to be entered therein.

PATENT OFFICE AND ITS ESTABLISHMENT

A. Controller and other officers:

1. The Controller General of patents, designs and trade marks appointed under the Trade and Merchandise Marks Act, 1958, shall be the controller of patents for the purposes of this Act.
2. For the purposes of this act, the Central Government may appoint as many examiners and other officers and with such designations as it thinks fit.
3. The officers appointed shall discharge under the superintendence and directions of the controller such functions of the controller under this Act as he may, from time to time by general or special order in writing, authorise them to discharge.
4. The Controller may, by order in writing and for reasons to be recorded therein withdraw any matter pending before an officer appointed and deal with such matter himself either *de novo* or from the stage it was so withdrawn or transfer the same to

another officer appointed who may, subject to special directions in the order of transfer, proceed with the matter either *de novo* or from the stage it was so transferred.

B. Patent office and its branches:

1. For the purposes of this act, there shall be an office which shall be known as the patent office.
2. The patent office provided by the Central Government under the Indian Patents and Designs Act, 1911, shall be the patent office under this Act.
3. The head office of the patent office shall be at such place as the Central Government may specify, and for the purpose of facilitating the registration of patents there may be established, at such other places as the Central Government may think fit, branch offices of the patent office.
4. There shall be a seal of the patent office.

WORKING OF PATENTS, COMPULSORY LICENSES, LICENSES OF RIGHTS AND REVOCATION

A. General principle applicable to working of patented inventions: Without prejudice to the other provisions contained in this Act, the following general considerations, namely:

- a. That patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay.
- b. That they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article.

B. Compulsory licenses:

1. At any time after the expiration of 3 years from the date of the sealing of a patent, any person interested may make an application to the Controller alleging that the reasonable requirements of the public with respect to the patented invention have not been satisfied or that the patented invention is not available to the public at a reasonable price and praying for the grant of a compulsory license to work the patented invention.

2. An application under this section may be made by any person notwithstanding that he is already the holder of a license under the patent and no person shall be estopped from alleging that the reasonable requirements of the public with respect to the patented invention are not satisfied or that the patented invention is not available to the public at a reasonable price by reason of any admission made by him, whether in such a license or otherwise or by reason of his having accepted such a license.
3. Every application under sub-section (1) shall contain a statement setting out the nature of the applicant's interest together with such particulars as may be prescribed and the facts upon which the application is based.
4. In considering the application filed under this section.
5. The Controller, if satisfied that the reasonable requirements of the public with respect to the patented invention have not been satisfied or that the patented invention is not available to the public at a reasonable price, may order the patentee to grant a license upon such terms as he may deem fit.
6. Where the Controller directs the patentee to grant a license.

C. Matter to take into account in granting compulsory licenses: The Controller shall take into account:

- i. The nature of the invention, the time which has elapsed since the sealing of the patent and the measures already taken by the patentee or any licensee to make full use of the invention.
- ii. The ability of the applicant to work the invention to the public advantage.
- iii. The capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted, but shall not be required to take into account matters subsequent to the making of the application.

D. Endorsement of patent with the words "licenses of rights": At any time after the

expiration of 3 years from the date of the sealing of a patent, the Central Government may make an application to the Controller for an order that the patent may be endorsed with the words "licenses of right" on the ground that the reasonable requirements of the public with respect to the patented invention have not been satisfied or that the patented invention is not available to the public at a reasonable price.

E. Revocation of patents by the controller for non-working: Where, in respect of a patent, a compulsory license has been granted or the endorsement "licenses of right" has been made or is deemed to have been made, the Central Government or any person interested may, after the expiration of two years from the date of the order granting the first compulsory license or, as the case may be, the date of the grant of the first license under Section 88 (endorsement of patent with the words "licenses of rights"), apply to the controller for an order revoking the patent on the ground that the reasonable requirements of the public with respect to the patented invention have not been satisfied or that the patented invention is not available to the public at a reasonable price. In the case of an application other than by the Central Government, shall also set out the nature of the applicant's interest. The Controller, if satisfied that the reasonable requirements of the public with respect to the patented invention have not been satisfied or that the patented invention is not available to the public at a reasonable price may make an order revoking the patent. Every application shall ordinarily be decided within 1 year of its being presented to the controller.

APPEALS

No appeal shall lie from any decision, order or correction made of issued under this act by the Central Government, or from any act or order of the controller for the purpose of giving effect to any such decision, order or direction. An appeal shall lie to a High Court from any decision, order or direction of the controller. Every appeal under this section shall be in

writing and shall be made within 3 months from the date of the decision.

OFFENCES AND PENALTIES

I. Contravention of secrecy provisions relating to certain inventions: If any person fails to comply with any secrecy directions given for defence purposes, he shall be punishable with imprisonment for a term which may extend to 2 years, or with fine or both.

II. Falsification of entries in register: If any person makes, or causes to be made, a false entry in any register kept under this Act, or a writing falsely purporting to be a copy of an entry in such a register, or produces or tenders, or causes to be produced or tendered, in evidence any such writing knowing the entry or writing to be false, he shall be punishable with imprisonment for a term which may extend to 2 years, or with fine, or both.

III. Unauthorized claim of patents rights: If any person falsely represents that any article sold by him is patented in India or is the subject of an application for a patent in India, he shall be punishable with fine which may extend to 500 rupees.

IV. Practice by non-registered patent agents: If any person contravenes the provisions of Section 129 (provision related to the restrictions on practice as patent agents), he shall be punishable with a fine which may extend to 500 rupees in the case of a first offence and two thousand rupees in the case of a second or subsequent offence.

V. Offences by companies:

1. If the person committing an offence under this act is a company, the company as well as every person in-charge of, and responsible to, the company for the conduct of its business at the time of the commission of the offence shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly.
2. Where an offence under this act has been committed by a company and it is proved that the offence has been committed with the

consent or connivance of, or that the commission of the offence is attributable to any neglect on the part of any director, manager, secretary or other officer of the company, such director, manager, secretary or other officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

PATENT AGENTS

A. Register of patent agents: The Controller shall maintain a register to be called the register of patent agents in which shall be entered the names and addresses of all persons qualified to have their names so entered under Section 126 (qualifications for registration as patent agents).

B. Qualifications for registration as patent agents:

1. A person shall be qualified to have his name entered in the register of patent agents if he fulfils the following conditions, namely:
 - a. He is a citizen of India.
 - b. He has completed the age of 21 years.
 - c. He has obtained a degree from any University in the territory of India or possesses such other equivalent qualifications as the Central Government may specify in this behalf, and, in addition:
 - i. Is an advocate within the meaning of the Advocates Act, 1961.
 - ii. Has passed the qualifying examination prescribed for the purpose.
 - d. He has paid such fee as may be prescribed.
2. A person who has been practicing as a patent agent before the 1st day of November, 1966 and has filed not less than 5 complete specifications before the said day, shall, on payment of prescribed fee, be qualified to have his name entered in the register of patent agents.

C. Rights of patent agents: Subject to the provisions contained in this act and in any rules made thereunder, every patent agent whose name is entered in the register shall be entitled

- a. To practise before the controller.
- b. To prepare all documents, transact all business and discharge such other functions as may be prescribed in connection with any proceeding before the Controller under this Act.

D. Subscription and verification of certain documents by patent agents:

1. The controller under this act may be signed by a patent agent authorised in writing in this behalf by the person concerned.
2. The following documents, namely:
 - i. Applications for patents.
 - ii. Applications for the restoration of lapsed patents.
 - iii. Applications for the sealing of patents after the time allowed has expired.
 - iv. Applications for leave to amend.
 - v. Applications for compulsory licenses or for revocation.
 - vi. Notices of surrender of patents.

Shall be signed and verified in the manner prescribed by the person making such applications or giving such notices. Provided that if such person is absent from India, they may be signed and verified on his behalf by a patent agent authorised by him in writing in that behalf.

INTERNATIONAL ARRANGEMENTS

A. Notification as to convention countries: With a view to the fulfillment of a treaty, convention or arrangement with any country outside India which affords to applicants for patents in India or to citizens of India similar privileges as are granted to its own citizens in respect of the grant of patents and the protection of patent rights, the Central Government may, by notification in the official gazette, declare such country to be a convention country for the purposes of this Act.

B. Convention applications:

1. Without prejudice to the provisions contained in Section 6 (persons entitled to apply for patents) where a person has made an application for a patent in respect of an invention in a convention country (here-

inafter referred to as the "basic application"), and that person or the legal representative or assignee of that person makes an application under this act for a patent within twelve months after the date on which the basic application was made, the priority date of a claim of the complete specification, being a claim based on matter disclosed in the basic application, is the date of making of the basic application.

2. Where applications for protection have been made in one or more convention countries in respect of two or more inventions which are cognate or of which one is a modification of another, a single convention application may, subject to the provisions contained in Section 10 (contents of specifications), be made in respect of those inventions at any time within twelve months from the date of the earliest of the said applications for protection.

PATENT PROTECTION FOR PHARMACEUTICAL PRODUCTS

Patent protection for pharmaceutical products has increased substantially since the 1980s. In fact, the EU currently boasts the highest level of market protection for pharmaceuticals in the world. Patents have been available for biotechnology products since 1998. The old 15 year patent regimes were replaced with modern 20-year product patent in the early 1990s. This 20 year protection can now be increased by up to 5 more years through a Supplementary Protection Certificate (SPC).

- SPCs were introduced in 1992 to compensate originator companies for the time for the time and cost of developing registration data.
- In addition to this 25 year protection, further patents for varying periods are regularly granted to pharmaceutical companies for new uses, indications, dosages and changes in formulation, colour or markings.
- Additional patents, may/may not be of new therapeutic use.

Strategic patenting: Pharmaceutical originators practice "total product strategies" or "life cycle maximization" by seeking to obtain as possible during the development and marketing cycle, and to extend them for new uses of established products, or to add on to the time-lag between patent grant and public health approval.

Common patenting practices:

- Basic composition
- Method of treatment
- Synthetic production
- Formulation and drug delivery
- Prodrugs releasing active ingredient
- Drug metabolites in the body
- Different crystalline or hydrated structures
- Devices such as patches for administration.

Risk of infringement: The complex science and the extent of coverage of pharmaceutical patents therefore introduce considerable risk of infringement into product development, making professional legal and scientific advice essential. There are many genuine disputes over patent validity in comparing inventions, requiring specialist court interpretation.

The business risk of infringement therefore arises in any drug or medical device development. For generics, it arises particularly because a generic medicine is defined as being identical to branded drug interims of active principle, and having the same pharmaceutical form, safety level, and therapeutic effect.

Further protection: Originator pharmaceutical companies in the EU also enjoy, in addition to patent protection, a separate period of regulatory data exclusivity during which the regulatory authorities are not allowed to refer to the data on file for an originator drug in order to process an application for an originator drug in order to process an application for marketing authorization for a generic medicine. The European Commissions has recognized the importance of allowing drugs originators time to recoup R and D investment by harmonizing this protection period in the pharma review.

MISCELLANEOUS

A. Protection of security of India: The Central Government shall not disclose any information relating to any patentable invention or any application relating to the grant of a patent under this act, which it considers prejudicial to the interest of security of India. The Central Government shall take action including the revocation of any patent which it considers necessary in the interest of security of India.

B. Power of High Court to make rules: The High Court may make rules consistent with this act as to the conduct and procedure in respect of all proceedings before it under this Act.

C. Power of Central Government to make rules: The Central Government may, by notification in the official gazette, make rules for carrying out the purposes of this Act.

COPYRIGHTS

Copyright is a form of intellectual property protection granted under the Indian Copyright Act, 1957.

Copyright is a right, which is available for creating an original literary or dramatic or musical or artistic work. Cinematographic films including sound track and video films and recordings on discs, tapes, perforated roll or other devices are covered by copyrights. Computer programs and software are covered under literary works and are protected in India under copyrights. Copyright is a negative right and the owner of a copyright gets the right to prevent others from copying his work without his consent towards a commercial end. However, at the same time it gives the author an exclusive right for the commercial exploitation of his work.

An author, an artist, a composer or a designer looks forward to the commercial benefits accruing from his work, apart from the intellectual satisfaction derived from creating the work. Many a times, unscrupulous traders copy best sellers, or produce pirated versions of a hit-movie or chart topping sound track and sell it at a price that is just a fraction of the original

work. This in turn, eats into the commercial benefits that the author of an original work rightly expects and deserves.

The Copyright Act, 1957 as amended in 1983, 1984, 1992, 1994 and 1999 governs the copyright protection in India. The total term of protection for literary work is the author's life plus sixty years. For cinematographic films, records, photographs, posthumous publications, anonymous publication, works of government and international agencies the term is 60 years from the beginning of the calendar year following the year in which the work was published. For broadcasting, the term is 25 years from the beginning of the calendar year following the year in which the broadcast was made.

Copyright law comes in here and secures the interests of the author, punishes the infringer and thus provides incentive to the creation of original works. A copyright can be transferred or can be assigned or licensed for a consideration. Copyright, unlike the other Intellectual property rights does not require any formal procedures as such and affords protection during the lifetime of the author and sixty-years thereafter.

Copyright gives protection for the expression of an idea and not for the idea itself. For example, many authors write textbooks on physics covering various aspects like mechanics, heat, optics, etc. even though these topics are covered in several books by different authors, each author will have a copyright on the book written by him/her, provided the book is not a copy of some other book published earlier. India is a member of the Berne Convention, an international treaty on copyright. Under this convention, registration of copyright is not an essential requirement for protecting the right. It would, therefore, mean that the copyright on a work created in India would be automatically and simultaneously protected through copyright in all the member countries of the Berne Convention. The moment an original work is created, the creator starts enjoying the copyright. However, an undisputable record of

the date on which a work was created must be kept. When a work is published with the authority of the copyright owner, a notice of copyright may be placed on publicly distributed copies. The use of copyright notice is optional for the protection of literary and artistic works. It is however, a good idea to incorporate a copyright notice. As violation of copyright is a cognizable offence, the matter can be reported to a police station. It is advised that registration of copyright in India would help in establishing the ownership of the work. The registration can be done at the office of the registrar of copyrights in New Delhi. It is also to be noted that the work is open for public inspection once the copyright is registered.

COPYRIGHT PROTECTS WORKS

Copyright protects "original works of authorship" that are fixed in "a tangible form of expression." The fixed form does not have to be directly perceptible so long as it can be communicated with the aid of a machine or other device.

A. Coverage Provided by Copyright

Copyright is a branch of Intellectual property concern with protecting the work of the Human Intellect.

Work protected by copyright:

- i. Literary, dramatic and musical work.
Computer programs/softwares are covered within the definition of literary work.
- ii. Artistic work.
- iii. Cinematographic films, which include sound track and video films, motion pictures and other audiovisual works.
- iv. Dramatic works.
- v. Pictorial (photographs), graphic, and sculptural works.
- vi. Sound recordings, recording on any disc, tape, perforated roll or other device.
- vii. Pantomimes and choreographic works.
- viii. Architectural works.

Note: Copyright protects works that is expression of thoughts, and not ideas.

For example: If you have the idea of painting "Sunset over the sea" any one can use the same idea, which is not protected. But when you actually produce painting of "Sunset over the sea" the painting itself is expression, and that is protected.

B. These Works are not Protected

These works are not protected by copyright:

- i. Ideas, concepts, or discoveries.
- ii. Titles, names, short phrases, and slogans.
- iii. Works that are not fixed in a tangible form of expression such as improvised speech or dance.
- iv. Works consisting entirely of information that is commonly available and contains no originality.
- v. Anything written or created by the US Government.

C. Person Owns Copyright

- i. A person owns copyright who is a freelance artist who created the copyrighted work.
- ii. A person owns copyright who is an employer who hires employees who create copyrighted works as part of their job.

RIGHTS UNDER COPYRIGHT

Two types of rights under copyright:

- i. Economic rights
- ii. Moral rights

Economic rights: These rights allow the owner of rights to drive financial reward from the use of his works by others.

Moral rights: These rights allow the author to take certain action to preserve the personal link between himself and the work.

No requirements that the literary and artistic work should be good or have artistic merits. It should be original. Nobody else can lawfully use it without owner's authorization. The owner of copyright in a protected work may use the work as he wishes, and may prevent others from using it without his authorization.

INFRINGEMENT OF COPYRIGHT

Rights of a copyright holder:

- Right of reproduction
- Right of performance
- Right of broadcasting
- Right of communication

Copyright gives the creator of the work the right to reproduce the work, make copies, translate, adapt, sell or give on hire and communicate the work to public. Any of these activities done without the consent of the author or his assignee is considered infringement of the copyright. There is a provision of 'fair use' in the law, which allows copyrighted work to be used for teaching and research and development. In other words making one photocopy of a book for teaching students may not be considered an infringement, but making many photocopies for commercial purposes would be considered an infringement. There is one associated right with copyright, which is known as the 'moral right', which cannot be transferred and is not limited by the term. This right is enjoyed by the creator for avoiding obscene representation of his/her works. Following acts are considered infringement of copyrights:

- a. In the case of **literary, dramatic or musical work**, not being a computer program:
 - i. To reproduce the work in any material form including the storing of it in any medium by electronic means.
 - ii. To issue copies of the work to the public not being copies already in circulation.
 - iii. To perform the work in public, or communicate it to the public.
 - iv. To make any cinematography film or sound recording in respect of the work.
 - v. To make any translation of the work; to make any adaptation of the work.
 - vi. To do, in relation to a translation or an adaptation of the work, any of the acts specified in relation to the work in sub-clauses (i) to (vi).

b. In the case of **computer program**:

- i. To do any acts specified in clauses (a).
- ii. To sell or give on hire, or offer for sale or hire any copy of the computer program, regardless of whether such copy has been sold or given on hire on earlier occasions.

c. In the case of an **artistic work**:

- i. To reproduce the work in any material form including depiction in three dimensions of a two-dimensional work or in two-dimensions of a three dimensional work.
- ii. To communicate the work to the public.
- iii. To issue copies of the work to the public not being copies already in circulation.
- iv. To include the work in any cinematography film.
- v. To make any adaptation of the work.
- vi. To do, in relation to a translation or an adaptation of the work, any of the acts specified in relation to the work in sub-clauses (i) to (vi).

d. In the case of a **cinematography film**:

- i. To make a copy of the film including a photograph of any image forming part thereof.
- ii. To sell or give on hire or offer for sale or hire, any copy of the film, regardless of whether such copy has been sold or given on hire on earlier occasions.
- iii. To communicate the film to the public.

e. In the case of **sound recording**:

- i. To make any other sound recording embodying it.
- ii. To sell or give on hire or offer for sale or hire, any copy of the ,sound recording, regardless of whether such copy has been sold or given on hire on earlier occasions.
- iii. To communicate the sound recording to the public.

Avoid Infringement

- Obtain a license for all the uses that will be needed.

- Obtain a license to create a derivative image.
- Obtain an art rendering or art reference license to change the medium.

LICENSE

Royalty free:

- May use same image for many uses without additional license—restrictions still apply
- No exclusive use available

Rights managed:

- License limited to particular use and time period—may request and pay for some exclusive use.

TERM OF A COPYRIGHT

- a. If published within the lifetime of the author of a literary work the term is for the lifetime of the author plus 60 years.
- b. For cinematography films, records, photographs, posthumous publications, anonymous' publication, works of government and international agencies the term is 60 years from the beginning of the calendar year following the year in which the work was published.
- c. For broadcasting the term is 25 years from the beginning of the calendar year following the year, in which the broadcast was made.

TRANSFER OF COPYRIGHT

The owner of the copyright in an existing work or prospective owner of the copyright in a future work may assign to any person the copyright, either wholly or partially in the following manner:

- i. For the entire world or for a specific country or territory.
- ii. For the full term of copyright or part thereof.
- iii. Relating to all the rights comprising the copyright or only part of such rights.

DURATION OF COPYRIGHT

- A copyright last for life plus 70 years for individuals for anything on or after 1978.

- A copyright lasts for 95 years for corporate authors after publication for anything on or after 1978 (it is 120 years after creation if not published).
- Works published before 1978 and after 1923 are protected for 95 years.

PUBLIC DOMAIN

- Anything in the public domain is useable by anyone in any way that they want. No one owns it.
- Everything published before 1923 is in the public domain.
- US federal works are in the public domain.
- Authors can choose to put work in the public domain by including a notice that the item is in the public domain.

LIMITATIONS

The "fair use" doctrine allows limited copying of copyrighted works for educational and research purposes. The copyright law provides that reproduction "for purposes such as criticism, news reporting, teaching (including multiple copies for classroom use), scholarship, or research" is not an infringement of copyright.

Fair Use

- Use of material for criticism, comment, news reporting, teaching, scholarship, and research.
- Limitations apply. This includes consideration of the purpose, nature, amount and substantiality, and the effect of the use on potential value of work.

More Fair Use

- Anyone can use excerpts from a book to write a review of it. However, he cannot reproduce whole chapters of the book for reviewing purposes without permission.
- A class dealing with film studies can screen a movie without payment for study purposes. However, no admission can be charged and only students in the class can attend the screening.
- Difficult area that can get people in trouble.

This is not Fair Use

Using a photograph or other image to illustrate a newsworthy story (because the subject of the story is newsworthy it does not make the image newsworthy).

Example of Fair Use

- Class studying an artist using samples to critique and analyze his/her work.
- Making a collage for a school project.
- Manipulating an image to learn Photoshop or other software.

ALTERNATIVES TO COPYRIGHT

- Licenses: Creators can retain copyright but allow people to use content under certain terms. For example, the copyright can give schools to use content for free and without permission.
- Open license: Others can use but must credit original source. Further, any version that others create must also have the open license and be useable by others as well.

COPYRIGHT IN THE NEWS

Many object to recent extensions of copyright terms. Recent legislation extended copyright terms keeping pre-1923 as the beginning of the public domain. Disney and other corporations lobbied for this but it also erodes the concept of public domain as content is staying protected longer.

TRADEMARKS

Trademarks existed in the ancient world also. about 3,000 years ago, Indian craftsmen used to engrave their signatures on their artistic creations before sending them to Iran. Trademark has been used to simplify the identification by consumers of goods or services, as well as their quality and value. Trademark may be considered as a tool of communication used by producers to attack consumers.

Trademark must be distinctive and it should not be deceptive. For example, "apple" while

"apple" is a very distinctive trademark for a computer, because it has absolutely nothing to do with computers, it should not be distinctive for actual apples.

Trademark registration in India gives you a presumption that you are the rightful owner of the mark. **The Trademarks Act, 1999** provides you with statutory damages against any person who uses your mark in bad faith and imposes criminal liabilities for the infringement of the Trademark owner's rights. There is no legal obligation for the Trademark registration in India. However, the user of an unregistered mark can be prevented from continuing or extending use by a later user who does secure a valid registration in good faith. Also, it is, with certain limited restrictions, the first applicant who will be granted registration of the Trademark.

A trademark is a distinctive sign or indicator used by an individual, business organization, or other legal entity to identify that the products or services to consumers with which the trademark appears originate from a unique source, and to distinguish its products or services from those of other entities.

A trademark is designated by the following symbols:

™ (for an unregistered trademark, that is, a mark used to promote or brand goods)

℠ (for an unregistered service mark, that is, a mark used to promote or brand services)

® (for a registered trademark)

A trademark is a type of intellectual property, and typically a name, word, phrase, logo, symbol, design, image, or a combination of these elements. There is also a range of non-conventional trademarks comprising marks which do not fall into these standard categories, such as those based on color, smell, or sound.

The owner of a registered trademark may commence legal proceedings for trademark infringement to prevent unauthorized use of that trademark. However, registration is not required. The owner of a common law trademark may also file suit, but an unregistered

mark may be protectable only within the geographical area within which it has been used or in geographical areas into which it may be reasonably expected to expand.

The term trademark is also used informally to refer to any distinguishing attribute by which an individual is readily identified, such as the well known characteristics of celebrities. When a trademark is used in relation to services rather than products, it may sometimes be called a service mark, particularly in the United States.

I. Concepts of a Trademark: The essential function of a trademark is to exclusively identify the commercial source or origin of products or services, such that a trademark, properly called, indicates source or serves as a badge of origin. In other words, trademarks serve to identify a particular business as the source of goods or services. The use of a trademark in this way is known as trademark use. Certain exclusive rights attach to a registered mark, which can be enforced by way of an action for trademark infringement, while unregistered trademark rights may be enforced pursuant to the common law tort of passing off. It should be noted that trademark rights generally arise out of the use or to maintain exclusive rights over that sign in relation to certain products or services, assuming there are no other trademark objections. Different goods and services have been classified by the International classification of goods and services into 45 trademark classes (1 to 34 cover goods, and 35 to 45 services). The idea of this system is to specify and limit the extension of the intellectual property right by determining which goods or services are covered by the mark, and to unify classification systems around the world.

The two symbols associated with U.S. trademarks ™ (the trademark symbol) and ® (the registered trademark symbol) represent the status of a mark and accordingly its level of protection. While ™ can be used with any common law usage of a mark, ® may only be used by the owner of a mark following registration with the relevant national authority,

such as the U.S. patent and trademark office (USPTO or PTO). The proper manner to display either symbol is immediately following the mark in superscript style.

Terms such as "mark", "brand" and "logo" are sometimes used interchangeably with "trademark". "Trademark", however, also includes any device, brand, label, name, signature, word, letter, numerical, shape of goods, packaging, colour or combination of colours, smell, sound, movement or any combination thereof which is capable of distinguishing goods and services of one business from those of others. It must be capable of graphical representation and must be applied to goods or services for which it is registered.

Specialized types of trademark include certification marks, collective trademarks and defensive trademarks. A trademark which is popularly used to describe a product or service (rather than to distinguish the product or services from those of third parties) is sometimes known as a genericized trademark. If such a mark becomes synonymous with that product or service to the extent that the trademark owner can no longer enforce its proprietary rights, the mark becomes generic.

A trademark is a distinctive sign, which identifies certain goods or services as those produced or provided by a specific person or enterprise. Trademarks may be one or combination of words, letters, and numerals. They may also consist of drawings, symbols, three-dimensional signs such as shape and packaging of goods, or colours used as distinguishing feature. Collective marks are owned by an association whose members use them to identify themselves with a level of quality. Certification marks are given for compliance with defined standards. (example ISO 9000). A trademark provides to the owner of the mark by ensuring the exclusive right to use it to identify goods or services, or to authorize others to use it in return for some consideration (payment).

Well-known trademark in relation to any goods or services, means a mark which has

become so to the substantial segment of the public which uses such goods or receives such services that the use of such mark in relation to other goods or services would be likely to be taken as indicating a connection in the course of trade or rendering of services between those goods or services and a person using the mark in relation to the first-mentioned goods or services.

Enactment of the Indian Trademarks Act 1999 is a big step forward from the Trade and merchandise Marks Act, 1958 and the Trademark Act, 1940. The newly enacted act has some features not present in the 1958 Act and these are:

1. Registration of service marks, collective marks and certification trademarks.
2. Increasing the period of registration and renewal from 7 years to 10 years.
3. Allowing filing of single application for registration in more than one class.
4. Enhanced punishment for offences related to trademarks.
5. Exhaustive definitions for terms frequently used.
6. Simplified procedure for registration of registered users and enlarged scope of permitted use.
7. Constitution of an appellate board for speedy disposal of appeals and rectification applications which at present lie before High Court.

II. Well-known trademarks and associated trademarks: A well-known trademark in relation to any goods or services means a mark which has become known to the substantial segment of the public that uses such goods or receives such services. Associated Trademarks are, in commercial terms, marks that resemble each other and are owned by the same owner, but are applied to the same type of goods or services. For example, a company dealing in readymade garments may use associated marks for shirts, trousers, etc. means trademarks deemed to be, or required to be, registered as associated trademarks under this Act.

III. Service marks: The Indian Act of 1958 did not have any reference to service marks. Service means service of any description that is made available to potential users and includes the provision of services in connection with the business of industrial or commercial matters such as banking, communication, education, financing, insurance, chit funds, real estate, transport, storage, material treatment, processing, supply of electrical or other energy, boarding, lodging, entertainment, amusement, construction, repair, conveying of news or information and advertising. Marks used to represent such services are known as service marks.

IV. Certification trademarks and collective marks: A certification trademark means a guarantee mark which indicates that the goods to which it is applied are of a certain quality or are manufactured in a particular way or come from a certain region or uses some specific material or maintains a certain level of accuracy. The goods must originate from a certain region rather from a particular trader. Certification marks are also applicable to services and the same parameters will have to be satisfied. Further these marks are registrable just like any other trademark. Agmark used in India for various food items is a kind of certification mark although it is not registered as a certification mark; the concept of certification mark was not in vogue at the time of introduction of agmark. A collective mark means a trademark distinguishing from those of others, the goods or services of members of an association of persons (not being a partnership within the meaning of the Indian Partnership Act, 1932), which is the proprietor of the mark.

V. Companies prevent other people from using trademark: It must first be registered in the trade register. Once it has been registered it is protected. Its owner is entitled to prohibit others from using it. To secure a trademark worldwide, it involves registration in every single country and indeed every single territory because trademarks are territorial rights, means that their protection is obtained by national registration.

VI. Registration: The law considers a trademark to be a form of property. Proprietary rights in relation to a trademark may be established through actual use in the marketplace, or through registration of the mark with the trademarks office (or "trademarks registry") of a particular jurisdiction. In some jurisdictions, trademark rights can be established through either or both means. Certain jurisdictions generally do not recognize trademarks rights arising through use. If trademark owners do not hold registrations for their marks in such jurisdictions, the extent to which they will be able to enforce their rights through trademark infringement proceedings will therefore be limited. In cases of dispute, this disparity of rights is often referred to as "first to file" as opposed to "first to use." Other countries such as Germany offer a limited amount of common law rights for unregistered marks where to gain protection, the goods or services must occupy a highly significant position in the marketplace—where this could be 40% or more market share for sales in the particular class of goods or services.

A registered trademark confers a bundle of exclusive rights upon the registered owner, including the right to exclusive use of the mark in relation to the products or services for which it is registered. The law in most jurisdictions also allows the owner of a registered trademark to prevent unauthorized use of the mark in relation to products or services which are identical or "colourfully" similar to the "registered" products or services, and in certain cases, prevent use in relation to entirely dissimilar products or services. The test is always whether a consumer of the goods or services will be confused as to the identity of the source or origin. An example may be a very large multinational brand such as "Sony" where a non-electronic product such as a pair of sunglasses might be assumed to have come from Sony Corporation of Japan despite not being a class of goods that Sony has rights in. Once trademark rights are established in a particular jurisdiction, these rights are generally only

enforceable in that jurisdiction, a quality which is sometimes known as territoriality. However, there is a range of international trademark laws and systems which facilitate the protection of trademarks in more than one jurisdiction.

VII. Term of a registered Trademark: The initial registration of a trademark shall be for a period of 10 years but may be renewed from time to time for an unlimited period by payment of the renewal fees.

VIII. Consumer protection: Trademark law is designed to fulfill the public policy objective of consumer protection, by preventing the public from being misled as to the origin or quality of a product or service. By identifying the commercial source of products and services, trademarks facilitate identification of products and services which meet the expectations of consumers as to quality and other characteristics.

Trademarks may also serve as an incentive for manufacturers, providers or suppliers to consistently provide quality products or services in order to maintain their business reputation. Furthermore, if a trademark owner does not maintain quality control and adequate supervision in relation to the manufacture and provision of products or services supplied by a licensee, such "naked licensing" will eventually adversely affect the owner's rights in the trademark.

IX. International law: It is important to note that although there are systems which facilitate the filing, registration or enforcement of trademark rights in more than one jurisdiction on a regional or global basis (e.g. the Madrid and CTM systems, see further below), it is currently not possible to file and obtain a single trademark registration which will automatically apply around the world. Like any national law, trademark laws apply only in their applicable country or jurisdiction, a quality which is sometimes known as "territoriality".

X. Territorial application: The inherent limitations of the territorial application of trademark laws have been mitigated by various intellectual property treaties, foremost amongst which is the

WTO agreement on Trade-Related Aspects of Intellectual Property Rights. TRIPS establish legal compatibility between member jurisdictions by requiring the harmonization of applicable laws. For example, article 15 (1) of TRIPS provides a definition for "sign" which is used as or forms part of the definition of "trademark" in the trademark legislation of many jurisdictions around the world.

MADRID AGREEMENT

International agreement on registration of service and trade marks under which a single application to World Intellectual Property Organization (WIPO) suffices to register a mark in all member countries.

The Madrid Agreement was adopted on April 14, 1891 to facilitate protection of a trademark or service mark in several countries by means of a single international registration. As on July 15, 1999, 54 countries are party to this Agreement mainly belonging to Europe, countries of Africa and four countries in the Far East namely, China, the Democratic People's Republic of Korea, Mongolia and Vietnam. The United Kingdom, the United States of America, most Latin American countries, Japan and India are not signatories to this agreement. The Agreement covers both trademarks and service marks.

Features of the Madrid Agreement: Main features of the Madrid Agreement are as follows:

1. An applicant must be a national of a member country. A person having his domicile or a real and effective industrial or commercial interest in such a country is also eligible. It may be noted that this would be governed by the national laws of the country in question.
2. A mark to be registered in member states should be first registered at the national level in the country of origin of the applicant. The first registration is called 'basic registration'.
3. The country having given the basic registration can only transmit there quest for

international filing to the International Bureau of the World Intellectual Property Organization (WIPO) along with the list of the countries in which protection is being sought. There is no provision for directly filing a request under the Agreement.

4. It may be iterated that the country of origin has to be a member state. The role of the office of the country of origin is not only to send the application for international registration but also to certify that the mark which is the subject of the international registration is the same mark which is the subject of the basic registration.
5. For each application fees has to be paid for each designated country and WIPO. The fees paid for the designated countries are called the 'complementary fee'.
6. The International Bureau notifies the international registration to the offices of the designated countries and publishes it in a monthly periodical called 'The WIPO Gazette of International Marks'.
7. If the basic registration is cancelled for some reasons, in the country of origin, during the first five years, the international registration automatically stands cancelled in all the designated countries. This also gives an advantage to a person to oppose the registration of a mark only in the country of origin and that person need not oppose it in all the designated countries. This possibility of challenging an international registration through a national registration is referred to as 'Central attack' feature of the agreement.

THE MADRID PROTOCOL

The Protocol relating to the Madrid Agreement concerning the international registration of marks was adopted at Madrid on June 27, 1989. The Protocol, which entered into force on December 1, 1995, retains the basic features of the Madrid Agreement. As on July 15, 1999, 39 countries have acceded to the Protocol. The Protocol was formed to remove some of the

features of the Madrid Agreement, which posed some obstacles to accession by several countries. These features are:

1. For an international registration, it is essential to first register a mark at the national level. The time required for obtaining a mark at the national level varies from country to country. Hence, some parties do suffer.
2. Within one year, a designated member country has to examine and issue a notice of refusal by giving all the grounds for refusal. The period was considered short.
3. A uniform fee is paid for the designation of a member country. This was found to be inappropriate for countries with high level of national fees.
4. An international registration is linked to the basic registration during the initial five years and the former gets cancelled if latter is cancelled. The fact, that grounds under which a mark is cancelled in the country of origin need not necessarily exist in every other designated country, is overlooked.
5. The only working language of the Madrid Agreement is French.

Innovations Introduced by the Madrid Protocol

1. An international application need not necessarily be based on a registration made by the office of origin but can also be based on an application filed with the office of origin. This makes it convenient for countries with full examination system where the national registration takes time. It also makes it possible to claim the right of priority of six months under the Paris Convention.
2. A contracting party can receive the fee under the existing Madrid Treaty system through its share in the international fees collected: for each designation made as in the Madrid Treaty. Alternatively, the member country can choose "Individual fee" system for each designation made, which should be an

amount not more than the national fee for a ten-year registration. The "Individual fee" system makes an attractive proposition for countries with high level of national fees.

3. It is possible to transform an international registration into national or regional application in the designated contracting Parties, if the basic registration is cancelled for some reasons, as in the case of "central attack".
4. An applicant may choose to base an international registration in any of the contracting States with which he has connection through nationality, domicile or establishment.

DIFFERENT BETWEEN THE TRADEMARKS ACT, 1999 AND THE TRADE AND MERCHANDISING MARKS ACT, 1958

Enactment of the Trademarks Act, 1999 is a big step forward from the Trade and Merchandise Marks Act 1958 and the Trademark Act 1940. The newly enacted Act has some features not present in the 1958 Act and these are:

1. Registration of service marks, collective marks and certification trademarks.
2. Increasing the period of registration and renewal from 7 years to 10 years.
3. Allowing filing of single application for registration in more than one class.
4. Enhanced punishment for offences related to trademarks.
5. Exhaustive definitions for terms frequently used.
6. Simplified procedure for registration of registered users and enlarged scope of permitted use.
7. Constitution of an appellate board for speedy disposal of appeals and rectification applications which at present lie before High Court.

REGISTERED (INDUSTRIAL) DESIGN

There are so many varieties and brands of the same product (e.g. car, television, personal

computer, a piece of furniture, etc.) in the market, which look quite different from each other. If the products have similar functional features or have comparable price tags, the eye appeal, or visual design of a product determines the choice. Even if the similarities are not close, a person may decide to go for a more expensive item because that item has a better look or colour scheme.

The external design or colour scheme or ornamentation of a product plays a key role in determining the market acceptability of the product over other similar products. A good design that gives an advantage, then a system must be available to protect its features otherwise there would be wide scale imitation.

Design as per the Indian act means the features of shape, configuration, pattern, ornament or composition of lines or colours applied to any article—whether in two-dimensional or three dimensional or in both forms by any industrial process or means, whether manual, mechanical or chemical, separate or combined, which in the finished article appeal to and are judged solely by the eye but it does not include any mode or principle of construction or anything which is in substance a mere mechanical device. In this context an article means any article of manufacture and any substance, artificial, or partly artificial and partly natural; and includes any part of an article capable of being made and sold separately. Stamps, labels, tokens, cards, etc. cannot be considered an article for the purpose of registration of design because once the alleged design, i.e. ornamentation is removed only a piece of paper, metal or like material remains and the article referred to ceases to exist. An article must have its existence independent of the designs applied to it. So, the design as applied to an article should be integral with the article itself. The design law in India is governed by the designs Act, 2000. The old Design Act, 1911 was amended in 2000 to incorporate the amendments which were rendered necessary because of the tremendous progress made by India in the field of science and technology. The said Act was

amended with a view to provide more protection to registered designs and to promote design activity in order to promote design element in an article of production.

Object of registration of designs: Object of the designs act is to protect new or original designs so created to be applied or applicable to particular article to be manufactured by industrial process or means. Sometimes purchase of articles for use is influenced not only by their practical efficiency but also by their appearance. The important purpose of design registration is to see that the artisan, creator, originator of a design having aesthetic look is not deprived of his bona fide reward by others applying it to their goods.

THE DESIGNS ACT, 1911

This Act may be called the Designs Act, 1911. It extends to the whole of India. It shall come into force on the first day of January, 1912.

DEFINITIONS

- a. **"Article"** means any article of manufacture and any substance, artificial or natural or partly artificial and partly natural.
- b. **"Controller"** means the controller general of patents, designs and trademarks appointed under sub-section (1) of Section 4 (registrar of trade marks) of the Trade and Merchandise Marks Act, 1958.
- c. **"Copyright"** means the exclusive right to apply a design to any article in any class in which the design is registered.
- d. **"Design"** means only the features of shape, configuration, pattern or ornament applied to any article by any industrial process or means, whether manual, mechanical or chemical, separate or combined, which in the finished article appeal to and are judged solely by the eye; but does not include any mode or principle of construction.
- e. **"Legal Representative"** means a person who in law represents the estate of a deceased person.

THE REGISTRATION OF DESIGN

A. The essential requirements for the registration of design:

1. The design should be new or original, not previously published or used in any country before the date of application for registration. The novelty may reside in the application of a known shape or pattern to a new subject matter. However, if the design for which the application is made does not involve any real mental activity for conception, then registration may not be considered.
2. The design should relate to features of shape, configuration, pattern or ornamentation applied or applicable to an article. Thus, designs of industrial plans, layouts and installations are not registrable under the act.
3. The design should be applied or applicable to any article by any industrial process. Normally, designs of artistic nature such as painting, sculptures and the like which are not produced in bulk by any industrial process are excluded from registration under the Act.
4. The features of the designs in the finished article should appeal to and are judged solely by the eye. This implies that the design must appear and should be visible on the finished article, for which it is meant. Thus, any design in the inside arrangement of a box, money purse or almirah may not be considered for showing such articles in the open state, as those articles are generally put in the market in the closed state.
5. Any mode or principle of construction or operation or any thing, which is in substance a mere mechanical device, would not be a registrable design. For instance, a key having its novelty only in the shape of its corrugation or bend at the portion intended to engage with levers inside the lock it is associated with, cannot be registered as a design under the act. However, when any design suggests any mode or principle of construction or mechanical or other action of a mechanism, a suitable disclaimer in

respect thereof is required to be inserted on its representation, provided there are other registrable features in the design.

6. The design should not include any trademark or property mark or artistic works.
7. It should be significantly distinguishable from known designs or combination of known designs.
8. It should not comprise or contain scandalous or obscene matter.

B. Application for registration of designs:

1. The Controller may, on the application of any person claiming to be the proprietor of any new or original design not previously published in India, register the design under this part.
2. The application must be made in the prescribed form and must be left at the patent office in the prescribed manner and must be accompanied by the prescribed fee.
3. The same design may be registered in more than one class, and, in case of doubt as to the class in which a design ought to be registered, the Controller may decide the question.
4. The Controller may, if he thinks fit, refuse to register any design presented to him for registration, but any person aggrieved by any such refusal may appeal to the Central Government.
5. An application owing to any default or neglect on the part of the applicant, has not been completed so as to enable registration to be effected within the prescribed time shall be deemed to be abandoned.
6. A design when registered shall be registered as of the date of the application for registration.

C. Registration of designs in new classes:

Where a design has been registered in one or more classes of goods, the application of the proprietor of the design to register it in some one or more other classes shall not be refused, nor shall the registration thereof be invalidated:

- a. On the ground of the design not being a new or original design, by reason only that it was so previously registered.
- b. On the ground of the design having been previously published in India, by reason only that it has been applied to goods of any class in which it was so previously registered.

D. Certificate of registration: The Controller shall grant a certificate of registration to the proprietor of the design when registered. The Controller may, in case of loss of the original certificate, or in any other case, in which he deems it expedient, furnish one or more copies of the certificate.

E. Duration of the registration of a design: The total term of a registered design is 15 years. Initially the right is granted for a period of 10 years, which can be extended, by another 5 years by making an application and by paying a fee of Rs. 2,000/- to the Controller before the expiry of initial 10 years period. The proprietor of design may make the application for such extension even as soon as the design is registered.

F. Register of designs:

1. There shall be kept at the patent office a book called the register of designs, wherein shall be entered the names and addresses of proprietors of registered designs, notifications of assignments and of transmissions of registered designs, and such other matters as may be prescribed.
2. The register of designs existing at the commencement of this act shall be incorporated with and form part of the register of designs under this Act.
3. The register of designs shall be prima facie evidence of any matters by this Act directed or authorised to be entered therein. Copyright in registered designs. Copyright in registered designs.

G. Copyright on registration:

1. When a design is registered, the registered proprietor of the design shall, subject to the provisions of this act, have copyright in the design during five years from the date of registration.

2. If before the expiration of the said five years application for the extension of the period of copyright is made to the Controller in the prescribed manner, the Controller shall on payment of the prescribed fee, extend the period of copyright for a second period of five years from the expiration of the original period of five years.
3. If before the expiration of such second period of five years application for the extension of the period of copyright is made to the Controller in the prescribed manner, the Controller may, subject to any rules under this act, on payment of the prescribed fee, extend the period of copyright for a third period of five years from the expiration of the second period of five years.

H. Inspection of registered designs:

1. During the existence of copyright in a design, or such shorter period not being less than two, years from the registration of the design as may be prescribed, the design shall not be open to inspection except by the proprietor or a person authorized in writing by him, or a person authorized by the Controller or by the Court, and furnishing such information as may enable the Controller to identify the design, and shall not be open to the inspection of any person except in the presence of the controller, or of an officer acting under him, and on payment of the prescribed fee and the person making the inspection shall not be entitled to take any copy of the design, or of any part thereof: Provided that, where registration of a design is refused on the ground of identity with a design already registered, the applicant for registration shall be entitled to inspect the design so registered.
2. After the expiration of the copyright in a design, or such shorter period as aforesaid, the design shall be open to inspection, and copies thereof may be taken by any person on payment of the prescribed fee.
3. Different periods may be prescribed under this section, for different classes of goods.

I. Information as to existence of copyright: On the request of any person furnishing such information as may enable the Controller to identify the design, and on payment of the prescribed fee, the Controller shall inform such person whether the registration still exists in respect of the design, and, if so, in respect of what classes of goods and shall state the date of registration, and the name and address of the registered proprietor.

CANCELLATION OF REGISTRATION

1. Any person interested may present a petition for the cancellation of the registration of a design:
 - a. At any time after the registration of the design, to the High Court on any of the following grounds, namely:
 - i. That the design has been previously registered in India.
 - ii. That it has been published in India prior to the date of registration.
 - iii. That the design is not a new or original design.
 - b. Within one year from the date of the registration, to the Controller on either of the grounds specified in sub-clauses (i) and (ii) of clause (a).
2. An appeal shall lie from any order of the Controller under this section to the High Court, and the Controller may at any time refer any such petition to the High Court, and the High Court shall decide any petition so referred.

PIRACY OF REGISTERED DESIGN

1. During the existence of copyright in any design it shall not be lawful for any person:
 - a. For the purpose of sale to apply or cause to be applied to any article in any class of goods in which the design is registered, the design or any fraudulent or obvious imitation thereof, except with the license or written consent of the registered proprietor, or to do anything with a view to enable the design to be so applied.

- b. To import for the purposes of sale, without the consent of the registered proprietor, any article belonging to the class in which the design has been registered, and having applied to it the design or any fraudulent or obvious imitation thereof.
- c. Knowing that the design or any fraudulent or obvious imitation thereof has been applied to any article in any class of goods in which the design is registered without the consent of the registered proprietor, to publish or expose or cause to be published or exposed for sale that article.
2. If any person acts in contravention of this section, he shall be liable for every contravention:
 - a. To pay to the registered proprietor of the design a sum not exceeding five hundred rupees recoverable as a contract debt.
 - b. If the proprietor elects to bring a suit for the recovery of damages for any such contravention, and for an injunction against the repetition thereof, to pay such damages as may be awarded and to be restrained by injunction accordingly: Provided that the total sum recoverable in respect of any one design under clause (a) shall not exceed one thousand rupees.
3. When the Court makes a decree in a suit under sub-section (2), it shall send a copy of the decree to the Controller, who shall cause an entry thereof to be made in the register of designs.

PENALTIES

Contraventions of a copyright in a design is an offence and for every such offence the person liable may have to pay to the registered proprietor a sum not exceeding rupees five hundred (500 rupees) subject to maximum of Rs. 1,000.

STRATEGY FOR PROTECTION

First to file rule is applicable for registrability of design. If two or more applications relating

to an identical or a similar design are filed on different dates, the first application will be considered for registration of design. Therefore the application should be filed as soon as you are ready with the design. After publication in the official gazette on payment of the prescribed fee of Rs. 500/- all registered designs are open for public inspection. Therefore, it is advisable to inspect the register of designs to determine whether the design is new or not. There is yet another important provision for ensuring that the design is different from anything published anywhere in the world. This is quite a strict condition. There would be many designs, which are not protected, and these would not be part of any database maintained by design offices. An applicant has to take the responsibility of ensuring that he has done an extensive search and satisfied himself of the novelty of his design. However, in practice as the cost involved in filing and obtaining a design registration is not high, a design application is made if the stakes involved are not high and you have not copied any design. The application for registration of design can be filed by the applicant himself or through a professional person (i.e. patent agent, legal practitioner, etc.). An agent residing in India has to be employed by the applicants not resident of India.

Prohibition of publication of specification, drawings, etc., where application abandoned, etc.: Where an application for a design has been abandoned or refused, the application and any drawings, photographs, tracings, re-presentations or specimens left in connection with the application shall not at any time be open to public inspection or be published by the controller.

PROTECTION OF INTEGRATED CIRCUIT (IC) LAYOUT DESIGN

It provides protection for semiconductor IC layout designs. India has now in place Semiconductor Integrated Circuits Layout Design Act, 2000 to give protection to IC layout design. Layout design includes a layout of transistors

and other circuitry elements and includes lead wires connecting such elements and expressed in any manner in a semiconductor IC. Semiconductor IC is a product having transistors and other circuitry elements, which are inseparably formed on a semiconductor material or an insulating material or inside the semiconductor material and designed to perform an electronic circuitry function. The term of the registration is 10 years from the date of filing.

PROTECTION OF GEOGRAPHICAL INDICATIONS

Indications which identify a good as originating in the territory of a member or a region or a locality in that territory, where a given quality reputation or other characteristics of the good is attributable to its geographical origin. The concept of identifying GI and protecting them is a new concept in India, perhaps in most developing countries, and has come to knowledge in these countries after they signed the TRIPS agreement. It may be noted that properly protected GI will give protection in domestic and international market. Stipulations of TRIPS would be applicable to all the member countries. According to TRIPS, GI which is not or cease to be protected in its country of origin or which has fallen into disuse in that country cannot be protected. Homonymous GI for wines will get independent protection. Each state shall determine conditions under which homonymous indications will be differentiated from each other. Principles of national treatment and fair competition are applicable. TRIPS provide for seizure of goods bearing false indications of GI. TRIPS provide for refusal or invalidation of registration of a trademark containing a GI with respect to goods not originating in the territory indicated. The geographical Indication of goods (registration and protection) act came into being in 2000.

Geographical indications: The term GI has been defined as "Geographical Indications", in relation to goods, means an indication which identifies such goods as agricultural goods,

natural goods or manufactured goods as originating, or manufactured in the territory of a country, or a region or locality in that territory, where a given quality, reputation or other characteristics of such goods is essentially attributable to its geographical origin and in case where such goods are manufactured goods one of the activities of either the production or of processing or preparation of the goods concerned takes place in such territory, region or locality, as the case may be.

PROTECTION OF UNDISCLOSED INFORMATION

The protected subject matter is information lawfully within the control of a natural person or legal person that is secret that has commercial value because it is secret and that has been subject to reasonable steps by the person lawfully in control of the information, to keep it secret. Secret is defined as "secret in the sense that it is not, as a body or in the precise configuration and assembly of its components known among or readily accessible to persons

within the circles that normally deal with the kind of information in question." Undisclosed information, generally known as trade secret/confidential information, includes formula, pattern, compilation, programme, device, method, technique or process. Protection of undisclosed information is least known to players of IPR and also least talked about, although it is perhaps the most important form of protection for industries, R and D institutions and other agencies dealing with IPRs.

Protection of undisclosed information/trade secret is not really new to humanity; at every stage of development people have evolved methods to keep important information secret, commonly by restricting the knowledge to their family members. Laws relating to all forms of IPR are at different stages of implementation in India, but there is no separate and exclusive law for protecting undisclosed information/trade secret or confidential information. The Contract Act of 1872 would however cover many aspects of trade secrets.

The Consumer Protection Act, 1986

INTRODUCTION

Though consumer, is the purpose and most powerful motivating force of production, yet at the same time consumer is equally vulnerable segment of the whole marketing system. Attempts have been made to guard the interest of the consumer in a sporadic way till 1986, when Government of India enacted a comprehensive legislation—Consumer Protection Act, to safe guard the interest of the consumer then ever before. The Consumer Protection Act, 1986, applies to all goods and services, excluding goods for resale or for commercial purpose and services rendered free of charge and under a contract for personal service. The provisions of the act are compensatory in nature. It covers public, private, joint and cooperative sectors.

The act enshrines the rights of the consumer such as right to safety, right to be informed, right to be heard, and right to choose, right to seek redressal and right to consumer education.

DEFINITIONS

Consumer: A consumer is any person who buys any goods for a consideration and user of such goods where the use is with the approval of buyer, any person who hires/avails of any service for a consideration and any beneficiary of such services, where such services are availed of with the approval of the person hiring the service. The consumer need not have made full payment.

Goods: Goods mean any movable property and also include shares, but do not include any actionable claims.

Service: Service of any description such as banking, insurance, transport, processing, housing construction, supply of electrical energy, entertainment, board or lodging.

Nature of Complaint

- a. Any unfair trade practice or restrictive trade practice adopted by the trader.
- b. Defective goods.
- c. Deficiency in service.
- d. Excess price charged by the trader.
- e. Unlawful goods sale, which is hazardous to life and safety when used.

Consumer courts: A three-tier-system.

National consumer dispute redressal commission: claims above ₹ 20 lakh.

Consumer dispute redressal commission or state commission: Claims from ₹ 5 to 20 lakh.

Consumer dispute redressal forum or district forum: Claims up to ₹ 5 Lakh.

Complaint

A complaint, hand written or typed, can be filed by a consumer, a registered consumer organization, Central or State Government and one or more consumers, where there are numerous consumers having the same interest.

No stamp or court fee is needed. The nature of complaint must be clearly mentioned as well

as the relief sought by the consumer. It must be in quadruplicate in district forum or state commission. Else, additional copies are required to be filed.

GRANT OF RELIEF

- a. Repair of defective goods.
- b. Replacement of defective goods.
- c. Refund of the price paid for the defective goods or service.
- d. Removal of deficiency in service.
- e. Refund of extra money charged.
- f. Withdrawal of goods hazardous to life and safety.
- g. Compensation for the loss or injury suffered by the consumer due to negligence of the opposite party.

- h. Adequate cost of filing and pursuing the complaint.

Normally, complaints should be decided within 90 days from the date of notice issued to the opposite party. Where a sample of any goods is required to be tested, a complaint is required to be disposed of within 150 days, it may take more time due to practical problems.

Consumer Protection Councils

Councils have been set up in all states and at the center to promote and protect the rights and interest of consumers. These councils are advisory in nature and can play an important role in recommending consumer oriented policies to the State and Central Government.

CHAPTER

18

The Standard of Weights and Measures Act, 1976

INTRODUCTION

With a view to provide a coherent scheme and uniform standards of weights and measures, the first act namely standards of W and M Act, 1956 was enacted based on metric system and international system of units recognized by International Organization of Legal Metrology (OIML). With regard to keep pace with rapid advances made in the field of science and technology all over the world, CGPM evolved a practical system of units known as SI units (abbreviated SI from the French *Le système International d'unités*) to facilitate working. It includes seven base units, two supplementary units and about 50 devised units enimated from six primary units established by 1956 Act. The OPML, responsible for preparation of International laws, on legal metrology prepared the draft of legislation for enactment by member countries adopting metric convention. India is one of the members of OIML (international organization of legal metrology).

Objectives

An Act to establish standards of weights and measures, to regulate inter-state trade or commerce in weights, measures and other goods which are sold or distributed by weight, measure or number, and to provide for matters connected therewith or incidental thereto be enacted by parliament in the twenty-seventh year of the republic of India.

DEFINITIONS

In this act, unless the context otherwise requires:

- a. “**Calibration**” means all the operations which are necessary for the purpose of determining the values of the errors of a weight or measure and, if necessary, to determine the other metrological properties of such weight or measure, and includes the actual fixing of the positions of the gauge-marks or scale-marks of a weight or measure, or in some cases, of certain principal marks only, in relation to the corresponding values of the quantity to be measured.
Explanation: Calibrating may also be carried out with a view to permitting the use of a weight or measure as a standard.
- b. “**Commodity in packaged form**” means commodity packaged, whether in any bottle, tin, wrapper or otherwise, in units suitable for sale, whether wholesale or retail.
- c. “**Dealer**”, in relation to any weight or measure, means person who, or a firm or a Hindu undivided family which carries on directly or otherwise, the business of buying, selling, supplying or distributing any such weight or measure, whether for cash or for deferred payment or for commission, remuneration or other valuable consideration, and includes:

- i. A commission agent who carries on such business on behalf of any principal.
- ii. An importer who sells, supplies, distributes or otherwise delivers any weight or measure to any user, manufacturer, repairer, consumer or any other person, but does not include a manufacturer who sells, supplies, distributes or otherwise delivers any weight or measure to any person or category of persons referred to in this clause.
- d. "**False package**" means any package which does not conform to the provisions of this act or any rule or order made there under in relation to such package.
- e. "**False weight or measure**" means any weight or measure which does not conform to the standards established by or under this act in relation to that weight or measure.
- f. "**International prototype of the kilogram**" means the prototype sanctioned by the first general conference on weights and measures held in Paris in 1889 and deposited at the International Bureau of Weights and Measures.
- g. "**Weighing or measuring instrument**" means any object, instrument, apparatus or device, or any combination thereof, which is, or is intended to be, used, exclusively or additionally, for the purpose of making any weighment or measurement, and includes any appliance, accessory or part associated with any such object, instrument, apparatus or device.
- h. "**Weight or measure**" means a weight or measure specified by or under this Act, and includes a weighing or measuring instrument.
- i. "**Working standard**" means the set of standard weight or measure which is made or manufactured by or on behalf of Government for the verification of any standard weight or measure, other than a national prototype or national reference or secondary standard.

ESTABLISHMENT OF STANDARDS OF WEIGHTS AND MEASURES

Standard Units

Every unit of weight or measure shall be based on the units of metric system.

Following shall be the base unit (Table 18.1).

The Central Government may, by rules made in this behalf, specify, in relation to the base units of weight or measure, such supplementary, derived, or other units or standard symbols or definitions as the general conference on weights and measures or the international organization of legal metrology may recommend. "derived unit" means a unit which is derived from the base, or supplementary units, or both. The Central Government may, by rules made in this behalf, specify, such multiples and sub-multiples of, and physical constants, and ratios or coefficients in relation to, units of weight or measure as the general conference on weights and measures or the international organization of Legal Metrology may recommend. The Central

Table 18.1: Base units

Length	Meter
Mass	Kilogram
Time	Second
Electric current	Ampere
Temperature	Kelvin
Luminous intensity	Candela
Amount of the substance	Mole

Government may, by notification, declare, for such period as it may consider necessary such special units of weight or measure as the general conference on weights and measures or the international organization of legal metrology may recommend.

The base unit of numeration shall be the unit of the international form of Indian numerals. Every numeration shall be made in accordance with the decimal system. The decimal multiples and sub-multiples of the numerals shall be of such denominations and be written in such manner as the Central Government may, after previous publication, specify by rules made in this behalf. Provided that no such rule shall be made before the expiry of 6 months from the date on which the draft of the proposed rules was first published in the official gazette.

PHYSICAL REPRESENTATION OF STANDARD UNITS

A. **National prototypes:** For the purpose of deriving the value of the kilogram or metre, the Central Government shall cause to be prepared a national prototype of the kilogram and shall cause its accuracy to be certified by the International Bureau of Weights and Measures in terms of the international prototype of the kilogram and shall deposit the same in such custody and at such place as that government may think fit.

B. **National standards:** For the purpose of deriving the value of the base units, other than the base unit of mass, and the value of the supplementary and other specified units, the Central Government shall cause to be prepared such objects or equipments, or both, as may be necessary.

C. **Reference, secondary and working standards:**

1. Every:
 - a. Reference standard.
 - b. Secondary standard.
 - c. Working standard, shall conform to the standards established by or under this act and be verified and authenticated at such periodical intervals and in such manner as may be prescribed.

2. Every reference standard, every secondary standard and every working standard shall be kept in such manner and under such conditions as may be prescribed.

D. **Power of Central Government to prescribe physical characteristics of weights and measures:** The Central Government shall, in relation to any weight or measure, prescribe the physical characteristics, configuration, constructional details, materials, equipment, performance tolerances, methods or procedures of tests in accordance with the recommendations made by the international organization of legal metrology.

STANDARD WEIGHTS AND MEASURES

A. **Standard weight or measure:** Any weight or measure which conforms to the standard unit of such weight or measure and also conforms to such of the provisions of Sections 15 to 19 (both inclusive) as are applicable to it shall be the standard weight of measure. Any numeral which conforms to the provisions of Section 13 shall be the standard numeral.

B. **Use of non-standard weight or measure prohibited:** No weight, measure or numeral, other than the standard weight, measure or numeral, shall be used as a standard weight, measure or numeral.

C. **Manufacture of non-standard weight or measure prohibited:** No weight or measure shall be made or manufactured unless it conforms to the standards of weight or measure established by or under this act. The Central Government may permit the making or manufacturing of any weight or measure which does not conform to the standards established by or under this act, if such weight or measure is made or manufacture exclusively for the purpose of any scientific investigation or research or for export and is made or manufactured under such conditions and restrictions as may be prescribed.

D. **Prohibition with regard to inscriptions:** No weight, measure or other goods shall bear thereon any inscription or indication of weight, measure or number except in accordance with

the standard unit of such weight, measure or numeration established by or under this Act.

APPOINTMENT AND POWERS OF DIRECTOR AND OTHER STAFF

Appointment of director and other staff:

1. The Central Government may, by notification, appoint a Director of Legal Metrology and as many additional, Joint, Deputy or Assistant Director and other officers and staff as may be necessary for exercising the powers and efficiently discharging the duties conferred or imposed on them by or under this Act.
2. Every additional, Joint, Deputy or Assistant Director and other officer, appointed shall exercise such powers, and discharged such functions of the director as the Central Government may, by notification, authorise in this behalf.
3. The director may, by general or special order, define the local limits within which each additional, Joint, Deputy or Assistant Director or other officer appointed shall exercise his powers and discharge the duties conferred or imposed on him by or under this Act.
4. Subject to the provision of this act, every additional, Joint, Deputy or Assistant Director and every other officer appointed shall exercises his powers and discharge the duties of his office under the general superintendence, direction and control of the Director and shall exercise those powers and discharge those duties in the same manner and with the same effect as if they had been conferred or imposed on him directory by this Act and not by way of authorization.
5. The Director and every Additional, Joint, Deputy and Assistant Director and every other officer authorised to perform any duty by or under this Act shall be deemed to be a public servant within the meaning of Section 21 of the Indian Penal Code, 1860.
6. No suit, prosecution or other legal proceeding shall lie against the Director,

Additional, Joint, Deputy or Assistant Director or any other officer authorised to perform any duty by or under this Act in respect of any thing which is in good faith done or intended to be done under this act or any rule or order made thereunder.

7. The Central Government may, with the consent of the State Government and subject to such conditions, limitations and restrictions as it may specify in this behalf, delegate such of the powers of the Director under this Act as it may think fit to the person for the time being holding of the office of the controller of legal metrology, in the state.
8. Where any delegation of powers is made, the powers so delegated shall be exercised under the general superintendence, direction and guidance of the Director.

Power of inspection:

1. The Director, or any person authorised to exercise the powers or discharge the functions of the Director, may, if he has any reason to believe, whether from any information given to him by any person and taken down in writing or from personal knowledge or otherwise, that any weight or measure or other goods in relation to which any inter-State trade or commerce has taken place or is intended to take place and in respect of which an offence punishable under this act appears to have been, or is likely to be, committed are either kept or concealed in any premises or are in the course of transportation from one State to another.
 - a. Enter at any reasonable time into any premises and search for and inspect any weight, measure or other goods in relation to which inter-State trade or commerce has taken place, or is intended to take place, and any record, register or other documents relating thereto;
 - b. Seize any weight, measure or other goods and any record, register or other document or article which he has reason

- to believe may furnish evidence indicating that an offence punishable under this Act has been, or is likely to be, committed in the course of, or in relation to, any inter-state trade or commerce.
2. Where any goods seized are subject to speedy or natural decay, the Director or the authorised person may dispose of such goods in such manner as may be prescribed.
 3. Every search or seizure made under this section shall be carried out in accordance with the provisions of the Code of Criminal Procedure, 1973 relating to searches and seizures made under the Code.

COMMODITIES IN PACKAGED FORM

Commodities in packaged form intended to be sold or distributed in the course of inter-State trade or commerce. Quantities and origin of commodities in packaged form to be declared:

1. No person shall:
 - a. Make, manufacture, pack, sell, or cause to be packed or sold.
 - b. Distribute, deliver, or cause to be distributed or delivered.
 - c. Offer, expose or process for sale, any commodity in packaged form to which this part applies unless such packages bears thereon or on a label securely attached thereto a definite, plain and conspicuous declaration, made in the prescribed manner of:
 - i. The identity of the commodity in the package.
 - ii. The net quantity, in terms of the standard unit of weight or measure, or the commodity in the package.
 - iii. Where the commodity is packaged or sold by number, the accurate number of the commodity contained in the package.
 - iv. The unit sale price of the commodity in the package.
 - v. The sale price of the package.

In this sub-section, the expression "unit sale price" means the price according to such unit

of weight, measure or number as may be prescribed.

2. Every package to which this Part applies shall bear thereon the name of the manufacturer and also of the packer or distributed.
3. Where the package of a commodity to which this Part applies or the label thereon bears a representation as to the number of servings, of the commodity contained therein, such package or label shall also bear a statement as to the net quantity (in terms of weight, measure or number) of each such serving.
4. The statement on a package or label as to the net weight, measure or number of the contents thereof shall not include any expression which tends to qualify, such weight, measure or number. Provided that the Central Government may, by rules, specify the commodity, the weight or measure of which is likely to increase or decrease beyond the prescribed tolerance limits by reason of climatic variations; and it shall be lawful for manufacturer or packer of the commodity so specified to qualify the statement as to the net content of such commodity by the use of the words "when packed".

The words "when packed" shall not be used in any case except a case to which the proviso to sub-section (4) applies.

5. Where the Central Government has reason to believe that there is undue proliferation of weight, measure or number in which any commodity is, or reasonably comparable commodities are, being packed for sale, distribution or delivery and such undue proliferation impairs in the opinion of that Government, the reasonable ability of the consumer to make a comparative assessment of the price after considering the net quantity or number of such commodity, that government may direct the manufacturers and also the packers or distributors to sell, distribute or deliver

- such commodity in such standard quantities or number as may be prescribed.
6. Whenever the retail price of a commodity in packaged form to which this chapter applies is stated in any advertisement, there shall be included in the advertisement, a conspicuous declaration as the net quantity or number of the commodity contained in the packages and retail unit sale price thereof.
 7. No person shall sell, distribute or deliver for sale a package containing a commodity which is filled less than the prescribed capacity of such package except where it

is proved by such person that the package was so filled with a view to:

- a. Giving protection to the contents of such package.
- b. Meeting the requirements of machines used for enclosing the contents of such package.
8. The Central Government may, by rules, specify such reasonable variation in the net contents of the commodity in a package as may be caused by the method of packing or the ordinary. The Central Government may, by rule, specify the classes of commodities.

OFFENCES AND THEIR TRIAL

<i>Offences</i>	<i>Penalties</i>	
	<i>First conviction</i>	<i>Second or subsequent conviction</i>
i. Use of non-standard weights or measures.	Imprisonment up to 6 months or fine up to ₹ 1,000 or both.	Imprisonment up to 2 years and fine
ii. Tampering with, or altering, in any way, any standard reference, secondary standard, or working standard.	Imprisonment up to 2 years or fine up to ₹ 5,000 or both.	
iii. Making or manufacturing any weight or measure not conforming to the standard established under this act, and the offence being not punishable under any other law.	Imprisonment up to 1 year or fine up to ₹ 2,000 or both.	Imprisonment up to 3 years and fine
iv. Obstructing the director or any other authorized officer in exercise of his powers or discharge of his functions.	Imprisonment up to 2 years	Imprisonment up to 5 years
v. a. Selling, delivering or causing to be delivered, to the purchaser any quantity or number of any article, less than the quantity or number contracted for or paid.	Fine up to ₹ 5,000	Imprisonment up to 5 years and fine
b. Rendering any service by weight or measure or number, less than the service contracted for or paid for it.	-do-	-do-
c. Demanding or causing to be demanded, or receiving, or causing to be received, while buying any article or anything.	Fine up to ₹ 5,000	Imprisonment up to 5 years and fine

Contd.

<i>Offences</i>	<i>Penalties</i>	
	<i>First conviction</i>	<i>Second or subsequent conviction</i>
quantity or number of goods in excess of the quantity or number contracted for or paid for.		
vi. Sale, etc. of unverified weights or measures in the course of inter-State trade or commerce.	Fine up to ₹ 1,000	Imprisonment up to 7 years and fine
vii. Selling, distributing, delivering or otherwise transferring, or causing to be sold, distributed, delivered or otherwise transferred any commodity in a packaged form not conforming to the provisions of this Act or any Rule made thereunder.	Fine up to ₹ 1,000	Imprisonment up to 5 years and fine
viii. Personation of officials.	Imprisonment up to 3 years	
ix. Giving false information.	Imprisonment up to 6 months or fine up to ₹ 1,000 or both.	
x. Submitting false returns.	Fine up to ₹ 2,000	Imprisonment up to 1 year
xi. Searching or causing to be searched any house, conveyance or place; or searching any person; or seizing any weight, measure or other movable property vexatiously by an authorized officer.	Imprisonment up to 1 year or fine up to ₹ 2,000 or both for every offence.	

OTHER PROVISION

Vexatious Actions

1. An authorized officer who knows that there are no reasonable grounds for doing so, and yet:
 - a. Searches, or cause to be searched, any house, conveyance or place.
 - b. Searches any person.
 - c. Seizes any weight, measures or other moveable property, shall for every such offence, be punished with imprisonment for a term which may extend to one year, or with fine which may extend to 2,000 rupees, or both.
2. If a local Inspector:
 - a. Without any reasonable cause verifies any weight or measure of first category.

- b. Without any reasonable cause obliterates any stamp on any such weight or measure, in contravention of the provisions of the first proviso to Section 42, he shall, for every such offence be punished with imprisonment for a term which may extend to one year, or with fine which may extend to 2,000 rupees, or both.

MISCELLANEOUS

- A. *Survey and statistics:* The Central Government shall make, or cause to be made, such surveys and collect, or cause to be collected, such statistics as it may consider necessary with a view to ascertaining the extent to which any standard of weight, measure or numeration established by or under this act has been implemented in any area or in relation to any

class of undertakings, users or goods and it shall be the duty of every person using weight or measure or making any muneration to render such assistance on the person making such survey or collecting such statistics may require
B. Conversion of non-metric weights and measures into standard units of weights or measures: The value expressed in terms of any unit of weight or measure other than in terms of the standard units of weight or measure may be converted into the value expressed in terms of a standard unit of weight or measure at the rate specified in the Schedule. All references in any enactment or in any notification, rule or order made under any enactment, or in any contract, deed or other instrument, for the time being in force, to a value expressed in terms of any unit of weight, measure or numeration other than that of a standard unit of weight, measure or numeration shall be construed as references to that value expressed in terms of standard units of weight, measure or numeration, as the case may be, converted at the rates specified in the Schedule.

C. Non-metric weight or measure not to be mentioned in any document, etc. or to form the basis of any contract after the commencement of this Act: No unit of weight, measure or

numeration shall, after the commencement of this act, be stated in any enactment, notification, rule, order, contract, deed or other instrument in terms of any unit of weight, measure or numeration other than that of a standard unit of weight, measure or numeration. On and from the commencement of this Act, no weight, measure or number other than the standard weight, measure or number shall be used in, or from the basis of, any contract or other agreement in relation to any inter-State or international trade of commerce. No written record of the results of any measurement shall be maintained in any unit other than the standard unit of weight, measure or numeration established by or under this Act.

D. Repeal and saving: The Standards of Weights and Measures Act, 1956, is hereby repealed. Without prejudice to the provisions contained in the General Clauses Act, 1897 with respect to repeals, any notifications, rule or order made under the Standards of Weight and Measures Act, 1956, shall, if in force, at the commencement of this Act, continue to be in force and have effect as if made under the corresponding provision of this Act.

E. Power to make rules: The Central Government may, by notification, make rules for carrying out the provisions of this Act.

Code of Pharmaceutical Ethics

INTRODUCTION

A code of ethics is a set of principles of conduct within an organization that guide decision making and behavior. The purpose of the code is to provide members and other interested persons with guidelines for making ethical choices in the conduct of their work. Professional integrity is the cornerstone of many employees' credibility. Member of an organization adopt a code of ethics to share a dedication to ethical behavior and adopt this code to declare the organization's principles and standards of practice.

'Ethics' is defined as the science of morals, moral principles or code. 'Moral' is defined as the 'standard of conduct respected by good men independently of positive law and religion'. Morality means good conduct or behaviour and consciousness.

Ethics is two things. First, ethics refers to well-founded standards of right and wrong that prescribe what humans ought to do, usually in terms of rights, obligations, benefits to society, fairness, or specific virtues. Ethics, for example, refers to those standards that impose the reasonable obligations to refrain from rape, stealing, murder, assault, slander, and fraud. Ethical standards also include those that enjoin virtues of honesty, compassion, and loyalty. And, ethical standards include standards relating to rights, such as the right to life, the right to freedom from injury, and the right to

privacy. Such standards are adequate standards of ethics because they are supported by consistent and well-founded reasons. Secondly, ethics refers to the study and development of one's ethical standards. As mentioned above, feelings, laws, and social norms can deviate from what is ethical. So it is necessary to constantly examine one's standards to ensure that they are reasonable and well-founded. Ethics also means, then, the continuous effort of studying our own moral beliefs and our moral conduct, and striving to ensure that we, and the institutions we help to shape, live up to standards that are reasonable and solidly-based.

PHARMACEUTICAL ETHICS

Pharmaceutical ethics is an important text, which aims to provide the ethical guidelines much needed by the pharmaceutical industry. By focusing on many of the central issues such as the ethical aspects of clinical trials, informed consent, physician or patient choice and pharmaceutical advertising, this text will provide very good coverage of an area which perhaps still lacks coherent instruction:

- Covers ethical issues involved in the testing and use of pharmaceuticals on human beings.
- Investigates issues such as whether choice of drug should lie with the physician or the patient.
- Looks at a wide variety of subjects connected with pharmaceutical ethics.

- Focuses specifically on the issues surrounding the pharmaceutical industry, not medicine in general.
- Fulfills an important need in the pharmaceutical industry.

CODE OF ETHICS

Definition: A code of ethics is a set of guidelines that governs the behavior of a company and its members. It is especially important in the event that a company has to decide what type of behavior conforms to acceptable or reasonable standards.

Purpose: Companies adopt codes of ethics to establish professional responsibility, integrity and credibility. It is important for companies to conduct their matters in their respective fields in a professional manner.

Components: A code of ethics usually starts off with a preamble, which is usually a statement penned by the top-ranking official of the company as an endorsement. Usually following the preamble is a statement of purposes and values, specific rules and regulations, and a section dealing with implementation of the code.

A code of ethics issued by a business is a particular kind of policy statement. A properly framed code is, in effect, a form of legislation within the company binding on its employees, with specific sanctions for violation of the code. If such sanctions are absent, the code is just a list of pieties. The most severe sanction is usually dismissal—unless a crime has been committed.

GENERAL INTRODUCTION TO CODE OF PHARMACEUTICAL ETHICS

The profession of pharmacy is noble in its ideals and pious in its character. Apart from being a career for earning livelihood it has inherent in it the attitude of service and sacrifice in the interests of the suffering humanity. In handling, selling, distributing, compounding and dispensing medical substances including poisons and potent drugs a pharmacist is, in collaboration with medical men and others, charged

with the onerous responsibility of safeguarding the health of people, as such he has to uphold the interests of his patrons above all things. The lofty ideals set up by charaka, the ancient philosopher, physician and pharmacist in his erunciation: "Even if your own life be in danger you should not betray or neglect the interests of your patients" should be fondly cherished by all pharmacists.

Government restricts the practice of pharmacy to those who qualify under regulatory requirements and grant them privileges necessarily denied to others. In return Government expects the pharmacist to recognise his responsibilities and to fulfill his professional obligations honorably and with due regard for the well-being of society.

Standards of professional conduct for pharmacy are necessary in the public interest to ensure an efficient pharmaceutical service. Every pharmacist should not only be willing to play his part in giving such a service but should also avoid any act or omission which would prejudice the giving of the services or impair confidence in any respect for pharmacists as a body.

The nature of pharmaceutical practice is such that its demands may be beyond the capacity of the individual to carry out or to carry out as quickly or as efficiently as the needs of the public require. There should, therefore at all times, be a readiness to assist colleagues with information or advice.

A pharmacist must, above all be a good citizen and must uphold and defend the laws of the State and the Nation.

OBJECTIVES OF CODE OF PHARMACEUTICAL ETHICS

- The code of pharmaceutical ethics is formulated by PCI for the guidance of Indian pharmacist.
- The code of pharmaceutical ethics helps to guide the pharmacist as to how he should conduct himself in relation to: (i) His job, (ii) His trade, (iii) His fellow pharmacist,

- (iv) His physician, (v) With medical profession, (vi) With his profession, (vii) With general public.

PHARMACISTS IN RELATION TO HIS JOB

The essential features of the code of pharmaceutical ethics framed by the PCI are as follows.

Code of Ethics Related to his Job

A. Scope of pharmaceutical services: When premises are registered under statutory requirements and opened as a pharmacy, a reasonably comprehensive pharmaceutical service should be provided. This involves the supply of commonly required medicines of this nature without undue delay. It also involves willingness to furnish emergency supplies at all times.

B. Conduct of the pharmacy: The condition in a pharmacy should be such as to preclude avoidable risk or error or of accidental contamination in the preparation, dispensing and supply of medicines.

The appearance of the premises should reflect the professional character of the pharmacy. It should be clear to the public that the practice of pharmacy is carried out in the establishment. Signs, notices, descriptions, wording on business, stationary and related indications, should be restrained in size, design and terms. Descriptions which denote or imply pharmaceutical qualifications should be limited to those of which the use is restricted by law and should not draw invidious distinction between pharmacists. A notice stating that dispensing under (Employees State Insurance Scheme) ESIS or any other such other schemes sponsored by Government is carried out may be exhibited at the premises. In every pharmacy there should be a pharmacist in personal control of the pharmacy who will be regarded as primarily responsible for the observance of proper standards of conduct in connection with it. Any obstruction of the pharmacist in the execution of his duty in the respect by the owner will be

regarded as a failure on the part of the owner to observe the standards in question.

C. Handling of prescriptions: When a prescription is presented for dispensing. It should be received by a pharmacist without any discussion or comment over it regarding the merits and demerits of its therapeutic efficiency. The pharmacist should not men show any physiognomic expression of alarm or astonishment upon the receipt of a prescription; as such things may cause anxiety in patients or their agents and may even shake their faith in their physician. Any question on a prescription should be answered with every caution and care; it neither should offend a patron nor should it disclose any information, which might have been intentionally, withheld from him.

It is not within the privilege of a pharmacist to add, omit or substitute any ingredient or alter the composition of a prescription without the consent of the prescriber, unless the change is emergent or is demanded purely by the technique of the pharmaceutical art and does not cause any alteration in the therapeutic action of the recipe. In case of any obvious error in it due to any omission, incompatibility or overdosage, the prescription should be referred back to the prescriber for correction or approval of the change suggested. While such an act is imperative in the best interest of the patient, in no case should it be done in a manner, which may jeopardize the reputation of the prescriber concerned.

In matter of refilling prescriptions a pharmacist should solely be guided by the instructions of the prescriber aid he should advise patients to use medicines or remedies strictly in accordance with the intention of the physician as noted on the prescription.

D. Handling of drugs: All possible care should be taken to dispense a prescription correctly by weighing and measuring all ingredients in correct proportions by the help of scale and measures: visual estimations must be avoided. Further, a pharmacist should always use drugs and medicinal preparations of standard quality

available. He should never fill his prescriptions with spurious, sub-standard and unethical preparations.

A Pharmacist should be very judicious in dealing with drugs and medicinal preparations known to be judicious or to be used for addiction or any other abusive purposes. Such drugs and preparations should not be supplied to anyone if there is reason to suppose that it is required for such purpose.

E. Apprentice pharmacists: While in-charge of a dispensary, drugstore or hospital pharmacy where apprentice pharmacists are admitted for practical training, a pharmacist should see that the trainees are given full facilities for their work so that on the completion of their training they have acquired sufficient technique and skill to make themselves dependable pharmacists. No certificate or credentials should be granted unless the above criterion is attained and the recipient has proved himself worthy of the same.

PHARMACISTS IN RELATION TO HIS TRADE

Following are some ethics in relation to his trade:

A. Trade price structure: Prices charged from customers should be fair and in keeping with the quality and quantity of commodity supplied and the labour and skill required in making it ready for use, so as to ensure an adequate remuneration to the pharmacist taking into consideration his knowledge, skill, the time consumed and the great responsibility involved, but at the same time without unduly taxing the purchaser.

B. Fair trade practices: No attempt should be made to capture the business of a contemporary by cut-throat competition, that is, by offering any sort of prizes or gifts or any kind of allurement to patronizers or by knowingly charging lower prices for medical commodities than those charged by fellow pharmacist if they reasonable. In case any order or prescription genuinely intended to be served by some dispensary is brought by mistake to another, the latter should be refuse to accept it and should

direct the customer to the right place. Labels, trademarks and other signs and symbols of contemporaries should not be imitated or copied.

C. Purchase of drugs: Drugs should always be purchased from genuine and reputable sources and a pharmacist should always be on his guard not to aid or abet, directly or indirectly the manufacture, possession, distribution and sale of spurious or sub-standard drugs.

D. Hawking of drugs: Hawking of drugs and medicinal should not be encouraged nor should any attempt be made to solicit orders for such substances from door-to-door. 'Self-service' method of operating pharmacies and drug-stores should not be used as this practice may lead to the distribution of therapeutic substances without an expert supervision and thus would encourage self-medication, which is highly undesirable.

E. Advertising and displays: No display material either on the premises, in the press or elsewhere should be used by a pharmacist in connection with the sale to the public of medicines or medical appliances which is undignified in style or which contains:

- a. Any wording design or illustration reflecting unfavourably on pharmacist's collectivity or upon any group or individual.
- b. A disparaging reference, direct or by implication to other suppliers.
- c. Misleading, or exaggerated statements or claims.
- d. The word "Cure" in reference to an ailment or symptoms of ill-health.
- e. A guarantee of therapeutic efficacy.
- f. An appeal to fear.
- g. An offer to refund money paid.
- h. A prize, competition or similar scheme.
- i. Any reference to a medical practitioner or a hospital or the use of the terms "Doctor" or "Dr." or "Nurse" in connection with the name of the preparation not already established.
- j. A reference to sexual weakness, premature ageing or loss of virility.

- k. A reference to complaints of sexual nature in terms which lack the reticence proper to the subject.

No article or preparation advertised to the public by means of display material of a kind mentioned above should be exhibited in a pharmacy if it is known or could reasonably be known that the article or preparation is so advertised.

Contraceptive preparations and appliances or their illustrations should not be exhibited except a notice approved by regulations or bearing the words "family planning requisites". Under no circumstances should lustful obscene and indecent publications of any kind or description be sold or distributed. As this practice is highly detrimental to the moral welfare of the nation.

PHARMACISTS IN RELATION TO MEDICAL PROFESSION

Following are some ethics in relation to medical profession:

A. Limitations of professional activity: Whereas it is expected that medical practitioners in general would not take to the practice of pharmacy by owing drug stores, as this ultimately leads to coded prescriptions and monopolistic practices detrimental to the pharmaceutical profession and also to the interest of patients, it should be made a general rule that pharmacists under no circumstances take to medical practice, that is to diagnosing diseases and prescribing remedies therefore even if requested by patrons to do so. In cases of accidents and emergencies a pharmacist may, however, render First Aid to the victim.

No pharmacist should recommend particular medical practitioner unless specifically asked to do so.

B. Clandestine arrangements: No pharmacist should enter into any secret arrangements or contract with a physician to offer him any commission or any advantage of any description in return for his favour of patronage by recommending his dispensary or drugstore or even his self to patients.

C. Liaison with public: Being a liaison between medical profession and people, a pharmacist should always keep himself abreast with the modern developments in pharmacy and other allied sciences by regularly reading books, journals, magazines and other periodicals, so that on the one hand he may be in a position to advise the physician on pharmaceutical matters like those of colours, flavours, vehicles and newer forms of administration of medicines, on the other, he may be able to educate the people for maintaining healthy and sanitary conditions of living.

Thus a pharmacist can contribute his share in the nation-building activities of the country. A pharmacist should at all times endeavour to promote knowledge and contribute his quota in the advancement of learning.

A pharmacist should never disclose any information which he has acquired during his professional activities to any third party or person unless requires by law to do so. He should never betray the confidence which his patrons repose in him or which he has won by virtue of his eminent character and conduct.

PHARMACIST IN RELATION TO HIS PROFESSION

Following are some ethics in relation to his profession:

A. Professional vigilance: It is not only sufficient for a pharmacist to be law-abiding and to deter from doing things derogatory to society and his profession, but it should be his bounden duty to make others also fulfill the provisions of the pharmaceutical and other laws and regulations. He should not be afraid of bringing or causing a miscreant to be brought to book, may be a member of his own profession. Whereas it is obligatory for a pharmacist to extend help and cooperation to a fellow member in his legitimate needs, scientific, technical or otherwise, he is to be, at the same time, vigilant to weed the undesirable out of the profession and thus help to maintain its fair name and traditions.

B. Law-abiding citizens: A pharmacist engaged in profession has to be an enlightened citizen

endowed with a fair knowledge of the land and he should strive to countenance and defend them. He should be particularly conversant with the enactments pertaining to food, drug, pharmacy, health, sanitation and the like and endeavour to abide by them in every phase of his life. A pharmacist is a unit whole and his life cannot be divided into compartments.

C. Relationship with professional organizations: In order to inculcate a corporate life in his own professional colleagues, a pharmacist should join and advance the cause of all such organizations, the aims and objects of which are conducive to scientific moral and cultural well-being of pharmacists and at the same time are in no way contrary to the code of pharmaceutical ethics.

D. Decorum and propriety: A pharmacist should always refrain from doing all such acts and deeds which are not in consonance with the decorum and propriety of pharmaceutical profession or which are likely to bring discredit or upgrade to the profession or to himself.

PHARMACIST'S OATH

Pharmacist's Oath According to the PCI

A young prospective pharmacist should feel no hesitation in assuming the following pharmacist oath:

1. I swear by the code of ethics of pharmacy Council of India in relation with the community and shall acts as an integral part of health care team.
2. I shall uphold the laws and standards governing my profession.
3. I shall strive to perfect and enlarge my knowledge to contribute to the advancement of pharmacy and public health.
4. I shall follow the system which I consider best for pharmaceutical care and counselling of patients.
5. I shall endeavour to discover and manufacture drugs of quality to alleviate sufferings of humanity.
6. I shall hold in confidence the knowledge gained about the patients in connection with

my professional practice and never divulge unless compelled to do so by the law.

7. I shall associate with organizations having their objectives for betterment of the profession of pharmacy and make contribution to carry out the work of those organizations.
8. While I continue to keep this oath unviolated, may it be granted to me to enjoy life and the practice of pharmacy respected by all, at all times.
9. Should I trespass and violate this oath, may the reverse be my lot.

Revised Oath of a Pharmacist's

The revised oath was adopted by the AACP house of delegates in July 2007 and has been approved by the American Pharmacists Association. AACP member institutions should plan to use the revised oath of a pharmacist during the 2008–09 academic years and with spring 2009 graduates.

"I promise to devote myself to a lifetime of service to others through the profession of pharmacy.

In fulfilling this vow:

- I will consider the welfare of humanity and relief of suffering my primary concerns.
- I will apply my knowledge, experience, and skills to the best of my ability to assure optimal outcomes for my patients.
- I will respect and protect all personal and health information entrusted to me.
- I will accept the lifelong obligation to improve my professional knowledge and competence.
- I will hold myself and my colleagues to the highest principles of our profession's moral, ethical and legal conduct.
- I will embrace and advocate changes that improve patient care.
- I will utilize my knowledge, skills, experiences, and values to prepare the next generation of pharmacists.

I take these vows voluntarily with the full realization of the responsibility with which I am entrusted by the public."

CHAPTER

20

Medical and Health Accessories

INTRODUCTION

A pharmacist plays a vital role in supplying health accessories to the patients. A comprehensive health accessories department may include a wide variety of surgical supplies and convalescent aids including wheelchair, walkers, hospital beds, hydraulic patient lifters, urology and incontinence supplies elastic supports, and orthopedic braces. Knowledge of surgical instrument is very important for a pharmacist working in a hospital. They are meant for surgical purposes. It includes wide variety of surgical and pharmacist is expected to handle the surgical instruments at the drug store or in a hospital. Pharmaceutics have an addition responsible of maintenance and supply of surgical instruments and other health accessories used in hospital, apart from distribution and dispensing of drugs. All in statement that are used for surgical operation are collecting called surgical instruments.

They are costly and important in safe guarding the welfare of the patient undergoing surgery: hence much care to be taken in their maintenance. The surgical items are not issued directing to the patient, but to the operation theatre, the actual place of their use each instruments has different shapes for different purposes. The hospital pharmacists must be familiar with some instruments which are illustrated here.

MEDICAL/ SURGICAL ACCESSORIES

There are many items used as medical accessories and as surgical instruments. As per D and C Act and Rules, some accessories come under the category of drug and hence drug manufacturing license is required for their production. Some of them are given below:

1. Bandages
2. Plaster of Paris bandage
3. Suspensory bandage
4. Absorbent cotton
5. Surgical cotton
6. Lint
7. *Catguts*: absorbable and non-absorbable
8. Sanitary napkins/pad
9. Infusion solution set/assembly (intravenous drip set)
10. Blood transfusion set/assembly
11. Disposable hypodermic syringe and needles
12. Disposable perfusion sets
13. Umbilical polyester tape-sterile
14. Umbilical cotton tape-sterile
15. Cardiac stents
16. Drug eluting stents
17. Catheters
18. I. V. cannulae
19. Heart valves
20. Scalp vein set
21. Orthopaedic implants
22. Internal prosthetic replacements
23. Bone cements

**OFFICIAL IN PHARMACOPOEIA/
PHARMACEUTICAL CODEX**

1. Adhesive bandages
2. *Dressings:* Elastic adhesive, paraffin gauze, Plastic wound and standered dressings
3. Plaster of Paris cotton cloth
4. Elastic tape
5. Crape bandage
6. Belladonna plaster
7. Capsicum plaster
8. Self-adhesive plaster
9. Wadding
10. Oxidized cellulose
11. Dextranomer
12. Absorbable dusting powder.

Items do not come Under the Category of Drugs

1. Enamel or PVC utensils: Basin, kidney tray, male urine collecting bottle, female urine collecting bottle, bed pan, bowls, dishes
2. Tongue holding forceps
3. Tongue depressor
4. *Scissors:* Smiths, listers and other types
5. Scalpes
6. *Forceps:* Artery forceps, dissecting forceps, sinus forceps, cheatles forceps, hemostatic forceps
7. Rubber or plastic sheets
8. Bone cutters

9. Nasal and aural speculae
10. Breast pumps
11. Dental instruments
12. Surgical dressing drums
13. Infusion pump
14. Needle sutures
15. Stethoscopes
16. Blood pressure apparatus
17. Clinical thermometer
18. Umbilical cord clamps
19. Uro-bag
20. Splints—multipurpose and pediatrics
21. Simple lock-up splint
22. Circumcision devices
23. Airways
24. Mouth-to-mouth resuscitation tube
25. Proctoscope
26. Elbow immobilizer
27. fracture cast brace
28. Stretcher
29. Ambulatory aids: Wheel chair, walkers canes wooden or metal—adjustable and non-adjustable—monopod or multipod)
30. Metal stand for hanging infusion bottle
31. Cot with beds (adjustable and with or without rails)
32. Nebulizer
33. Hot water bag
34. Infrared lamp
35. Wax bath

Prescription and Non-prescription Drugs and Diagnostic Aids

INTRODUCTION

Prescription drugs are drugs that are not locally available without a physician's prescription. Non-prescription drugs are medicines, which can be bought at a pharmacy without a prescription of a doctor, at the pharmacist's advice.

Prescription is a written order, especially by a physician, for the preparation and administration of a medicine or other treatment. In other words prescription is an order for medication, therapy, or therapeutic device given by a properly authorized person, which ultimately goes to a person properly authorized to dispense or perform the order. A prescription is usually in written form; can be emailed from a secure encrypted computer system, written, phoned, or faxed; and includes the patient's name and address, the date, the symbol (superscription), the medication prescribed (inscription), directions to the pharmacist or other dispenser (subscription), the acceptability of dispensing a generic, directions to the patient that must appear on the label, prescriber's signature, and, in some instances an identifying number.

- **Medical prescription**, a plan of care written by a physician or other health care professional.
- **Prescription drug**, a drug available only by a medical prescription.

PRESCRIPTION'S DRUGS

A prescription medication is a licensed medicine that is regulated by legislation to require a prescription before it can be obtained. The term is used to distinguish it from over-the-counter drugs which can be obtained without a prescription. Different jurisdictions have different definitions of what constitutes a prescription drug.

Dispensation of prescription drugs often includes a monograph (in Europe, a Patient Information Leaflet or PIL) that gives detailed information about the drug.

Environmental problems: Traces of prescription drugs—including antibiotics, anti-convulsants, mood stabilizers and sex hormones—have been detected in drinking water. If ingested these may be harmful to wildlife and humans.

PRESCRIPTION DRUGS IN INDIA

The Health Ministry has re-organised the category of prescriptions drugs—medicines that can be sold in retail only against a registered medical practitioner's prescription—through an amendment to the Schedule H of the Drugs and Cosmetics Act. As per a notification issued a few days ago, 520-odd drugs now belong to the Schedule H, as against over 300 drugs earlier. The comprehensive revision of the Schedule comes after a gap of over 10 years.

Under the act, “prescription drugs” fall under two Schedules: **Schedule H** and **Schedule X**. The latter consists of habit forming, abusable drugs requiring double prescription.

Drugs Controller General of India, Ashwini Kumar told FE that a large number of new drugs licensed by the Centre and various State Drug Controllers as prescription medicines in the last few years have now been formally added to the Schedule H. Apart from Schedules H and X, there is another class of popular drugs reckoned to be household remedies that are listed on Schedule K. Drugs outside these three schedules are considered to be over-the-counter drugs. Multinational drug companies have been pitching for a separate Schedule for OTC drugs for better market access, but the government has decided not to accede to the demand. “There is no need for a separate OTC list as drugs outside the prescription drugs automatically have OTC status,” Mr Kumar said.

Commonly known drugs like cetirizine, omeprazole, etc. find a mention in the new Schedule H. The drugs newly added to the list include tramadol, cisplatin, tizanidine, vinblastin, etc. says a senior ministry official, this revision has been carried out after 1996. “A number of new drugs have been introduced in the market since then. It is thus the need of the hour to include them in the Schedule H list in view of patient protection,” he said. After inclusion in the Schedule, these drugs will have to follow the requirements of the prescription drug category as specified under the Drugs and Cosmetics Act, 1945.

The containers of the preparations containing Schedule H or Schedule X drugs must display the warning: To be sold by retail on the prescription of a registered medical practitioner only” conspicuously on their labels.

Types of Prescription Drugs are Misused or Abused

Three types of drugs are misused or abused most often:

- I. Opioids: Prescribed for pain relief.

- II. CNS depressants: Barbiturates and benzodiazepines prescribed for anxiety or sleep problems (often referred to as sedatives or tranquilizers).
- III. Stimulants: Prescribed for attention-deficit hyperactivity disorder (ADHD), the sleep disorder narcolepsy, or obesity.

List of Prescription's Drugs

The major prescription drugs are:

1. Anti-convulsant drugs
2. Anti-anginal drugs
3. Anti-fungal drugs
4. Anti-itch drugs
5. Anti-viral drugs
6. Anti-diabetic drugs
7. Anti-asthmatic drugs
8. Anti-hypertensive drugs
9. Antibiotics
10. Anti-migraine drugs
11. Anti-rheumatic drugs
12. AntiProtozoal drugs
13. Tricyclic anti-depressants
14. Anti-arrhythmic drugs
15. Anti-nausea drugs
16. Anti-Parkinson drugs
17. Anti-psychotic drugs
18. Muscle relaxant
19. Digitalis drugs
20. Anti-gastroesophageal reflux drugs
21. Anti-retroviral drugs
22. Anti-tuberculosis drugs
23. Anti-ulcer drugs
24. Anti-hemorrhoid drugs
25. Anti-spasmodic drugs
26. Anti-malarial drugs
27. Non-steroidal anti-inflammatory drugs: Some can bought over the counter; other is available only with a prescription from a physician or dentist.
28. Immunosuppressant drugs
29. Anti-imsomnia drugs
30. Anti-helminthic drugs
31. Central nervous system stimulants
32. *Decongestants*: Some decongestant products require a physician’s prescription but

there are also many non-prescription (over-the-counter) products.

33. Anticoagulant drugs
34. Bone disorder drugs
35. Infertility drugs
36. **Topical antibiotics:** Some topical antibiotics are available with a prescription only.
37. Diuretics
38. **Vasodilators:** In the form used for treating high blood pressure (tablets or injections), these drugs are available only with a physician's prescription.
39. Blood viscosity reducing drugs
40. Beta-blockers
41. Corticosteroids
42. Benzodiazepines
43. Cephalosporin
44. **Expectorants:** Some products that contain are available only with a physician's prescription.
45. Sulfonamides
46. Calcium channel blockers
47. Gout drugs
48. **Anti-histamines:** Some anti-histamine products are available only with a physician's prescription.
49. Penicillins
50. Barbiturates
51. Laxatives
52. ACE inhibitors
53. Anti-anxiety drugs
54. Urinary anti-infectives
55. MAO inhibitors
56. Opioid analgesics
57. Bronchodilators
58. Ophthalmic antibiotics
59. Smoking cessation drugs: Some products are available only with a prescription.
60. Protease inhibitors
61. Anti-depressant drugs
62. Alpha-1-adrenergic blockers
63. Tetracycline

NON-PREScription DRUGS

NON-PREScription DRUG PRESCRIPTIONS

Prescriptions are also used for things that are not strictly regulated as a prescription drug. Prescribers will often give non-prescription drugs out as prescriptions because drugs benefit plans may reimburse the patient only if the over-the-counter medication is taken under the direction of a medical practitioner. Conversely, if a medication is available over-the-counter, prescribers may ask patients if they want it as a prescription or purchase it themselves. Pharmacists may or may not be able to price the medication competitively with over-the-counter equivalents. If the patient wants the medication not under prescription, the prescriber is usually careful to give the medication name to the patient on a blank piece of paper to avoid any confusion with a prescription. This is applied to non-medications as well. For example, crutches, and registered massage therapy may be reimbursed under some health plans, but only if given out by a prescriber as a prescription.

Prescribers will often use blank prescriptions as general letterhead. Legislation may define certain equipment as "prescription devices". Such prescription devices can only be used under the supervision of authorized personnel and such authorization is typically documented using a prescription. Examples of prescription devices include dental cement (for affixing braces to tooth surfaces), various prostheses, gut sutures, sickle cell tests, cervical cap and ultrasound monitor.

In some jurisdictions, hypodermic syringes are in a special class of their own, regulated as illicit drug use accessories separate from regular medical legislation. Such legislation will often specify a prescription as the means by which one may legally possess syringes.

Regulation of Non-prescription Products

Over-the-counter (OTC) drugs play an increasingly vital role in America's health care

system. OTC drug products are those drugs that are available to consumers without a prescription. There are more than 80 therapeutic categories of OTC drugs, ranging from acne drug products to weight control drug products. As with prescription drugs, CDER oversees OTC drugs to ensure that they are properly labeled and that their benefits outweigh their risks.

OTC drugs generally have these characteristics:

- Their benefits outweigh their risks
- The potential for misuse and abuse is low
- Consumer can use them for self-diagnosed conditions
- They can be adequately labeled
- Health practitioners are not needed for the safe and effective use of the product.

List of Non-prescription Drugs

These are medicines, which can be bought at a pharmacy without the prescription of a doctor, at the pharmacist's advice.

1. Anti-hemorrhoid drugs
2. **Topical antibiotics:** Some topical antibiotics are available without a prescription
3. Cough-suppressants
4. Anti-acne drugs
5. **Non-steroidal anti-inflammatory drugs:** Some can be bought over the counter; others are available only with a prescription from a physician or dentist.
6. Antiseptics
7. Analgesics
8. **Decongestants:** Some decongestant products require a physician's prescription but there are also many non-prescription (over-the-counter) products.
9. Aspirin
10. **Vasodilators:** Some vasodilators such as Minoxidil are sold without prescription.
11. Antacids
12. **Expectorants:** Many expectorants are available without a physician's prescription.

13. Anti-fungal drugs
14. **Anti-histamines:** Some can be bought without prescription.
15. Anti-gas agents
16. **Smoking cessation drugs:** Many drugs can be bought over the counter, without prescription.

DIAGNOSIS

Diagnosis (Greek: dia- “apart-split”, and gnosi “to learn, knowledge”) (plural *diagnoses*) is the identification of the nature of anything, either by process of elimination or other analytical methods. Diagnosis is used in many different disciplines, with slightly different implementations on the application of logic and experience to determine the cause and effect relationships. Below are given as examples and tools used by the respective professions in medicine, science, engineering, business. Diagnosis also is used in many other trades and professions to determine the causes of symptoms, mitigations for problems, or solutions to issues.

Uses

In medicine:

- Medical diagnosis
- Differential diagnosis
- Retrospective diagnosis.

DIAGNOSTIC AIDS

Diagnostic is concerned with diagnosis used for furthering diagnosis “a diagnostic reading test”. Diagnostic describes a procedure or test which is performed to determine what is wrong with a patient, or what illness they have. Diagnostic procedures do not attempt to treat or cure anything, but are more informational and exploratory in nature.

Diagnostic aids means an apparatus that aids in the purpose of diagnose, manage disease and reach a prognosis for patients.

Diagnostic Aids for Medical Professionals

Scans and Imaging

Magnetic resonance imaging (MRI): Can qualify and quantify iron in the liver, heart and anterior pituitary, but requires special technique called T2* MRI. This is presently the only non-invasive approach to qualify iron deposits in the heart. FerriScan and Squid are two aids that use the T2* relaxation approach.

Fibroscan® Noninvasive way to determine the rigidity (hardness) of the liver. A mechanical pulse goes through the skin to the liver. The speed (velocity) with which the pulse moves and reaches its target is measured with ultrasound. The velocity of the pulse is directly correlated to the stiffness of the liver, which in turn reflects the degree of fibrosis—the stiffer, the liver is the greater the degree of fibrosis.

Fibroscan® should not be used on patients with ascites (fluid in the abdomen), patients who are pregnant or patients under the age of 18 years of age. Fibroscan is available mostly in Canada and Europe.

Ferriscan® is software that allows for a non-invasive (does not puncture the skin) way to measure the amount of iron in the liver (hepatic iron concentrations). The technology works with standard magnetic resonance imaging (MRI) equipment. In a very simplistic description, MRI uses a powerful magnet and radio frequencies (signals, pulses) which are sent through the person's body producing a reading that is sent to a computer. Using a specialized technique a trained radiologist can demonstrate differences in the rate at which a signal/pulse transverses (passes through) the body. A reading is taken of these rates (proton transverse relaxation rates, or R2) which yield the relaxation time (recovery time) of the signal/pulse. If nothing stands in the way of the signal/pulse, the relaxation time is normal and the output or reading of the organ scanned demonstrates no abnormalities. When the signal is interrupted by a tumor or in this case, iron, the relaxation time is "shortened". If iron is present in the liver, the output reading

shows a "black" area where the signal/pulse recovery time was abbreviated. A radiologist must have additional training to perform this specialized imaging technique.

SQUID: Superconducting quantum interference device (SQUID) uses a low-power magnetic field with sensitive detectors that measure the interference of iron within the field. The procedure is expensive, experimental with limited locations in the world providing this technology. Read more about this type of technology.

Genetic testing examines DNA for mutations in genes that define a particular disease. This type of test examines DNA from a blood, saliva, or tissue sample for certain mutations. Genetic information does not provide information about iron levels, but it does expose the potential risk of developing iron disorders.

SOME OTHER DIAGNOSTIC AIDS

Electronic goniometer—canine electronic goniometer: The electronic goniometer is useful in measuring angles to determine pathology, and return of function in joints. The LED display provides ease in measurement and immediate accuracy. The adjustable probe can be reversed for each hip, or removed for other joint ranges. Enables measurement of the angle of subluxation and reduction, the limits of internal and external rotation, and functional joint angle in active animals.

DAR template: The dorsal acetabular rim template was designed for accurate measurement of the angle of the dorsal acetabular rim as taken from the DAR view radiograph. Placed over the radiograph, the template can be aligned with the dorsal lumbar spines and rotated to measure acetabular rim angle. It is an invaluable aid in differentiating the severity of hip dysplasia, and in determining the correct amount of osteotomy rotation for triple pelvic osteotomy to best benefit the patient.

Slocum® protractor: For accurate measurement of the tibial plateau slope, the Slocum®

protractor has the additional benefit of a blade size and placement guide. With our protractor and preoperative radiographs the surgeon is able to determine the appropriate degrees of rotation, the optimal size of blade to use, and the most beneficial placement of the cut prior to surgery.

Slocum® stainless steel TPLO rotation charts: Keep all your TPLO rotation information in your surgery pack. New slocum® stainless steel TPLO rotation charts are now steam autoclavable. One chart for the 24 mm–30 mm biradial saw blades, another for the 12 mm–18 mm biradial saw blades. Measure the tibial plateau slope on the radiograph, choose your blade size, do the rotation from the chart in surgery. It's that simple. No mathematics required, built in caudal cruciate ligament protection.

Radiographic positioning for hindlimb alignment: Improve the quality of radiographs being taken in your practice. With the information provided on our disc you and your staff can increase the effectiveness of radiographs while decreasing the occurrence of positional errors. Demonstrates correct positioning and how to recognize errors radiographically. Supplies technique recommendations for adjusting positioning to clarify pathology. Includes example radiograph for easy recognition of bony markers. Clarifies femoral/tibial alignment correction radiographically. Simplifies measuring the tibial plateau angle, including tips for measuring "hard to read" radiographs.

APPLIANCE

Appliance may refer to a device with a narrow function:

- Home appliance, household machines, using electricity or some other energy input
 - Small appliances
 - Major appliances
- In medicine and dentistry, custom-fitted appliances to an individual for the purpose of correction of a physical or dental problem such as prosthetic, orthotic appliances, and dental braces.
- Computer appliance, a computing device with a specific function and limited configuration ability.
- Software appliance, software application combined with just enough operating system (JEOS).
- Fire apparatus, a fire engine or fire truck in British English.

Name of Some Medical Appliances Available in the Market

Surgical Gloves, Exam Gloves, Medical Gloves, Glove Box Gloves, Drybox Gloves, Isolator, Endoscope, Forceps and a Hook to Extract, Dressing Trolley, First-aid Trolley, Adjustable Stool for Surgeon, Appliance Trolley, Medicine Trolley, Nursing Trolley, Ambulance Stretcher, Patient Trolley, Stretcher Trolley, Chair for Transfusion, Sleeping Chair, Sell Over Bed Table, Bedside Locker, Children's Bed, Manual ICU Bed, Electric Bed, Electric ICU Bed.

New Drug Approval and Export Registration

INTRODUCTION

Once pre-clinical studies have been completed on a drug, the pharmaceutical company will assess the scientific evidence and decide whether it wants to proceed to clinical trials. Usually, this will happen if the drug has the desired effect in animal tests, demonstrates a distinct advantage over established therapies, has acceptable pharmacokinetics, few metabolites, a reasonable half-life and no serious side effects. If the company decides to go ahead, the reports are submitted to the regulatory authority. In the USA, this takes the form of an Investigational Exemption to a New Drug (IND) Application which is submitted to the FDA. The IND should contain information regarding the chemistry, manufacture and quality control of the drug. It should also include information regarding the drug's pharmacology, distribution and toxicology in animals, and any clinical information that may be known about the drug. The IND is a confidential document and is not released to the public.

The FDA is responsible for assessing this information and approving the start of clinical trials. Dialogue then continues between the FDA and the companies as the clinical trials are carried out. Any adverse results must be reported to the FDA who will discuss with the company whether the trials should be stopped. If the clinical trials proceed smoothly, the FDA

advises the company how to present its application for the drug's approval.

NEW DRUG APPLICATION

The **New Drug Application** (NDA) is the vehicle in the United States through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing. The goals of the NDA are to provide enough information to permit FDA reviewers to establish the following:

- Is the drug safe and effective in its proposed use (s) when used as directed, and do the benefits of the drug outweigh the risks?
- Is the drug's proposed labelling (package insert) appropriate, and what should it contain?
- Are the methods used in manufacturing (Good Manufacturing Practice) the drug and the controls used to maintain the drug's quality adequate to preserve the drug's identity, strength, quality, and purity?

The purpose of clinical research: All new drugs need proof that they are effective, as well as safe, before they can be approved for marketing. It is important to realize, however, that no drug is absolutely safe. There is always some risk of an adverse reaction. But the FDA uses a cost benefit analysis to determine if the drug can be released to the public. The FDA determines that when the

benefits outweigh the risks the FDA considers a drug safe enough to approve. So the purpose of clinical research is to determine the safety and efficacy of the Investigational New Drug (IND) for the treatment of a particular disease or condition in humans. Clinical research is divided into three phases in the normal course of testing.

Before Trials

To legally test the drug on human subjects in the US the maker must first obtain an Investigational New Drug (IND) designation from FDA. This application is based on pre-clinical data, typically from animal studies, that shows the drug is safe enough to be tested in humans.

Often the “new” drugs that are submitted are not new molecular entities, but old medications that have been modified.

Clinical trials: Before a drug can be approved for sale to the public there is a set of clinical tests that must be performed. There is the Pre-clinical Research Stage. Here the drug is synthesized and purified. Animal tests are performed, and institutional review boards assess the studies and make recommendations on how to proceed. If the recommendations are positive, then an application to the FDA occurs and clinical tests begin.

The legal requirement for approval is “substantial” evidence of efficacy demonstrated through controlled clinical trials. This standard lies at the heart of the regulatory program for drugs. It means that the clinical experience of doctors, the opinion of experts, or testimonials from patients, even if they have experienced a miraculous recovery, have minimal weight in this process. Data for the submission must come from rigorous clinical trials.

The trials are typically conducted in three phases:

- **Phase 1:** The drug is tested in a few healthy volunteers to determine if it is acutely toxic.
- **Phase 2:** Various doses of the drug are tried to determine how much to give to patients.

- **Phase 3:** The drug is typically tested in double-blind, placebo controlled trials to demonstrate that it works. Sponsors typically confer with FDA prior to starting these trials to determine what data is needed, since these trials often involve hundreds of patients and are very expensive.
- **Phase 4:** These are post-approval trials that are sometimes a condition attached by the FDA to the approval.

The legal requirements for safety and efficacy have been interpreted as requiring scientific evidence that the benefits of a drug outweigh the risks and that adequate instructions exist for use, since many drugs are toxic and technically not “safe” in the usual sense.

Many approved medications for serious illnesses (e.g. cancer) have severe and even life-threatening side effects. Even relatively safe and well understood OTC drugs such as aspirin can be dangerous if used incorrectly.

The actual application: The results of the testing program are codified in an FDA-approved public document that is called the product label, package insert or full prescribing information. The prescribing information is widely available on the web, from the FDA, drug manufacturers, and frequently inserted into drug packages. The main purpose of a drug label is to provide healthcare providers with adequate information and directions for the safe use of the drug.

The documentation required in an NDA is supposed to tell the drug’s whole story, including what happened during the clinical tests, what the ingredients of the drug formulation are, the results of the animal studies, how the drug behaves in the body, and how it is manufactured, processed and packaged. Once approval of an NDA is obtained, the new drug can be legally marketed starting that day in the US.

Once the application is submitted, the FDA has 60 days to conduct a preliminary review which will assess whether the NDA is

"sufficiently complete to permit a substantive review". If the NDA is found to be insufficiently complete (and reasons for this can vary from a simple administrative mistake in the application to a requirement to reconduct much of the testing), then the FDA rejects the application with the issue of a Refuse to File letter which is sent to the applicant explaining where the application has failed to meet requirements.

Assuming that everything is found to be acceptable, the FDA will decide if the NDA will get a standard or accelerated review and communicate the acceptance of the application and their review choice in another communication known as the 74-day letter. A standard review implies an FDA decision within about 10 months while a priority review should complete within 6 months.

Requirements for similar products: Biologics, such as vaccines and many recombinant proteins used in medical treatments are generally approved by FDA via a Biologic License Application (BLA), rather than an NDA. Manufacture of biologics is considered to differ fundamentally from that of less complex chemicals, requiring a somewhat different approval process.

Generic drugs that have already been approved via an NDA submitted by another maker are approved via an Abbreviated New Drug Application (ANDA), which does not require all of the clinical trials normally required for a new drug in an NDA. Most biological drugs, including a majority of recombinant proteins are considered ineligible for an ANDA under current US law. However, a handful of biologic medicines, including biosynthetic insulin, growth hormone, glucagon, calcitonin, and hyaluronidase are grandfathered under governance of the federal food, drug, and cosmetics Act, which appears to be because these products were already approved when legislation aimed at regulating biotechnology medicines was later passed as part of the Public Health Services Act.

Biologic medicines governed under the federal food, drugs, and cosmetics Act has been an area of considerable confusion and dispute for the FDA, because under Section 505 (b) (2) of the federal food, drug, and cosmetic Act, a "generic" need not be an exact duplicate of the brand-name original in order to be approved. In July 2003, the sandoz generics unit of novartis filed, and the FDA accepted, an ANDA for a "follow-on" version of Pfizer's brand-name human growth hormone (Genotropin) that that sandoz named Omnitrope using the 505 (b) (2) pathway. The application was submitted following lengthy discussions with the FDA and contained preclinical, clinical, and comparability data, as well as literature references to the FDAs original decision on Pfizer's Genotropin. But on September 2, 2004, the FDA told sandoz that the agency was unable to reach a decision on whether to approve the company's application for Omnitrope. Frustrated with the FDAs failure to give them a decision on Omnitrope, sandoz then sued the FDA in US District court in Washington, DC citing a statutory requirement that the FDA is required by law to act on drug applications within 180 days. Medications intended for use in animals are submitted to a different center within FDA, the Center for Veterinary Medicine (CVM) in a New Animal Drug Application (NADA). These are also specifically evaluated for their use in food, animals and their possible effect on the food from animals treated with the drug.

Medical devices are approved by a variety of methods depending on the class of the device. A Pre-market Application (PMA) largely equivalent to an NDA is required for Class III devices, and a 510(k) approval that shows the device is equal to or better than a predicate device already on the market is required for class II devices. Class I medical devices (such as a toothbrush) do not require any approval at all.

Laws, regulations, policies and procedures: The mission of FDA is to enforce laws enacted

by the US congress and regulations established by the agency to protect the consumer's health, safety, and pocketbook. *The Federal Food, Drug, and Cosmetic Act* is the basic food and drug law of the US with numerous amendments it is the most extensive law of its kind in the world. The law is intended to assure consumers that foods are pure and wholesome, safe to eat, and produced under sanitary conditions; that drugs and devices are safe and effective for their intended uses; that cosmetics are safe and made from appropriate ingredients; and that all labelling and packaging is truthful, informative, and not deceptive.

Code of Federal Regulations (CFR): The final regulations published in the *Federal Register* (daily published record of proposed rules, final rules, meeting notices, etc.) are collected in the *CFR*. The *CFR* is divided into 50 titles that represent broad areas subject to Federal regulations. The FDAs portion of the *CFR* interprets the *Federal Food, Drug, and Cosmetic Act* and related statutes. Section 21 of the *CFR* contains most regulations pertaining to food and drugs. The regulations document all actions of all drug sponsors that are required under federal law.

The following regulations apply to the IND application process:

Investigational New Drug (IND) application: Current federal law requires that a drug be the subject of an approved marketing application before it is transported or distributed across state lines. Because a sponsor will probably want

to ship the investigational drug to clinical investigators in many states, it must seek an exemption from that legal requirement. The IND is the means through which the sponsor technically obtains this exemption from the FDA.

During a new drug's early preclinical development, the sponsor's primary goal is to determine if the product is reasonably safe for initial use in humans and if the compound exhibits pharmacological activity that justifies commercial development. When a product is identified as a viable candidate for further development, the sponsor then focuses on collecting the data and information necessary to establish that the product will not expose humans to unreasonable risks when used in limited, early-stage clinical studies.

FDAs role in the development of a new drug begins when the drug's sponsor (usually the manufacturer or potential marketer) having screened the new molecule for pharmacological activity and acute toxicity potential in animals, wants to test its diagnostic or therapeutic potential in humans. At that point, the molecule changes in legal status under the federal food, drug, and cosmetic Act and becomes a new drug subject to specific requirements of the drug regulatory system.

There are Three IND Types

- An Investigator IND is submitted by a physician who both initiates and conducts an investigation, and under whose

21CFR part 312
21CFR part 314
21CFR part 316
21CFR part 58
21CFR part 50
21CFR part 56
21CFR part 201
21CFR part 54

Investigational new drug application
INDA and NDA applications for FDA approval to market a new drug (new drug approval)
Orphan drugs
Good lab practice for no clinical laboratory (animal) studies
Protection of human subjects
Institutional review boards
Drug labelling
Financial disclosure by clinical investigators

immediate direction the investigational drug is administered or dispensed. A physician might submit a research IND to propose studying an unapproved drug, or an approved product for a new indication or in a new patient population.

- Emergency Use IND allows the FDA to authorize use of an experimental drug in an emergency situation that does not allow time for submission of an IND in accordance with 21CFR, Sec. 312.23 or Sec. 312.34. It is also used for patients who do not meet the criteria of an existing study protocol, or if an approved study protocol does not exist.
- Treatment IND is submitted for experimental drugs showing promise in clinical testing for serious or immediately life-threatening conditions while the final clinical work is conducted and the FDA review takes place.

There are Two IND Categories

- Commercial
- Research (non-commercial)

The IND application must contain information in three broad areas:

- Animal Pharmacology and Toxicology Studies: Preclinical data to permit an assessment as to whether the product is reasonably safe for initial testing in humans. Also included are any previous experience with the drug in humans (often foreign use).
- Manufacturing Information: Information pertaining to the composition, manufacturer, stability, and controls used for manufacturing the drug substance and the drug product. This information is assessed to ensure that the company can adequately produce and supply consistent batches of the drug.

Clinical protocols and investigator information—detailed protocols for proposed clinical studies to assess whether the initial-phase trials will expose subjects to unnecessary risks. Also, information on the qualifications of clinical investigators—professionals (generally physicians) who oversee the administration of the

experimental compound to assess whether they are qualified to fulfill their clinical trial duties. Finally, commitments to obtain informed consent from the research subjects, to obtain review of the study by an Institutional Review Board (IRB), and to adhere to the investigational new drug regulations.

Guidance documents for INDs: Guidance documents represent the Agency's current thinking on a particular subject. These documents are prepared for FDA review staff and applicants/sponsors to provide guidelines to the processing, content, and evaluation/approval of applications and also to the design, production, manufacturing, and testing of regulated products. They also establish policies intended to achieve consistency in the Agency's regulatory approach and establish inspection and enforcement procedures. Because guidances are not regulations or laws, they are not enforceable, either through administrative actions or through the Courts. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. For information on a specific guidance document, please contact the originating office.

Regulatory stages for new drug approvals: Regulatory bodies such as the Food and Drugs Administration (FDA) in the USA are responsible for approving whether a drug can proceed to clinical trials and whether it should be allowed into the market. The regulatory body has to evaluate the scientific and clinical data to ensure that the drug can be produced with consistently high purity, that it has the clinical effect claimed, and that it does not have unacceptable side effects. It must also approve the labelling of the drug and the directions for its use. In general, the regulatory body is interested in all aspects of a drug once it has been identified as a potentially useful medicine.

Once preclinical studies have been completed on a drug, the pharmaceutical company will assess the scientific evidence and decide whether it wants to proceed to clinical trials. Usually, this will happen if the drug has the

desired effect in animal tests, demonstrates a distinct advantage over established therapies, has acceptable pharmacokinetics, few metabolites, a reasonable half-life and no serious side effects. If the company decides to go ahead, the reports are submitted to the regulatory authority. In the USA, this takes the form of an Investigational Exemption to a New Drug Application (IND) which is submitted to the FDA. The IND should contain information regarding the chemistry, manufacture and quality control of the drug. It should also include information regarding the drug's pharmacology, distribution and toxicology in animals, and any clinical information that may be known about the drug. The IND is a confidential document and is not released to the public.

The FDA is responsible for assessing this information and approving the start of clinical trials. Dialogue then continues between the FDA and the company as the clinical trials are carried out. Any adverse results must be reported to the FDA who will discuss with the company whether the trials should be stopped. If the clinical trials proceed smoothly, the FDA advises the company how to present its application for the drug's approval.

DRUG DOCUMENTS

Background regulatory information: The Center for Drug Evaluation and Research (CDER) is the FDA division responsible for ensuring that human drugs are safe, effective, and properly labeled.

The approval process involves two stages. First, before CDER will permit a new drug to be tested on humans, the drug's sponsor must file an **IND**—a "Notice of Claimed Investigational Exemption for a New Drug." The IND contains the drug's structural formula, animal testing results, the proposed protocol for clinical testing, and other data.

After the trials, but before marketing, the manufacturer files a New Drug Application (**NDA**), which must contain full information about the product and clinical trial results. Each

NDA is reviewed by various FDA scientists. In some instances, the NDA is also reviewed by a public advisory committee.

IND (investigational new drug) documents: Except in rare circumstances, documents regarding an IND are not disclosable under the Freedom of Information Act. FDA maintains that even the acknowledgment of the existence of an IND could damage a drug sponsor's competitive position.

NDA documents: Once the NDA is approved, information about the approval may be released under FOIA. The basic information package relating to the approval of a **New drug application** includes:

- Approval letter, package insert and labelling
- FDA final reviews
- Summary Basis of Approval (SBOA)

Note: SBOAs are no longer prepared for most new drug approvals. However, the same information is released in the reviews mentioned above, although not in the same format.

- View a sample approval letter
- View sample pages from a drug review
- View sample pages from a summary basis of approval.

ANDA documents (generic drugs): When the patent and marketing exclusivity for a particular drug has expired, the drug may be manufactured by other companies as well. Manufacturers of these generic or "me-too" forms are not required to repeat the extensive preclinical and clinical testing required for new drugs. Rather, they may submit an **Abbreviated New Drug Application** (ANDA) documenting the bioequivalence of their formulation of the drug. The FDA reviews ANDAs to compare the generic product to the original product to ensure that comparable blood levels of active ingredients are produced. After approval, basic information about an ANDA is available:

- Approval letter, Package insert and labeling
- Bioavailability and dissolution reviews
- View a sample approval letter
- View a sample dissolution review

Adverse reaction reports: Adverse Reaction Reports are summaries of all of the adverse experiences with specific drug products reported to FDA. Special FDA-assessed computer charges apply to procuring these documents; our information specialists can advise you as to the current availability and cost.

EXPORT REGISTRATION

Export: The term “export” is derived from the conceptual meaning as to ship the goods and services out of the port of a country. The seller of such goods and services is referred to as an “exporter” who is based in the country of export whereas the overseas based buyer is referred to as an “importer”. In International Trade, “exports” refers to selling goods and services produced in home country to other markets.

Any good or commodity, transported from one country to another country in a legitimate fashion, typically for use in trade. Export goods or services are provided to foreign consumers by domestic producers.

Export of commercial quantities of goods normally requires involvement of the customs authorities in both the country of export and the country of import. The advents of small trades over the internet such as through Amazon and e-Bay have largely bypassed the involvement of Customs in many countries because of the low individual values of these trades. Nonetheless, these small exports are still subject to legal restrictions applied by the country of export. An export's counterpart is an import.

Registration: The filing process a company performs, in accordance with SEC (Securities and Exchange Commission) regulations, prior to offering a new issue to the public. This process enables the SEC to confirm that the issue meets all the regulatory requirements.

Export license: A license issued to exporters by governments to permit them to export certain goods to certain countries. Such goods may be of strategic importance, or simply in short

supply, or are controlled to comply with foreign agreements.

EXPORT REGISTRATION PROCEDURE

Formalities of registration for export units/documents prepared for export registration: few steps for an enterprise to become an export organization are:

1. **Registration as a business entity:** No additional registration formalities are required for a domestic unit if it wants to enter exports. A new export unit can be started as a proprietorship concern, a partnership concern or as a company with limited liability and the formalities remain the same as for domestic units.
2. **IEC Number:** Every individual, firm or a company seeking to export or import is required to obtain a code number, called Import-Export Code (IEC) number, from the office of Regional licensing authority of DGFT. This number is required for communication with any office related to export and import.
3. **Registration-Cum-Membership Certificate (RCMC):** RCMC means the certificate of registration and membership granted by an export promotion council/commodity board/development authority or other competent authority as prescribed by foreign trade policy to an exporting unit.

Any person, applying for (i) a license/authorization/certificate/permission to import/export, or (ii) any other benefit or concession under foreign trade policy is required to furnish Registration-Cum-Membership Certificate (RCMC). RCMC is also required for executing a bond before central excise authorities, which exempts exporters to furnish bank guarantees.

Export Promotion Councils have been set up by various ministries of the Central Government to promote and develop the exports of particular group of products, projects and services. For certain group of products, which are sensitive

from the viewpoint of national consumption, there are commodity boards instead. Thus while we have export promotion councils for apparel, leather, software, chemicals, engineering goods, etc. we have commodity boards for tea, coffee, jute, etc.

4. **Registration with sales tax office:** Goods exported from India are exempt from Central and State sales tax. However, for getting exemption of such taxes or claiming their refund, wherever, permissible under

Foreign Trade Policy, the exporting unit should be registered with sales tax authorities.

5. **Registration with excise department:** If the exporting unit is engaged in manufacture of the product, it needs registration with excise department and the formalities remain the same as for any domestic unit. This registration is required for claiming refund of excise duties under various schemes of the government.

Pharmacy, Pharmaceutical Education, Regulation and Career Option

INTRODUCTION

Pharmacy is the health profession that links the health sciences with the chemical sciences and it is charged with ensuring the safe and effective use of pharmaceutical drugs. The word derives from the Greek word *pharmakon* “drug medicine”.

The **scope** of pharmacy practice includes more traditional roles such as compounding and dispensing medications, and it also includes more modern services related to health care, including clinical services, reviewing medications for safety and efficacy, and providing drug information. Pharmacists, therefore, are the experts on drug therapy and are the primary health professionals who optimize medication use to provide patients with positive health outcomes. An establishment in which pharmacy (in the first sense) is practiced is called a pharmacy, chemists or drug store. These stores commonly sell not only medicines, but also miscellaneous items such as candy (sweets), cosmetics, and magazines, as well as light refreshments or groceries. The word *pharmacy* is derived from its root word *pharma* which was a term used since the 1400–1600s. In addition to pharma responsibilities, the pharma offered general medical advice and a range of services that are now performed solely by other specialist practitioners, such as surgery and midwifery. The pharma often operated through a retail shop which, in addition to ingredients for

medicines, sold tobacco and patent medicines. The pharmas also used many other herbs not listed. In its investigation of herbal and chemical ingredients, the work of the pharma may be regarded as a precursor of the modern sciences of chemistry and pharmacology, prior to the formulation of the scientific method.

Disciplines

The field of pharmacy can generally be divided into three primary disciplines:

- Pharmaceutics
- Medicinal chemistry and pharmacognosy
- Pharmacy practice

The boundaries between these disciplines and with other sciences, such as biochemistry, are not always clear-cut; and often, collaborative teams from various disciplines research together.

Pharmacology is sometimes considered a fourth discipline of pharmacy. Although pharmacology is essential to the study of pharmacy, it is not specific to pharmacy. Therefore it is usually considered to be a field of the broader sciences.

Other specializations in pharmacy practice recognized by the Board of Pharmaceutical Specialties include: cardiovascular, infectious disease, oncology, pharmacotherapy, nuclear, nutrition, and psychiatry. The Commission for Certification in Geriatric Pharmacy certifies pharmacists in geriatric pharmacy practice. The

American Board of Applied Toxicology certifies pharmacists and other medical professionals in applied toxicology.

Pharmacists

Pharmacists are highly-trained and skilled healthcare professionals who perform various roles to ensure optimal health outcomes for their patients. Many pharmacists are also small-business owners, owning the pharmacy in which they practice.

Pharmacists are represented internationally by the International Pharmaceutical Federation (FIP). They are represented at the national level by professional organizations such as the Dutch Pharmacists Association (VNA) Royal Pharmaceutical Society of Great Britain (RPSGB), the Pharmacy Guild of Australia (PGA), the Pakistan Pharmacists Society (PPS) and the American Pharmacists Association (APhA). In some cases, the representative body is also the registering body, which is responsible for the ethics of the profession. Since the Shipman Inquiry, there has been a move in the UK to separate the two roles.

TYPES OF PHARMACY PRACTICE AREAS

Pharmacists practice in a variety of areas including retail, hospitals, clinics, nursing homes, drug industry, and regulatory agencies. Pharmacists can specialize in various areas of practice including but not limited to: hematology/oncology, infectious diseases, ambulatory care, nutrition support, drug information, critical care, pediatrics, etc.

I. **Community pharmacy:** A pharmacy (commonly the chemist in Australia, New Zealand and the UK. or drugstore in North America. retail pharmacy in industry terminology, or Apothecary, historically) is the place where most pharmacists practice the profession of pharmacy. It is the community pharmacy where the dichotomy of the profession exists—health professionals who are also retailers.

II. **Hospital pharmacy:** Pharmacies within hospitals differ considerably from community

pharmacies. Some pharmacists in hospital pharmacies may have more complex clinical medication management issues whereas pharmacists in community pharmacies often have more complex business and customer relations issues.

III. **Clinical pharmacy:** Clinical pharmacists provide direct patient care services that optimize the use of medication and promote health, wellness, and disease prevention. Clinical pharmacists care for patients in all health care settings but the clinical pharmacy movement initially began inside hospitals and clinics. Clinical pharmacists often collaborate with physicians and other health care professionals to improve pharmaceutical care. Clinical pharmacists are now an integral part of the interdisciplinary approach to patient care. They work collaboratively with physicians, nurses and other health care personnel in various medical and surgical areas. They often participate in patient care rounds and drug product selection. In most hospitals in the United States, potentially dangerous drugs that require close monitoring are dosed and managed by clinical pharmacists.

IV. **Compounding pharmacy:** Compounding is the practice of preparing drugs in new forms. For example, if a drug manufacturer only provides a drug as a tablet, a compounding pharmacist might make a medicated lollipop that contains the drug. Patients who have difficulty swallowing the tablet may prefer to suck the medicated lollipop instead. Another form of compounding is by mixing different strengths (g, mg, mcg) of capsules or tablets to yield the desired therapy indicated by the doctor. This form of compounding is found at community or hospital pharmacies or in-home administration therapy. Compounding pharmacies specialize in compounding, although many also dispense the same non-compounded drugs that patients can obtain from community pharmacies.

V. **Consultant pharmacy:** Consultant pharmacy practice focuses more on medication regimen

review (i.e. "cognitive services") than on actual dispensing of drugs. Consultant pharmacists most typically work in nursing homes, but are increasingly branching into other institutions and non-institutional settings. Traditionally consultant pharmacists were usually independent business owners, though in the United States many now work for several large pharmacy management companies (Primarily Omnicare, Kindred Health care and Phar Merica). This trend may be gradually reversing as consultant pharmacists begin to work directly with patients, primarily because many elderly people are now taking numerous medications but continue to live outside of institutional settings. Some community pharmacies employ consultant pharmacists and/or provide consulting services. The main principle of consultant pharmacy is pharmaceutical care developed by hepler and strand in 1990.

VI. Internet pharmacy: Since about the year 2000, a growing number of internet pharmacies have been established worldwide. Many of these pharmacies are similar to community pharmacies, and in fact, many of them are actually operated by brick-and-mortar community pharmacies that serve consumers online and those that walk in their door. The primary difference is the method by which the medications are requested and received. Some customers consider this to be more convenient and private method rather than traveling to a community drugstore where another customer might overhear about the drugs that they take. Internet pharmacies (also known as online pharmacies) are also recommended to some patients by their physicians if they are homebound.

VII. Veterinary pharmacy: Veterinary pharmacies, sometimes called animal pharmacies, may fall in the category of hospital pharmacy, retail pharmacy or mail-order pharmacy. Veterinary pharmacies stock different varieties and different strengths of medications to fulfill the pharmaceutical needs of animals. Because the needs of animals, as well as the regulations

on veterinary medicine, are often very different from those related to people, veterinary pharmacy is often kept separate from regular pharmacies.

VIII. Nuclear pharmacy: Nuclear pharmacy focuses on preparing radioactive materials for diagnostic tests and for treating certain diseases. Nuclear pharmacists undergo additional training specific to handling radioactive materials, and unlike in community and hospital pharmacies, nuclear pharmacists typically do not interact directly with patients.

IX. Military pharmacy: Military pharmacy is an entirely different working environment due to the fact that technicians perform most duties that in a civilian sector would be illegal. State laws of Technician patient counseling and medication checking by a pharmacist do not apply.

X. Pharmacy informatics: Pharmacy informatics is the combination of pharmacy practice science and applied information science. Pharmacy informaticists' work in many practice areas of pharmacy, however, they may also work in information technology departments or for health care information technology vendor companies. As a practice area and specialist domain, pharmacy informatics is growing quickly to meet the needs of major national and international patient information projects and health system interoperability goals. Pharmacists are well-trained to participate in medication management system development, deployment and optimization.

THE FUTURE OF PHARMACY

In the coming decades, pharmacists are expected to become more integral within the health care system. Rather than simply dispensing medication, pharmacists will be paid for their patient care skills.

Medication Therapy Management (MTM): A practice of pharmacy currently being taught at schools of pharmacy nationwide includes the clinical services that pharmacists can provide for their patients. Such services include the thorough analysis of all medication (prescription,

non-prescription, and herbals) currently being taken by an individual. The result is a reconciliation of medication and patient education resulting in increased patient health outcomes and decreased costs to the health care system.

This shift has already commenced in some countries for instance, pharmacists in Australia receive remuneration from the Australian Government for conducting comprehensive Home Medicines Reviews. In Canada, pharmacists in certain provinces have limited prescribing rights (as in Alberta and British Columbia) or are remunerated by their provincial government for expanded services such as medications reviews (Medschecks in Ontario). In the United Kingdom, pharmacists who undertake additional training are obtaining prescribing rights. They are also being paid for by the government for medicine use reviews. In the United States, pharmaceutical care or clinical pharmacy has had an evolving influence on the practice of pharmacy. Moreover, the Doctor of Pharmacy (Pharm. D.) Degree is now required before entering practice and some pharmacists now complete one or two years of residency or fellowship training following graduation. In addition, consultant pharmacists, who traditionally operated primarily in nursing homes are now expanding into direct consultation with patients, under the banner of "Senior Care Pharmacy."

Drugstore

Drugstore is a common American term for a type of store centrally featuring a pharmacy. Drugstores sell not only medicines, but also miscellaneous items such as candy, cosmetics, and magazines, as well as light refreshments.

The Difference between 'Drugstore' and 'Pharmacy'

Same in general. But maybe **drugstores** are not always required to have a pharmacist if they only sell medicine but not make them. In **pharmacies** they can prepare prescription medicine.

The Difference between a 'Dispensary' and a 'Pharmacy'

A '**pharmacy**' is usually a retail store where prescription medication is dispensed and sold, along with other goods.

A '**dispensary**' is usually a designated area in an institution such as a school, office building, hospital, and so on, where medications are dispensed, usually without charge.

A dispensary could also be, or be part of, a clinic in an institution of some sort, or a separate, stand-alone medical center or clinic, where diagnosis, treatment and dispensing of medication takes place.

PHARMACEUTICAL EDUCATION

Pharmaceutical courses in India are broadly classified into three categories:

- i. Diploma in pharmacy (D. Pharm Course).
- ii. Degree course in pharmacy, i.e. B. Pharm course.
- iii. Postgraduate courses leading to M. Pharm and PhD Degrees.

PHARMACY EDUCATION

Formal pharmacy education in India started much before the enactment of Pharmacy Act, 1948 and the Education Regulations (1953). As discussed earlier, the pharmacy education is currently regulated by the Pharmacy Council of India under the provision of the Pharmacy Act.

The Present Education Regulations (1991) framed under the Act prescribes 10+2 in science stream as minimum qualification for admission to Diploma or Degree courses. The Diploma course is of 2 years duration. On completion of which, a candidate has to undergo 500 hours of practical training in a pharmacy organization for not less than three months duration for obtaining the minimum registrable qualification—Diploma in pharmacy (D. Pharm). Bachelor in pharmacy is a four year course with 10+2 in science stream as minimum qualification for admission. A Diploma holder can get lateral entry into IIInd year B. Pharm course. A bachelor

in pharmacy becomes eligible for two-year masters course (M. Pharm) and subsequently for PhD Degree which is of variable duration.

Pharmacy education especially bachelor and higher studies have industrial learning. During 1940s and 50s, hospitals and industries were established in large numbers in India. Consequently, there was great demand for qualified pharmacists and pharmaceutical chemists. Hence, pharmacy education was developed in such a way to satisfy the requirement of industry and hospital, i.e. D. Pharm course for hospital and medicine shops and B. Pharm course for the industry were started. This is proved by the fact that in the last few decades D. Pharm holders are not employed by the industry and B. Pharm holders are not in great numbers in hospitals or medical shops.

It is a common belief that the medical practitioner is better placed for pharmacists' job than the pharmacists themselves. Several arguments have been put forward regarding scrapping diploma courses as it does not fulfill the task of producing pharmacists who can advice doctors as well as patients regarding the right drugs and regime. It has been further argued that the bachelor's course in pharmacy should be separated into B. Pharm-clinical and B. Pharm-industrial where the syllabus should be oriented towards hospital/community pharmacy and industrial pharmacy respectively.

The quality of education offered by pharmacy institutions in the country varies widely. There are only a few institutions which maintain internationally recognized standard. The main drawback is that the graduates emerging from the pharmacy institutions, lack the skills needed for practice. Most of the academic institutions providing education in pharmacy are away from practice environment. Much of what is taught, though pedagogically relevant, does not offer the student a feel for what to expect in industry, hospitals or in community setting. There is very little, if any, interaction with industry and healthcare organization to know

of its needs and include whatever is possible and appropriate, into the educational system.

Quality issues in teaching and training have not received adequate attention. Shortage of trained and committed teachers is a major problem in pharmacy institutes. This impacts the quality of teaching and training. Academic position in pharmacy institutes is not an attractive option for the pharmacists as compared to many areas of industrial pharmacy.

The quality of education and training in pharmacy institution can be effectively improved through accreditation. The process of accreditation helps in assuring minimum quality in education and training. Currently the pharmacy programmes (Diploma, Degree and postgraduate programmes) are accredited by National Board of Accreditation (NBA) constituted by the all India Council for Technical Education (AICTE), as an Autonomous Body, under Section 10 (u) of the AICTE Act, 1987. NBA conducts periodic evaluation of the programme on the basis of guidelines, norms and standards specified by it. The aim is to develop a quality conscious system of technical education where excellence, relevance to market needs and participation by all stakeholders are prime the major determinants.

Besides NBA, the National Assessment and Accreditation Council (NAAC) an autonomous body established by the University Grants Commission (UGC) of India also accredit institutions of higher education in the country. While NBA accredits programmes/courses, NAAC provides accreditation to universities/colleges/institutions. NAAC promotes establishment of quality system within institutions that can undertake quality improvement on a continuous basis.

The PCI is exploring the option of tying up with the US Accreditation Council for Pharmacy Education (ACPE) with a view to help Indian Pharmacists get job openings in the US. The spin off benefits of updating curriculum, training, and improving the quality of education,

would also help recognition of Indian pharmacy education in other countries of the world.

CONTINUING PHARMACY EDUCATION

The recent report on "Global Pharmacy Workforce and Migration" by FIP states "maintaining competence throughout a career during which new and challenging professional responsibilities will be encountered, is an ethical requirement for all health professionals". FIP has recognized in its code of ethics for pharmacists "to ensure competency in each pharmaceutical service provided by continually updating knowledge and skills".

In India, there is complete lack of any training or incentive to professionalize among retail pharmacists—as a result of which even the most enthusiastic pharmacists gradually convert into mere traders. This is also fuelled by the lack of expectation in the community for services other than mere dispensing. Attempt to keep one's knowledge updated and work professionally is perceived as strong economic disincentives in Indian retail pharmacy practice.

The current regulations do not require pharmacists to periodically update their knowledge and skills. In developed countries like US, UK, Germany, and Japan CPE is mandatory for licensing continued competency to practice the pharmacy profession. There exists a system of continuing education for academic staff of pharmacy institutions. The AICTE and University Grants Commission (UGC) provide opportunities for upgradation of knowledge and skill of teachers in Pharmacy institutions. The continuing education is in the form of induction programme and periodic refresher courses. These courses are also linked to salary increments, promotions and career development. AICTE has established centres for undertaking in-service training and CPE. Besides the AICTE also provide various grants and assistance for attending conference/seminar/symposium at national/international levels, assistance for short term training in new emerging areas and master/doctoral pro-

gramme and other incentives under various schemes.

The need for CPE has been widely felt and advocated by the stakeholders in the pharmacy sector. PCI has initiated a number of measures for updation of knowledge bank of pharmacists by conducting refresher courses in collaboration with State Pharmacy Councils, sourcing of books from Commonwealth Pharmaceutical Association, London and free of cost distribution to pharmacy institutions and State Pharmacy Councils for dissemination of scientific and professional knowledge. PCI has requested financial assistance from the Planning Commission under the 11th Five-Year-Plan for important professional activities like continuing education for teachers and working pharmacists, travel grants for exchange programmes between India and Foreign countries, grants to institution for upgradation of infrastructural facilities, etc.

REGULATION OF PHARMACY EDUCATION, PROFESSION AND PRACTICE IN INDIA

Policies and Regulations

Pharmacy education, profession and practice in India are regulated by the **Pharmacy Act 1948**. Under the Act, a person fulfilling the prescribed eligibility criteria has to get registered with the State Pharmacy Council in order to practice pharmacy. The PCI is a main regulatory body formed under the Pharmacy Act to implement its provisions. The Act also mandates the constitution of State Pharmacy Councils for the purpose of registration of pharmacists and regulation of pharmacy practice. The Act provide authority to the State Pharmacy Council to inspect any premises where drugs are compounded or dispensed, enquire whether a person who is engaged in compounding or dispensing of drugs is a registered pharmacist and institute prosecution under the order of the executive committee of the State Council.

For the purpose of regulating pharmacy education under the Pharmacy Act, the first

Education Regulation was framed in 1953 and amended in 1972 and 1981. Currently, the **Education Regulation, 1991** is in force which regulates Diploma course in pharmacy. The Education Regulation 1991 has defined minimum qualification for admission in Diploma course and curriculum for the same. The Pharmacy Council of India provides approval and regulates Diploma (D. Pharm) and Degree (B. Pharm) courses.

Pharmacy education is also regulated by the All India Council for Technical Education (AICTE) which has been established under the **AICTE Act, 1987**. The AICTE focuses on maintaining norms and standards in technical education which also include pharmacy. It regulates the Degree, postgraduate and other higher level courses. However, an educational institution imparting pharmacy training needs to be recognized and approved by the PCI for the qualifications to be accepted for registration as a pharmacist.

Besides the pharmacy Act, pharmacy practice is also governed by **Drugs and Cosmetics Act, 1940** together with **Drugs and Cosmetics Rules, 1945** (framed under the Act). The Act regulates the import, manufacture, distribution and sale of drugs.

The practitioners of Indian system of medicine and homeopathy together called **AYUSH**, roughly equals the number of allopathic practitioners in the country. These practitioners are also the drug dispenser and in some cases engaged in compounding. In order to regulate the profession and practice of pharmacy under these schools of medicines, the Government has introduced the **Indian Medicine and Homeopathy Pharmacy Bill, 2005** in the parliament. Once passed by the parliament, the bill will become an Act. This Act will lead to constitution of Pharmacy Council for AYUSH similar to PCI.

Currently, the focus and priorities of the government in the health sector is governed by the **National Health Policy, 2002 (NHP)**. Pharmacy being an important component of the

health sector is also governed by the National Health Policy. The main objective of this policy is to achieve an acceptable standard of good health amongst the general population of the country.

More recently, the Government of India has launched the **National Rural Health Mission (NRHM) in 2005** to carry out necessary architectural correction in the basic health care delivery system. The National Rural Health Mission (2005–12) seeks to provide effective health care to rural population throughout the country with special focus on 18 States, which have weak public health indicators and/or weak infrastructure.

National Pharmaceutical Policy, 2002 and Draft Policy, 2006 are the only policies having bearing on the human resources in the pharmacy sector especially those in industrial pharmacy. The Pharmaceutical Policy emphasizes on strengthening production capabilities, quality assurance and encouraging research and development in pharmaceutical industry. These policies are likely to increase employment opportunities for pharmacists. Further the policy also emphasizes on the role of National Institute of Pharmaceutical Education and Research (NIPER) in upgrading the standards of pharmacy education and R and D and plans to open more such institutions.

There is no specific policy for promoting the role of pharmacists in the Indian health care system. While the health related policies are governed by the ministry of health and family welfare, policies related to drugs and pharmaceutical industry are placed under the ministry of chemical and fertilizer.

CAREER OPTIONS FOR PHARMACISTS (Fig. 23.1)

Areas of pharmacy profession: The spectrum of pharmacy profession in India is very wide. It covers opportunities in pharmaceutical industry—manufacturing and retail, healthcare sector, pharmacy education, and regulatory bodies. While more than 98% of individuals with D. Pharm Degree are mainly engaged in

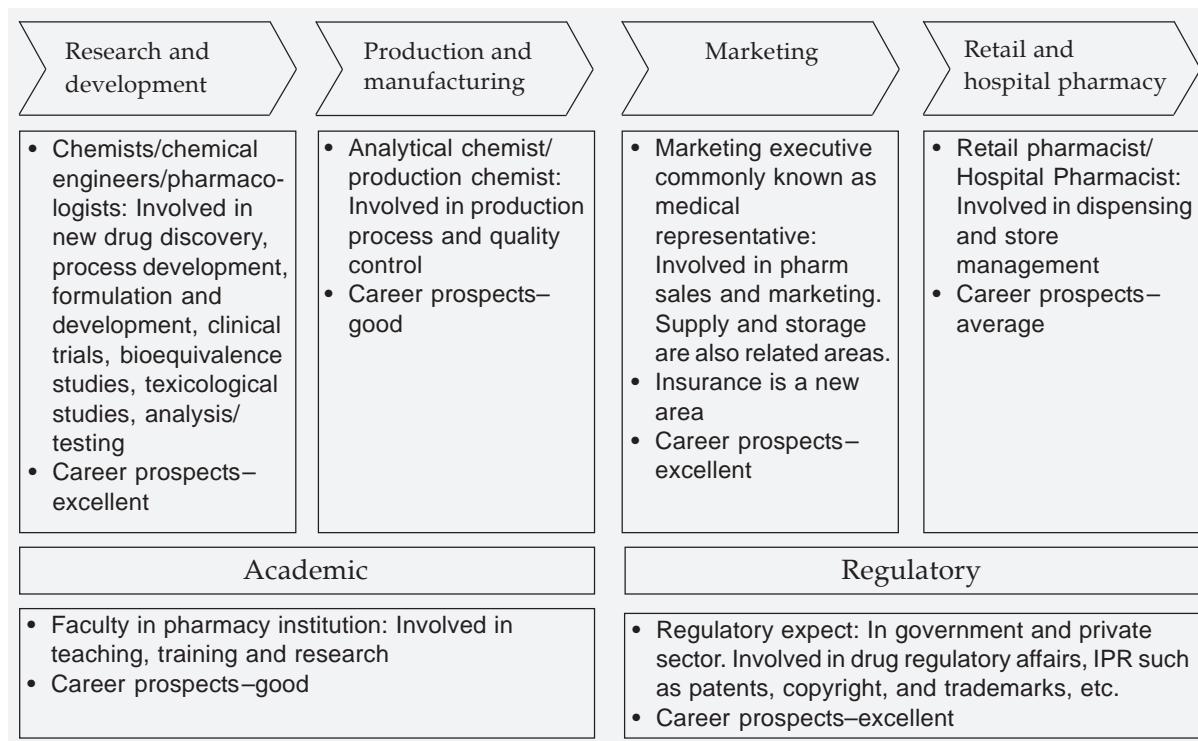


Fig. 23.1: Career options for pharmacists

dispensing medicine at retail or hospital pharmacies, those with B. Pharm or higher degree have a variety of opportunities to choose from. Some of these areas are given above.

DEMAND OF PHARMACISTS

Some of the important factors influencing the demand of pharmacists in India. These factors include population, expanding pharmaceutical and biotechnology industry, widening role of pharmacists and standardization of healthcare services in public sector.

Population: Pharmacist ratio. There is no internationally established minimum recommended pharmacist to population ratio. Many countries have developed their own recommendations based on demand for pharmaceutical services. The demand for pharmacists is determined by a range of factors including

the population demographics; disease burden; economic status; market forces; pharmacist roles and competencies; legislation relating to medicines dispensing and prescribing; roles of other health workers; health systems and technology.

Growth of pharmaceutical industry: The Indian Pharmaceuticals sector has come a long way, being almost non-existing during 1970, to a prominent provider of healthcare products, meeting almost 95% of country's pharmaceutical needs. The domestic pharmaceutical output has increased at a compound growth rate (CAGR) of 13.7% per annum. Currently the Indian pharma industry is valued at approximately \$ 8.0 billion. Globally, the Indian industry ranks 4th in terms of volume and 13th in terms of value. Indian pharmaceuticals industry has over 20,000 units. Around 260

constitute the organized sector, while others exist in the small scale sector. In the present product patent regime, Indian pharmaceutical industry is poised for even bigger gains. Some of the potential areas of growth are as follows.

Research and development: Research and Development is the key to the future of pharmaceutical industry. Before the patent regime, the R and D expenditure by the Indian pharmaceutical industry is around 1.9% of the industry's turnover. This obviously, is very low when compared to the investment on R and D by foreign research-based pharma companies. They spend 10–16% of the turnover on R and D. However, now that India has entered into the new patent protection era, companies are rapidly increasing their R and D budgets aimed at NCEs (new chemical entities) and new drug delivery systems.

India is fast becoming the contract research hub for Pharmaceutical R and D. According to a survey by the Pharmaceutical Outsourcing Management Association and Bio/Pharmaceutical Outsourcing Report, pharmaceutical companies are utilizing substantially the services of Contract Research Organizations (CROs). In 2002, the industry for clinical trials in India was \$ 70 million. This market is growing at a rate of 20% per annum. According to experts, it will be an industry worth anywhere between \$ 500 million and \$ 1.5 billion by 2010. The global R and D spend is to the tune of \$ 60 billion, of which the non-clinical segment accounts for \$ 21 billion and the clinical segment accounts for \$ 39 billion. In terms of Indian prices, this translates into \$ 7 billion (at 1/3rd of US/EU costs) and \$ 7.8 billion (at 1/5th of US/EU costs) respectively. This constitutes a total potential of \$ 14.8 billion for the Indian pharma companies.

R and D in the pharma industry is multi-faceted and draws upon the expertise of chemists, chemical engineers, pharmacologists and medical practitioners. The different activities include drug development (synthesis and manufacture), formulation, clinical trials and evaluation and finally, launch. Closely

associated with these are regulatory and quality assurance functions. If the above functions are translated into manpower requirements, it will lead to increased demand for pharmacists besides other professionals.

Manufacturing: The Indian pharmaceuticals industry with over 20,000 units globally ranks 4th in terms of volume. The domestic pharmaceutical output has increased at a compound Annual growth rate (CAGR) of 13.7% per annum. Further, many global pharmaceutical majors are looking to outsource manufacturing from Indian companies, which enjoy much lower costs (both capital and recurring) than their Western counterparts. Many Indian companies have made their plants GMP compliant and India is also having the largest number of USFDA-approved plants outside USA. The Pharma companies are going for compliance with International regulatory agencies like USFDA, MCC, etc. for their manufacturing facilities. The Boston Consulting Group estimated that the contract manufacturing market for global companies in India would touch \$ 900 million by 2010. Industry estimates suggest that the Indian companies bagged manufacturing contracts worth \$ 75 million in 2004 (FICCI, 2005).

Retail pharmacies: The retail sector remains the biggest employer of diploma pharmacists. There are about 5,00,000 community pharmacists in the country. As per the statutory requirement under the Drugs and Cosmetics Act, each pharmacy has to be manned by a registered pharmacist. The retail sector is fast expanding as new license is liberally granted even in places already having retail shops and also as a result of entry of major retail pharmacy chains. These factors are likely to push the demand for community pharmacists.

Health care sector: National Health care spending in India is expected to rise at 12% per annum through 2005–2009 and will double over the next 10 years. The spending in terms of GDP is expected to rise from about 5.2% in 2004 to 5.5 % in 2009. Other estimates suggest that by 2012 health care spending could contribute

8% of the GDP. This large increase in health care spending will also have impact on the availability, accessibility and the demand for drugs which in turn will have direct impact on the requirement of pharmacists from manufacturing, marketing to dispensing. In the public sector in rural areas, every PHC and CHC should have a pharmacist. Out of a requirement of 25,885 pharmacists for PHCs and CHCs, there is a shortfall of 25.8% in sanctioned posts at these levels; 10.7% of the sanctioned posts lay vacant in 2002. The National Rural Health Mission is making all out efforts to fill up all vacant positions and further augment the existing workforce in the rural areas. In recent times hospitals especially in the private sector are focusing on quality of care. Medication being an important aspect of the patient care, there has been emphasis on knowledge and skill of pharmacists to suggest appropriate drugs and the regimen. Also the hospitals are taking steps to reduce medication error. All these factors are pushing the demand for adequately trained pharmacists in hospital pharmacies. Hospital sector is witnessing a strong growth and expansion. The number of hospital beds in the country is currently estimated to be 1.2 million which includes public and private beds in urban and rural areas. The beds strength is likely to expand to approximately 2.2 million by the year 2012. As per the Indian Public Health Standard (IPHS), there should at least 5 pharmacists for 200 bedded secondary care hospital. Hence, there is a requirement of 25,000 additional pharmacists in the hospital sector by 2012. The growth of hospital sector is also fueled by gradual expansion of health insurance in the country. This has opened a new opportunity for pharmacists who are in demand because of their expertise in understanding prescription and other hospitalization issues.

INTERNATIONAL DEMAND OF A PHARMACIST

Despite having a high population to pharmacist ratio, it has been observed that there is high demand in Western countries and they are

unable to meet this demand. A shortfall of over 1,50,000 pharmacists by 2020 in the USA was projected in a study. Similarly, in Australia the demand for pharmacists is projected to increase between the years 2000 to 2010 from 13,000 to 17,200; thus leading to a shortfall of about 3,000 pharmacists by 2010. The European Union needs to address a shortfall of around 700,000 researchers, or 1.2 million, research related personnel, to accomplish its goal of becoming a powerhouse knowledge-based economy by 2010. These projections include pharmacists also.

QUALITY OF PHARMACISTS IN INDIA

Pharmacists in India do not have any laid down norms on competencies and quality of services. In countries like New Zealand, a pharmacist has to maintain his competencies throughout his career. In order to practice, the pharmacist has to obtain Annual Practicing Certificate (APC) from the Pharmacy Council. The APC has to be renewed every year by undertaking accredited rectification programme which is on the lines of continuing professional development (CPD). Besides the council conducts audit of competencies of 20% of randomly selected pharmacists every year. In contrast, the minimum qualification for registration ensures minimum level of competency at the time of registration. However, there is no system of evaluating pharmacist's competency later in their career. Hence, the level of competencies and the quality of services provided may vary greatly among Indian pharmacists.

RECOMMENDATIONS

The recommendations are as follows:

1. *Role of PCI in regulating pharmacy education:* The current arrangement of PCI and AICTE playing complementary role in regulating pharmacy education should be further strengthened by clearly specifying the role of each agency. In case the PCI is made the sole authority to regulate

pharmacy education as per the provisions of the Pharmacy Act (PCI has proposed amendments to Pharmacy Act), it should also undertake all functions related to faculty development currently undertaken by AICTE. While doing so PCI and state pharmacy councils needs to be strengthened in terms of infrastructure, manpower and resources. The strengthening should lead to capacity development of the PCI and state pharmacy council to respond to the need for orienting pharmacy education to fulfill the demand and opportunities in this vast sector and maintaining standard.

2. *Redefining the role of pharmacists:* Pharmacists have the potential to fill (at least partially if not fully) the gap created due shortage/unavailability of doctors and nursing personnel in health facilities in rural areas. This can be achieved through a policy initiative to redefine the role of pharmacists in the Indian health care system so as to better utilize the capabilities of pharmacists. This would also necessitate a change in the pharmacy curriculum giving more emphasis on community practice. The National Health Policy 2002 has also envisaged such role for nursing and paramedical personnel including pharmacists.
3. *Licensing chemist shops:* Crowding of chemist shops due to liberal grant of license often leads to unhealthy competition where pharmacists indulge in unethical practices for promoting sales and boosting revenue. However, granting license to only a few may adversely affects the availability of medicines and lack of competition may lead to monopoly practices. Therefore, the criteria for license should be redefined which would take care of various factors such as population, disease profile, etc. Government should also take necessary steps to promote planned growth of chemist shops in the country. Secondly the demand for defining B. Pharm as the minimum requirement for licensing of chemist shops under the

Drugs and Cosmetics Act has been gaining momentum to widen the scope of pharmacy services. However, any such initiative should take into account Diploma holders currently manning most of the pharmacies across the country. The transition should be gradual and the Diploma holders should be given an opportunity to upgrade their skills and hence widen the scope of practice.

Further the economic feasibility of such a policy change should also be carefully looked into. Factors such as willingness of graduate pharmacists to practice in rural and remote areas, cost of employing graduate pharmacists and the paying capacity and willingness of rural population for pharmacist's services are relevant to such a policy decision.

4. *Need for Diploma courses:* It has already been proposed that the chemist shops should have a graduate pharmacist. However, a large chunk of pharmacists currently working in chemist shop or hospital are Diploma holders. The existing Diploma pharmacists should be given an opportunity to upgrade their knowledge and skills to the level of graduate pharmacists. This task can be undertaken by securing seats in Degree courses for those who opt for regular programme or by developing specifically designed programme for the existing Diploma holders. These programmes should preferably be a part time course and staggered over a long duration. The flexibility in timings is necessary as most the Diploma holders are practicing. Going by the experience of several countries around the globe pharmacy technician or assistant will be required to assist the graduate pharmacists. Therefore, the existing Diploma courses should be reoriented for pharmacy assistant with reduced duration of training. The existing institutions conducting Diploma courses should be given the option of upgrading to Degree courses or to

reduced technician/assistant courses in a phased manner.

5. ***Changes in curriculum:*** The current pharmacy curriculum has industrial leaning. The training for community pharmacy practice is clearly lacking. The industrial pharmacy itself is becoming a highly specialized field. Whereas in healthcare the expectations are different. In order to cater to both industrial and healthcare aspect of pharmacy profession, the graduate level courses should be separated as B. Pharm-industrial and B. Pharm-health care. Likewise the syllabus should also be reorganized with the later giving more emphasis on training in hospital pharmacy, community pharmacy and healthcare management. Most of the institutions are away from practice environment resulting into graduates lacking in skills needed for industry, hospitals or in community setting. This requires orientation of the curriculum to fulfill skill requirement in both industrial as well as healthcare sectors.

6. ***Improving quality of education and training:*** Inspite of having uniform provisions for curriculum and teaching infrastructure, the quality of education offered by pharmacy institutions in the country varies widely. There exist a mechanism to regularly monitor the infrastructure, manpower and other critical inputs for delivering quality education and training, however PCI and AICTE needs to strengthen the implementation of the monitoring mechanism.

There exists a system of teachers training and skill enhancement to develop teaching faculty for short- and long-term requirement implemented by AICTE and UGC. However, it should be ensured that all teachers in the pharmacy sector should undergo training and skill enhancement on a regular basis.

7. ***Continuing pharmacy education:*** The current regulation does not mandate knowledge/skill updation as prerequisite

for continuing practice. The PCI should initiate measures to make CPE mandatory for all practicing pharmacists. This could be linked to periodic renewal of license for practice. PCI should also develop accredited CPE programmes at select canters. The involvement of professional bodies associated with pharmacy besides the PCI will be crucial in establishing and sustaining CPE activities on a long-term basis.

8. ***Demand, supply and existing numbers:*** Demand for Indian pharmacists will definitely go up not only within the country but also abroad. Lack of planned approach will lead to haphazard growth of pharmacy manpower with varying skills. Following steps are needed to capitalize on the growing opportunities in the pharmacy sector:

- a. The government should institute a comprehensive study to map out the existing pharmacy manpower in the country. The study should also reflect their training and practice status. This data will help in understanding the existing manpower and planning future human resource development.
- b. PCI should undertake a drive to update the practice status of registered pharmacists. Further licensing should be made compulsory renewable every year or every two years. The renewal would be granted on the basis of certain minimum level of CPE undertaken. This when enforced strictly, will also help in maintaining and updating data on workforce status in the pharmacy sector. This will help in maintaining active register of practicing pharmacists.
- c. Catering to the demand of pharmacists would need producing skills suited to various areas of opportunity. The orientation of pharmacy courses can be continuously improved and adapted through a dynamic process of interaction with the industry and health sector

professionals. Such interaction should also be undertaken at the level of institutions. Promoting affiliation with foreign institutions will also help in updating the curriculum and bringing it to international standards.

d. There exists a strong regional imbalance in the distribution of pharmacy institutions. PCI should undertake educational planning in order to promote setting up pharmacy institutions in undeserved areas.

9. **Setting benchmarks:** The demand for pharmacists is determined by a range of factors including the population demographics; disease burden; economic status, market forces, pharmacist roles and com-

petencies, legislation relating to medicines dispensing and prescribing; roles of other health workers, health systems and technology. There is a need for establishing benchmark of availability of pharmacists in different areas of practice. (For example, community pharmacists vis a population, hospital pharmacist as per number of beds, etc. This will help in forecasting the future demand. There is also a need for benchmarking performance parameters for services and competency of pharmacists. These benchmarks should be publicised so as make people aware regarding expectations from a pharmacist. This should be supported by a system of monitoring and audit.

CHAPTER

24

Pharmaceutical Legislation, Pharmaceutical Industry

INTRODUCTION

Legislation, a set of rules created by the legislature or governing body, can serve various purposes. Judge-made law or case law is another source of law. Before becoming law, legislation is referred to as a bill and broadly referred to as "legislation" even as efforts are being made to distinguish it from other businesses. Legislation ("statutory law") is capable of serving multiple purposes: To allow, regulate, authorize, proscribe, offer budget, sanction, grant, declare, or limit.

The Act of Parliament is the name given to an item of primary legislation under the Westminster system after its enactment. Pharmaceutical terms are used to describe pharmacies or pharmacists. Legislation that relates to pharmacies or pharmacists is known as **pharmaceutical legislation**.

National drug laws cover licensing, inspection, control of employees and facilities, manufacturing, import, distribution, marketing, prescribing, dispensing, and pricing of pharmaceutical products. Pharmacy education and practice are regulated by a government body, the Pharmacy Council of India (PCI) as per The Pharmacy Act passed in 1948. The Drug and Magic Remedies Act, 1954 was passed to restrict certain types of advertisements related to drugs and magic remedies. To collect the levy and excise duties on medical and toilet preparations that contain alcohol, opium, Indian hemp, or other narcotic drugs, the Medicinal and Toilet Preparations

(Excise Duty) Act was passed in 1955. The central government enacted the Drug Price Control Order in 1987, control and regulate the price of different medicines in India. The Narcotic and Psychotropic Substance Act, 1985 aims to consolidate and amend laws regarding narcotic drugs and psychotropic substances in India.

SCOPE AND OBJECTIVES

Scope and Objectives of Pharmaceutical Legislation in India:

1. To make sure the availability of drugs to the citizens at reasonable prices and through qualified persons.
2. To promote healthcare by regulating the manufacture, supply, and distribution of high-quality drugs.
3. To safeguard individuals from misleading and false advertisements concerning drugs and magic remedies under the Act.
4. To promote the use of indigenous research technology.
5. To understand the origin of modern medicine in India.
6. To compare pharmacy status in India and other countries before the appointment of the Hathi Committee, the Chopra Committee, and the Mudaliar Committee.
7. To apply the recommendations of various committees in India.

8. To know the role of committees in introducing the Pharmacy Act of 1948.
9. To understand the salient features of the Pharmacy Act of 1948.
10. To regulate the pharmacy education and profession in India.

FUNCTIONS

Functions of Pharmaceutical Legislation in India:

1. The pharmaceutical legislation helps pharmacists understand their legal and ethical responsibilities, and thus avoid the danger of unnecessary legal proceedings.
2. Pharmaceutical legislation safeguards people's health by providing the correct medication and regulating the pharmacy business and profession.
3. The legal system regulates pharmacy business and practices through pharmaceutical legislation.
4. It is imperative to have a thorough understanding of all pharmacy laws, and those who want to operate a pharmacy business must meet all legal requirements.
5. The legal aspects of drug manufacturing in the pharmaceutical industry, their storage, sale, and distribution are also covered.
6. The patient should receive drugs of good quality that have been tested and evaluated for safety and efficacy.

DEFINITIONS

1. A **law** is a system of rules, usually enforced through a set of institutions. Laws can shape or reflect politics, economics, and society in numerous ways and serve as a primary social mediator of relations between people.
2. **Legislation** is the creation of general laws to meet current and future needs, enabling government regulation. New laws must be passed by a nation's legislative body, which is a time-consuming procedure.

3. **Regulations** are rules established by an agency to facilitate the practical implementation of laws. Compared to legislation, they can be passed more easily and fast.
4. **Pharmaceutical regulations** are legal, administrative, and technical measures implemented by governments to ensure the safety, efficacy, quality, and relevance of medicines, as well as the accuracy of information on the product.
5. **Pharmaceutical legislation** is a comprehensive legal system that encompasses both social and economic aspects.
6. **Pharmacy** is the practice or profession of preparing, preserving, compounding, and dispensing medical drugs, or a medical shop or a hospital dispensary. The word pharmacy originates from the Greek word 'pharmakon' (drug or medicine) or 'remedy' (A medicine or treatment that cures or relieves).
7. **Forensic pharmacy** refers to the application of pharmaceutical knowledge to address legal issues.
8. **Pharmacists**, including drug custodians, makers, counselors, dispensers, analyzers, and educators, must adhere to professional discipline and forensic pharmacy (pharmaceutical jurisprudence), a field of legal provisions.
9. A **drug** is a chemical entity that is administered for a specific duration of time or regularly to treat, cure, prevent, diagnose, or improve physical or mental health issues.
10. **Jurisprudence** is the study of fundamental legal principles, encompassing the science, theory, and philosophy of law.
11. **Pharmaceutical jurisprudence** deals with the knowledge of laws relating to drugs and pharmaceuticals and the study of the rules and regulations of the pharmacy profession.

Scope of Forensic Pharmacy

1. Forensic pharmacy is the application of drug science to legal matters, offering significant scope in industry and research.

2. Forensic pharmacists specialize in litigation, regulatory compliance, and the criminal justice system.
3. Forensic pharmacy can be employed in various fields such as labs, crime scenes, drug laboratories, journalism, law firms, corporate offices, para-medical laboratories, security agencies, and defense forces laboratories.

Pharmacy students are always instructed about the legislation of their field. The significant laws that control their profession and its operations are always taught to professional students. These topics are covered in pharmacy classes under the headings of pharmaceutical jurisprudence and forensic pharmacy. In the past, forensic pharmacy covered pharmacy-related laws, including acts, rules, orders, regulations, and other similar aspects. The subject of professional ethics is also taught as part of pharmaceutical jurisprudence or forensic pharmacy. These days, the more appealing term "**pharmaceutical jurisprudence**" is frequently used in place of "**forensic pharmacy**." **Sir Mahadeva Lal Schroff**, known as the Father of Indian Pharmacy Education, founded the first three-year pharmacy program at Banaras Hindu University in 1937.

Pharmacy, a clinical health science, combines medical science and chemistry, managing pharmaceuticals and treatments, with specialties requiring data collection and evaluation skills. Prof Mahadeva Lal Schroff is India's founder of pharmacy, credited with guiding the pharmaceutical sector and educational system.

Prof. Mahadeva Lal Schroff, known as the Father of Pharmacy Education in India, influenced generations of pharmacists and provided opportunities, despite facing challenges and obstacles throughout his career. Prof. Mahadeva Lal Schroff, passed away in 1971, inspiring all pharmacists and guiding the Indian industry with his aptitude and vision.

On March 6, 1902, in the Bihar city of Darbhanga, was Prof. Mahadeva Lal Schroff born. In 1920, he completed his studies in

Bhagalpur, Bihar, and passed the intermediate exam. After that, he registered at Banaras Hindu University (BHU) in Varanasi, India, in the Engineering College. In 1921, Prof. Schroff faced expulsion from the institution for his criticism of Charles A. King, the principal at the time. After completing his engineering studies, Prof. Schroff traveled to China, Japan, and the United States before returning to India. He graduated from the Massachusetts Institute of Technology (MIT) in 1927 with a PG degree in chemistry and microbiology after earning his UG degree in arts with honors in chemistry in 1925.

The Indian Institute of Pharmaceutical Sciences (IPA) has awarded the Prof ML Schroff Medal to students who achieve top grades in final year BPharm examinations across all Indian universities and colleges, including a merit certificate and a monetary prize of ₹ 1,000.

PHARMACEUTICAL LEGISLATION

Legislation means the law intends to regulate and control numerous aspects of life. These components may be political, social, or economic. Ensuring that patients obtain medications of the necessary caliber, tested, and assessed for both safety and efficacy for their intended purpose is the objective of pharmaceutical legislation. Pharmaceutical legislation is concerned with the health of society.

The role and importance of pharmaceutical legislation and regulation:

Role: Pharmaceutical regulation plays a crucial role in global agendas due to the strong correlation between health indicators and a nation's ability to develop successfully. With the increase in global trade, the legal and economic challenges associated with drugs have become more complicated and political.

Importance: To ensure the safety of the public's health, governments must establish comprehensive laws and regulations, establish robust national regulatory bodies, and ensure that the manufacturing, distribution, and

use of pharmaceuticals are properly regulated. Additionally, reliable information on medications should be made available to the general public.

Pharmaceutical Legislation in India

- Throughout history, every society or culture has attempted to develop its unique system of medicine. In the majority of cases, the traditional systems of medicine have utilized animals, plants, or minerals as sources for medicinal preparations. Trial and error led to the use of proven materials, which were documented in books and used as the foundation for indigenous healers' treatment.
- The arrival of the modern, or allopathic, medical system in India with the British caused a shock to the Indian ancient medical systems. In this scientifically based medical system, a medication must be proven safe and effective in treating a specific ailment to be authorized for sale. The fact that allopathy is still widely utilized in India, however, simply serves to highlight how deeply embedded the ancient medical practice is in India even today.
- The manufacturing, importing, distribution, marketing, labeling, dispensing, prescription, and occasionally pricing of pharmaceutical items, as well as the licensing, inspection, and control of employees and facilities, are all covered by national drug laws. Administrative control typically involves the establishment of a regulatory authority. Legislation frequently uses medicine registration as a key component to guarantee that particular goods fulfill the standards of quality, safety, and efficacy. Nations that must enact comprehensive laws can use the guidelines provided by WHO (2001a guidelines) and other experiences.
- The International Conference on Drug Regulatory Authorities (ICDRA) is a platform for WHO member states'

drug regulatory authorities to enhance cooperation and collaboration.

Background of Pharmaceutical Legislation in India

Pharmacy is a traditional and old profession that focuses on the creation of drugs to treat and comfort the sick. Indian society, with the varied culture of its rulers, has always been fascinating to the world. The Indian medical system uses relatively weak medications and does not require specific skills to dispense them; this also holds for the pharmacy profession.

Origin and nature of pharmaceutical legislation in India

- In 1811, Mr Scotch Bathgate opened the first chemist shop in Calcutta, and in the 19th century, the London Pharmacopoeia outlined various pharmacy actions.
- In 1821, an apothecary/drugstore was established by Mr Smith Stanistreet and Co.
- The 'Bengal Dispensatory and Pharmacopoeia', created by the government in 1841 at Bishop's College Press in Calcutta, reflects the decline in the traditional use of medications in India.
- In 1870, India held its first pharmacy examination for chemists and druggists, marking the beginning of the pharmacy profession in India.
- In Bengal, organized training for compounders began in 1881.
- Between 1901 and 1930, common diseases and ailments were treated using Ayurvedic, Unani, and Allopathy approaches.
- In 1901, Acharya PC Ray (Prafulla Chandra Ray) established a small plant at Bengal Chemical and Pharmaceutical Works in Calcutta.
- In 1903, Alembic Chemical Works Ltd. in Baroda and a small facility for the development of pharmaceutical units were established at Parel by Prof TK Gajjar.
- In 1910, they initiated the production of tinctures and spirits.

- Due to a lack of units in India to meet public demand, most drugs were imported from other nations, namely Germany, France, and the United Kingdom.
- During World War I, the demand for locally produced drugs also surged.
- Because of unhealthy competition, the Indian market is becoming saturated with possibly hazardous and poor drugs.
- At that time, the majority of drugs were exported in their raw or unprocessed state and imported in their finished form.
- There was no regulatory body in place for pharmaceuticals, so anything could be made, distributed, or imported under their name.
- Due to a lack of restrictions on drug import and quality, numerous adulterated and spurious drugs entered India.
- India has been importing numerous adulterated and spurious drugs due to the lack of restrictions on drug import and quality.

History of Pharmaceutical Legislation in India

- In the past, the allopathic system of medicine was brought by Britishers to India, and allopathic medicines were mostly imported. The laws passed before and after independence are known as pre- and post-constitution laws, respectively.
- To have some control over the imports of medicines, the British Rulers introduced acts, the Indian Merchandise Marks Act, 1889; the Sea Customs Act, 1898; and the Indian Tariff Act, 1894.
- In the early 20th century, there was no legislative regulation for pharmaceuticals or the pharmacy profession. Despite being in effect, the Dangerous Drugs Act of 1930, the Poison Act of 1919, and the Opium Act of 1878 were insufficiently broad to regulate the disorderly and appalling circumstances present in the drug trade and production.
- **1930:** By the resolution, the Indian government established the Drugs Enquiry

Committee in 1928. On August 11, 1930, the Indian government appointed the Chopra Committee, which was presided over by the late Col RN Chopra.

- **1935:** The United Province Pharmaceutical Association was founded in 1935 and afterward changed its name to the Indian Pharmaceutical Association. In 1939, Prof. ML Schröff founded the Indian Journal of Pharmacy.
- **1937:** In 1937, the Government of India introduced the "Import of Drugs Bill," which was later withdrawn.
- The Pharmaceutical Conference held its sessions at various locations to promote pharmacy as a whole.
- **1940:** In 1940, the government brought the 'Drugs Bill' to regulate the import, manufacture, sale, and distribution of drugs in British India. Finally, this bill was adopted as the "Drugs Act of 1940."
- **1941:** Under the Drug Act of 1940, the first Drugs Technical Advisory Board (DTAB) was established. In Calcutta, the Central Drugs Laboratory (CDL) was established.
- **1945:** Drugs Rule under the Drugs Act of 1940 was founded in 1945. The Drugs Act has been modified from time to time, and at present, the provisions of the Act cover cosmetics, Ayurvedic, Unani, and Homeopathic medicines.
- **1945:** In 1945, the government brought the Pharmacy Bill to standardize pharmacy education in India.
- **1946:** The late Col RN Chopra (Colonel Sir Ram Nath Chopra) served as the chairman for the publication of the Indian Pharmacopoeial List. It includes listings of medications that were not part of the British Pharmacopoeia but were utilized in India at the time.
- **1948:** After independence, the Pharmacy Act, 1948, was published.
- **1948:** Under the chairmanship of the late Dr BN Ghosh, the Indian Pharmacopoeial Committee was incorporated.

- **1949:** The Pharmacy Council of India (PCI) was established under the Pharmacy Act, 1948.
- **1954:** The Education Regulation has been implemented in some states, but others have been slow to implement it.
- **1954:** The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 was enacted to prevent misleading advertisements.
- **1955:** The Medicinal and Toilet Preparations (Excise Duties) Act, 1955, aims to establish uniform duty for alcohol products across all states.
- **1955:** The Indian Pharmacopoeia's first edition was released.
- **1955:** The Essential Commodities Act, 1955 was enacted to guarantee the easy availability of essential commodities to consumers and safeguard them from exploitation by unjust traders.
- **1966:** The Drug Price Control Order (DPCO) is a government order established under the Essential Commodities Act, 1955, to regulate the prices of certain essential bulk drugs and their formulations.
- **1985:** The Narcotic and Psychotropic Substances Act, 1985 protects society from addictive drugs, while the Indian government regulates drug prices through Drugs Price Orders under the Essential Commodities Act, 1955.

Origin of Modern Medicine and Pharmacy

Medicine, an art form and scientific study, involves maintaining health through medication or surgery. By examining artifacts and historical records, historians can examine ancient medicine and uncover important distinctions from contemporary civilization. The Vedas, which were composed between 1500 and 500 BCE, include comprehensive knowledge about traditional Indian cultural and medical customs. Herbs, natural remedies, magic, gods, and talismans were all part of the ancient Indian belief systems used for healing.

Modern medicine followed the Industrial Revolution of the 18th century and the rapid economic growth of both Europe and the Americas. The 19th century saw great advancements in the identification and prevention of diseases due to scientific discoveries, inventions, and economic growth; nevertheless, the treatment of infectious diseases was not kept up to date because of major changes in work methods and lifestyle.

The Evolution of Pharmacy

Studying history is crucial for learning from the past, particularly in the areas of pharmacy and medicine, which have evolved through advancements in technology and science. The word "pharmacy" origins are debated, with some suggesting it originated from the Egyptian term "the bestower of security" and others implying it comes from the Greek word "phar-mak-on".

Ancient times: Pharmacists in ancient Greece and Egypt were regarded as celestial healers who used plants and herbal remedies with a religious and metaphysical foundation to treat a wide range of ailments.

The middle ages: During the Middle Ages, alchemists developed new medications like mercury-based treatment of syphilis, demonstrating a scientific shift in the field of pharmacy.

The renaissance: During the Renaissance, pharmacy evolved with the printing press, promoting medical knowledge dissemination, forming associations, and focusing on medication mixing and manufacturing, leading to novel disease treatments.

Previous centuries: Throughout the 19th and 20th centuries, the pharmaceutical industry kept evolving and changing to meet new challenges and opportunities. Thanks to the advancement of modern technologies like the microscope, pharmacists are now better able to understand the composition of drugs and the many sickness mechanisms. The pharmaceutical industry was transformed and disease treatment was

enhanced by the discovery of new drugs, such as antibiotics.

The modern era: In recent years, the pharmaceutical industry has become increasingly specialized and regulated. Pharmacists are skilled professionals who collaborate with physicians and healthcare providers to ensure patients receive safe and effective prescription medications and treatments. They must not only prescribe and synthesize medications but also give patients instructions on how to use them properly and safely. To sum up, the history of pharmacy is a rich and intricate one that stretches back thousands of years. From its beginnings in prehistoric societies to its current state as a strictly regulated and specialized industry, pharmacy has been instrumental in enhancing people's health and well-being all over the world. Pharmacy will always be a vital component of patient care and an integral part of the healthcare system as long as it can adapt to new opportunities and challenges.

Pharmaceutical Regulations in Western Countries

The main objectives of medicine regulation, which was initially enacted in England and then subsequently in the United Kingdom, were to raise government revenue, prevent poisoning deaths, and regulate pharmacy operations. Authorities did not begin to try to stop drug abuse and ensure that pharmaceuticals were of good quality, reasonably safe, and at least somewhat effective until much later. Here, we offer a historical synopsis of England's poison and drug laws from the perspective of healthcare providers with an interest in medicine.

The Pharmaceutical Society of Great Britain governed the pharmacy profession in England, and state regulations in the USA restricted the ability of pharmacists to distribute, manufacture, and sell pharmaceutical preparations and other medications to those who were properly trained and licensed.

By 1920, nations like the US and the UK were able to enact stringent legislation prohibiting

unethical practices in the production and distribution of subpar pharmaceuticals. In the United Kingdom, the Food and Drug Adulteration Act of 1928 and the Therapeutic Substance Act of 1925 sufficiently regulate nearly all activities about medications, thereby protecting the interests of the British people. The Federal Food and Drug Act of 1906 was successfully amended in the United States in 1912, 1913, and 1927 to effectively prohibit the manufacture, distribution, and transshipment of pharmaceuticals and medicines that are adulterated, misbranded, toxic, or harmful.

The Patent and Proprietary Medicines Act and the Food and Drug Act of 1920 both contribute to the efficient regulation and management of pharmaceuticals and other therapeutic preparations in Canada. By the early 20th century, Western nations and other free nations could impose strict regulations on the type and caliber of medications that were sold in their markets.

Evolution of Pharmacy Practice and Education in 19th and early 20th Centuries

Since the 1920s, community pharmacies in America have gradually improved their professional status through advancements in pharmacy practice and education. The post-pharmaceutical care era (2010—present), the soda fountain era (1920–1949), the pharmaceutical care era (1980–2009), and the lick, stick, pour, and more (1950–1979) era comprise the history of American community pharmacy in the modern age. Community pharmacy executives have made an effort to refocus their attention from products to patients in light of the falling need for traditional compounding.

Increased degree requirements and postgraduate training have improved pharmacists' ability to provide patient care services unrelated to selling medications. Nevertheless, idealized ideas of patient-centered community pharmacy frequently fall short of meeting the demands of actual practice. In the twenty-first century, community pharmacists may find greater

possibilities to provide patient care due to advances in our awareness of the importance of pharmacists' contributions to healthcare and the need for more optimal medication management.

Development of Pharmacy Practice in European Countries

Pharmacy practices in Poland and European countries are evolving, integrating pharmaceutical treatment into practice, and improving patient outcomes and resource allocation, despite pharmacists' limited role in EU member countries. Logistically, Poland still has a relatively high ratio of community pharmacies per 1,000 population, thus access to pharmaceutical services is not hampered.

Pharmaceutical services improve cardiovascular treatment efficacy by enhancing glycemic control, reducing blood pressure, improving lipid profiles, and enhancing medication adherence.

There have been notable requests to restrict the distribution of drugs outside of pharmacies; at the moment, many over-the-counter medications are also available in convenience stores and gas stations, where they are dispensed by people with not even the most basic training in pharmacy.

The government has also made an effort to lessen the financial burden associated with elderly people's prescription drug purchases. Poland maintains one of the highest percentages of patient co-payments for pharmaceuticals in Europe, and the nation has a convoluted system for paying for medical supplies with public monies.

LEGISLATION DRUGS ENQUIRY COMMITTEE

Drugs Enquiry Committee (DEC)/Chopra Committee

The Council of States passed a resolution in 1927 recommending to the Governor General in Council that all interim governments act immediately to control drug abuse and enact laws standardizing the production and sale of

drugs. On August 11, 1930, the Indian government established a commission chaired by the late Col RN Chopra (Sir Colonel Ram Nath Chopra) to investigate the issues faced by pharmacies in India and provide appropriate solutions. Later, the committee was called the "Drug Enquiry Committee" or the "Chopra Committee."

The purpose of the DEC, or Chopra Committee, was to:

1. Find out how many medications were being produced, imported, or sold in India that were of impure quality or inadequate strength.
2. Suggest actions to regulate such import, production, and sale for the benefit of the general population.
3. Look into whether legislation is required to limit the practice of pharmacy to individuals who meet the requirements and to provide recommendations.

The Chopra Committee responded to the circumstances, putting all of its seriousness and professional significance into examining the issues and formulating suggestions. They visited different parts of the nation and observed the circumstances. In 1931, the committee submitted and published its final report.

Recommendations of the Chopra Committee or Drug Enquiry Committee

1. Enact a central law to control and regulate the quality of drugs and the pharmacy profession.
2. Formation of the Central Pharmacy Council and the State Pharmacy Council to regulate drugs and pharmacy education.
3. Established testing laboratories in all states of India to control the quality of production of drugs, a central laboratory to control the quality of the imported drugs, and also to act as an expert referee in the case of samples sent by the local or state government.

4. Appointment of an advisory board to advise the government in making rules for the implementation of the objectives of the act.
5. Setting up the courses for training pharmacists and prescribing minimum qualifications for registration as pharmacists.
6. Registration of all patents and proprietary medicines manufactured in India or imported from overseas.
7. Putting under control the compounded medications and crude single drugs employed in the native therapeutic system.
8. The focus is on monitoring the growth of the Indian pharmaceutical industry.
9. A gradual decrease in the production of medical supplies in depots and warehouses.
10. The Indian Pharmacopoeia's compilation.

Actions taken by the government on the recommendations of the Chopra Committee: The Chopra Committee report could not be implemented immediately by the Indian government. One of the key reasons for the delay in implementing the Chopra Committee's recommendations immediately was World War II. Even though it will be many years before those suggestions are put into legislation or otherwise implemented, it is a source of great satisfaction that the Chopra Committee's significant recommendations molded the future of India's pharmacy and pharmaceutical industries.

The following pharmaceutical legislation and actions of the central government can be linked back to the above recommendations:

1. The Drug Act was enacted in 1940 to regulate the import, manufacture, and sale of drugs. The Drug Rules were passed in 1945 to give effect to the provisions of the act.
2. The Pharmacy Act was passed in 1948 and provides regulations for the profession and practice of pharmacy. The educational regulations prescribed the minimum qualifications for registration as pharmacists.

3. Drug testing laboratories have been established at the state and central government levels.
4. Suitable advisory boards, such as the Drugs Technical Advisory Board (DTAB) and the Drugs Consultative Committee (DCC), have been established.
5. Drugs produced according to the indigenous systems of medicine (Ayurveda, Siddha, and Unani-Tibb) and homeopathic medicines have been brought under the purview of the Drugs and Cosmetics Act, 1940.
6. Registration of all drugs and formulations marketed in India due to the Indian pharmaceutical industry's quick and remarkable growth, which today makes the majority of bulk drugs and formulations required in the country as well as exports them to various countries. Many Indian pharmaceutical companies have gone global.
7. Pharmacopoeias for medications used in indigenous medical systems are being developed.
8. As more standard-quality formulations become commercially available, manufacturing at medical stores and hospital pharmacies is reduced.
9. An Indian Pharmacopoeia has been established.

EVALUATION OF THE CONCEPT OF PHARMACY

Bhore Committee, Health Survey, and Development Committee

The Government of India established a Health Survey and Development Committee in October 1943, under the chairmanship of the late Sir Joseph Bhore, to survey the current state of healthcare delivery organizations in India and make recommendations for future developments, among other things. The committee submitted its report in 1946. The committee observed that if the health of the nation is adequately built, the healthcare system should be made based on preventive health work, and such operations

should take place alongside those associated with patient treatment.

The committee has identified two distinct types of workers:

- i. *One for personal care:* Nurses, midwives, and pharmacists for personal care.
- ii. *Another for public health:* Public health nurses, and sanitary inspectors for public health.

Public health and personal care services were combined as a result of the recommendations made by succeeding health committees.

The Bhore Committee considered the following factors when establishing its recommendations:

1. No one should be refused access to appropriate medical treatment due to unable to pay.
2. Proper medical diagnostic and treatment facilities for all.
3. The health program has to focus on measures to prevent illness.
4. The huge rural population should be supplied with as much medical relief and preventive healthcare as possible.
5. To maximize community value, health services should be placed close to people.
6. The doctor ought to work as a social doctor who safeguards people.
7. Medical services should be free and available to everyone, without difference.

The committee made the following observations:

1. The country's health state, as reflected by numerous measures, was poor.
2. The mortality rate was extremely high.
3. At the time of birth, the average life expectancy was around 27 years.
4. The number of cases of communicable diseases was extremely high.
5. Many of the health issues may have been avoided.
6. According to the committee, health and development are bound together.

7. Improvements in non-health sectors will also lead to improvements in health such as water supply, sanitation, nutrition, and the removal of unemployment.

The Bhore Committee made the following recommendations:

1. The formation of an All-India Pharmaceutical Council (PCI) and a Provincial Pharmaceutical Council to stand for the pharmaceutical education, trade, and other pharmaceutical sectors in India.
2. Enactment of legislation to protect the public from incompetence or to protect the interests of certified pharmacists involved in drug handling.
3. Maintaining control over the practice of pharmacy profession, as well as pharmacist registration.
4. Strengthening the pharmacy profession and pharmacist's standards.
5. Start revising the course for licensed pharmacists, graduate pharmacists, and pharmaceutical technologists.
6. Start establishing the Central Drug Laboratory (CDL)
7. Throughout the nation, the Drug and Cosmetic Act, 1940 is strictly enforced.
8. Coordinating preventive and curative services at all levels of government.
9. The minimum required ratio per 1,00000 population (one lakh) is 567 hospital beds, 62 doctors, and 151 nurses. The committee envisioned the establishment of PHC (primary healthcare) in two stages—a short-term measure, and a long-term program with three tiers of healthcare—the primary unit, the secondary unit, and the district hospital.
10. Health committee of the village, medical research focuses on diseases such as plague, cholera, malaria, tuberculosis, smallpox, leprosy, venereal disease, filariasis, and mental illness.
11. Special programs should be run for the health of mothers and children, environmental hygiene, and industrial employee health at work.

Bhatia Committee

On February 14, 1953, the Government of India appointed a "Pharmaceutical Inquiry Committee" headed by Major General SL Bhatia to conduct a comprehensive inquiry into the functioning of the pharmaceutical industry and recommend what steps the Government should take to establish it credibly from the point of view of the provision of health services and the economic interests of the state. The report was published by the commission in June 1954 and the majority of its recommendations were implemented.

Terms of Reference

Bhatia Committee was appointed:

1. To study the current operations of pharmaceutical manufacturing companies in India, particularly in relation to:
 - a. Demand for pharmaceuticals;
 - b. Costs of production;
 - c. The effectiveness of the process used; and
 - d. Whether the product is made from imported intermediate products or basic raw materials and chemicals.
2. To investigate the activities of Indian or foreign pharmaceutical import and packaging groups in the country.
3. We encourage manufacturers of essential medicines to import.
4. To study the distribution system, business, and profit margin of the industry of imported, manufactured, or packaged pharmaceuticals
5. Any other issues related to the previously stated.

Mudaliar Committee

In 1959, the Government of India established a 'Health Survey and Planning Committee' under the chairmanship of Dr A Lakshman Swamy Mudaliar. The committee discovered that the level of healthcare given was inadequate. The Committee issued its findings in 1962, and among other things, it suggested that

indigenous systems of medicine be brought under the jurisdiction of the Drug Act. Based on its suggestions, drugs made according to indigenous medical systems were placed into the jurisdiction of the Drugs and Cosmetic Act, 1940.

Terms of Reference

The Mudaliar Committee was appointed to:

1. The assessment (or evaluation) of the progress made in the fields of medical aid and public health since the submission of the Health Survey and Development Committee's Report (the Bhore Committee).
2. Review of the First and Second Five-Year Plans' Health Projects.
3. Development of recommendations for the country's future health development plan.

The Mudaliar Committee made the following observations:

1. Basic health facilities had not reached at least half of the country.
2. Massive improper allocation of hospitals and beds in favor of urban areas.
3. The quality of services given by PHCs was severely inadequate, with poor functioning, no referral mechanism, and gross understaffing due to a lack of funding.

The major recommendations of the committee are:

1. Consolidate the progress results of the first two five-year plans.
2. Establishment of an 'All India Health Service' on the model of the 'Indian Administrative Service'.
3. Rather than establishing new primary healthcare centers, strengthen existing ones.
4. A single primary healthcare center should serve a maximum of 40,000 people.
5. District hospitals should be strengthened so that they can serve as good referral centers
6. Create a regional administrative level between the state and district levels, with a regional deputy or assistant director in

charge of supervising two or three district medical and health officers.

7. The Bhore Committee suggested that health and medical services be integrated.

Hathi Committee

The establishment of a committee by the Government of India on February 8, 1974, under the chairmanship of Jaisukh Lal Hathi, to take a comprehensive look into the drug industry and inquire into various facets of the drug industry, was another significant milestone in the pharmaceutical legislative history of India. In 1975, the committee issued its report. This committee's report included everything from licensing to price control, imports, the function of the foreign sector, quality control, and so on. In contrast to the foreign-dominated multinational drug firms, it encouraged the growth of indigenous industries. In the interest of the consumer, it also further restricted the price of a significant number of pharmaceuticals. The study also emphasizes the importance of developing an essential drug list under the recommendations of the Hathi Committee and the WHO.

Terms of References

The committee was appointed/formed to:

1. Investigate the industry's progress and its current standing.
2. To recommend measures to ensure that the public sector takes a leading role in the production of basic pharmaceuticals and formulations, as well as in research and development.
3. To propose recommendations to encourage the quick growth of the pharmaceutical business, particularly the Indian and small-scale industries sector. The committee will consider the requirement for a balanced regional distribution of the industry when making its recommendations.
4. To review the current arrangements for the introduction of new technologies into the sector and give recommendations.

5. To recommend measures for successful drug quality control and to support small-scale units in this regard.
6. To review the steps taken so far to lower drug prices for consumers and to recommend any additional steps that may be required to rationalize the pricing of basic medications and formulations.
7. To recommend steps to make essential drugs and simple household remedies available to the general public, particularly in rural regions.
8. To recommend institutional and other arrangements to promote equitable distribution of basic medications and raw materials, particularly to small-scale producers.

Main Recommendations

The Hathi Committee Report (1975) is a significant milestone in the growth of the pharmaceutical industry in India. The Hathi Committee pointed out the achievement of self-sufficiency in pharmaceuticals as well as the ample availability of essential medicines at affordable rates. Since the year 1975, India's drug industry has risen to be the most diverse and highly integrated in the whole developing world.

Pharmacy and Healthcare System

The role and contribution of pharmacists in the healthcare system:

1. The profession of pharmacy is an essential component of the healthcare system, where men traditionally design treatments based on their past experiences. Later, some physicians handed the task of creating medications to their helpers, known as compounders. The medical profession was concerned with both the fields of pharmacy and medicine.
2. The Hindu medical system originated with 'Atharva Veda' and was followed by Ayurveda and Rigveda. The 'Unani-Tibb system' introduced by Muslims in India

had an impact on the Ayurvedic medical system. The British developed a highly popular allopathic system. With the advent of the allopathic system in India, the professions of medicine and pharmacy became separated.

3. Advancements in research and technology have increased pharmacists' role in providing feedback on medications, transforming the healthcare system into a comprehensive service aimed at promoting, maintaining, or restoring health.
4. Pharmacists play a crucial role in healthcare, requiring knowledge of drugs, handling systems, legal aspects, quality assurance principles, and medicinal product pricing.
5. Pharmacists serve as a bridge between doctors and patients, providing advice on minor illnesses. The pharmacy profession in our country consists of industrial pharmacists; hospital pharmacists; academic pharmacists; and community pharmacists.
6. Pharmacists play an important role in areas such as:
 - a. Preservation of drugs;
 - b. Prescription adherence;
 - c. Drug choice;
 - d. Drug monitoring;
 - e. Information on medicine and pharmacy education;
 - f. Clinical pharmacokinetics;
 - g. Drug research and development;
 - h. Selection of essential drugs; and
 - i. Storage and distribution of drugs.
7. Pharmacists are considered an essential part of the healthcare system because they are accountable for making sure the right patient receives the right medication at the right amount for the right condition, in the right dosage form, and regularly.

NEW DRUG POLICY

- The Drugs Price Control Order (DPCO) has classified medications into four categories:

I (life-saving), II (essential), III (less essential), and IV (non-essential/simple remedies). Categories I to III are subject to price control with a markup of 40%, 55%, and 100%, respectively.

- In 1994, the Federal Constitutional Court declared that drug addiction was not a crime, and possessing small amounts of drugs for personal use was also not considered a crime.
- The National Pharmaceutical Pricing Authority (NPPA) is a government organization in India that was established to regulate the prices of controlled bulk drugs and formulations. Its main responsibilities include fixing and revising drug prices, enforcing the availability and affordability of medicines in the country, and ensuring compliance with the Drugs (Prices Control) Order, 1995.
- The Indian Government in 2016, declared a ban on the production, sale, and circulation of 344 drug combinations. This announcement came after an expert panel, created by the Supreme Court, stated that these drug combinations were being sold to patients without sufficient scientific evidence. The manufacturers of these drugs challenged the decision in court.
- The Drugs, Medical Devices, and Cosmetics Bill, 2023 (the "Drugs Bill") intends to replace the Drugs and Cosmetics Act, 1940 (the "Drugs Act") as the governing law over the production, sale, and distribution of drugs, medical devices, and cosmetics.
- Prime Minister Narendra Modi announced a new drug policy mandating doctors to prescribe generic names instead of brand names for medicines.
- The Drug Policy of 1986 listed the main goals and purposes of the government's drug and pharmaceutical policy. These basic objectives of the policy are still widely applicable. However, the country's drug and pharmaceutical business now faces novel difficulties as a result of the

liberalization of the Indian economy, globalization of the world economy, and new commitments assumed by India under the World Trade Organization (WTO Agreements). To attract foreign investment as well as technology, a New Drug Policy in the form of "Modifications in Drug Policy, 1986" was introduced in September 1994, so that policy efforts are directed more towards promoting increased growth of the pharmaceutical industry and making it more internationally competitive.

Objectives of the Drug Policy

As per the Modifications in Drug Policy, 1986, announced in September 1994, the main objectives of the drug policy are as follows:

- Guaranteeing the wide and affordable availability of high-quality, necessary, and preventative medications;
- Strengthening the nation's system of drug production quality control and encouraging the responsible use of medications;
- Creating an atmosphere that encourages the flow of fresh capital into the pharmaceutical sector to support economically scaled, cost-effective production as well as the introduction of novel products and technology; and
- Strengthening the country's ability to produce drugs domestically.

Salient Features of the New Drug Policy of 1994 are:

- i. Industrial licensing for each bulk drug approved by the Drug Controller General (India), including their intermediates and formulations, shall be removed, subject to the requirements outlined in the Industrial Policy from time to time, save in the situations of:
 - a. Production of bulk drugs by the use of recombinant DNA technology,
 - b. Bulk drugs requiring *in vivo* use of nucleic acids as active principles, and
 - c. Specific cell/tissue-targeted formulations.

- ii. In February 1999, the reservation of five medications for manufacturing by the public sector was repealed, allowing them to be manufactured by the private sector as well.
- iii. The current two lists of 142 price-controlled drugs will be replaced with a single list of 76 drugs.
- iv. Establish a national drug authority.
- v. The establishment of a National Pharmaceutical Pricing Authority to revise and fix drug prices.
- vi. Gives exemption from price control and regulation for 10 years for a new drug produced with locally available technology.
- vii. Commits to provide incentives for pharmaceutical research and development.
- viii. Provides automatic approval of foreign technological agreements.
- ix. Lifts the foreign company equity cap from 40 to 51%. Globalization of the economy is projected to boost output, enhance quality, and facilitate the movement of products and services, especially medications, across national borders.

PHARMACOPOEIA

The word pharmacopoeia is derived from two Greek words 'Pharmakon' meaning 'drug' and 'Poiein' meaning 'to make'. A pharmacopeia is an official book containing a list of pharmaceutical substances and formulae along with their description and standard with their uses, preparation, and dosages. It is a legal book issued by recognized authorities, appointed by the government of each country or pharmaceutical society. Charles Rice (1841–1901) is known as the Father of Pharmacopeia, creator of modern scientific pharmacopeia, and Father of the National Formulary.

The role of modern pharmacopeia is to provide quality specifications for drug substances and general requirements for dosage forms. The regulatory control of drugs requires specific specifications and requirements to function

effectively. Pharmacopoeia serves as an official and legal book that collects quality standards and specifications for drugs and their ingredients. The information should be made publicly available, shared, and utilized by those concerned about the quality of drugs. The European Pharmacopoeia, British Pharmacopoeia, and Japanese Pharmacopoeia are major pharmacopeias globally that publish and produce quality standards for pharmaceuticals, alongside USP.

A. Indian Pharmacopoeia (IP): The Indian Pharmacopoeia is a mandatory book of standards for pharmaceutical producers and drug trade individuals under the Government of India's Drugs and Cosmetics Act, 1940. Indian Pharmacopoeia (IP) is published by the Indian Pharmacopoeia Commission (IPC) on behalf of the Ministry of Health and Family Welfare, Government of India in fulfillment of the requirements of the Drugs and Cosmetics Act, 1940 and Rules, 1945 thereunder. The origin of Indian Pharmacopoeia can be traced back to the publication of Bengal Pharmacopoeia and General Conspectus of Medicinal Plants (1844), generally known as Bengal Pharmacopoeia. The Indian Pharmacopoeia, first released in 1868, was in use until 1885 before being replaced by the British Pharmacopoeia, which became the sole authority on pharmacy matters.

After India gained independence in 1948, a committee was established to create the Pharmacopoeia of India, which was first published in 1955 and, a supplement was released in 1960. Both traditional and Western medications were included in this pharmacopoeia; this approach was followed in the preparation of the Pharmacopoeia of India 1966 and 1975 updates. Traditional medications were excluded from the pharmacopoeia of India 1985 and its Addenda 1989 and 1991 because the pharmacopoeia of traditional systems was published separately and only those herbal drugs that had conclusive quality control standards backing them were included.

Salient features of the Indian Pharmacopoeia (IP)

1. IP is written in English, and monograph titles are officially provided.
2. 986 monographs are covered by IP 1955.
3. In 1960, an addition to this edition was released.
4. In 1966, the second edition of IP was released, with Dr B Mukkerji serving as the chairman.
5. Monographs' official titles are provided in English.
6. The metric system was used to express the doses.
7. Injections and pills have been administered at "Usual Strength".
8. The drug monograph was followed promptly by the drug formulations.
9. The IP55 monographs and their supplements totaling 274 were eliminated.
10. An additional 93 monographs were included.
11. This edition's supplement was released in 12.
12. There are now 126 brand-new monographs and 250 revised monographs.
13. The vaccination for cholera has been developed.

The Indian Pharmacopoeia Commission (IPC) released the eighth edition of IP. IP-2018, published in four volumes, includes 220 new monographs: 366 revised monographs, 14 veterinary monographs, immunosera and vaccines for human use monographs (02), radiopharmaceutical monographs (03), blood and blood-related products (10), chemical monographs (170), herbal monographs (15), vaccines and immunosera for human use monographs (02), biotechnology-derived therapeutic products (06), and seven omissions.

There are also standards for newly developed medications and medications used in national health programs. There are now 53 new fixed-dose combination (FDC) monographs, 25 of which are not mentioned in any pharmacopoeia.

Indian Pharmacopoeia-2022, Ninth Edition. The 9th edition of the Indian Pharmacopoeia

was released at Vigyan Bhawan in New Delhi, where Dr. Mansukh Mandaviya, the Union Minister for Health and Family Welfare, Chemicals, and Fertilizers, presided over the 2022 IPC Conference.

B. United States Pharmacopeia (USP): A small group of medical professionals joined together to create the US Pharmacopeia (USP), an independent, scientific, non-profit organization devoted to enhancing public health, out of concern for the risks associated with poor medicines in America. Over 5,000 quality criteria for pharmaceuticals (chemical and biological); excipients (inactive substances); and active pharmaceutical ingredients are included in the United States Pharmacopeia National Formulary (USP-NF). It is the world's most comprehensive collection of information on pharmaceutical quality standards.

The legally recognized criteria for identification, strength, quality, purity, packaging, and labeling of drug substances, dosage forms, and other therapeutic products including dietary and nutritional supplements are contained in the United States Pharmacopeia (USP), a publication that was first published in 1820. Since then, 43 editions have been published till 2020. The current version is USP-NF (the National Formulary) 2023. The USP DC (Direct Compression) 2023 contains a listing of single-entity drug products, combination drug products, and vaccines.

The USP, the official pharmacopeia of the US, is issued annually by the USP-NF, a nonprofit organization. It requires all pharmaceuticals, over-the-counter medications, and healthcare goods to adhere to its requirements.

C. British Pharmacopoeia (BP): The national pharmacopeia of the United Kingdom is called the British Pharmacopoeia (BP). The UK's annual publication of quality standards and reference guides for pharmaceutical substances is utilized by individuals and organizations engaged in pharmaceutical development, manufacturing, testing, quality assurance, and analysis.

The British Pharmacopoeia (BP), which includes the BP (Veterinary) and the European Pharmacopoeia (Ph. Eur.), is the pharmacopeia that is legally recognized in the United Kingdom. In 1864, the first British pharmacopeia (BP) was published. The BP serves as the only comprehensive compilation of official standards that are authoritative for pharmaceutical substances and medicines in the UK. BP is published annually in August takes effect on January 1st of the following year, and includes all of the Ph. Eur. monographs and texts.

First published in 1907, the British Pharmaceutical Codex (BPC) was intended to be a supplement to the British Pharmacopoeia, which, despite its vast scope, failed to cover all of the medications that a pharmacist would need daily.

Compared to the British pharmacopeia, the codex has a more extensive list of drugs and preparations, some of which were also featured in earlier editions. Additionally, several medications that were included in past editions but are still widely used today are included in the codex.

The following are the ways that BPC and BP differ: First released in 1907, the British Pharmaceutical Codex (BPC) was intended to be a supplement to the British Pharmacopoeia, which, despite its vast scope, did not include all of the medications that a pharmacist would require daily.

D. British Pharmacopoeia (Veterinary): Published with the British Pharmacopoeia, The BP (Veterinary) is a companion publication. It includes specifications for drugs and goods used only in the UK's veterinary medical profession. Texts and monographs from the European Pharmacopoeia are also included in the BP (Vet).

Difference between BP and USP: The USP is an independent scientific body that creates quality standards for medications, dietary supplements, and food ingredients. This is how it differs from BP. A book of published and publicly available standards for pharmaceutical components and

finished pharmaceutical products is called the BP.

E. European Pharmacopoeia: Ph. Eur publications are the responsibility of the European Pharmacopoeia Commission. The UK is a member of the EP Commission and is actively involved in creating all stages of the Ph. Eur. monograph. The European Pharmacopoeia Commission has been producing the European Pharmacopoeia since 1964, with its first edition published in 1967 and the eighth edition released in 2013.

The European Pharmacopoeia (Ph. Eur.) specifies standards for the material and substance composition used in pharmaceutical production, as well as the tests that must be performed on medications and their qualitative and quantitative composition. It includes antibiotics; dosage forms and containers; active ingredients, excipients; chemical, animal, human, or herbal medicines; homeopathic preparations, and stocks. It also contains texts on vaccinations, radiopharmaceutical preparations, and biological, blood, and plasma derivatives. The European Pharmacopoeia and its requirements are legally obligatory in the member states of the European Union and the European Pharmacopoeia Convention.

EP is different from BP: The European Pharmacopoeia (EP) is a significant regional pharmacopeia that provides uniform quality standards for the pharmaceutical sector in Europe, regulating the quality of pharmaceuticals and the materials used in their production. The national pharmacopeia of the United Kingdom is known as the British Pharmacopoeia (BP).

PHARMACEUTICAL INDUSTRY

The pharmaceutical industry involves the discovery, development, production, and distribution of pharmaceutical drugs. They are intended to be used as oral medications (other routes of administration also) by patients to treat, prevent, or reduce the symptoms of illnesses. The pharmaceutical industry manages both generic and brand medications, including

medical devices, adhering to various laws and regulations for testing, marketing, and patenting. With "Pharma Vision 2020," the Indian government outlined its strategy for becoming the world leader in the production of drugs from start to finish. The Indian government plans to create an online pharmacy electronic platform in compliance with a new guideline.

The Role of the Pharmaceutical Industry Globally

The role of the pharmaceutical industry is to research, develop, discover, manufacture, and market drugs for use as medications. The pharmaceutical industry also aims to cure patients from diseases or reduce symptoms.

PHARMACEUTICAL INDUSTRIES IN INDIA

Among developing nations, India has one of the biggest and most advanced pharmaceutical industry sectors. Millions of people are employed by it. It guarantees that the large population of India has access to necessary medications at reasonable costs. The pharmaceutical sector in India has developed vast capabilities in the complex field of medication production and technology. Almost all drug types, from basic painkillers to complicated cardiac chemicals and advanced antibiotics, are now produced domestically.

The development of the essential field of medicine is being supported and advanced in large part by the Indian pharmaceutical industry. The Indian pharmaceutical industry supplies over 70% of the nation's needs for bulk medications, drug intermediates, drug formulations, chemicals, tablets, capsules, orals, and vaccines. Many Indian pharmaceutical businesses have received approval from US and UK regulatory organizations and fulfill the strictest quality standards.

The Indian pharmaceutical industry is extremely complicated and fragmented, with over 20,000 registered units. The pharmaceutical industry's top 250 companies hold 70% of the market, with the market leader holding nearly

7% of the share. More than 85% of the formulations manufactured in the country are sold on the domestic market. Multinational companies (MNCs) sell life-saving, new-generation under-patent formulations in India after importing them. Over 60% of India's bulk drugs are exported, with the remaining amount being purchased by local formulators.

The Indian pharmaceutical industry appears positive, to have a bright future. Indian pharmaceutical businesses are competing to establish their worldwide presence in the branded and generic medicine market. Indian pharmaceutical companies have acquired businesses in the US and Europe, and are raising capital to do the same. For instance, Ranbaxy purchased Terapia in Romania, and Ethimed NV in Belgium. German generic medication manufacturer Betapharm was purchased by Dr. Reddy's. Businesses seeking profitable acquisitions include Glenmark Pharma, Lupin, Aurobindo, and Jubilant Organosys (Jubilant Life Sciences).

The objectives of the pharmaceutical industry in India include

- To promote drug research across every field, including Indian drug production.
- To encourage the nation's research and development of new drugs.
- The purpose is to highlight the common challenges faced by members in various departments and local bodies such as municipality, central, and state governments.

The role of the pharmaceutical industry in India

The pharmaceutical industry is a rapidly growing global sector, providing employment and foreign exchange earnings to India. India's pharmaceutical industry significantly contributes to global healthcare, manufacturing high-quality, cost-efficient medicines. The company faces significant competition from branded generics, local brands, and low-priced alternatives.

India boasts a robust network of over 10,500 production facilities, 3,000 pharmaceutical enterprises, and a highly skilled manpower pool. India's major pharmaceutical hubs include Vadodara, Ahmedabad, Ankleshwar, Vapi, Baddi, Sikkim, Kolkata, Visakhapatnam, Hyderabad, Bangalore, Chennai, Margao, Navi Mumbai, Mumbai, Pune, Aurangabad, Pithampur, and Paonta Sahib.

With a 20% share of all pharmaceutical exports worldwide, India is the world's largest supplier of generic medications by volume. With over 60% of all vaccines produced globally, it is also the world's largest supplier of vaccinations by volume. The World Health Organization (WHO) also demands Tetanus and Pertussis (DPT), Diphtheria, and Bacillus Calmette Guerin vaccines. As of March 31, 2023, Sun Pharmaceutical Industries Ltd holds the top position as the leading pharma company in India.

HISTORY OF THE INDIAN PHARMACEUTICAL INDUSTRY

The pharmaceutical industry, a complex network of organizations, processes, and activities, emerged from the early 20th-century discoveries of penicillin and insulin, leading to mass production in industrialized nations.

1. At the beginning of the 20th century, Prof. PC Ray founded India's first pharmaceutical industry, "The Bengal Chemical and Pharmaceutical Works," in Calcutta in 1901.
2. In 1907, Alembic Chemical Works was the first company established in Baroda, Western India.
3. During the early part of the century, Sarabhai Chemical Works and Bengal Immunity Laboratories were two large units that were added for the production of vaccines and sera.
4. In 1920, Sir Ram Nath Chopra established the School of Tropical Medicine in Calcutta, launching modern drug research in

India, and integrating traditional medical knowledge.

5. Urea Stibamine was first introduced in 1922 as a treatment for kala-azar thanks to the work of Dr Upendra Nath Brahmachari of the Campbell Medical School in Calcutta.
6. During World War I, Ayurvedic formulations were developed by foreign and national residents, addressing the increased demand for allopathic medicine in the area.
7. Government factories in Darjeeling and the Nilgiris began producing quinine salts. By 1930, the nation had begun manufacturing anesthetics like ether and chloroforms, biological goods like sera and vaccinations, and a few essential medications derived from coal-tar distillation products.
8. The Second World War facilitated the Indian pharmaceutical sector, enabling the production of various synthetic and plant-based medications.
9. During this time, the production of chemotherapeutic medications like arsenical, antileprotic medications, and colloidal calcium, silver, iodine, etc. was initiated, as well as anti-dysentery medications like iodophor. In addition to these, efforts were made to produce biologicals such as pituitary extracts, liver extracts, and adrenaline solutions.
10. On March 12, 1942, the "Council of Scientific and Industrial Research (CSIR)" was established as an independent organization to coordinate the numerous industrial research and development initiatives in India.
11. With a network of 39 laboratories and 101 extension sites, the CSIR is a leading research institution today. It is in charge of organizing, directing, and promoting research and development initiatives in India.
12. India's pharmaceutical sector, initially small, experienced significant growth after independence, producing approximately 10 crores of formulations, vaccines, and

sera, now ranking among the most advanced and well-organized sectors globally. Since then, the Indian pharmaceutical sector has grown significantly, ranking among the most advanced and well-organized sectors in the world today.

PRESENT (CURRENT) SCENARIO OF THE PHARMACEUTICAL INDUSTRY

India, a developing pharmaceutical industry, has significantly grown in the past 50 years, implementing new manufacturing technologies and effective distribution channels, currently producing 70% of bulk medication requirements.

1. *Manufacturing of Bulk Drugs:* India's pharmaceutical industry has reduced the nation's dependency on imported medications by synthesizing drugs through alternative methods. India's global presence for certain products is significant, despite higher input costs like power and raw materials. However, the cost of pharmaceuticals in India is much lower due to advancements in process technology. India ranks fourth in the world for producing bulk medicines, following the US, Western Europe, and Japan. The industry has developed new manufacturing processes for synthetic medications like fluoroquinolones and cephalosporins. All contemporary medications are available at reasonable prices, leading to a notable decrease in the cost of life-saving drugs. India currently produces antibiotics and anti-cancer drugs for export and domestic markets.
2. *Production of Formulations:* The Indian pharmaceutical formulations industry is currently valued at around ₹ 14,000 crores and is growing steadily at a rate of 13–15% per year. India manufactures all the conventional dosage forms like tablets, capsules, topicals, liquid orals, injectables, etc. for both domestic and international markets.

3. *Fermentation Products:* A range of fermentation-based products, such as tetracycline, streptomycin, and penicillin, are currently produced by the Indian pharmaceutical industry.
4. *Exports:* India's pharmaceutical industry has experienced tremendous growth in exports in the last 20 years. In 1980, exports were worth just ₹ 46 crore, but now they stand at almost ₹ 5000 crore. India exports drugs to more than 50 nations, including both developed and developing countries. For some crucial medications, such as ampicillin, amoxicillin, cephalexin, trimethoprim, sulfamethoxazole, ethambutol, metronidazole, ibuprofen, and fluoroquinolones, Indian producers have been able to establish a unique presence in the market, despite a significant portion of global demand being met by Indian exports. Since various Indian manufacturing facilities have been accredited by the US Food and Drug Administration (US FDA) for following their GMP (good manufacturing practice) regulations, the Indian pharmaceutical industry gained significant respect and recognition on a global scale. Many Indian pharmaceutical companies have formed collaborative ventures abroad, particularly in wealthy nations.

FUTURE AVENUES FOR THE INDIAN PHARMACEUTICAL INDUSTRY

It is the responsibility of the Indian pharmaceutical industry to discover, develop, produce, and distribute new drugs for conditions that currently have no available therapy or ineffective treatments with unacceptable safety standards and side effects. Furthermore, the industry must advance diagnostic tools and develop prophylactics for preventable diseases. There are several opportunities for the industry to explore in the future:

1. *New Drug Discovery:* After joining the General Agreement on Trade and Tariffs

(GATT), India's pharmaceutical companies had to prepare themselves for the new patent regime, especially when it came to discovering new drugs. India amended its patent law to comply with the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, which mandated stronger product patents for drugs and pharmaceuticals. India's ten-year transition period for product patents began in 1995, but the industry is rapidly shifting towards drug companies involved in basic research.

The Indian drug industry should concentrate on crucial areas like infectious diseases like malaria, filarial infections, viral infections like HIV, and opportunistic infections like tuberculosis for global relevance. Research in the US and Europe primarily focuses on developed world diseases, chronic conditions like arthritis, lipid disorders, liver diseases, memory disorders, and emerging areas like neuronal regeneration.

2. *Process Development and Drug Synthesis:* The Indian drug industry should focus on developing non-infringing chemical entities and generic drugs, utilizing inventive capabilities and Indian scientists' experience in developing cost-effective routes for drug synthesis. The Indian drug industry shows promise in chiral drug synthesis as well. However, upgrading infrastructure with world-class scale-up and manufacturing facilities is necessary to keep pace with the changing international scenario and to be successful. Other areas require care, like GMP and regulatory issues.
3. *Formulations:* The Indian pharmaceutical industry has achieved self-sufficiency in producing conventional dosage forms. However, there is still a need for more efforts in the development of modern drug delivery systems, especially site-specific or targeted drug delivery systems. Indian R&D should focus on developing advanced

drug delivery systems for diseases like tuberculosis, leprosy, and filariasis, which are relevant to developing countries but not widely studied. Upgrading existing facilities to international standards is crucial for conventional dosage forms, and new products must meet regulatory and quality requirements.

4. *Biotechnological Products:* The Indian pharmaceutical industry can leverage molecular biology and genetic engineering advancements to develop improved immuno-diagnostics, vaccines, and therapeutic agents, particularly targeting developing countries. India's fermentation industry holds significant potential due to readily available raw materials. Focus on improving microbial strains and processes for fermentation-based products and tissue culture-based products.
5. *Indigenous Systems of Medicine:* The Indian pharmaceutical industry can leverage its rich traditional knowledge by integrating modern systems of medicine and globalizing these systems to address therapeutic gaps. Legal recognition, regulatory agency recognition, pharmacopoeial standards,

clinical research guidelines, open trial protocols, and dedicated R&D centers are crucial for promoting these systems.

6. *Clinical research:* Developing expertise in clinical research to discover new indications for existing drugs can be a significant area of focus for the Indian pharmaceutical industry. This approach has been successful in the past. For instance, metronidazole, which was initially developed as an anti-amylase drug, was later found to be effective in treating trichomoniasis as well.
7. *Collaborative Research:* Research costs in India are significantly lower than those in the USA, Europe, or Japan, ranging from 1/7th to 1/10th of the cost. As a result, Indian drug companies can offer contract research and development services to foreign companies at a lower cost. Collaborative research between Indian companies and foreign research-based companies can be mutually beneficial. Additionally, partnering with national laboratories, research institutions, and universities can also be highly advantageous.

CHAPTER 25

The National Pharmaceutical Pricing Authority (NPPA) and The Drug Price Control Order Act, 2013

INTRODUCTION

The National Pharmaceutical Pricing Authority (NPPA) is an independent government regulatory body of experts that controls the prices of essential and life-saving pharmaceutical drugs in India. The NPPA sets the ceiling price for medications in the controlled category per the DPCO's regulations.

On August 29, 1997, the Department of Chemicals and Petrochemicals (now the Department of Pharmaceuticals since July 2008) established the National Pharmaceutical Pricing Authority (NPPA) as an attached office to serve as an independent regulator of drug prices and to guarantee the availability and affordability of medications. The Department of Pharmaceuticals (DOP) Drugs (Prices Control) Orders and the National Pharmaceutical Pricing Policy of 2012 are both implemented by NPPA.

The NPPA (whose office is located in New Delhi) releases lists of medications together with their maximum ceiling prices regularly. All pharmaceuticals announced under Schedule-I of the DPCO, 2013 have a ceiling price set by NPPA, which also monitors annual price increases for scheduled and non-scheduled drugs. Thus far, it has set a ceiling price for 950 new medications and 856 scheduled formulations. It has restricted the costs of 106 anti-diabetic and cardiovascular medications, stents, and knee implants in the public interest

by using the authority granted by Paragraph 19 of the DPCO, 2013.

Within the parameters of the DPCOs, NPPA works to balance the interests of the pharmaceutical industry with the needs of the consumer.

The NPPA manages the "Pharma Sahi Dam" and "Pharma Jan Samadhan" portals, which provide public grievance registration and information on drug prices. Pharma manufacturers' internet information is being collected through the Integrated Public Database Management System (IPDMS).

NPPA's role: In addition to ensuring a healthy nation by lowering the cost of medicine, the role of NPPA is to provide an atmosphere that will allow the Indian Pharmaceutical Industry to become a global leader. NPPA invites the cooperation of all stakeholders in this endeavor.

Functions of NPPA/Drugs Price Control Order

1. To put the DPCO, 2013's provisions into effect and enforce them in line with the powers granted to it.
2. To support relevant research on medicine and formulation price.
3. To keep an eye on medicine availability, spot any shortages, and take corrective action.
4. To collect information on the manufacturing, imports and exports, market share, profitability, and other factors of bulk medications and formulations.

5. To manage any legal issues that may arise from the Authority's decisions.
6. To advise the Central Government on alterations or modifications to the drug policy.
7. To support the Central Government in the legislative affairs concerning medicine prices.
8. To appoint authority officials and other staff members under the policies and guidelines established by the government.

PRICE MONITORING AND RESOURCE UNIT (PMRU)

In several States and UTs, the National Pharmaceutical and Pricing Authority (NPPA) has established 12 price monitoring and resource units as part of its "consumer awareness, publicity, and price monitoring" initiative. To improve NPPA outreach throughout the states, it is intended to establish such units in all 36 states and the district of Columbia. These units will support NPPA and State drug controller efforts to guarantee drug accessibility at reasonable costs. Under the direct supervision of the state drug controller, the PMRUs are societies formed under the Societies Registration Act, 1860. Their "board of governors" is composed of nominees from the state and federal governments as well as other stakeholders. Both their recurrent and non-recurring costs will be covered by NPPA.

INTRODUCTION TO THE DPCO ACT, 2013

For more than 30 years, there has been price control on medications and formulations. Consumers have some degree of control over the price of pharmaceuticals in the majority of nations. During the Sino-Indian War in 1962, the Indian government began regulating the price of drugs. The government began imposing limits on pharmaceutical companies' capacity to turn a profit for the first time. The government established the Drug Price Control Order (DPCO) under the Important Commodities Act of 1955, giving it the authority to determine the

cost of several necessary bulk drugs and their formulations. Price controls are applicable for both branded and generic products.

The DPCO is issued under the Essential Commodities Act because drugs are essential for maintaining society's health. Since drugs have been declared essential and fall under the essential commodities Act.

The Drug Price Control Order (DPCO)

- *Drug:* A drug is a chemical compound that is used to treat, mitigate, diagnose, or prevent disease.
- *Price:* The amount of money received in exchange for a medicine's sale.
- *Control:* The ability to exert influence that restrains or guides.
- *Order:* An order is a formal directive, command, or guideline.

History: In 1966, parliament members observed that manufacturers of medicines charging high rates on drugs, so they decided to control high rates of drugs. In 1966, The DPCO Act was passed under Section 3 of the Essential Commodities Act, 1955. The DPCO Act, 1966 was replaced by the DPCO Act, 1970. In 1974, the Hathi Committee was constituted in 1975 and submitted its reports. The report of the Hathi Committee was an important landmark in the development of the Indian Pharmaceutical Industry. DPCO Act, 1970 revised in 1979 based on the recommendations of the Hathi Committee. The DPCO Act, 1979 was replaced by the DPCO Act, 1987. DPCO Act, 1987 was replaced by DPCO Act, 1995. Currently, 74 bulk drugs are in Schedule I of the DPCO, 1995, and their formulations are under price control. Finally, the DPCO Act, 1995 was replaced by the DPCO Act, 2013. 680 scheduled medication formulations from 27 therapeutic categories are included in the DPCO 2013. On the other hand, if it is in the public interest, the pricing of other medications may be regulated.

Amendments: (1) DPCO, 1970, (2) DPCO, 1979, (3) DPCO, 1987, (4) DPCO, 1991, (5) DPCO, 1995, (6) DPCO, 2013.

The criteria for bringing drugs under the DPCO regime: The essential nature of medicine is currently the criterion for bringing it under control. Essential drugs are those that meet the population's top healthcare needs, according to the World Health Organization. There are 354 medications on the National List of Essential Medicines, 74 of which have price controls. However, in 2003, the Supreme Court issued a ruling ordering the government to make sure that price controls remain in place for all necessary and life-saving medications.

THE DRUG PRICE CONTROL ORDER (DPCO) ACT, 2013

The Central Government of India made the following order in the exercise of the powers granted by Section 3 of the Essential Commodities Act, 1955 (10 of 1955) and the substitution of the Drug (Prices Control) Order, 1995, except what was done or neglected to be done previous to such supersession.

Drugs that will come under price control: Patented medicines are not covered by this order. The Department of Pharmaceuticals (DOP) published a draft proposal on price negotiation of patented pharmaceuticals earlier in March of this year. In terms of pricing, DPCO, 2013 regulates 652 formulations that span more than 27 therapeutic classifications. The ruling will now control the cost of several other anti-cancer drugs, including the much-discussed Imatinib, Dacarbazine, Daunorubicin, Chlorambucil, and Oxaliplatin; it will also control the cost of some anti-retroviral combinations, such as Zidovudine–Lamivudine–Nevirapine and Stavudine–Lamivudine.

1. Short title and commencement

1. This Order may be known as the Drugs (Prices Control) Order, 2013.
2. On the day of its publication in the Official Gazette, it will become enforceable.

Objectives of DPCO

This order has been passed with the following objectives/aims:

- To ensure that everyone in the nation has access to basic healthcare and basic medications at an affordable price,
- To achieve ample production,
- To regulate the equal distribution of essential bulk drugs,
- To increase and regulate the supplies of bulk drugs and formulations,
- To make these drugs available at affordable prices,
- To guarantee that necessary, life-saving, and preventative medications of high quality are available at fair costs,
- To set a maximum price for drugs sold in bulk,
- To set the maximum retail cost for drug formulations,
- Encouraging the country to use drugs sensibly to support affordable, large-scale production.

Role of DPCO

DPCO Provides:

- The list of price-controlled drugs.
- Procedures for fixation of prices of drugs.
- Method of implementation of prices fixed by the government.
- Penalties for contravention of provisions.

Note: All formulations containing the bulk drugs either in a single or combination form fall under the price control category.

Main Features of the DPCO, 2013

Features of DPCO are given below:

- This Act (DPCO, 2013) is governed by NPPA based on NLEM (National List of Essential Medicines).
- The Act is divided into thirty-two paragraphs and two schedules.
- Schedule-I of the DPCO, 2013 consists of NLEM-2011 and it covers 27 therapeutic categories and includes medicines for diseases like cancer, HIV, diabetes, and heart diseases amongst others. There were 628 formulations covering 348 medicines.

- Schedule-I of the DPCO 2013 was revised on 10.3.2016 based on the National List of Essential Medicines, 2015, and it covers 30 therapeutic categories and includes medicines for diseases like HIV, cancer, diabetes, heart diseases, and ENT amongst others. There were 948 formulations covering 376 medicines. Coronary stents were added later on 22.12.2016 making the total of medicines 377 and the number of therapeutic categories 31.
- A drug's price is specified, both with a ceiling and non-ceiling.
- The previously suggested cost-plus strategy is replaced by a market-based pricing mechanism in the new policy. The ceiling price for a medicine with a market share of 1% or more would be determined by taking the simple average of all brand prices.
- Retailers' and wholesalers' margins have been cut to 8% and 16%, respectively.
- Under the proposed restrictions, companies selling drugs over the government-mandated ceiling rate would have to lower their prices to comply, but drug companies selling drugs below the ceiling price would not be permitted to increase their prices.
- The companies that release novel drugs may sell them at price caps set by the government or below.
- Without authorization from the official government, existing companies will not be permitted to stop manufacturing any drugs.
- A yearly increase in retail pricing following the wholesale price index will be permitted for drug producers.

2. Definitions

1. In this order, unless the context otherwise requires:

- a. "Act" means the Essential Commodity Act, 1955 (10 of 1955).
- b. "Active pharmaceutical ingredients or bulk drug" means any pharmaceutical,

chemical, biological, or plant product including its salts, esters, isomers, analogues, and derivatives, conforming to standards specified in the Drugs and Cosmetics Act, 1940 (23 of 1940) and which is used as such or as an ingredient in any formulation.

c. "Brand" means a name, term, design, symbol, trademark, or any other feature that identifies one seller's drug as distinct from those of other sellers.

d. "Ceiling price" means a price fixed by the government for scheduled formulations under the provisions of this order:

A scheduled drug's ceiling price is established by first calculating the simple average of price to retailer (PTR) for all branded-generic and generic versions of that specific drug formulation with a market share of one percent or more. To this PTR, a sixteen percent notional retailer margin is then added. Periodically, the NPPA publishes a notice in the Extraordinary Gazette of India regarding the ceiling price that it has set or changed. The ceiling prices are typically disclosed as exempt from municipal taxes, excise duties, and other charges.

e. "Dealer" means a person carrying on the business of purchase or sale of drugs, whether as a wholesaler or retailer, and includes his agent.

f. "Distributor" means a person engaged in the work of distribution of drugs and includes an agent or a stockiest for stocking drugs for sale to a dealer.

g. "Existing manufacturer" means manufacturer existing on the date of publication of this order in the Official Gazette.

h. "Form" means a form specified in the second schedule.

i. "Formulation" means a medicine processed out of or containing one or more drugs with or without the use of any pharmaceutical aids, for internal or external use for or in the diagnosis, treatment, mitigation, or prevention of disease and, but shall not

- include: (i) any medicine included in any bona fide Ayurvedic (including Siddha) or Unani (Tibb) systems of medicines; (ii) any medicine included in the Homeopathic system of medicine; and (iii) any substance to which the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) do not apply.
- j. "**Generic version of a medicine**" means a formulation sold in pharmacopeial name or the name of the active pharmaceutical ingredient contained in the formulation, without any brand name.
 - k. "**Government**" means the Central Government.
 - l. "**Import**" with its grammatical variations and cognate expressions means bringing a drug into India from a place outside India for its sale.
 - m. "**Local taxes**" means any tax or levy (except excise or import duty included in retail price) paid or payable to the Central Government or the State Government or any local body under any law for the time being in force by the manufacturer or his agent or dealer.
 - n. "**Manufacturer**" for the purpose of this order means any person who manufactures or imports or markets drugs for distribution or sale in the country.
 - o. "**Market share**" means the ratio of domestic sales value (on the basis of moving annual turnover) of a brand or a generic version of a medicine and the sum of total domestic sales value of all brands and generic versions of that medicine sold in the domestic market having same strength and dosage form.
 - p. "**Margin to retailer**" for the purposes of this order shall mean a percentage of price to retailer.
 - q. "**Market-based data**" means the data of sales related to a drug collected or obtained by the government as deemed fit, from time to time.
 - r. "**Maximum retail price**" means the ceiling price or the retail price plus local taxes and duties as applicable, at which the drug shall be sold to the ultimate consumer and where such price is mentioned on the pack.
- s. "**Moving annual turnover**" in a particular month means cumulative sales value for twelve months in the domestic market, where the sales value of that month is added and the corresponding sales of the same month in the previous year are subtracted.
 - t. "**National List of Essential Medicines**" means National List of Essential Medicines, 2011 published by the Ministry of Health and Family Welfare as updated or revised from time to time and included in the first schedule of this order by the government through a notification in the Official Gazette.
 - u. "**New drug**" for the purposes of this order shall mean a formulation launched by an existing manufacturer of a drug of specified dosages and strengths as listed in the National List of Essential Medicines by combining the drug with another drug either listed or not listed in the National List of Essential Medicines or a formulation launched by changing the strength or dosages or both of the same drug of specified dosages and strengths as listed in the National List of Essential Medicines.
 - v. "**Non-scheduled formulation**" means a formulation, which is not included in Schedule-1.
 - w. "**Pharmacoeconomics**" means a scientific discipline that compares the therapeutic value of one pharmaceutical drug or drug therapy to another.
 - x. "**Price-list**" means a price list referred to in paragraphs 24 and 25 and includes a supplementary price list.
 - y. "**Price to retailer**" means the price of a drug at which it is sold to a retailer which includes duties and does not include local taxes.
 - z. "**Retail price**" means the price fixed by the government for a new drug under paragraph 5.

- za. "**Retailer**" means a dealer carrying on the retail business of the sale of drugs to customers.
 - zb. "**Scheduled formulation**" means any formulation, included in the first schedule whether referred to by generic versions or brand names.
 - zc. "**Schedule**" means a schedule appended to this order.
 - zd. "**Wholesaler**" means a dealer or his agent or a stockiest engaged in the sale of drugs to a retailer, hospital, dispensary, medical, educational or research institution, or any other agency.
 - ze. "**Wholesale price index**" means annual wholesale price index of all commodities as announced by the Department of Industrial Policy and Promotion, Government of India, from time to time.
2. All other words and expressions used herein and not defined but defined in the act or the Drugs and Cosmetics Act, 1940 (23 of 1940) shall have the meanings respectively assigned to them in the said acts.

Essential Medicines

WHO defines essential medicines as those that "satisfy the priority healthcare needs of the population". WHO first proposed the idea of essential medicines in 1977. The below points are given importance, to denote a medicine as an essential medicine:

- Relevance to public health,
- Data regarding safety and effectiveness, and
- Comparative cost-effectiveness.

Features of Essential Medicines

- Essential medications must be readily available at all times in sufficient quantities (within the framework of functioning health systems).
- Appropriate dosage forms of essential medicines should always be available.
- These medications ought to always be accessible, accompanied by sufficient information and assured quality.

- These medications are offered since their costs are reasonable for both the general public and an individual patient.

Formulations fall into two categories under the DPCO: Scheduled formulations, which contain bulk pharmaceuticals that are scheduled, and non-scheduled formulations, which contain non-scheduled bulk drugs.

Margins are allowed to a wholesaler and a retailer as per DPCO of 2013: For scheduled (controlled) drugs the margin is fixed at 16%. For non-scheduled formulations, the companies are free to choose the margin.

If a manufacturer sells a medicine above the price approved by the Government: Overcharging the customer would be considered non-compliance with the announced ceiling price, or the MRP exceeding the ceiling price plus any applicable local taxes. This would be subject to recovery together with interest from the date of overcharging. The Public Demand Recovery Act allows for the recovery of excess money resulting from overcharging, coupled with interest, as arrears to land revenue.

Scheduled Formulation

As per the DPCO 2013, "Scheduled formulation" means any formulation, included in the First Schedule whether referred to by generic versions or brand names. A scheduled medicine is no longer scheduled if the dosage form and strength are changed.

Example:

- i. Amoxicillin capsule 250 mg is covered under the schedule.
- ii. Amoxicillin tablet 125 mg shall not be called a scheduled drug.

Non-Scheduled Formulation

As per the DPCO 2013, "Non-Scheduled Formulation" means a formulation, containing the molecule, the dosage and strengths of which are not specified in the first schedule. Non-scheduled drugs which are out of price control.

The producers of non-scheduled drugs (drugs not under direct price control) do not necessarily take price approvals from NPPA. Nonetheless, the NPPA has the authority to set and regulate these prices in addition to being obligated to keep an eye on the costs of non-scheduled medications and take appropriate corrective action when needed.

Example (Non-NLEM Formulation)

- i. Aceclofenac
- ii. Norfloxacin
- iii. Rabeprazole

New Drug /New Formulation

A. NLEM (National List of Essential Medicines)

Formulations mixed with other NLEM formulations that have the same prescribed dosage and strength mixtures that have the same specified strength and dosage.

Example:

- i. Paracetamol 500 mg tablet is scheduled formulation
- ii. Diclofenac 50 mg tablet is scheduled formulation
- iii. New drug = Paracetamol 500 mg + diclofenac 50 mg tablet is new drug/formulation

B. NLEM Formulations Mixed with Other Non-NLEM Formulations at the Same Specified Dosage and Strength

Example:

- i. Paracetamol 500 mg tablet is scheduled formulation
- ii. Aceclofenac 100 mg tablet is non-scheduled formulation
- iii. Paracetamol 500 mg + aceclofenac 100 mg tablet is new drug

C. NLEM Formulations by Changing its Strength

Example:

- i. Paracetamol 500 mg tablet is a scheduled drug
- ii. Paracetamol 325 mg tablet is a new drug

D. NLEM Formulations by Changing their Dosage

Example:

- i. Diclofenac 50 mg tablet is a scheduled drug.
- ii. Diclofenac 50 mg ointment is a new drug

Not New Drug

Examples:

- i. Paracetamol 500 mg is scheduled drug
- ii. Aceclofenac 100 mg is not a scheduled drug
- iii. Paracetamol 325 mg + aceclofenac 100 mg is not a scheduled drug and is not a new drug under DPCO for price approval.

POWER OF DIRECTIONS

3. Directions for producers of bulk drugs, formulations, or active pharmaceutical substances:

The Government may:

- i. To achieve adequate availability and regulate the distribution of drugs, in case of emergency or in case of non-commercial use in the public interest, direct any manufacturer of any active pharmaceutical ingredient or bulk drug or formulation to increase the production and to sell such drug to such other manufacturers of formulations and to direct formulators to sell the formulations to institutions, hospitals or any agency as the case may be;
- ii. To give any direction under sub-paragraph (i), such manufacturer shall furnish the required information within such time the government may fix.

PRICE CALCULATION

4. Calculation of ceiling price of a scheduled formulation:

- 1. The ceiling price of a scheduled formulation with specified strengths and dosages, as per the first schedule, will be calculated accordingly:

Step 1: The average price to the retailer of the scheduled formulation, denoted as P(s), will be calculated as follows:

Average price to retailer, P(s) = (Sum of prices to a retailer of all the brands and generic versions of the medicine having market share more than or equal to one percent (1%) of the total market turnover based on moving annual turnover of that medicine)/(Total number of such brands and generic versions of the medicine having market share more than or equal to one percent (1%) of total market turnover based on moving annual turnover for that medicine.)

Step 2: Thereafter, the ceiling price of the scheduled formulation, i.e. P(c) shall be calculated as below:

$$P(c) = P(s) \cdot (1 + M/100), \text{ where}$$

P(s) = The average price to the retailer for the same medicine strength and dosage, as calculated in step 1, is provided.

M = % Margin to retailer and its value = 16

2. The government has notified that the ceiling price calculated under sub-paragraph (1) will apply to scheduled imported formulations.

5. Calculation of the retail price of a new drug for existing manufacturers of scheduled formulations:

1. The retail price of the new drug available in the domestic market shall be calculated as provided in sub-paragraph (1) of paragraph 4.
2. i. The Government sets the price for a new drug not available in the domestic market based on "Pharmacoconomics" principles, recommending it from a Standing Committee of experts.
ii. The retail price of a new drug will be fixed by adding a 16% margin to the retailer's fixed price.

6. Ceiling price of a scheduled formulation in case of no reduction in price due to the absence of competition: (1) Where the average price to a retailer of a scheduled formulation, arrived at as per the formula specified in sub-paragraph (1) of paragraph 4, has the effect of:

- a. No reduction in average price to the retailer concerning the prices to the retailer of the schedule formulation; and
- b. There are less than five manufacturers for that formulation having one percent (1%) or more market share, the ceiling price shall be calculated as under:

- i. If other strengths or dosage forms of the same scheduled formulation are available in the list, the average price to the retailer will be calculated accordingly:

Step 1: The average price to the retailer of a scheduled formulation, denoted as P(s), is calculated as follows:

$$P(s) = P_m \{1 - (P_{i1} + P_{i2} + \dots) / (N * 100)\}$$

Where,

P_m = Price to retailer of highest priced scheduled formulation under consideration.

P_i = % Reduction in average price to retailer of other strengths and dosage forms (calculated as in step of sub-paragraph (1) of paragraph (4) in the list of scheduled formulations w.r.t the highest priced formulation taken for calculating the average price to the retailer of such strengths and dosage forms).

N = Number of such other strengths or dosage forms or both in the list of scheduled formulations

Step 2: The scheduled formulation's ceiling price, i.e.

P(c) shall be calculated as under:

$$P(c) = P(s) \cdot (1 + M/100), \text{ where}$$

P(s) = Average price to retailer of the scheduled formulation as calculated in step 1 above and

M = % Margin to retailer and its value = 16

- ii. If the scheduled formulation's other strengths or dosage forms are unavailable, other scheduled formulations in the same sub-therapeutic category are available.

- The provisions of sub-paragraph (1) shall not apply when the price has been fixed and notified by the government under the Drugs (Prices Control) Order, 1995.

7. Margin to the retailer: While fixing a ceiling price of scheduled formulations and retail prices of new drugs, sixteen percent (16%) of the price to the retailer as a margin retailer shall be allowed.

8. Maximum retail price (MRP):

- The maximum retail price of scheduled formulations shall be fixed by the manufacturers based on the ceiling price notified by the government plus local taxes wherever applicable, as under:

Maximum retail price = Ceiling price + local taxes as applicable

- Manufacturers must set the maximum retail price of a new drug based on the government's retail price plus applicable local taxes:

Maximum retail price = Retail price + local taxes as applicable

RETAIL PRICE OF FORMULATION

Calculation of retail price of formulation: The retail price of a formulation shall be calculated by the government in accordance with the following formula:

$$RP = (MC + CC + PM + PC) \times (1 + MAPE/100) + ED.$$

- "RP" means 'retail price'.
- "MC" means 'material cost' and includes the cost of drugs and other pharmaceutical aids used including overages, if any, plus process loss thereon specified as a norm from time to time by notification in the Official Gazette in this behalf.
- "CC" means 'conversion cost' worked out in accordance with established procedures of costing and shall be fixed as a norm every year by notification in the Official Gazette on this behalf.

- "PM" means the cost of the 'packing material' used in the packing of the concerned formulation, including process loss, and shall be fixed as a norm every year by, notification in the Official Gazette on this behalf.

- "PC" means 'packing charges' worked out in accordance with established procedures of costing and shall be fixed as a norm every year by notification in the Official Gazette on this behalf.

- "MAPE" ('Maximum Allowable Post-Manufacturing Expenses') means all costs incurred by a manufacturer from the stage of ex-factory cost to retailing and includes trade margin and margin for the manufacturer and it shall not exceed 100% for indigenously manufactured scheduled formulations.

- "ED" means 'excise duty'. As long as the imported formulation's landed cost is used to determine its price and a margin that does not surpass 50% of the landed cost to cover selling and distribution costs, interest, and the importer's profit, the landed cost will serve as the foundation for pricing determination.

- For this proviso, "landed cost" means the cost of import of formulation inclusive of customs duty and clearing charges.

REFERENCE DATA

9. Reference data and source of market-based data: Market-based data for pharmaceuticals will be sourced from IMS Health, with government validation through surveys or evaluations deemed necessary.

PRICING OF THE FORMULATIONS UNDER DPCO, 1995

10. Pricing of the formulations covered under Drugs (Prices Control) Order, 1995:

- The prices of scheduled formulations which are also listed in the first schedule to the Drugs (Prices Control) Order, 1995-

that were set and announced under the terms of that order, up until May 31, 2012, will stay in effect for an additional year, or until May 30, 2013. After that, the manufacturers may adjust the prices of these scheduled formulations under the Department of Industrial Promotion and Policy's announcement of the annual wholesale price index for the preceding calendar year, and the DPCO formula will be used to determine the ceiling prices of such formulations.

2. After May 31, 2012, the prices of scheduled formulations which are also listed in the first schedule to the Drugs (Prices Control) Order, 1995 are fixed and notified under the provisions of the Drugs (Prices Control) Order, 1995 will stay in effect for a year following the date on which the Drugs (Prices Control) Order, 1995 was notified.
3. The Drugs (Prices Control) Order, 1995 specifies the prices of scheduled formulations that are not specified in the first schedule of this order. These prices are fixed and notified under the provisions of the said order, and they will remain effective until May 31, 2012, or one more year, until May 30, 2013. After that, the prices of these formulations will be regulated as for other non-scheduled formulations, as stated in paragraph 20 of this order.
4. The Drugs (Pricing Control) Order, 1995 specifies the pricing of scheduled formulations that are not included in the first schedule of this order. These prices are determined and notified under the said order's provisions after May 31, 2012.

CEILING PRICE OR RETAIL PRICE OF A PACK

11. Ceiling price or retail price of a pack:

1. The ceiling price, or retail price, of a pack will be determined by multiplying the average price to the retailer, as determined by the provisions in paragraphs 4, 5, and 6.

This will be done on a dosage basis, meaning that each tablet, capsule, or injection in volume, as specified in the first schedule, will be paid on an average basis.

2. The smallest pack size allowed by the Drugs and Cosmetics Act, 1940 (23 of 1940) for that category of medication if the unit of dosage for a scheduled formulation is not available in the first schedule.
3. In the case of injections or inhalation or any other medicine for which dosage form or strength or both are not specified in Schedule-I of the Drugs (Prices Control) Order, 2013, the Government may fix and notify separate ceiling price or retail price for such formulations with specified therapeutic rationale, considering the type of packaging or pack size or dosage compliance or content in the pack namely liquid, gaseous or any other form, in the unit dosage as the case may be, conforming to India Pharmacopeia or other standards as specified in the Drugs and Cosmetics Act, 1940 (23 of 1940) and the rules made thereunder for the same formulation.
4. The government shall form a committee of experts, as it may deem fit, within a period of fifteen days (15 days) from the date of issue of this order, to recommend fixing of separate ceiling price of scheduled formulations or retail price of a new drug as per the above parameter.

PRICE OF FORMULATIONS IN NLEM

12. Price of formulations (branded or generic version) listed in the National List of Essential Medicines, launched by a manufacturer:

1. When introducing a scheduled formulation, a producer is allowed to set the price of the formulation at or below the maximum price that the government has set for that schedule formulation.
2. The rules in paragraph 13 of the Act will apply if an established brand is relaunched by a different producer.

PRICE FOR THE EXISTING MANUFACTURERS

13. Price of scheduled formulations for the existing manufacturers:

1. The prices of all currently operating manufacturers of scheduled formulations must be revised downward so as not to exceed the ceiling price (plus local taxes as applicable) if they are selling the branded, generic, or both versions of scheduled formulations at a price higher than the ceiling price (plus local taxes as applicable) that has been set and notified by the government: Provided, that the manufacturers must make sure that the maximum retail price of any scheduled formulation that is produced or made available in the market prior to the date of the notification of the ceiling price does not surpass the ceiling price within 45 days of the notification date.
2. All currently operating scheduled formulation producers shall keep their current maximum retail price, even if they are offering branded, generic, or both versions of scheduled formulations at a lower price than the ceiling price set and announced by the government.
3. As per the DPCO's provision, a yearly increase in the maximum retail price may be implemented based on the wholesale price index increase from the previous year. Provided that, as long as a decline in a wholesale price index results in a proportional drop in pricing, as per the DPCO's guidelines.

FIXATION OF CEILING PRICE

14. Fixation of ceiling price of scheduled formulations:

1. No manufacturer shall sell the scheduled formulations at a price higher than the ceiling price so fixed and notified by the government.
2. Where any manufacturer sells a scheduled formulation at a price higher than the

ceiling price fixed by the government, such manufacturers shall be liable to deposit the overcharged amount along with the interest thereon.

FIXATION OF RETAIL PRICE

15. Fixation of the retail price of a new drug for existing manufacturers of scheduled formulations:

1. The government shall form a Standing Committee of such experts, as it may deem fit, within 60 days of notification of this order to recommend the retail prices of new drugs on the principles of "Pharmacoeconomics".
2. Where an existing manufacturer of a drug with dosages and strengths as specified in the National List of Essential Medicines launches a new drug, such existing manufacturers shall apply for prior price approval of such new drug from the Government in Form-I specified under Schedule-II of this Order.
3. The Government shall fix the retail price of the new drug under the provision of the DPCO and if the new drug is not available in the domestic market, the government shall forward the same to the Standing Committee of experts who shall examine the application on the principles of "Pharmacoeconomics" and make recommendations of the retail price of the new drug to the government within thirty days (30 days) of the receipt of application.
4. The government shall, on receipt of a recommendation under subparagraph (3), within thirty days (30 days), fix the retail price of such new drug and such price shall apply to such applicant of such new drug.
5. Where the existing manufacturer of scheduled formulation fails to apply for prior approval of the price of the new drug in Form-I, such manufacturer shall be liable to deposit the overcharged amount over and above such price fixed and notified by

the government, if any, along with interest thereon from the date of launch of the new drug, in addition to the penalty.

6. No existing manufacturer of a scheduled formulation shall sell such a new drug at a price higher than the retail price fixed by the government, if they are found to sell, such manufacturer of the new drug shall be liable to deposit the overcharged amount along with interest from the date of overcharge, in addition to the penalty.

REVISION OF CEILING PRICE

16. Revision of ceiling price of scheduled formulations:

1. The government shall revise the ceiling prices of scheduled formulations as per the annual wholesale price index (WPI) for the preceding calendar year on or before 1st April of every year and notify the same on the 1st day of April every year.
2. The manufacturers may increase the maximum retail price (MRP) of scheduled formulations once a year, in April.
3. Information about the revision, if carried out, shall be forwarded to the government in either electronic or physical form in Form-II within 15 days of such revision and non-submission of information under this subparagraph shall be construed as non-revision of maximum retail price (MRP) and the concerned manufacturer shall be liable to deposit the amount charged over and above the pre-revised maximum retail price (MRP), along with interest thereon from the date of overcharging.
4. In case of a decline in the wholesale price index, the manufacturers shall ensure within 45 days of the date of such notification that the maximum retail price (MRP) of such scheduled formulation does not exceed the revised ceiling price and information about the revision shall be sent to the government in either electronic or physical form in Form-II within 15 days of such revision.
5. Non-submission of the information under sub-paragraph (4) shall be construed as non-reduction in maximum retail price (MRP) and the concerned manufacturer shall be liable to deposit the amount charged over and above the maximum retail price revised based on the decline in wholesale price index, along with interest thereon as the overcharged amount from the date of overcharging.

AMENDMENT OF THE LIST

17. Amendment of the list of scheduled formulation:

1. A decision to amend the first schedule, clearly stating the reasons thereof, shall be taken by the government within 60 days of receipt of communication from the Ministry of Health and Family Welfare and the amendment(s) or revision, if required, in the first schedule shall be notified and thereafter, the ceiling price(s) for the medicine(s) added in the first schedule shall be fixed as per the provisions of this order within sixty days (60 days) from the date of the notification.
2. The medicines omitted from the first schedule shall fall under the category of non-scheduled formulations.

REVISION OF CEILING PRICE

18. Revision of ceiling price based on moving annual turnover (MAT): The revision of ceiling prices based on moving annual turnover value shall be carried out:

- i. The National List of Essential Medicines will be revised by the Ministry of Health and Family Welfare or five years after setting the ceiling price;
- ii. The number of manufacturers of a scheduled formulation with a price exceeding 75% of the government's ceiling price decreases by 25% or more;
- iii. The number of manufacturers of a scheduled formulation with prices below

25% of the government's ceiling price has increased by 25% or more than the existing number.

FIXATION OF CEILING PRICE

19. Fixation of ceiling price of a drug under certain circumstances: In addition, where the ceiling price or retail price of the drug has already been set and notified, the government may permit an increase or decrease in the ceiling price or the retail price, as the case may be, irrespective of the annual wholesale price index for that year. These provisions of this order shall not apply in the event of extraordinary circumstances where the government considers it necessary to do so in the public interest.

MONITORING THE PRICES AND AVAILABILITY

20. Monitoring the prices of non-scheduled formulations:

1. The government will keep an eye on the maximum retail prices (MRP) of all medications, including those with non-scheduled formulations. It will also make sure that no manufacturer raises the MRP of medication by more than ten percent (10%) during the previous twelve months (12 months). If the increase exceeds ten percent (10%) of the maximum retail price, the manufacturer must lower the price to ten percent (10%) of the maximum retail price for the following twelve months (12 months).
2. The manufacturer will be responsible for paying the penalty as well as the overcharged amount, plus interest starting on the day of the price increase.

21. Monitoring the availability of scheduled formulations:

1. In addition to the manufacturer of scheduled formulations and the active pharmaceutical ingredients included in the scheduled formulations providing the information specified in Form-III of schedule-II of this order quarterly, the government will keep

an eye on the production and availability of these formulations.

2. If a manufacturer of scheduled formulation plans to remove any scheduled formulation from the market, they must notify the government in writing using Form-IV of Schedule II of this order at least six months in advance of the intended date of discontinuation. If the government determines that it is in the public interest, it may order the manufacturer to maintain the necessary level of production or import for a maximum of one year after the intended date of discontinuation, provided that the government receives notice 60 days in advance of the intended date of discontinuation.

RECOVERY OF DUES

22. Recovery of dues accrued under the Drugs (Prices Control) Order, 1979 and to deposit the same into the Drugs Prices Equalization Account:

1. Notwithstanding anything in this order, the government may, by notice, demand that a distributor, importer, or producer, as applicable, deposit the sum that has accumulated as a result of the Drugs (Prices Control) Order, 1979.
2. The sum deposited as well as any balance that was in the Drugs Prices Equalization Account on the day this order started, if any.

RECOVERY OF OVERCHARGED AMOUNT UNDER DPCO, 1987 AND 1995

23. Recovery of overcharged amount under Drugs Prices Control Orders, 1987 and 1995: Notwithstanding anything else in this order, the government may, by notice, require the manufacturers, importers, distributors, or whoever may be involved, to deposit the money that has been accrued as a result of charging prices that are higher than those set or announced by the government following the terms of the

Drugs (Prices Control) Order, 1987 and Drugs (Prices Control) Order, 1995.

CARRYING INTO EFFECT THE PRICE FIXED OR REVISED BY THE GOVERNMENT

24. Carrying into effect the price fixed or revised by the government, its display and proof thereof:

1. The manufacturers are required to modify the maximum retail price (MRP) so that it does not surpass the ceiling price (plus local taxes as applicable) for all scheduled formulations with an MRP that is higher than the ceiling price (plus local taxes as applicable). As long as the manufacturers make sure that, within 45 days of the notification date, the maximum retail price of any scheduled formulation that was produced or made available on the market before the date of the ceiling price notification does not surpass the ceiling price.
2. The maximum retail price of a schedule formulation based on the ceiling price notified in the Official Gazette or ordered by the government in this regard must be displayed by every manufacturer of a formulation intended for sale in an indelible print mark on the label of the formulation container and the minimum pack thereof offered for retail sale. The words "inclusive of all taxes" should come after the words "maximum retail price."
3. Each producer is required to release a pricing list along with a supplementary price list.
4. Every retailer and dealer is required to display the price list along with the supplementary price list.

DISPLAY OF PRICES

25. Display of prices of non-scheduled formulations and price list thereof:

1. The maximum retail price of a non-scheduled formulation, followed by the

words "inclusive of all taxes," and preceded by the words "maximum retail price," must be displayed in an indelible print mark on the label of the formulation's container and the minimum pack that is offered for retail sale by the manufacturer.

2. Every producer must periodically provide dealers, state drug controllers, and the government with a price list and supplemental price list, if necessary, of the non-scheduled formulations in Form-V, identifying any modifications.
3. Every retailer and dealer are required to display the price list and the supplementary price list.

CONTROL OF SALE PRICES OF BULK DRUGS

26. Control of formulation selling prices: It is not permitted to sell any formulation to a customer for more than the price shown in the current price list or the price indicated on the label of the container or pack, whichever is lower.

27. Split quantities of formulations: Dealers are not permitted to charge more than the prorated price of any formulation when selling a loose quantity of that formulation.

28. Manufacturer, distributor, or dealer not to refuse sale of the drug: No manufacturer, distributor, or dealer may refuse to sell a drug to a dealer without giving a good and convincing reason; similarly, no dealer may refuse to sell a drug that is in stock to a customer who is planning to buy it, as long as the refusal stays within the bounds of the Drug and Cosmetics Act, 1940 (23 of 1940) and its implementing regulations.

RECORDS

29. Maintenance of records and production thereof for inspection: Manufacturers must maintain records of every sale of their goods, including formulation units and packs, individual active components in pharmaceuticals, bulk medications they produce, import, and sell,

as well as any other documentation that the government may occasionally request. Additionally, the government can visit the manufacturer's facility and request access to these documents.

MISCELLANEOUS

30. Power of entry, search, and seizure:

1. Any Central Government or State Government Gazette Officer authorized in this regard has been compiled with:
 - a. Enter and search any place;
 - b. Seize any drugs that he believes are being used in violation of any of the terms of this order, as well as any containers, packaging, or coverings that the drug is found in;
 - c. Seize any document he believes may be used to contradict any of the terms of this order, including books of accounts, cash memos, or credit memo books.
2. The provisions of the 1973 Code of Criminal Procedure (2 of 1974) regarding search and seizure will, to the extent possible, apply to searches and seizures conducted under this order.

31. Power to review: Any individual who feels wronged by a notification or order made under paragraphs 4, 5, and 6 of this order may request a review of the notification or order from the government within 30 days of the date the notification was published in the official gazette or the date he received the order, whichever is applicable. The government may then issue any appropriate order in response to the request: Provided that a manufacturer may sell a scheduled formulation or a new drug at a price higher than the ceiling price or retail price set by the government for which a review has been requested, as long as the government has not made a decision on the application submitted under the above paragraph.

32. Non-application of the provisions of this order in certain cases (power of exempt): The provisions of this order shall not apply to:

- i. A manufacturer creating a novel medication that is patented under the Indian Patent Act, 1970, provided that the research and development was conducted domestically; this exemption applies for a period of five years from the date the drug's commercial production in the nation began.
- ii. A producer creating a novel medication using a technique created by national research and development that is granted a five-year patent from the date the drug's commercial production in the nation began.
- iii. A producer of a novel medication using an innovative delivery method.

PENALTIES

Experts claim DPCO 2013 omits the penalty clause for violators in the drug manufacturing and pharmacy industries. It is astonishing to learn that the Drug Price Control Order (DPCO) 2013 did not include a penalty clause for violators in the wholesale, retail, and production of drugs. Now, criminals can operate with greater freedom and avoid paying taxes. Any violation of the Essential Commodities Act, 1955's provisions will result in penalties under this order.

AMENDMENTS

Amendments Made in DPCO, 2019

- For five years from the date of marketing, a pharmaceutical manufacturer that introduces a novel, patented medication will not be subject to price control laws.
- Price controls will not apply to medications intended to treat uncommon or "orphan" diseases, in an effort to stimulate their manufacture.
- The center will keep setting pricing based on the most recent market-based data available for medications. The government-designated pharmaceutical market data specialized company's data will serve as the source of market-based data.

SCHEDULE**Schedules under the DPCO Act***A. The First Schedule (Schedule-I):*

National List of Essential Medicines 2015 [see paragraphs-2(t), 2(zb)].

Therefore, NLEM serves as the foundation for selecting which medications should be subject to DPCO price restriction. Price fixing may apply to any formulation that is based on a combination of any one of these medications that is listed under NLEM.

It contains the names of essential drugs.

List of Price Controlled Drugs (DPCO, 1995)—**Bulk Drugs**

1. Sulphamethoxazole
2. Penicillins
3. Tetracycline
4. Rifampicin
5. Streptomycin
6. Ranitidine
7. Vitamin C
8. Betamethasone
9. Metronidazole
10. Chloroquine
11. Insulin
12. Erythromycin
13. Vitamin A
14. Oxytetracycline
15. Prednisolone
16. Cephazolin
17. Methyldopa
18. Aspirin
19. Trimethoprim
20. Cloxacillin
21. Sulphadimidine
22. Salbutamol
23. Famotidine
24. Ibuprofen
25. Metamizol (analgin)
26. Doxycycline
27. Ciprofloxacin
28. Cefotaxime
29. Dexamethasone
30. Ephedrine
31. Vitamin B₁ (thiamine)
32. Carbamazepine
33. Vitamin B₂ (riboflavin)
34. Theophylline
35. Levodopa
36. Tolnaftate
37. Vitamin E
38. Nalidixic acid
39. Griseofulvin
40. Gentamicin
41. Dextropropoxyphene
42. Halogenated hydroxyquinoline
43. Pentazocine
44. Captopril
45. Naproxen
46. Pyrental
47. Sulphadoxine
48. Norfloxacin
49. Cefadroxyl
50. Panthonates and panthenols
51. Furazolidone
52. Pyrithioxine
53. Sulphadiazine
54. Framycetin
55. Verapamil
56. Amikacin sulphate
57. Glipizide
58. Spironolactone
59. Pentoxyfylline
60. Amodiaquin
61. Sulphamoxole
62. Frusemide
63. Pheniramine maleate
64. Chloroxylenols
65. Becampicillin
66. Lincomycin
67. Chlorpropamide
68. Mebhydroline
69. Chlorpromazine
70. Methendienone
71. Phenyl butazone
72. Lynestranol
73. Salazosulphapyrine
74. Diosmine
75. Trimipramine
76. Mefenamic acid

B. The Second Schedule (Schedule-II):

It contains various forms for approval, fixation, or revision of prices of scheduled bulk drugs or formulations.

FORMS

Form I	Proforma for application for price fixation/revision of a new drug formulation related to NLEM formulation (<i>see</i> paragraphs 2(u), 5, 7, 8, 9, 15)	Form III	Proforma for Quarterly Return in Respect of Production/Import and Sale of NLEM Drugs (<i>see</i> Paragraphs 21(1))
Form II	Proforma for Submission of Revised Prices for Scheduled Formulations (<i>see</i> Paragraph 16)	Form IV	Proforma for Submission of the Details in Respect of Discontinuation of the Production and/or Import of Scheduled Formulation (<i>see</i> Paragraphs 21(2))
		Form V	Proforma for Price List (<i>see</i> Paragraphs 2(X), 24, 25, 26)

C. The third schedule

Specified maximum pre-tax return on sales turnover of manufacturers or importers of formulations.

The Right to Information (RTI) Act, 2005

INTRODUCTION

The right to information (RTI) is a fundamental right that ensures the free flow of information between the government and the citizens. With the help of the Act, corruption and inefficiency in government can be uncovered, and citizens have the power to demand better services from their government. Transparency and accountability in government have improved and increased the government's responsiveness to public demands. A powerful instrument for good government is the RTI Act. It is a crucial instrument for encouraging transparency and sound decision-making, and it is necessary to guarantee that the government is answerable to the people. The Right to Information Act has come a long way from being nonexistent during British rule to becoming one of the most often used fundamental rights, it has continued to develop and support inclusion and representation of India's underprivileged.

The Right to Information Act (RTI) 2005 is the replacement of the former freedom of Information Act, 2002. RTI Act was enacted by the Indian Parliament that establish the practical framework for citizens' rights to information. All Indian states and union territories are covered by RTI, except Jammu & Kashmir.

As per the Right to Information Act, any citizen has the right to request information from a public authority, which includes any

government body or agency. The public authority is obligated to respond to the request either immediately or within a maximum of 30 days. Additionally, the Act mandates that every public authority must digitize their records to make them widely available and must proactively disclose certain categories of information to reduce the need for citizens to make formal requests. The law was passed by the Parliament on 15 June 2005 and came into full effect on 12 October 2005.

The RTI Act, 2005 is defined as the legislation that outlines the rules for citizens to access information held by public authorities. Its purpose is to promote transparency and accountability in the functioning of public authorities. The act also mandates the creation of a central information commission and state information commissions and covers all related matters.

Objectives of the RTI Act

- The Right to Information Act aims to enhance transparency and accountability in the government and empower citizens.
- Another objective is to effectively combat corruption and ensure our democracy truly serves the people.
- The Act is a significant step towards informing citizens about the government's activities.
- The implementation of the RTI Act will enhance public trust in the government.

- Effective and efficient records management techniques are necessary to provide information in response to public interest.
- To establish a practical system for providing citizens with access to information held by public authorities.
- To promote citizen participation in official decisions that affect their lives, the law empowers citizens.

DEFINITIONS

1. The term "Appropriate Government" refers to a public authority that is established, constituted, owned, controlled, or substantially financed by funds from the Central or State Government.
2. "Information" includes various forms, including documents, records, emails, opinions, and contracts. Public authorities can access private body information under the RTI Act, 2005, as per current laws.
3. The term "public authority" refers to any institution of self-governance, including government-owned and non-government organizations, that was founded by the government, state legislatures, the constitution, or other legal notification.
4. A record refers to various types of documents, including manuscripts, files, microfilms, images, and materials produced by computers or other devices.
5. The "right to information" refers to the right to access information held by or under public authority, including inspection of work, document and record inspection, note-taking, sample collection, and information retrieval through electronic means or printouts.
6. A "third party" is an individual who requests information from a public authority, not a citizen.

RIGHT TO INFORMATION ACT, 2005

The Right to Information Act, 2005 came into effect on 12th October 2005 and is one of the

most significant legislations enacted by the Indian Parliament. This act is aimed at making the government more accountable and transparent. It provides citizens with the practical regime of the right to information to secure access to information under the control of public authorities, thereby promoting transparency and accountability. The Act will put an end to the culture of governmental secrecy and fulfill its potential as a truly great democracy.

Scheme of the Act

The Act is divided into six chapters and two schedules.

Chapter I: Deals with the preliminary aspects, definitions, scope, and extent of the Act.

Chapter II: Deals with the right to information and the obligations of public authorities.

Chapters III and IV: Deal with the constitution of the Central Information Commission and the State Information Commission.

Chapter V: Deals with appeals and penalties.

Chapter VI: Deals with miscellaneous aspects.

Salient Features of RTI Act, 2005

- Every citizen has the right to access information.
- In normal cases, information can be obtained within 30 days from the date of request. However, if the information requested pertains to the life or liberty of a person, it can be obtained within 48 hours from the time of the request.
- All public authorities are required to provide information upon writing or electronic request. Certain data is prohibited.
- Information about third parties is restricted.
- Refusing to accept an application for information or failing to provide information carries a penalty of ₹ 250 per day, with a maximum penalty of ₹ 25,000.
- The Central Government and the corresponding state governments are to establish the Central Information Commission and the State Information Commission.

- One senior-ranking officer may be the target of an appeal against a Central Information Commission or State Information Commission judgment.
- No court may consider a lawsuit, an application, or any other legal action of an order issued under the Act.

Applicability of the Act

- Applicability to all states and union territories of India excluding the state of J&K.
- Only government bodies are included. The Act does not directly cover private bodies.
- RTI applications can only be submitted by individuals.
- Any authority of self-government established under; the constitution/parliament/state legislature, the body owned, controlled, or substantially financed directly or indirectly by the appropriate government.

Exclusions

The following information is exempted from disclosure (under Section 8).

Information that would prejudicially:

- Affect India's integrity and sovereignty.
- Affect the state's security, strategic, scientific, or economic interests.
- Affect the relationship with foreign states.
- Leads to the support of an offense.
- Information that any court or tribunal has forbidden to be published, or whose disclosure could be construed as a breach of court orders.
- Cause a breach of the state legislature's or parliament's privileges.
- Affect intellectual property, trade secrets, or commercial confidence that, if revealed, might hurt a third party's ability to compete.
- Information that a person in a fiduciary relationship has access to; competent authority if it is determined that disclosing such information will serve the greater public interest.

- Confidential information from a foreign government.
- Information that could reveal the identity of the source of information or information that would endanger someone's life or physical safety.
- Data that would complicate the investigation process.
- Data about personal information whose disclosure is unrelated to any activity or interest, or whose disclosure would result in an unjustified invasion of the person's privacy.
- Data whose disclosure would result in a copyright infringement committed by someone other than the state.

GOVERNMENT ORGANIZATIONS

RTI covers various governments, organizations, and bodies, and they are subject to it:

- Local, state, and central governments.
- All agencies or bodies owned, controlled, or substantially financed by the government.
- NGOs (non-government organizations) substantially financed directly or indirectly by government funds.
- The wing structure includes executive, judicial, and legislative branches.
- The RTI Act applies to all states and union territories of India, except J & K.

PUBLIC AUTHORITIES AND THEIR OBLIGATIONS

Public authorities:

- Constitutional bodies,
- Statutory bodies,
- Public corporations,
- Public undertakings, NGOs receiving financial assistance.

Structure of RTI at the state level:

- State Public Information Officers
- State Assistant Public Information Officer at the organizational level
- Public Information Officer (PIO)
- Assistant Public Information Officer (APIO)
- Appellate authority in public authority.

Obligations of Public Authorities:

- Maintaining all of its documentation to support the right to information.
- Computerization of records whenever possible.
- Make data available online.
- Every year, organizations must update their records.
- Publish specific information within 120 days.
- When drafting laws or making other actions that have an impact on the public, publish relevant information.
- Give affected parties the justification for administrative or quasi-judicial decisions.
- Information should be available for free or at a minimal cost.

PUBLIC INFORMATION OFFICER AND THEIR DUTIES

Public Information Officers (PIOs): Public Information Officers (PIOs) are officers appointed by the public authorities in all administrative units or offices to provide information to the public and seek data under the RTI Act of 2005. A key component of the Right to Information Act of 2005's implementation is the Public Information Officer.

Duties of public information officers (PIOs):

- To deal with requests for information.
- To offer reasonable assistance to the applicant.
- To accept the application, assign several requests per the RTI Act, and record it in a register assigned a number.
- To forward the application, within 48 hours, to the relevant department.
- To accept appeals on behalf of the appellate authorities.
- To accept a reply or information from the concerned department.
- To ensure the delivery of information to the applicants.
- To determine whether it has anything to do with life, liberty, or urgency.
- To ensure disposal of the requests within the prescribed time.

- To determine whether a third party is involved if so to issue notice and to obtain the third party's representation (if required).
- To seek assistance from any other officer as considered necessary.
- To compile weekly reports and inform Member Secretary NCW (National Commission for Women) about the circumstances.
- To maintain all RTI records, receipts of RTI, disposal, and submit an annual statement.
- To violate this act, another officer will be regarded as PIO.

CENTRAL INFORMATION COMMISSION (CIC) AND STATE INFORMATION COMMISSION (SIC)

- The Act calls for the constitution of State and Central Information Commissions (Sec. 12 and Sec. 15).
- It is an autonomous body to inquire about public complaints.
- The Central Information Commission is constituted by the Central Government through a Gazette Notification.
- The Commission includes one Chief Information Commissioner (CIC) and not more than 10 Information Commissioners (ICs) will be appointed by the President of India.
- The Central Information Commission (CIC)/State Information Commission (SIC) has to receive complaints from any person.
- CIC will have the power of a civil court.
- The State Information Commission will be constituted by the State Government through a Gazette Notification.
- It will have one State Chief Information Commissioner (SCIC) and not more than 10 State Information Commissioners (SICs) to be appointed by the Governor.

Powers and Duties of the Commission (SEC. 18)

The Act casts a duty on the Information Commission to receive and inquire into complaints from any person who:

- Has been unable to submit a request for information to a public authority because a PIO has not been appointed.
- Has been refused access to information.
- Has received no response to his application seeking information, within the time frame specified by the Act.
- Considers the fee charged by the public authority to declare information.
- Believes that he has been given incomplete, misleading, or false information under the Act.
- With regard to any issue pertaining to access to records under the Act.

MANDATORY DISCLOSURE OF INFORMATION BY AUTHORITY

- The specifics of its duties, roles, and organization.
- The responsibilities and authority of its officers and staff.
- The method used for making decisions, including the lines of accountability and oversight.
- The norms set by it for the discharge of its functions.
- The rules, regulations, instructions, manuals, and records to be followed by employees.
- A statement of the categories of documents.
- The specifics of any system in place for public representation or consultation about the creation or application of policy.
- A summary of the committees, boards, and councils, as well as the meeting minutes.
- An index of its officials and staff members.
- The monthly salary that each of its executives and staff receives.
- The amount of money allotted to each agency within it.
- The way in which subsidy schemes are implemented.
- Specifics of those who have received permits, concessions.
- Information on the data that it has access to or possesses in electronic format.

- The specifics of information-gathering spaces accessible to the general public, such as the hours of operation of any public libraries or reading rooms.
- The public information officers' names, titles, and other details.

PROCEDURE TO FILE THE RTI

You must send a written application to the PIO along with the prescribed fee. Application can be submitted personally, by mail, or electronically to the Public Information Officer (PIO) in English, Hindi, or the official language of the region. They must include a description of the information requested and any applicable fees (if not falling under the category of those below the poverty line). It is not necessary to give the reason for seeking information.

Proof of Receipt for RTI application: Applicant must retain a copy of the application for RTI, given to the Public Information Officer (PIO) with the signature of the PIO for its receipt in any of the following ways:

- i. Given by hand;
- ii. By registered mail;
- iii. By speed post through postal department services.

There is a three-level regime for receiving information:

- The first-level officers are designated by every public authority to receive applications from citizens.
- At the second level senior officers are designated by every public authority to look into those applications of citizens where the information sought for is refined by first-level officers. If the information sought is refused or the supplied information is unsatisfactory to the applicant, he has every right to make an appeal before the Departmental Appellate Authority (DAA) of the same department.

- At the third level the state government sets up an independent State Information Commission (SIC).

Information Website: You can file an RTI application online with 431 public authorities through a new government portal. <https://rtionline.gov.in/request/request.php>

Reason for requesting the information: Not required to give any reason for requesting the information.

Application fees: The application fee is ₹ 10. A fee of ₹ 10 is payable by cash/bankers cheque/demand draft/court fee in favor of the concerned PIO. Documents cost is ₹ 2 per page.

Exemption from fees: No such fee shall be charged to persons who are below the poverty line.

Time limit for disposal of request: Within thirty days of the receipt of the request.

Urgency of information: If a request for information relates to someone's life or liberty, it must be fulfilled within 48 hours of the request being received.

Late information: Information free of charge where a public authority fails to comply with the time limits specified.

Monitoring and reporting: Each PIO is required to submit an annual report to SIC detailing how the Act's provisions were implemented in that year, along with a copy to the relevant government.

Report on: The number of applications received, disposed of, not disposed of, etc.

APPEAL

If information is not received within the time specified aggrieved by the decision of the PIO.

- *First appeal with appellate authority in Public Authority:* Apply within 30 days of PIOs order Decision on appeals within 30–45 days
- *Second appeal to SIC:* Within 90 days of the order of appellate authority or from the date on which the order was due.

PENALTY AND COMPENSATION

A penalty of 250/- rupees each day till application is received or information is furnished, so however, the total amount of such penalty shall not exceed 25,000 rupees shall be imposed, and/or disciplinary action against the concerned officer may be taken.

If PIOs are found guilty of:

- Not accepting an application,
- Delay in providing necessary information without reasonable cause,
- Misleading, incomplete, or incorrect information.
- Destroying the requested information, and
- Any kind of obstruction against the exchange of information.

SIC can recommend disciplinary action against the errant PIO and compensation to the applicant.

RTI: TRANSPARENCY AND ACCOUNTABILITY IN GOVERNMENT

RTI act has brought in transparency:

1. The RTI Act has given voice to common citizens' desires on matters of government. It provided the general public with significant power over the plans and policies of the government. It empowered the people to challenge, audit, review, analyze, and evaluate government actions and choices to make sure they adhere to the values of justice, good governance, and the public interest.
2. The most effective tool to combat corruption is the right to information, which gives citizens the freedom to ask the government for information and in doing so, encourages accountability, openness, and transparency in government by opening up the government to public scrutiny. The RTI Act dispersed power and democratized access to information. Power was distributed equitably to all citizens and was no longer restricted to a small group of people.

3. People are more interested in government activities and are looking for knowledge on a range of topics that impact their lives and well-being. The RTI Act gave the public the right to ask government officials for clear, concise explanations of their actions. Every year, the number of RTI petitions has grown eight or ten times. According to a 2009 survey, about two million RTI requests were sent across the nation in the Act's first three years alone. The right information is therefore widely used. Less than 5% of the millions of information requests have had their requests for information refused for a variety of exemptions. Therefore, efficiency and a sense of duty among government officials have always followed accountability.
4. The goal of the Right to Information Act is to increase government transparency and accountability by opening up the decision-making process. Even though this Act does not apply to some Union government departments, information about human rights violations can still be obtained. Only the controlling authority may request information, even from private authorities, and only then will the controlling authority notify the relevant institution under section 11 of the Act.
5. More RTI usage has been observed in areas of youth development, women empowerment, democratic rights, underprivileged people's rights and entitlements, abuse of executive discretion, and strengthening of good and participatory governance.
6. In Shyam Yadav, Department of Personnel Training, for example, the Central Material Commission ruled that property declarations submitted by civil personnel are not confidential and that material can be released following the RTI Act's provisions after considering the opinions of relevant officials.
7. There is still a poor level of general public awareness regarding the RTI Act and how it might be used to their advantage. There are also more instances of the RTI Act being abused. The PIOs lack proper training and understanding of the many Act provisions and guidelines about the protocols that must be adhered to when sharing information.

RECENT AMENDMENTS

- The RTI Amendment Bill-2013 excludes political parties from the definition of public authorities and the RTI Act's scope.
- The draft provision 2017 allowing case closure in the event of an applicant's death may potentially increase attacks on whistleblowers' lives.
- The RTI Amendment Act, 2018 seeks to grant the centre the power to determine the tenures and salaries of state and central information commissioners.
- The Act proposes to replace the fixed 5-year tenure with as much prescribed by the government.
- The Act proposes to replace the fixed 5-year tenure with the amount prescribed by the government.

OTHER ISSUES

- Information commissioners do not have adequate authority to enforce the RTI Act.
- In case of award of compensation to activists by public authority as ordered by the commission, compliance cannot be secured.
- Poor record-keeping practices.
- Lack of adequate infrastructure and staff for running information commissions.
- Dilution of supplementary laws like the Whistleblowers Protection Act.

SCHEDULE

A. The First Schedule [see Sections 13 (3) and 16(3)]

Form of oath or affirmation to be made by the Chief Information Commissioner/

the Information Commissioner/the State Chief Information Commissioner/the State Information Commissioner.

B. The Second Schedule (*see Section 24*)
Intelligence and security organizations established by the Central Government.

SAMPLE APPLICATION

Application for obtaining information under the RTI Act, 2005

Applicant's Name:

Address:

Email:

Mobile No.

Aadhaar No.

To,

The Public Information Officer

Concern Department

Address of the Department:

Subject: Requesting to furnish information about (mention the subject) under Section 6 (1) of RTI Act, 2005.

Sir,

Kindly provide following information under RTI Act, 2005.

Please supply the certified copies in the format convenient to you (mention the subject) from (time period).

(Mention all the questions regarding the subject)

If the above information is not available in your office, kindly forward my application to the concerned public authority as per Section 6 (3) of RTI Act, 2005.

Required fee will be paid for issue of certified copies.

Thank You

Place:

Applicant's Name

Date:

Signature

CHAPTER

27

Drugs and Cosmetics Act, 1940, Schedules (P, T, U, F, M) and Detailed Study of Schedules

SCHEDULE G, H, M, M-I, M-II, N, X, Y

(see Chapter-2: *The Drugs and Cosmetics Act, 1940 and Rules, 1945*)

SCHEDULE P

(Schedule P outlines regulations regarding the life period and storage of various drugs.)

Schedule P details the life period of drugs in months from manufacture to expiry, with the labelled potency period not exceeding the

storage conditions specified in column no. 4 of Schedule P.

- Column no. 1 defines the serial number of drugs listed.
- Column no. 2 defines the name of the drug listed.
- Column no. 3 defines the period in months of the expiry date of the drug listed.
- Column no. 4 defines the conditions for the storage of drugs listed.

Table 27.1: Schedule P [Rule 96]: Life Period of Drugs

Sl no.	Name of the drug	The period in months (unless otherwise specified) between the date of manufacture and the date of expiry which the labelled potency period of the drug shall not exceed under the condition of storage specified in column no. 4.	Conditions of storage
Antibiotics			
1	Adramycin	30	In cool place
2	Ampicillin	36	In cool place
3	Ampicillin capsules	24	In cool place
4	Ampicillin dry syrups	24	In cool place
5	Ampicillin injection	24	In cool place
Vitamins			
1	Vitamin A injection	24	In a well closed container, protected from light, in a cool place.

Contd...

Table 27.1: Schedule P [Rule 96]: Life Period of Drugs Contd...

<i>Sl no.</i>	<i>Name of the drug</i>	<i>The period in months (unless otherwise specified) between the date of manufacture and the date of expiry which the labelled potency period of the drug shall not exceed under the condition of storage specified in column no. 4.</i>	<i>Conditions of storage</i>
2	Vitamin B ₁ injection	24	-do-
3	Thiamine mononitrate Tablets	36	-do-
4	Thiamine hydrochloride	48	-do-
5	Thiamine mononitrate	48	-do-
Insulin preparations			
1	Gobbuline zinc insulin Injection	24	At temp. between 2°C and 8°C, must not be allowed to freeze.
2	Insulin injection	24	-do-
3	Insulin zinc suspended	24	-do-
4	Insphane insulin injection	24	-do-
5	Human insulin injection	30	-do-
Normal human plasma			
1	Anti-haemophilic Human globulin	12	In a cool place
2	Dried plasma	60	At a temp. not-exceeding 25°C
3	Dried normal human Serum albumin	60	At a temp. not-exceeding 25°C
4	Frozen plasma	60	In deep freeze
5	Liquid normal human serum albumin	24	In a cold place
Sera toxin and toxoid			
1	Alum precipitated Diphtheria toxoid	24	In a cold place
2	Alum precipitated Diphtheria and tetanus Toxoid and pertussis Vaccine combined	18	In a cold place
3	Alum precipitated tetanus toxoid	24	In a cold place
4	Aluminium hydroxide Absorbed diphtheria Toxoid	24	In a cold place

Contd...

Table 27.1: Schedule P [Rule 96]: Life Period of Drugs Contd...

<i>Sl no.</i>	<i>Name of the drug</i>	<i>The period in months (unless otherwise specified) between the date of manufacture and the date of expiry which the labelled potency period of the drug shall not exceed under the condition of storage specified in column no. 4.</i>	<i>Conditions of storage</i>
5	Aluminium hydroxide Absorbed diphtheria Tetanus toxoid and Pertusis vaccine combined	18	In a cold place
Other vaccines			
1	Alum precipitated Pertussis Vaccine	18	In cold place
2	BCG Vaccine	24	In cold place
3	Cholera Vaccine	18	In cold place
4	DHL Vaccine (for dog)	12	In cold place
5	Measles Vaccine	24	In cold place
Antitoxin (for serum extracted preparations)			
1	20% excess potency	12	In cold place
2	30% excess potency	24	In cold place
3	40% excess potency	36	In cold place
4	50% excess potency (For enzyme preparations)	48	In cold place
5	5% excess potency	12	In cold place
Miscellaneous drugs			
1	Adrenaline for injection	12	In a cold place
2	Chorionic gonadotrophin for injection (lyophilised)	36	In a cold place
3	Corticotrophin	24	In a cold place
4	Corticotrophin lyophilised	36	In a cold place
5	Heparin injection	36	In a cold place

Note:

- The term "cool place" means a temperature between 10°C and 25°C.
- The term "cold place" means a place having a temperature not exceeding 8°C.
- Capsules should be kept in a well-closed container at a temperature not exceeding 30°C.
- Wherever the condition of storage is not specified in column 4, it may be stored under normal room temperature.

SCHEDULE P1

(Contains regulations regarding retail package size of various drugs)

Schedule P1: Schedule P1 details the pack size of drugs, including their names, dosage forms, and listed drugs' pack size.

Packing of Drugs

1. The pack sizes of drugs for retail sale are as specified in Schedule P1 of these rules.
2. The pack sizes of drugs not covered by the Schedule P1 shall be as given below:

Unless specified otherwise in Schedule P1:

- i. The pack sizes for tablets/capsules are determined by the integral number for numbers less than 10, and for numbers above 10, the pack sizes contain multiples of 5, as per the guidelines.
- ii. The pack sizes for liquid oral preparations are 30 ml for pediatrics, 60 ml for adults, 100 ml for children, 200 ml for adults, and 450 ml for children.
- iii. The pack sizes for pediatric oral drops should be 5 ml/10 ml/15 ml.
- iv. The pack sizes for eye/ear/nasal drops should be 3 ml/5 ml/10 ml.
- v. The pack sizes for eye ointment should be 3 gm/5 gm/10 gm.

3. The package sizes of dosage forms are intended for retail sale to hospitals, registered medical practitioners, and nursing homes.
4. Pack sizes of large-volume intravenous fluids: The new drug's pack sizes must be approved by the licensing authority appointed under Rule 21, and if not covered, they must be examined for approval with specific justification. [The Oxytocin injection for sale is intended to be sold in a single-unit blister pack only.]

SCHEDULE S (STANDARDS FOR COSMETICS)

Standards for cosmetics in finished form:

The Bureau of Indian Standards (BIS) regularly sets specifications for the finished form of certain cosmetics.

1. Skin powders
2. Skin powder for infants
3. Tooth powder
4. Toothpaste
5. Skin creams
6. Hair oils
7. Shampoo, soap-based
8. Shampoo, synthetic-detergent based
9. Hair creams
10. Oxidation hair dyes, liquid
11. Cologne.

Table 27.2: Schedule P1 (Rule 109): Pack size of Drug

Name of drug 1	Dosage form 2	Pack size 3
Albendazole	Suspension	10 ml
Atenolol	Tablet	14
Cholecalciferol or ergocalciferol	Granules	1 gm sachet
Ciclopiroxolamine	Vaginal cream	30 gm
Catalin	Ophthalmic drops	15 ml
Famotidine	Tablet	14
Glyceral trinitrate	Spanules (long acting)	25
Isoniazide	Syrup	200 ml
Oral rehydration salt (ORS)	Powder	Pouches to be reconstituted to one liter in one pack or in 5-unit dose sachet in one pack
Potassium chloride	Syrup	60 ml and 200 ml
Roxatidine acetate hydrochloride	Tablets	14

12. Nail polish (nail enamel)
13. After shave lotion
14. Pomades and brilliantines
15. Depliators chemicals
16. Shaving creams
17. Cosmetic pencils
18. Lipstick
19. Toilet soap
20. Liquid toilet soap
21. Baby toilet soap
22. Shaving soap
23. Transparent toilet soap
24. Lipsalve IS: 10284
25. Powder hair dye IS: 10350
26. Bindi (liquid) IS: 10998
27. Kumkum powder IS: 10999
28. Henna powder IS: 11142

SCHEDULE T

Schedule T: This document outlines the regulations and requirements for the production of Ayurvedic, Siddha, and Unani products.

Part 1: This part outlines the good manufacturing practices of Ayurvedic, Siddha, and Unani medicines.

GOOD MANUFACTURING PRACTICES FOR AYURVEDIC, SIDDHA, AND UNANI MEDICINES

The good manufacturing practices (GMPs) are prescribed as follows in Part I and Part II to ensure that:

- Raw materials used in drug manufacturing are authentic of prescribed quality, and free from contamination.
- The manufacturing process adheres to the prescribed standards.
- The implementation of adequate quality control measures is ensured.
- The drug released for sale is of acceptable quality.
- Licensees must develop methodology and procedures for drug manufacturing, documented as manuals for reference and inspection. However, registered Vaidyas, Siddhas, and Hakeems under the IMCC

Act (1970) who prepare medicines on their own and not sell them in the market are exempt from GMP, allowing them to dispense their drugs to patients.

General Requirements

1. *Location and surroundings:* The factory building for Ayurveda, Siddha, and Unani Medicine manufacturing must be designed to prevent contamination from sources such as open sewerage, drains, unpleasant odors, dust, and smoke.
2. *Buildings:* A manufacturing unit for Ayurvedic, Sidha, and Unani Medicines must ensure hygienic conditions, be free from insects/rodents, have adequate light and ventilation, and be free from cracks and dampness, following factory act provisions.

Factory premises: A manufacturing premises should have adequate space for all daily activity like:

- Receiving and storage of herbs, packaging material and other raw materials.
- Production and manufacturing activity area.
- Quality control section.
- Finished goods store.
- Office and administration.
- Rejected products/drugs store.

The Ayurveda, Sidha, and Unani medicine manufacturing unit requires a minimum area of 1200 square feet, with separate cabins and partitions for each activity, and an additional 400 square feet if Unani medicines are produced alongside Ayurvedic medicine.

3. *Water supply:* The manufacturing process requires pure, potable water, and adequate water waste management is necessary to ensure proper disposal.
4. *Disposable of waste:* It is imperative to ensure proper waste management care.
5. *Container's cleaning:* The cleaning, cleaning and drying section of containers should be

kept separate from the manufacturing operations.

6. *Stores:* The store should have sufficient space to store raw material, packaging material, and finished products separately and independently.
7. *Working space:* Manufacturing area should be adequate for orderly placement of equipment, machinery and material used during manufacturing operations and quality control to facilitate easy and safe working and to minimize or eliminate any risk of mix-up between different drugs, raw materials and to prevent the cross contamination during manufacturing, storage and handling operations.
8. *Health clothing, sanitation and hygiene of workers:* Workers should be healthy and free from contagious diseases, provided with clean uniforms suited to their work environment and climate, and have access to lavatories and changing rooms.
9. *Medical services:* The manufacturer should ensure that they provide adequate facilities for first aids.
10. *Machinery and equipment:* The manufacturing process necessitates sufficient machinery and equipment, as detailed in Part II of Schedule T.
11. *Batch manufacturing record:* Batch records should be maintained for all products, including classic preparations, patents, and proprietary medicines, and signed by both production and analytical chemists.
12. *Distribution record:* The distribution record, or dispatch register, is crucial for prompt and complete batch recall, and should be maintained until the batch's expiry, and for drugs without expiry dates, up to five years after stock exhaustion.
13. *Record of market complaints:* A complain register should be maintained to record all reports of market complaints received regarding products sold in the market.
14. *Quality control:* A manufacturer can establish its own quality control section or conduct

testing through a government-approved laboratory.

Part II (Schedule T)

Part II lists recommended machinery, equipment, and minimum manufacturing premises for various Ayurvedic and Siddha system medicines.

SCHEDULE U

(Contains Various Regulations and Requirements for Record-keeping) (Rules 74, 74A, 74B, 78 and 78A).

I. Particulars to be shown in Manufacturing Records

A. Substances, other than Parenteral Preparations in General

(1) Serial number, (2) Name of the product, (3) Reference of master formula records, (4) Lot/Batch size, (5) Lot/Batch number, (6) Date of commencement of manufacture and date of completion of manufacture and assigned date of expiry, (7) Name of all ingredients, specifications quantities required for the lot/batch size, and quantities used. All weighing and measurements shall be carried out by a responsible person and initiated by him and shall be counter-checked and signed by the competent technical staff under whose personal supervision the ingredients are used for manufacture, (8) Control numbers of raw materials used in the formulation, (9) Date, time, and duration of mixing, (10) Details of environmental controls like room temperature, and relative humidity, (11) Date of granulation, wherever applicable, (12) Theoretical weight and actual weight of granules/powder blend, (13) Records of in-processes controls (Periodically whenever necessary): (a) Uniformity of mixing, (b) The moisture content of granules/powder in the case of tablets/capsules, (c) the pH of the solution in the case of liquid. (d) Weight variation, (e) Disintegration time, (f) Hardness (g) Friability test, (h) Leak test in case of strip packing, (i) Filled volume of liquids, (j) Quantity of tablets/capsules in the final container, (k) Content of ointment in the filled containers,

(14) Date of compression in case of tablets/date of filling in case of capsules, (15) Date of sealing/coating/polishing in case of capsules/tablets wherever applicable, (16) Reference to analytical report number stating the result of test and analysis, (17) Separate records of the disposal of the rejected batches and batches withdrawn from the market, (18) The theoretical yield and actual production yield and packing particulars indicate the size and quantity of finished packings, (19) Specimen of label/strip, carton with batch coding information like batch number, date of manufacture, date of expiry, retail price as applicable stamped thereon, and inserts used in the finished packings, (20) Signature with the date of competent technical staff responsible for the manufacture, (21) Countersignature of the head of the testing units or other approved person-in-charge of testing for having verified the batch records and for having released and batch for sale and distribution, the quantity released and date of release, (22) Date of release of finished packings and quantity released for sale and distribution, (23) Quantity transferred to warehouse, (24) For hypodermic tablets and ophthalmic preparations, which are required to be manufactured under aseptic conditions, records shall be maintained indicating the precautions taken during the process of manufacture to ensure that aseptic conditions are maintained.

B. Parenteral Preparations

(1) Serial number, (2) Name of the product, (3) Reference of the master formula record, (4) Batch /lot size, (5) Batch no. and/or lot no., (6) Date of commencement of manufacture and date of completion, (7) Names of all ingredients, specifications, and quantity required for the lot/batch size and quantity used. All weighing and measurements shall be carried out by a responsible person and initiated by him and shall be countersigned by the technical staff under whose personal supervision the stock is issued and by another competent technical staff under whose supervision the ingredients are

used for manufacture, (8) Control numbers of raw materials used in the formulation, (9) Date, time, and duration of mixing, (10) Details of environmental controls like temperature, humidity, and microbial count in the sterile working areas, (11) pH of the solution, wherever applicable, (12) Date and method of filtration, (13) Sterility test, reference on bulk batch wherever applicable, (14) Record of check on volume filled, (15) Date of filling, (16) Records of tests employed: (a) To ensure that sealed ampoules are leakproof (b) To check the presence of foreign particles. (c) Pyrogen test, wherever applicable (d) Toxicity test, wherever applicable, (17) Records of checking of instruments and apparatus of sterilization (indicators), (18) Records of cleaning and sterilization of containers and closures, if necessary, (19) Records of sterilization in case of parenteral preparations that are heat sterilized including particulars of time, temperature, and pressure employed. Such records should be marked to relate to the batch sterilized, (20) Number and size of containers filled and quantity rejected, (21) The theoretical yield and actual yield and the percentage yield thereof, (22) Reference to analytical report numbers stating whether of standard quality or otherwise, (23) Specimen of labels, cartons, etc. with batch coding information like batch number, date of manufacture, date of expiry, as applicable, stamped thereon, and inserts used in the finished packings, (24) Signature with the date of the component technical staff responsible for the manufacture, (25) Particulars regarding the precautions taken during the manufacture to ensure that aseptic conditions are maintained, (26) Countersignature of the head of the testing unit or person in charge of testing for having verified the documents and for having released the product for sale and distribution, the quantity released, and date of release, (27) Records for having transferred to warehouse giving packings and quantities, (28) Separate records of the disposal of the rejected batches and all batches withdrawn from the market, (29) Records

of reprocessing if any and particulars of reprocessing.

II. Records of Raw Materials

Raw material records should include the date of receipt, invoice number, manufacturer / supplier name/address, batch number, quantity received, pack size, manufacture date, expiry date, analysis and release/rejection date, analytical report number, quantity issued, date of issue, and details of the product name and batch numbers for manufacture. Proper stock disposal is also essential.

III. Particulars to be Recorded in the Analytical Records

A. Tablets and Capsules

(1) Analytical report number, (2) Name of the sample, (3) Date of receipt of sample, (4) Batch/ Lot number, (5) Protocols of tests applied: (a) Description, (b) Identification, (c) Uniformity of weight, (d) Uniformity of diameter (if applicable), (e) Disintegration test (time in minutes), (f) Any other tests, (g) Results of assay, (6) Signature of the analyst, (7) Opinion and signature of the approved analyst.

B. Parenteral Preparations

(1) Analytical report number, (2) Name of the sample, (3) Batch number, (4) Date of receipt of samples, (5) Number of containers filled, (6) Number of containers received, (7) Protocols of tests applied: (a) Clarity, (b) pH wherever applicable, (c) identification, (d) volume in container, (e) sterility: (i) Bulk sample wherever applicable, (ii) container sample, (f) pyrogen test, wherever applicable, (g) toxicity test, wherever applicable, (h) any other tests, (i) results of assay, (8) Signature of the Analyst, (9) Opinion and signature of the approved analyst.

Pyrogen test

(1) Test report number, (2) Name of the sample, (3) Batch number, (4) Number of rabbits used, (5) Weight of each rabbit, (6) Normal temperature of each rabbit, (7) Mean initial temperature

of each rabbit, (8) Dose and volume of solution injected into each rabbit and time of injection, (9) Temperature of each rabbit noted at suitable intervals, (10) Maximum temperature, (11) Response, (12) Summed response, (13) Signature of the analyst, (14) Opinion and signature of the approved analyst.

Toxicity test

(1) Test report number, (2) Name of the sample, (3) Batch number, (4) Number of mice used and weight of each mouse, (5) Strength and volume of the drugs injected, (6) Date of injection, (7) Results and remarks, signature of analyst, (8) Opinion and signature of the approved analyst.

C. For other Drugs

(1) Analytical report number, (2) Name of the sample, (3) Batch/lot number, (4) Date of receipt of sample, (5) Protocol of tests applied. (a) Description, (b) Identification, (c) Any other tests, (d) Results of assay, (6) Signature of analyst, (7) Opinion and signature of the approved analyst.

D. Raw Materials

(1) Serial number, (2) Name of the materials, (3) Name of the manufacturer/supplier, (4) Quantity received, Invoice/Challan number and date, (5) Protocols of tests applied.

E. Container, Packing Materials, etc.

(1) Serial number, (2) Name of the item, (3) Name of the manufacturer/supplier, (4) Quantity received, (5) Invoice/Challan number and date, (6) Results of tests applied, (7) Remarks, (8) Signature of the examiner.

SCHEDULE U(I)

Schedule U(I) describes the particulars to be shown in the manufacturing record for cosmetics.

SCHEDULE F

This contains regulations and standards for running a blood bank.

Schedule F I: This contains regulations and standards for vaccines.

Schedule F II: This contains regulations and standards for surgical dressing.

Schedule F III: This contains regulations and standards for umbilical tapes.

Note: The Licensing Authority and Central Licence Approving Authority may simplify accommodation and area requirements for blood banks in hospitals with common pathological laboratories and sterilization-cum-washing rooms. Donors will receive refreshments post-phlebotomy.

SCHEDULE F “PART XII B”

Requirements for the functioning and operation of a blood bank and/or for preparation of blood components.

I. Blood Banks/Blood Components

A. General

- 1. Location and surroundings:** The blood bank should be situated in a clean, hygienic environment away from open sewage, drains, public lavatory, or similar unhygienic environments.
- 2. Building:** The building used for blood bank operations must be hygienic, well-lit, ventilated, and screened to prevent insects, rodents, and flies. Rooms should be smooth, washable, and clean. Adequate drains and traps should be installed for sewer connections to prevent back siphonage.
- 3. Health, clothing, and sanitation of staff:** Employees must be free from infectious diseases, and provided with clean overalls, head-gears, footwear, gloves, and adequate hand washing and toilet facilities.

B. Accommodation for a Blood Bank

A blood bank should have a 100-square-meter area for operations and 50 square meters for component preparation. It should have rooms for registration, medical examination, blood collection, component preparation, blood group serology, blood-transmissible diseases like hepatitis, syphilis, malaria, and HIV antibodies, sterilization and washing, refreshment and rest room, and a store for blood components. The air-conditioned facilities should maintain a temperature between 20°C and 25°C.

C. Personnel

Every blood bank shall have the following categories of whole-time competent technical staff:

- a. Medical Officer, possessing the qualifications specified in condition of Rule 122-G.
- b. Blood bank technicians must have a Medical Laboratory Technology degree with 6 months of experience in blood testing, or a Diploma with one year of experience, from a recognized university or institution, and have at least one year of experience in blood testing.
- c. Registered nurse(s).
- d. A Technical Supervisor in blood component manufacturing must have a degree in Medical Laboratory Technology (MLT) with 6 months of experience or a diploma with one year's experience, both from a recognized university or institution and have 6 months or one year of experience in blood component preparation.

Note: The qualifications and experience of the Technical Supervisor and blood bank technician are approved by the Licensing Authority or Central Licence Approving Authority after the Drugs and Cosmetics Amendment Rules, 1999. Blood banks must adhere to the Directorate General of Health Services Manual's requirements for competent technical personnel. Licensees must ensure blood banking personnel are adequately trained in good manufacturing practices/standard operating procedures and receive initial and continuing training.

D. Maintenance

The premises must be kept clean and well-maintained to ensure proper operations and cleaning. The facilities shall include.

The guidelines outline the procedures for blood donation, including ensuring privacy and thorough examination of donors, collecting blood with minimal risk of contamination, storing blood or components pending test completion, providing quarantine and storage facilities, and disposing of unsuitable products and reagents. They also outline the storage and handling of potentially harmful products and reagents.

The policy outlines the storage of finished products, proper collection, processing, compatibility testing, storage, and distribution of blood and blood components, adequate performance of procedures related to plasmapheresis, plateletpheresis, and leukapheresis, proper conduct of packaging and labelling, and ensuring safe disposal of blood components not suitable for use, distribution, or sale, as well as trash and items used during collection, processing, and compatibility testing.

E. Equipment

The equipment used in blood collection, processing, testing, storage, and distribution must be maintained cleanly and properly, ensuring easy cleaning and maintenance. Regularly observed, standardized, and calibrated according to the standard operating procedures manual, the equipment should operate in a manner designed to ensure compliance with official requirements for blood and its components.

Equipment list

(1) Temperature recorder, (2) Refrigerated centrifuge, (3) Hematocrit centrifuge, (4) General lab centrifuge, (5) Automated blood typing, (6) Haemoglobinometer, (7) Refractometer or Urinometer, (8) Blood container weighing device, (9) Water bath, (10) Rh view box (wherever necessary), (11) Autoclave, (12) Serologic rotators, (13) Laboratory thermometers, (14) Electronic thermometers, (15) Blood agitator

F. Supplies and Reagents

The guidelines for blood and blood components collection, processing, compatibility, testing,

storage, and distribution emphasize the importance of proper storage at a safe temperature and hygienic conditions. All supplies and reagents should be sterile, pyrogen-free, and not adversely affect the product's safety, purity, potency, or effectiveness. Non-expiry supplies should be stored in a manner where the oldest is used first. Blood components not intended for transfusion should be clean and free of contaminants. Blood collecting and satellite containers should be visually examined for damage or contamination before and after use.

<i>Reagents and solutions</i>	<i>Frequency of testing along with controls</i>
1. Anti-human serum	Each day of use
2. Blood grouping serums	Each day of use
3. Lectin	Each day of use
4. Antibody screening and reverse grouping cells	Each day of use
5. Hepatitis test reagents	Each run
6. Syphilis serology reagents	Each run
7. Enzymes	Each day of use
8. HIV I and II reagents	Each run
9. Normal saline (LISS and PBS)	Each day of use
10. Bovine albumin	Each day of use

G. Good Manufacturing Practices (GMPs)/ Standard Operating Procedures (SOPs)

Written standard operating procedures shall be maintained and shall include all steps to be followed in the collection, processing, compatibility testing, storage, and sale or distribution of blood and/or preparation of blood components for homologous transfusion, autologous transfusion, and further manufacturing purposes. Such procedures shall be available to the personnel for use in the concerned areas.

The Standard Operating Procedures shall inter alia include:

1. This document outlines donor suitability criteria, donor qualifying tests, phlebotomy

site preparation, blood collection procedures, adverse reactions management, storage temperatures, expiry dates, returned blood suitability, quality control procedures, equipment maintenance, labelling, plasmapheresis, plateletpheresis, and leucapheresis.

2. Licensee can use current standard operating procedures from organizations or blood bank manuals, as long as they align with the Part's requirements, pending approval from the State Licensing Authority and Central Licence Approving Authority.

H. Criteria for blood Donation

Conditions for donation of blood:

1. **General:** Blood donation is restricted to individuals aged 18–60, with a minimum weight of 45 kg, normal temperature and pulse, systolic and diastolic blood pressures, and a haemoglobin level of 12.5 grams. Donors must be in good health, mentally alert, and physically fit, and not inmates of jail, multiple partners, or drug addicts. They must also be free from acute respiratory diseases, skin diseases at the phlebotomy site, and any disease transmissible by blood transfusion.

2. Additional qualifications of a donor: Blood donation and blood bank drawing are prohibited under certain conditions in column (1) of the table before the expiry of the period of deferment in column (2) of the same (Table 27.2).
3. No person shall donate blood and no blood bank shall draw blood from a person, suffering from any of the diseases mentioned below, namely: (a) Cancer, (b) Heart disease, (c) Abnormal bleeding tendencies, (d) Unexplained weight loss, (e) Diabetes-controlled on insulin, (f) Hepatitis infection, (g) Chronic nephritis, (h) Signs and symptoms, suggestive of AIDS, (i) Liver disease, (j) Tuberculosis, (k) Polycythaemia vera, (l) Asthma, (m) Epilepsy, (n) Leprosy, (o) Schizophrenia, (p) Endocrine disorders

I. General Equipment and Instruments

1. **For blood collection room:** The blood collection room should have comfortable donor beds, chairs, tables, sphygmomanometers, stethoscopes, recovery beds, refrigerators, digital dial thermometers, recording thermographs, alarm devices, continuous

Table 27.2: Deferment of blood donation

<i>Conditions</i>	<i>Period of deferment</i>
1	2
a. Abortions	6 months
b. History of blood transfusion	6 months
c. Surgery	12 months
d. Typhoid	12 months after recovery
e. History of malaria and duly treated	3 months (endemic) 3 years (nonendemic area)
f. Tattoo	6 months
h. Breastfeeding	12 months after delivery
i. Immunization (cholera, typhoid, diphtheria, tetanus, plague, gamma globulin)	15 days
j. Rabies vaccination	1 year after vaccination
k. History of hepatitis in family or close contact	12 months
l. Immunoglobulin	12 months

power supply, weighing devices for donors, and blood containers.

2. **For haemoglobin determination:** (i) Copper sulfate solution (specific gravity 1.053), (ii) sterile lancet and impregnated alcohol swabs, (iii) capillary tube ($1.3 \times 1.4 \times 96$ mm or Pasteur pipettes), (iv) rubber bulbs for capillary tubing, (v) Sahli's haemoglobinometer/colourimetric method.
3. **For temperature and pulse determination:** (i) Clinical thermometers, (ii) watch (fitted with a second hand) and a stopwatch.
4. **For blood containers:**
 - a. *Disposable PVC bags:* Disposable PVC blood bags (closed system) are strictly adhered to according to IP/USP/BP specifications.
 - b. *Anti-coagulants:* The anti-coagulant solution, either citrate phosphate dextrose adenine solution (CPDA) or citrate phosphate dextrose adenine-1 (CPDA-1) - 14, must be sterile, pyrogen-free, and safe for the whole blood or all separated blood components, and should be required for 100 ml of blood.

Note: CPDA blood collection bags can be used for blood component preparations. A 15 ml acid citrate dextrose solution is required for 100 ml of blood. Additive solutions like SAGM, ADSOL, and NUTRICEL can be used for storing and retaining red blood corpuscles for up to 42 days.

The Licensee must ensure that the anti-coagulant solutions used in blood bags are from a licenced manufacturer and have a certificate of analysis.

5. **Emergency equipment/items:** Emergency equipment includes an oxygen cylinder, glucose saline, disposable sterile syringes, needles, IV infusion sets, medications, aspirin, and other necessary items for immediate medical assistance.
6. **Accessories:** This list includes cleaning items like blankets, emesis basins,

haemostats, dressing jars, cotton balls, adhesive tapes, denatured spirit, tincture iodine, green soap, paper napkins, autoclaves, incinerators, standby generators, and various tools and equipment.

7. **Laboratory equipment:** (i) Refrigerators, diagnostic kits, and reagents are stored in refrigerators with a digital dial thermometer and continuous power supply, maintaining a temperature range of 4 to 6°C, (ii) Compound microscope with low and high-power objectives, (iii) Centrifuge table model, (iv) Water bath: Having range between 37°C and 56°C, (v) Rh viewing box in case of slide technique, (vi) Incubator with thermostatic control, (vii) Mechanical shakers for serological tests for syphilis, (viii) Hand-lens for observing tests conducted in tubes, (ix) Serological graduated pipettes of various sizes, (x) Pipettes (Pasteur), (xi) Glass slides, (xii) Test tubes of various sizes/micrometre plates (U or V type), (xiii) Precipitating tubes 6 mm × 50 mm of different sizes and glass beakers of different sizes, (xiv) Test tube racks of different specifications, (xv) Interval timer electric or spring wound, (xvi) Equipment and materials for cleaning glass wares adequately, (xvii) Insulated containers for transporting blood, between 2°C to 10°C temperatures, to wards and hospitals, (xviii) Wash bottles, (xix) Filter papers, (xx) Dielectric tube sealer, (xxi) Plain and EDT A vials, (xxii) Chemical balance (wherever necessary), (xxiii) ELISA reader with printer, washer, and micro-pipettes.

J. Special Reagents

1. Standard blood grouping sera anti A, anti B, and anti D with known controls are supplied in double quantity, with each supply of different lot numbers from the same supplier.

2. The package includes reagents for serological tests for syphilis and positive sera for controls.
3. Anti-human globulin serum (Coomb's serum).
4. Bovine albumin 22 percent enzyme reagents for incomplete antibodies.
5. ELISA or RPHA test kits for hepatitis and HIV I and II.
6. Detergent and other agents for cleaning laboratory glassware.

K. Testing of Whole Blood

1. The licensee is obligated to ensure that the whole blood collected, processed, and supplied adheres to the standards set by the Indian Pharmacopoeia and other government-published tests.
2. Licensee must undergo HIV I and II antibody tests before using blood units, either from central government-specified or their labs, and record the results on the container label.
3. Blood units must be tested for hepatitis B surface antigen, hepatitis C virus antibody VDRL, and malarial parasite, with results recorded on the container label.

Note: Blood samples should be preserved for 7 days post-issue, and transfusion blood should not be frozen or exposed to ice.

L. Records

The licensee is required to maintain records that include specific details, including:

1. The blood donor record should include the donor's serial number, date of bleeding, name, address, signature, age, weight, haemoglobin, blood grouping, blood pressure, medical examination, bag number, and patient details.
2. Master records for blood and its components should include bag serial number, collection date, expiry date, quantity, results for HIV/AIDS, malaria, VDRL, hepatitis B, C, irregular antibodies, donor's name, utilization issue number, components prepared or discarded.

3. The issue register should include serial number, date, bag serial number, ABO/Rh Group, total quantity, recipient name, address, recipient group, unit/institution, cross-matching report details, and transfusion indication.
4. The records include the quantity of components supplied, compatibility report, recipient details, and signature of the issuing person.
5. The records of ACD/CPD/CPD-A/SAGM bags provide information on the manufacturer, batch number, date of supply, and testing results.
6. The register includes details of diagnostic kits and reagents used, including their names, batch numbers, expiry dates, and use dates.
7. The blood bank is required to provide a cross-matching report of the patient's blood and the blood unit.
8. Transfusion adverse reaction records.
9. Maintaining records of purchase, use, and stock of disposable needles, syringes, and blood bags is essential for healthcare professionals.

Note: The licensee is required to maintain these records for five years.

M. Labels

The labels on bags containing blood or components must include specific details, such as the rules require prominent product names, blood bank addresses, licence, and serial numbers, drawing dates and expiry dates, and a coloured label on every bag containing blood, all of which must be displayed in bold letters on the bag.

The following colour scheme for the said labels shall be used for different groups of blood:

Blood group	Colour of the label
O	Blue
A	Yellow
B	Pink
AB	White

The text outlines the procedures for testing blood for hepatitis B surface antigen, hepatitis C virus antibodies, syphilis, HIV I and II antibodies, and malarial parasites. It also mentions the Rh group, total blood volume, preparation, nature, and anti-coagulant percentage. The temperature should be maintained at 2 degrees centigrade to 6 degrees centigrade for whole human blood and components. Disposable transfusion sets with filters should be used in administration equipment. Compatible cross-matched blood without typical antibodies should be used in recipients. The bag contents should not be used if there is visible evidence of deterioration.

II. Blood Donation Camps

A blood donation camp: A blood donation camp can be organized by a Licenced Regional Blood Transfusion Centre, a government blood bank, the Indian Red Cross Society, or a licenced blood bank run by registered voluntary or charitable organizations recognized by the State or Union Territory Blood Transfusion Council.

Note: A Regional Blood Transfusion Centre is a state-approved facility responsible for collecting, processing, and distributing blood to meet regional needs. It must be licenced and approved by the Licensing Authority and Central Licence Approving Authority and must inform them within seven days of the blood camp venue and group-wise collection details.

For holding a blood donation camp, the following requirements shall be fulfilled/complied with, namely:

A. Premises, Personnel, etc.

The blood donation camp must be sized and hygienic for proper operation, maintenance, and cleaning. It should have well-documented personnel, equipment, and facilities, including uninterrupted electrical supply, lighting, hand-washing, communication systems, refreshments, medical examinations, and waste disposal. The camp should also have a reliable communication system with the central office.

B. Personnel for Out-door Blood Donation Camp

A team of medical officers, nurses, social workers, blood bank technicians, attendants, and a vehicle with 8–10 people must be present to collect blood from 50–70 donors in 3 hours or 100–120 donors in 5 hours.

C. Equipment

(1) BP apparatus, (2) Stethoscope, (3) Blood bags (single, double, triple, quadruple), (4) Donor questionnaire, (5) Weighing devices for donors, (6) Weighing device for blood bags, (7) Artery forceps, scissors, (8) Stripper for blood tubing, (9) Bed sheets, blankets/mattress, (10) Lancets, swab stick/toothpicks, (11) Glass slides, (12) Portable Hb meter/copper sulfate, (13) Test tube (big) and 12 × 100 mm (small), (14) Test tube stand, (15) Anti-A, Anti-B and Anti-AB, Antisera and Anti-D, (16) Test tube sealer film (17) Medicated adhesive tape, (18) Plastic waste basket, (19) Donor cards and refreshments for donors, (20) Emergency medical kit, (21) Insulated blood bag containers with provisions for storing between 2°C and 10°C, (22) Dielectric sealer or portable sealer, (23) Needle destroyer (wherever necessary).

III. Processing of Blood Components from Whole Blood by a Blood Bank

Blood banks prepare blood components as part of their services, and the conditions for granting or renewing a licence to prepare blood components include:

A. Accommodation

The room specifications for preparing blood components are specified in item B under "Blood banks/blood components" of this part. Blood components are prepared under a closed system using single, double, triple, or quadruple plastic bags, except for red blood cells concentrates.

B. Equipment

(i) Air conditioner, (ii) Laminar air flow bench, (iii) Suitable refrigerated centrifuge, (iv) Plasma

expresser, (v) Clipper and clips and or dielectric sealer, (vi) Weighing device, (vii) Dry rubber balancing material, (viii) Artery forceps, scissors, (ix) A refrigerator with a digital dial thermometer, recording thermograph, alarm device, and continuous power supply, maintaining a temperature range of 2°–6°C, (x) Platelet agitator with incubator (wherever necessary), (xi) Deep freezers are used to store food and other items at temperatures ranging from -30° to -40°C and -75°C to -80°C, (xii) Refrigerated water bath for plasma thawing, (xiii) Insulated blood bag containers with provisions for storing at appropriate temperature for transport purposes.

C. Personnel

The competent technical staff for processing blood components, including the medical officer, technical supervisor, blood bank technician, and registered nurse, must adhere to the Act.

D. Testing Facilities

General: Facilities for A, B, AB, and O groups, as well as Rh(D) grouping.

Hepatitis: Blood units must undergo mandatory testing for B surface antigen, hepatitis C virus antibody, VDRL, HIV I and II antibodies, and malarial parasites before being used for blood component preparation, with label results.

E. Categories of Blood Components

1. Concentrated human red blood corpuscles

“Packed red blood cells” is a product that contains the remaining red blood cells from the separation of plasma from human blood.

General requirements

- Storage:** Following processing, packed red blood cells should be stored at a temperature between 2°C and 6°C.
- Inspection:** The component must be inspected immediately after plasma separation,

storage, and issue, and not issued if it shows colour, physical appearance, or microbial contamination.

- Suitability of donor:** The source blood for packed red blood cells shall be obtained from a donor who meets the criteria for blood donation as specified in item H under the heading.
- Testing of whole blood:** The preparation of packed red blood cells requires testing of whole blood according to item K under “blood banks/blood components” of this part.
- Pilot samples:** Pilot samples, whether collected in integral tubing or separate tubes, must adhere to specific specifications.

Packed red blood cell units must contain pilot samples of original or processed blood, marked for donor identification, and attached tamper-proof. They must be filled immediately after blood collection or preparation to ensure product safety and integrity.

F. Processing

- Separation:** Packed red blood cells are separated from whole blood within 21 days if stored in ACD solution, and 35 days if stored in CPDA-1 solution. They can be prepared through centrifugation or normal sedimentation, with a portion of plasma left for optimal cell preservation. The process ensures optimal cell preservation.
- Packed red blood cells frozen:** A chemical substance can be added to packed red blood cells for extended storage below -65°C, provided the manufacturer submits data to the Licensing Authority and Central Licence Approving Authority. The substance must meet safety, purity, and potency standards for packed red blood cells, and the frozen product must maintain those properties for the specified expiry period.
- Testing:** The packed red blood cells must adhere to the standards set by the Indian Pharmacopoeia.

2. Platelets concentrates

"Platelets Concentrates" is a product containing platelets collected from one unit of blood and re-suspended in an appropriate volume of original plasma.

General requirements

- i. *Source:* Platelets are produced from platelet-rich plasma or buffy coat, which can be obtained from whole blood or through plateletpheresis.
- ii. *Processing:*
 - a. The process involves the separation of buffy-coat or platelet-rich plasma and platelets using a closed system centrifugal method with appropriate speed, force, and time.
 - b. After blood collection, whole blood or plasma should be stored between 20°C and 24°C. When transported to the processing laboratory, maintain a temperature close to 20° to 24°C. Platelet concentrates should be separated within 6 hours of blood collection.
 - c. The centrifugation process must produce an unclamped product with a platelet count of 3.5×10^{10} and 4.5×10^{10} per unit from 350 ml and 450 ml blood, respectively. One percent of the prepared platelets must be tested, with 75% conforming to the count.
 - d. The original plasma volume for re-suspension of platelets must maintain a pH of at least 6 during storage, measured on a platelet sample stored at 20–24°C for the permissible maximum expiry period.
 - e. Platelets should be stored in colourless, transparent containers with a hermetic seal to prevent contamination. The container material should not affect the product's safety, purity, potency, or efficacy. The final container should be marked or identified by number to relate it to the donor during filling.

iii. *Testing:* Platelets should be stored at 20°–24°C for 5 days after re-suspension, with continuous gentle agitation of the concentrates.

iv. *Storage:* The storage period of prepared units from various donors is crucial for testing for platelet count, pH, plasma volume, sterility, functional viability, and compatibility. A percentage of the total platelets is tested for sterility, and if the results do not meet requirements, corrective action is taken. If the platelets concentrate is contaminated with red blood cells, compatibility tests are conducted to group the cells into A, B, AB, and O groups.

3. Granulocyte concentrates

- i. *Storage:* The temperature should be maintained between 20°C and 24°C for a maximum of 24 hours.
- ii. The unit of granulocytes shall not be less than 1×10^{10} (i.e. 1×10 raised to the power of 10) when prepared on the cell separator.
- iii. Group-specific tests and HLA tests will be conducted as needed.

4. Fresh frozen plasma

Plasma, frozen within 6 hours of blood collection and stored at a temperature below –30°C, should be preserved for up to one year.

5. Cryoprecipitate

The anti-haemophilic factor concentration will be created by thawing fresh plasma stored at –30°C.

- a. *Storage:* Cryoprecipitate should be stored at a temperature below minus –30°C and for a maximum of one year from the date of collection.
- b. *Activity:* The final product must have an anti-haemophilic factor activity of 80 units per bag, with 75% of units conforming to the specified specification.

6. Plasmapheresis, plateletpheresis, leucapheresis using a cell separator

Apheresis in blood banks must adhere to specific criteria, require donor consent, explain potential hazards, and be certified by a Medical Officer. The procedure must be carried out by a trained person under the Medical Officer's supervision, covering an area of 10 square meters.

A. Plasmapheresis, plateletpheresis, and leucapheresis

Donors undergoing plasmapheresis, plateletpheresis, and leucapheresis must also undergo protein estimation post-pheresis/first sitting, ensuring total plasma and periodicity follow validated standard operating procedures, and the results serve as a reference for subsequent procedures.

Note: The guidelines for apheresis include a minimum of 48 hours between successive apheresis and not more than twice a week. Extracorporeal blood volume should not exceed 15% of the donor's estimated blood volume. Plateletpheresis is not recommended for donors taking aspirin medication within 3 days. If RBCs cannot be re-transfused, 12 weeks must elapse before a second cataphoresis procedure.

B. Monitoring for apheresis

Before apheresis, haemoglobin or haematocrit tests, platelet, WBC, and differential counts are conducted. In repeated plasmapheresis, serum protein should be 6 gm/100 ml.

C. Collection of plasma

The donor's plasma volume should not exceed 500 ml per sitting, once a fortnight, or 1000 ml per month.

SCHEDULE M

(See Chapter 2 The Drugs and Cosmetics Act, 1940 and Rules, 1945)

Schedule M of the Drugs and Cosmetics Act of 1940 outlines Good Manufacturing Practices

(GMP) for Indian pharmaceuticals, ensuring quality, safety, and efficacy. The Ministry of Health and Family Welfare recently conducted a quality control drive, inspecting 137 firms, and 105 firms faced regulatory action for violating GMP norms.

Background

Schedule M, a drug policy in India, was influenced by the recommendations of the 1975 Hathi Committee. The committee recommended mandatory GMP for all drug manufacturers and added a separate schedule to the Drugs and Cosmetics Act. The schedule was later revised to align with WHO guidelines.

Features of Schedule M

- This document covers various aspects of manufacturing, including premises, equipment, personnel, raw materials, documentation, quality control, storage, distribution, and recall.
- The document outlines the minimum requirements for various drug categories including sterile, biological, oral solids, oral liquids, and topical preparations.
- The document offers guidelines for the validation, calibration, maintenance, cleaning, and sanitation of facilities and equipment.
- The text emphasizes the significance of training, hygiene, and personal protective equipment for manufacturing staff.
- The task involves creating and maintaining various records and reports, including batch records, standard operating procedures, quality control reports, stability studies, and distribution records.

Objectives

- To assist a manufacturer in more accurately identifying, looking into, and planning the proper course of action for the production of medications and cosmetics.
- To shield customers and the general public from potentially dangerous substances or methods.

- Should register their manufacturing plant as a good manufacturing practice facility and implement stringent, risk-based policies and procedures.

Types

Schedule M-1

- Schedule M-1, Good Manufacturing Practices and Requirements of premises, plant and equipment for homoeopathic medicines.
- The schedule outlines GMP requirements for manufacturing premises for homoeopathic medicines, including building construction, ventilation systems, waste disposal, quality control procedures, and documentation.
- The schedule outlines the necessary equipment and facilities for various manufacturing processes, including potentiation, container filling, lotion preparation, and ophthalmic product preparation.

Schedule M-2

- Schedule M-2, Requirements of Factory Premises for Manufacture of Cosmetics.
- The schedule outlines GMP requirements for cosmetic product manufacturing premises, including building construction, equipment maintenance, basic sanitation, and hygiene.
- The schedule outlines the necessary equipment and facilities for various manufacturing processes like creams, nail polish, lipstick, hair dyes, and powders production.

Schedule M-3

- Schedule M-3, Quality Management System-For notified medical devices and in-vitro diagnostics.
- The schedule outlines the GMP requirements for the manufacturing premises where notified medical devices and in-vitro diagnostics are produced.

- This includes building construction, equipment validation, design and development validation, record keeping, and traceability for medical devices and diagnostic products.

Significance of Schedule M

- It guarantees that the pharmaceuticals produced in India fulfill all national and international quality, safety, and efficacy criteria.
- It shields consumers from counterfeit, phony, contaminated, or mislabeled medications that could be harmful to their health or result in unfavorable side effects.
- It enables trade and exports for the Indian pharmaceutical industry and improves its credibility and reputation in the international market.
- It encourages the pharmaceutical industry to innovate and develop new medications and technology.

Schedule M

Schedule M of the Drugs and Cosmetics Act, 1940 outlines good manufacturing practices for pharmaceuticals in India, covering company premises, quality control systems, quality check laboratories, production, equipment cleaning, housekeeping, and cross-contamination, among other related topics.

- Part I Good Manufacturing Practices (GMP)
- Guidelines are meant to assure the quality of drugs.
- Draft of GMP was prepared in 1975 and finalized and implemented in 1988.
- Part I deals with good manufacturing practices relating to factory premises.
- Part II deals with plant and equipment for the manufacture of drugs.

Schedule M Part I

I. Factory Premises

1. General requirements

- The factory's location and surroundings must be free from contamination from

sewage drains, unpleasant odors, fumes, soot, dust, or smoke.

- The factory building should be constructed to ensure the production of drugs under hygienic conditions.
- The operations of manufacturing, processing, packing labeling, and testing should be conducted in a manner that prevents cross-contamination and mixing.
- Premises should be constructed to prevent insects and rodents, with smooth interior surfaces, adequate lighting, ventilation, humidity, underground drainage systems, concealed sanitary fittings, and drinkable water, and treated before disposal.
- A validated water treatment system should produce purified water to IP specification, ensuring microbial growth, storage in tanks, periodic tank cleaning, and maintaining records.
- Proper storage for materials awaiting disposal is necessary, and sewage and effluents must be disposed of according to Environmental Pollution Control Board regulations.

2. Warehousing area

- Proper storage and warehousing areas for materials, products, machines, and equipment must be designed, maintained, and equipped with appropriate house-keeping, rodent, pest, and vermin control procedures.
- The active raw materials and excipients necessitate the need for a separate sampling and warehousing area.
- Regular checks should be conducted to ensure proper measures are taken against spillage, breakage, and leakage of containers.

3. Production area

- The production process should be designed to allow for a uniform and logical sequence of operations.
- The orderly placement of equipment and materials, as well as the restriction of

personnel movement, is crucial to prevent cross-contamination.

- Dedicated self-containing facilities should be established for the production of sensitive pharmaceutical products like penicillin or biological preparations containing live microorganisms.
- The design of pipe works, electrical fittings, ventilations, openings, and similar service lines must prevent the creation of recesses.
- Service lines should be identified by color, supply nature, and flow direction.

4. Quality control area

- The analysis should be conducted independently of the production area and divided into sections for physio-chemical, biological, microbiological, and radioisotope analysis.
- Laboratory design should prevent cross-contamination and mix-ups, with separate instrument rooms for sensitive and sophisticated instruments.
- The storage space must be adequately prepared for test samples, retained samples, reference standards, reagents, and records.

5. Personnel

- The head of the quality control laboratory, independent of the manufacturing unit, will direct supervision of manufacturing and testing.
- Quality control personnel must be qualified and experienced, and they must receive appropriate training in their assigned duties and responsibilities.

6. Health, Clothing and Sanitation of workers

- Personnel handling products and raw materials must be free from contagious diseases and undergo regular health checks. A room for cleanliness facilities should be provided before entering the manufacturing area.

- Before employment, personnel must undergo a medical examination to ensure they are free from communicable/contagious diseases such as TB and skin.
- A medical examination may be required at least once a year.
- All individuals, both before and during employment, must undergo training in practices that ensure personnel hygiene.
- Individuals handling beta-lactam antibiotics, sex hormones, cytotoxic substances, and potent drugs must undergo penicillin sensitivity testing before employment and periodically undergo adverse effects examination.
- Direct contact between unprotected hands of personnel handling raw materials, intermediate, or finished unpacked products is strictly prohibited.
- It is mandatory for all individuals to wear clean body coverings.
- Smoking, eating, drinking, chewing, or keeping plants or food or personnel medicines in production, laboratory storage, and other areas are strictly prohibited.

7. Ancillary areas

- The recommendation is for separate rest and refreshment rooms to be located separately from the manufacturing area.
- The facility should be adequately equipped for changing, storing, washing, and toileting, catering to the needs of the numerous users.

8. Sanitation in manufacturing premises

- The manufacturing area should be kept clean and organized, free from waste and debris, and a routine sanitation program should be implemented.
- The production areas must be well-lit, especially for visual online controls.

Raw materials: All raw materials must be purchased from approved sources under valid purchase vouchers, possibly from producers directly.

- The containers were identified, examined for damage, and assigned a control number.
- Separate areas should be designated for materials under test, approved, and rejected.
- All incoming materials must be quarantined immediately upon receipt or processing.
- The first in/first expiry, first out principle should be applied to the storage of materials.
- The QC department will only use raw materials within their shelf life that have been released.

9. Sterile products

- It is recommended to have separate enclosed areas with airlocks, dust-free ventilation, and HEPA filters for better air quality.
- During the manufacturing operation, it is necessary to conduct routine microbial counts of the area.
- The design of the area should prevent the mixing of sterile and non-sterile products.
- The manufacturing area should only be accessible to authorized personnel.

10. Working space

- The text emphasizes the importance of providing sufficient working space, orderly equipment placement, and preventing cross-contamination between different drugs.
- The storage area should be designated for materials under test, approved, and rejected.

II. Medical Services

The manufacturer must provide facilities for:

- The statement provides a summary of the provided information.
- The policy mandates regular medical examinations of workers upon their employment and conducts periodic check-ups at least once a year.
- The text provides information on facilities for vaccination or other exigencies.

III. Equipment

Equipment used for manufacture must be constructed, designed, installed and maintained to:

- The goal is to achieve operational efficiency to achieve the desired quality.
- This statement aims to prevent any physical, chemical, or physiochemical change that may occur through surface contact.
- The main objective is to prevent the contact of any substances necessary for the operation of equipment, such as lubricants.
- The task involves ensuring a thorough cleaning process is carried out as needed.
- The objective is to minimize the contamination of drugs and their containers during manufacture.

IV. Master Formula Records

The licensee is responsible for maintaining master formula records for all manufacturing procedures for each product. The master formula record shall give:

- The product's patent or proprietary name, along with its generic name, strength, and dosage form.
- The description or identification of final containers and packaging materials.
- Labels and closures to be used.
- The document outlines the identification, quality, and quantity of each raw material to be utilized.
- The description includes the equipment and vessels used in the process, along with their respective sizes.
- The document provides manufacturing and control instructions, along with parameters for critical steps like mixing, drying, blending, sieving, and sterilizing the product.
- Theoretical yield to be expected from the formulation.
- The document provides detailed instructions and precautions for the manufacture, storage, and quality control of drugs and semi-finished products at each stage of production.

V. Batch Manufacturing Records

The licensee is required to maintain batch manufacturing records for each drug batch, providing a comprehensive account of its manufacturing, testing, and analysis as per master formulae.

Manufacturing operations and control: The manufacturing operations must be conducted under the direct supervision of competent technical staff, including those involved in the selection, weighing, and measurement of raw materials.

VI. Product Containers and Closures

Pharmacopoeial requirements are met through proper test methods, cleaning, and sterilization procedures to ensure drug package components are suitable and not reactive, additive, or leach-prone.

VII. Labels and other Printed Materials

Printed labels and packaging materials, including leaflets, must be properly handled and accounted for to prevent intermixing and thoroughly examined before being issued for quality control personnel's use.

VIII. Distribution of Records

The importance of maintaining drug distribution records cannot be overstated, as they enable prompt and accurate recalls if needed.

IX. Quality Control System

The main responsibilities of the quality control department include:

- The individual has prepared detailed instructions for conducting each test and analysis.
- The process involves releasing or rejecting each batch of raw material, semi-finished products, packaging materials, labeling materials, and finished products ready for distribution.
- The objective is to assess the suitability of the storage conditions for raw materials,

semifinished products, and finished products.

- The objective is to assess the quality and stability of the final products.
- The purpose is to establish and, when necessary, revise control procedures and specifications.
- The objective is to evaluate the fate of returned products, determining whether they will be released, reprocessed, or destroyed.

Part-IA: Requirements for the manufacture of sterile products, parenteral preparations, and sterile ophthalmic preparations.

Part-IB: Requirements for the manufacture of oral solid dosage forms (tablets and capsules).

Part-IC: Requirements for the manufacture of oral liquids (syrups, emulsions, suspensions, elixirs, etc.).

Part-ID: Requirements for the manufacture of topical products, i.e. external preparations.

Part-IE: Requirements for the manufacture of metered dose inhalers (MDI).

Part-IF: Specific requirements of premises, plant, and materials for the manufacture of active pharmaceutical ingredients (bulk drugs).

Schedule-M, PART II

Requirements of Plant and Equipment

The Part II of Schedule M details the plant and equipment needed for manufacturing, quality control, and assurance of various dosage forms, categorizing requirements into 11 groups for clarity.

1. External preparations

This category encompasses various preparations such as ointments, emulsions, lotions, solutions, pastes, creams, dusting powders, and similar products.

- a. *Minimum area:* The basic installation area is 30 square meters, while the ancillary area is 10 square meters.
- b. *Requirements:* This includes various equipment such as mixing tanks, kettles,

electric mixers, planetary mixers, colloid mills, triple roller mills, liquid and tube filling machines, and more.

2. Oral liquid preparations

It covers syrups, elixirs, emulsions, and suspensions.

- a. *Minimum area:* The basic installation area is 30 square meters, while the ancillary area is 10 square meters.
- b. *Requirements:* The equipment includes SS mixing and storage tanks, jacketed kettles, an electric stirrer, an electric colloidal mill, an emulsifier, filtration equipment, bottle filling machines, cap sealing machines, de-ionizer units, and clarity testing units.

3. Tablets

The tablet production department is divided into four sections for efficient production.

- i. Mixing, granulation and drying section
- ii. Tablet compression section
- iii. Packaging section (strip/blister)
- iv. Coating section

a. *Minimum area:* The installation area for uncoated tablets is 60 square meters, while for coated tablets, it is 30 square meters for the coating section and 10 square meters for the ancillary area.

- b. *Requirements:* This summary describes various equipment used in various industries, including disintegrators, sifters, powder mixers, planetary mixers, granulators, hot air ovens, weighing machines, compression machines, storage cabinets, table de-dusters, dissolution test apparatuses, packaging machines, leak tests, tablet counters, jacketed kettles, coating and polishing pans, weighing balances, exhaust systems, vacuum dust collectors, and air-conditioning systems.

4. Powders

Area: The minimum area required is 30 square meters, with additional space for actual blending.

Requirements: The equipment includes a disintegrator, electric mixer, sifter, suitable-sized SS vessels (single screws vessel) and scoops, filling equipment, and weighing balance.

5. Capsules

Area: The installation requires a separate, air-conditioned, and dehumidified area of 25 square meters for basic setup and 10 square meters for penicillin and non-penicillin sections.

Requirements (for hard gelatin capsules): The equipment includes electrical mixing and blending units, capsule filling units, capsule counters, weighing balances, disintegration test apparatus, and capsule polishing equipment.

6. Surgical dressings

Area: The basic installation requires a minimum of 30 square meters, and additional room is required for medicated dressing.

Requirements: The equipment includes rolling, staining, cutting, folding, pressing machines, mixing tanks, hot air ovens, steam sterilizers, and work tables.

7. Ophthalmic preparations

The package includes eye-ointment, eye lotions, and other external preparations, and requires separate enclosed areas with air-lock arrangements.

Area: The basic installation requires a minimum of 25 square meters, while the ancillary area should be 10 square meters.

Requirements: The equipment includes hot air ovens, kettles, colloid mills, ointment mills, storage tanks, tube washing, drying, cleaning, filling machines, automatic vial washing machines, sintered glass funnels, autoclaves, liquid filling equipment, laminar flow units, air conditioning, and dehumidification.

8. Pessaries and suppositories

Area: The basic installation requires a minimum of 25 square meters.

Requirements: The requirements for mixing, pouring, molding, and weighing devices for

pessaries made by granulation and compression are as per the "tablet" section.

9. Inhalers

Area: The basic installation requires a minimum of 25 square meters.

Requirements: The equipment used for mixing, graduated delivery, and sealing is essential for efficient and accurate production.

10. Repacking of drugs and pharmaceuticals

Area: The basic installation requires a minimum of 30 square meters, and an exhaust system will be provided for operations involving floating particles.

Requirements: The equipment used for weighing, measuring, and filling includes powder disintegrators, electrically operated powder sifters, electric sealing machines, SS scoops, and vessels.

11. Parenteral preparations

The manufacturing process for glass and plastic preparations, including small volume injectables and large volume parenteral, is divided into separate areas or rooms.

Parenteral preparations in glass containers:

The process involves water management, container preparation, closures, solution preparation, filling, capping, sealing, sterilization, quarantine, visual inspection, and packaging.

Area: The basic installation requires a minimum of 150 square meters, while the ancillary area for small volume injectables requires 100 square meters.

Requirements: The facility includes a distillation unit, de-ionized water unit, thermostatically controlled water storage tank, transfer pumps, service lines, automatic rotary washing machine, dryer, double-ended sterilizer, storage equipment, benches, stools, mixing tanks, filtration equipment, gas lines, steam sterilizer, hot air sterilizer, storage cabinets, visual inspection units, batch coding, machine labeling unit, and pressure leak test apparatus.

The basic installation and ancillary area for large volume parenteral requires 150 square meters each for both basic and ancillary areas.

Parenteral preparations in plastic containers by Form—Fill- Seal/Blow, Fill- Seal technology. The operational activities are divided into areas for water management, solution preparation, container-molding-cum-filling, sealing, sterilization, quarantine, visual inspection, and packaging.

Area: The installation area should be 250 square meters, with 150 square meters for ancillary space, separate formulation areas for external and internal use, and 100 square meters for large volume parenteral.

Requirements: The facility includes a de-ionized water treatment unit, distillation unit,

thermostatically controlled water storage tank, transfer pumps, service lines, storage tanks, solution preparation tanks, cartridge and membrane filters, sterile form-fill-seal machine, plastic granule feeding device, super-heated steam sterilizer, and various storage racks.

Schedule M-1: Good manufacturing practices and requirements of premises, plant and equipment for homoeopathic medicines.

Schedule M-2: Deals with the requirements of premises, plant (factory), and equipment for manufacture of cosmetics.

Schedule M-3: Deals with the requirements of premises, plant, and equipment for manufacture of medical devices.

Important Questions for the Exam

A. Give Very Short Answers to the Following. (2 marks each)

1. Define loan licence.
2. Define RMP and its role.
3. What is proprietary medicine?
4. Write about cannabis.
5. Explain DEC?
6. What is trademark?
7. Define an advertisement.
8. Full form of MEPE.
9. Write about medicinal hemp and poppy straw.
10. List of permitted colors?
11. Central drug laboratory?
12. Schedule G?
13. Hathi Committee?
14. National List of Essential Medicines?
15. Drug Consultative Committee?
16. Loan Licence?
17. Schedule Y?
18. Who could be registered in the first register?
19. Differentiate between adulterated and spurious drugs.
20. Import of drugs for self-usage?
21. Define chemist.
22. Define bulk drugs.
23. Schedule F.
24. Qualifications required to become a Government Drug Analyst?
25. Code of ethics.
26. Loan licence.
27. Drug abuse.
28. Full form of NLEM and DPCO?
29. Define IPR?
30. Define psychotropic substance.
31. Schedule H.
32. Import of new drugs.
33. Registered pharmacist.
34. Differentiate between manufacture in bond and outside bond.

35. MAPE
36. Implementation of education regulations by the PCI.
37. Full form CPCSEA.
38. Define coca leaf.
39. Define the terms ethics and law.
40. Differentiate between a drug store and a pharmacy.
41. Define the toilet preparations under the Act.
42. Define ceiling price and bulk drugs under the DPCO Act.
43. Who is the legal person and what is the legal place for termination of pregnancy under the MTP Act, 2017?
44. Differentiate between bonded and nonbonded manufactorys.
45. Explain the offenses and respective penalties under the Pharmacy Act, 1948.
46. Define cocoa derivatives and opium derivatives.
47. Give the ex-office members of PCI.

B. Give Long Answers to the Following.**(5 marks each)**

48. What does Schedule J prescribe?
49. Define Ayurveda, Siddha and Unani drugs under the Drugs and Cosmetics Act, 1940?
50. Give in brief minimum requirements prescribed for pharmacy in Schedule N to the drug rules.
51. What is the procedure for obtaining spirit from a distillery or a warehouse?
52. Define qualified person under the D and C Act.
53. Give any three conditions of the licence granted to a person for import of drugs for examination, test, or analysis.
54. What procedure is to be followed by a government analyst on receipt of samples of drugs for test?
55. Give a formula which is used to calculate the retail price of the formulation, and the TDPCO, 1979.
56. What are the labelling particulars required to appear on label of preparations which are 'ophthalmic use only'.
57. Recommendations of DEC.
58. Define denatured spirit and denatured alcohol.
59. Define 'Networth' and 'bulk drugs' under the DPCO.
60. Mention any five classes of cosmetics of which import is prohibited under the D and C Act.
61. State the subclasses into which drugs and cosmetics to be imported can be subdivided.
62. Write in brief on the manner of labelling of the Drugs and Cosmetics Act.
63. Write in brief about the conditions required to be satisfied before obtaining a manufacturing licence for the Drugs and Cosmetics Act.
64. Write short notes on loan licence and repacking licence.
65. What is Form no 21.
66. Define opium and dutiable goods.

Important Questions for the Exam (Pharmaceutical Jurisprudence)

Questions for 5 marks

1. What are the classes of drugs prohibited to import into India?
2. Discuss in detail about loan licenses.
3. Define spurious drugs as under the Drugs and Cosmetics Act.
4. Mention the rules for drugs and cosmetics.
5. Describe the aims and objectives of the Drugs and Cosmetics Act.
6. Define drugs and cosmetics as per the Drugs and Cosmetics Act.

Questions for 10 marks

1. Explain the conditions to grant a license for the manufacture of drugs specified in schedules C, C1, and X.
2. Explain the conditions to grant a license for the manufacture of drugs specified other than schedule H and X.
3. Discuss the penalties for manufacturing and sale of drugs in contravention of the Drugs and Cosmetics Act 1940.
4. Explain in detail about the prohibition of manufacture and sale of certain drugs under the Drugs and Cosmetics Act 1940.
5. Write the conditions to grant license for the manufacture of:
 - a. Drugs for examination, test, and analysis.
 - b. Loan licenses.

Questions for 5 marks

1. Write a note on Central Drug Laboratory (CDL).
2. Define and write the qualifications and duties of a government analyst.
3. Describe about the restricted license.
4. What are the qualifications and duties of a Drug Inspector?
5. Write a note on schedules M, N, G, X
6. Write a note on the schedule which deals with narcotic drugs.
7. Write a short note on Schedule F.

Questions for 10 marks

1. Write the constitution and functions of the Drug Technical Advisory Board (DTAB).
2. What are the criteria for running a retail and wholesale shop?
3. Write a note on the labeling and packaging of the drug.
4. Write a note on the Drug Inspector and the duties of the Drug Inspector.
5. Discuss briefly about clinical trials as per Schedule Y.

Questions for 5 marks

1. Mention the offenses and penalties in contravention of the Pharmacy Act.
2. Discuss in detail about manufacture in the bonded laboratory.
3. What are the requirements of the bonded laboratory?
4. Explain in brief about alcoholic preparations.
5. Define cannabis, coca derivatives, narcotic drugs, and opium derivatives.
6. Describe the manufacture, sale, and export of opium under the NDPS Act.

Questions for 10 marks

1. Write the constitution and functions of PCI.
2. Define Education Regulation. Mention the standards, and regulations prescribed for Education Regulation.
3. Give the design of the bonded laboratory. Discuss in detail the manufacturing of alcoholic preparations in the bonded laboratory.
4. Write the objectives of the NDPS Act, 1985. Discuss briefly about offences and penalties of the NDPS Act, 1985.

Questions for 5 marks

1. Define magic remedies. Write the classes of advertisements prohibited under the D&MR Act.
2. Define magic remedies. Give the classes of advertisements.
3. Give the constitution and functions of the Institutional Animal Ethical Committee.
4. Write the objectives and prevention of cruelty to animals. What are the parts of CPCSEA guidelines?
5. Explain Drugs Price Control Order (DPCO). CO4 Remember 6 Write a short note on the National List of Essential Medicines (NLEM).

Questions for 10 marks

1. Define magic remedies. Give the classes of advertisements and explain them.
2. Write the offenses and penalties in contravention of the D&MR Act, define advertisement, and mention the objectives of the DMR Act.
3. Describe the facilities to be maintained for experimentation on animals under CPCSEA guidelines.

Questions for 5 marks

1. Give the significance of the Drugs Enquiry Committee (DEC), and What is the Hathi Committee?
2. Define Pharmaceutical Legislation CO5 Apply
3. Discuss the code of ethics for pharmacists concerning their trade.
4. Write a note on the health survey of Pharmaceutical Legislation.
5. Mention the objectives of the MTP Act.
6. Define the Right to Information.

Questions for 10 marks

1. What is Chopra's Committee? and mention the objectives of Pharmaceutical Legislation.
2. Mention the responsibilities of the Right to Information Act. Define copyright.
3. Mention the circumstances under which pregnancy can be terminated. Mention the offenses and penalties of MTP.

Model Paper 1

Pharmaceutical Jurisprudence

(Forensic Pharmacy)

Time: 3 Hours

Total Marks: 75

Note: 1. Attempt all Sections.

SECTION A

- 1. Attempt all questions in brief.** $10 \times 2 = 20$
- a. What do you mean by misbranded drug?
 - b. What are the objectives of the Patent Act?
 - c. What is the Hathi Committee?
 - d. Define Pharmaceutical Jurisprudence.
 - e. Give examples of any four Narcotic drugs.
 - f. Write in brief about the code of pharmaceutical ethics.
 - g. Write the full form of CPCSEA and IAEC.
 - h. Define the term poison.
 - i. What are schedules G and N?
 - j. What are the objectives of the Trademark Act?

SECTION B

- 2. Attempt any two parts of the following:** $2 \times 10 = 20$
- a. Write in detail about Schedule M (GMP) under the D and C Act, 1940.
 - b. Describe the classes of drugs that can be import, export, and transshipment under narcotic drugs and psychotropic substances.
 - c. Write in detail the constitution and functions of PCI.

SECTION C

- 3. Attempt any five parts of the following:** $7 \times 5 = 35$
- a. Write in brief the constitution and function of DTAB.
 - b. Write in brief the qualifications, powers, and duties of a Drug Inspector.
 - c. Give the specimen label for Schedule H and Schedule X drugs with a suitable example.
 - d. Write a note on the Drug and Cosmetic Act, 1940 and explain the requirement for obtaining a retail license.
 - e. Write a note on the registration of pharmacists.
 - f. Write short notes on:
 - i. Pharmacist's role as a member of the healthcare team.
 - ii. Spurious drugs.
 - g. Define the term advertisement. Mention the objective of the Drug and Magic Remedies Act.

Model Paper 2

Pharmaceutical Jurisprudence

Time: 3 Hours

Total Marks: 75

Note: 1. Attempt all Sections.

SECTION A

- 1. Attempt all questions in brief.** $10 \times 2 = 20$
- a. Define adulterated drugs.
 - b. What are schedules J and M?
 - c. What do you mean by the forensic pharmacy?
 - d. Define the term "retail sale".
 - e. Define the term "restricted license"
 - f. Write the objectives of the Medicinal and Toilet Preparation Act.
 - g. Define magic remedy.
 - h. What are CPCSEA guidelines?
 - i. Give a short note on the patent.
 - j. Write the pharmacist's oath.

SECTION B

- 2. Attempt any two parts of the following:** $2 \times 10 = 20$
- a. Discuss in detail about Right to Information Act (RTI).
 - b. What is the national list of essential medicines (NLEM)? Write objectives of drug price control order (DPCO).
 - c. Write the constitution and functions of the narcotic and psychotropic consultative committee.

SECTION C

- 3. Attempt any five parts of the following:** $7 \times 5 = 35$
- a. Explain the qualifications, powers, and duties of drug inspectors.
 - b. Write offense and penalties under the sale of drugs.
 - c. Discuss the classes of drugs and cosmetics prohibited from import.
 - d. What do you understand by loan license and repacking license?
 - e. Write terms and conditions for the cultivation and collection of the opium poppy.
 - f. What do you mean by intellectual property rights (IPR)?
 - g. Define advertisement; What do you mean by exempted advertisement?

Model Paper 3

Pharmaceutical Jurisprudence

ATTEMPT ANY FIVE QUESTIONS

All Questions Carry Equal Marks (15 marks).

Maximum marks: 75

1. Enumerate Schedule B. Describe in detail Schedule M (GMP) under the D and C Act.
2. Mention the places from which drugs are imported in India. Detail the classes of drugs and cosmetics which are prohibited from import and import under licence.
3. Write in detail about the constitution and functions of the Institutional Animal Ethics Committee (IAEC).
4. Differentiate between State and Joint State Pharmacy Council. Write the salient features, constitution, and functions of PCI.
5. Discuss in detail about the RTI Act. The process to file RTI?
6. Write short notes on:
 - a. Hathi Committee
 - b. National List of Essential Medicines (NLEM)
 - c. Adulterated Drugs
7. a. Define the term advertisement. Describe the classes of advertisement exempted provisionally under the DMR Act.
b. Write briefly the power, qualifications, and duties of the Drug Inspector.
8. What is the objective of The Medical Termination of Pregnancy Act, 1971 (the MTP Act). Explain in detail about the manufacturing of ayurvedic preparations.

Model Paper 4

Pharmaceutical Jurisprudence

ATTEMPT ANY FIVE QUESTIONS

All Questions Carry Equal Marks

1. a. What do you understand by first register and subsequent register under the Pharmacy Act?
b. Give an account of the constitution and functions of the PCI constituted under the Pharmacy Act, 1948.
2. a. What classes of drugs and cosmetics cannot be manufactured and imported in India?
b. What are education regulations and how are they implemented by the PCI?
3. a. Define patents. Write the provisions for getting the patent rights quoted in the Patent Act.
b. List out the patentable and non-patentable inventions.
4. b. Write general labeling requirements of drugs. Give specific labeling requirements of Schedule H and Schedule X.
b. Write the constitution and functions of the Drug Technical Advisory Board (DTAB).
5. a. Discuss in brief about the DMR Act and Rules.
b. Give the qualifications and duties of a Drug Inspector.
6. a. Explain in brief about cultivation, production, and sale of opium under the Narcotic and Psychotropic Act.
b. Discuss the various prohibited operations as per the Narcotic and Psychotropic Act.
7. a. What is manufacturing in bond? Describe the layout and requirements of the bonded laboratory.
b. Write a short note on the Poison Act.
8. a. What is the role of the Excise Commission in alcoholic preparations premises under the Medical and Toilet Preparation Act?
b. Discuss the provisions of the Factory Act to "Health and Safety".
9. a. Describe the conditions and procedure for the removal of the name of a pharmacist from the register.
b. Write a note on the calculation of the retail price of formulation under the DPCO Act.

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