THE DRUGS AND COSMETICS ACT, 1940

CONTENTS

CHAPTER IV

Manufacture, Sale and Distribution of

Drugs and Cosmetics

CHAPTER IV-A

Provisions relating to Ayurvedic, Siddha and Unani Drugs

THE DRUGS AND COSMETICS ACT, 1940

(Act No. 23 of 1940) [1]

[10th April, 1940]

An Act to regulate the import, manufacture, distribution and

Sale of drugs 2[and cosmetics]

1. The Act came into force in Pondicherry on Ist October 1963, vide Regulation 7 of 1963, Sec. 3 and Sch. 1. For Statement of Objects and Reasons, see Gazette of India, 1940, Pt. V, p. 34

2. Ins. by Act 21 of 1962, Sec. 2 (w.e.f. 27th July, 1964).

CHAPTER I

Introductory

1. Short title, extent and commencement. –

(1) This Act may be called the Drugs **1**[and Cosmetics] Act, 1940.

(2) It extends to the whole of India **2[** *].**

(3) It shall come into force at once; but Chapter III shall take effect only from such date**3** as the Central Government may, by notification in the Official Gazette, appoint in 4 this behalf and Chapter IV shall take effect in a particular State only from such date as the State Government may, by like notification, appoint in this behalf:

4[Provided that in relation to the State of Jammu and Kashmir, Chapter III shall take effect only from such date**5** after the commencement of the Drugs and Cosmetics (Amendment) Act, 1972 as the Central Government may, by notification in the Official Gazette, appoint in this behalf].

1. Subs. by the A.0. 1950,for certain words.

2. The words "except the State of Jammu and Kashmir" omitted by the Drugs and Cosmetics (Amendment) Act, 1972 (19 of 1972), Sec. 2.

3. The Act came into force on lst April 1947; see Notification F 28 (10) (3) 45-H (1), dated the 2nd September 1946, Gazette of India, 1946, Pt. 1, p. 1349. Chapter IV came into force in the States of Delhi, Ajmer and Coorg on the lst April 1947, see ibid. Chapters III and IV came into force in the States of Himachal Pradesh, Bilaspur, Kutch. Bhopal, Tripura, Vindhya Pradesh, and Manipur on the lst April 1953, vide Notification No. S.R.O. 663, dated the 30th March 1953, vide Gazette of India, Pt. II, Sec. 3, p. 451. Chapter IV enforced in Dadra and Nagar Haveli, w.e.f. lst August, 1968 (vide Notifn. No. A.D.M./Law 117 (74), dated 20th July 1968 and the Act extended there by Reg.6 of 1963, Sec. 2 and Sch. I.

The Act enforced in Goa, Daman and Diu by Reg. 11 of 1963, Sec. 3 and Schedule and in Laccadive, Minicoy and Amindivi Islands by Reg. 8 of 1965, Sec. 3 and Schedule and also applied in partially excluded areas of Orissa vide Orissa Govt. Notn. No. 3358-L.S.G., dated25th August 1941.

4. Added by the Drugs and Cosmetics (Amendment) Act, 1972 (19 of 1972), Sec. 2.

5. 24th August 1974, vide Notn. No. S.O. 2185 dated 9th August 1974.

2. Application of other laws not barred. -The provisions of this Act shall be in addition to and not in derogation of the Dangerous Drugs Act, 1930 (2 of 1930), **1** and any other law for the time being in force.

1. The said Act repealed by Narcotic Drugs and Psychotropic Substances Act, 1985, vide Sec. 82.

3. Definition. -In this Act, unless there is anything repugnant in the subject or context-

1[(a) **2**[Ayurvedic, Siddha or Unani] drug "includes all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of **3**[disease or disorder in human beings or animals and manufactured] exclusively in accordance with the formulae described in the authoritative books of **4**[Ayurvedic, Siddha and Unani] Tibb Systems of medicine] specified in the First Schedule;]]

5[(aa) “The Board” means-

(i) In relation to **6**[Ayurvedic, Siddha or Unani] drug, the **7**[Ayurvedic, Siddha and Unani Drugs Technical Advisory Board] constituted under Sec. 33-C; and

(ii) In relation to any other drugs or cosmetic, the Drugs Technical Advisory Board constituted under Sec; 5]

8[**9**[(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, **10**[* *];

11(b) “drug” includes-

12[(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 the human body or intended to be used for the destruction of **13**[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;]

14[(iii) All substances intended for use as components of a drug including empty gelatin capsules; and

(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];

15(C) “Government Analyst” means-

(i) In relation to **16**[Ayurvedic, Siddha, or Unani] drug, a Government Analyst appointed by the Central Government or a State Government under Sec. 33-F; and

(ii) In relation to any other drug or cosmetic, a Government Analyst Appointed by the Central Government or a State Government under Sec.20;]

17[* * * *]

18[(e) "Inspector" means-

(i) In relation to **12**[Ayurvedic, Siddha, or Unani] drug, an Inspector appointed by the Central Government or a State Government under Sec. 33-G; and

(ii) In relation to any other drug or cosmetic, an Inspector appointed by the Central Government or a State Government under Sec. 21;]

19[(f)] "Manufacture" in relation to any drug **20**[or cosmetic] includes any process or part of a process for making, altering,1 ornamenting, finishing, packing, labelling, breaking up or otherwise treating or adopting any drug **20**[or cosmetic] with a view to its **21**[sale or distribution) but does not include the compounding or dispensing **22**[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;]

23[(g) "To import" with its grammatical variations and cognate expressions means "to bring into **24** [India]";

25(h) "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 Ayurvedic, 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 as specified in Cl. (a);

(ii) In relation to any other systems of medicines, a drug which is a remedy or 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 the Indian Pharmacopoeia for the time being or any other Pharmacopoeia authorised in this behalf by the Central Government after consultation with the Drugs Technical Advisory Board constituted under Sec. 5;]

26[(i) "Prescribed" means prescribed by rules made under this Act.)

27[* * * *]

1. Ins. by Act 13 of 1964, Sec. 2 (w.e.f. 15th September, 1964).

2. Subs. by Act 68 of 1982, Sec. 2 (w.e.f. lst February, 1983).

3. Subs. by ibid. Sec. 3 (w.e.f lst February, 1983).

4. Subs. by ibid.

5. Original Cl. (a) was re-lettered as Cl. (aa) and subs. by Act 13 of 1964, Sec. 2 (w.e.f. 15th September, 1964).

6. Subs. by Act 68 of 1982, Sec. 2 (w.e.f. lst February, 1983).

7. Subs. by Sec. 3, ibid.

8. Ins. as Cl. (aa) by Act 21 of 1962, Sec. 4 (w.e.f. 27th July, 1964).

9. Re-lettered by Act 13 of 1964, Sec. 2 (w.e.f. 15th September, 1964).

10. Omitted by Act 68 of 1982, Sec. 3 (w.e.f. lst February, 1963).

11. Subs. by Act 11 of 1955, Sec.2 for Cl. (b).

12. Subs. by Act 68 of 1982, Sec. 3 (w.e.f. Ist February, 1983).

13. Subs. by Act 13 of 1964, Sec. 2for 'vermins' (w.e.f. 15th September, 1964).

14. Ins. by Act 68 of 1982, Sec. 3 (w.e.f. Ist February, 1983).

15. Subs. by Act 13 of 1964, Sec. 2,for Cl. (c) (w.e.f. 15th September, 1964).

16. Subs. by Act 68 of 1982, Sec. 2 (w.e.f. lst February, 1983).

17. Clause (d) omitted by the Drugs and Cosmetics (Amendment) Act, 1972 (19 of 1972), Sec. 3.

18. Subs. by Act 13 of 1964, Sec. 2,for Cl. (e) (w.e.f. 15th September, 1964).

19. Re-lettered as Cl. (f) by Act 35 of 1960, Sec. 2 (w.e.f. 16th March, 1964).

20. Ins. by Act 21 of 1962, Sec. 4 (w.e.f. 27th fuly, 1964).

21. Subs. by Act 68 of 1982, Sec. 3 (w.e.f. lst February, 1983).

22. Subs. by Act 21 of 1962, Sec. 4,for 'or packing of any drug'.

23. Clauses (c), (d) and (e) re-lettered as Cls. (g), (h) and (i), respectively by Act 35 of 1960, Sec. 2 (w.e.f. 16th March, 1961).

24. Subs. by Act 3 of 1951, Sec. 3 and Schedule for 'the States'.

25. Subs. by Act 68 of 1982, Sec. 3 (w.e.f. lst February, 1983).

26. Subs. by Act 11 of 1955, Sec. 2for Cl. (e).

27. Ins. by A.0. 1950 and omitted by Act 3 of 1951, Sec. 3 and Schedule.

1[3-A. Construction of references to any law not inforce or any functionary not in existence in the State of Jammu and Kashmir: -Any reference in this Act to any law which is not in force, or any functionary not in

existence, in the State of Jammu and Kashmir, shall, in relation to that State, be construed as a reference to the corresponding law in force, or to the corresponding functionary in existence, in that State.]

1. Ins. by the Drugs and Cosmetics (Amendment) Act, 1972 (19 of 1972), Sec. 4.

4. Presumption as to poisonous substances. -Any substance specified as poisonous by rule made under Chapter 11 or Chapter IV **1**[or Chapter IV-A], shall be deemed to be a poisonous substance for the purposes of Chapter III or Chapter IV **1**[or Chapter IV-Al as the case may be.

1. Ins. by Act 13 of 1964, Sec. 3 (w.e.f. 15th September, 1964).

CHAPTER II

The Drugs Technical Advisory Board, the Central Drugs Laboratory and the Drugs Consultative Committee

5. The Drugs Technical Advisory Board. -

(l) The Central Government shall, as soon as may be, constitute a Board (to be called the Drugs Technical Advisory Board) to advise the Central Government and the State Government on technical matters arising out of the administration of this Act and to carry out the other functions assigned to it by this Act.

1[(2) The Board shall consist of the following members, namely:

(i) The Director-General of Health Services, ex officio, who shall be Chairman;

(ii) The Drugs Controller, India, ex officio;

(iii) The Director of the Central Drugs Laboratory, Calcutta, ex officio;

(iv) The Director of the Central Research Institute, Kasauli, ex officio;

(v) The Director of the Indian Veterinary Research Institute, Izatnagar, ex officio;

(vi) The President of the Medical Council of India, ex officio;

(vii) The President of the Pharmacy Council of India, ex officio;

(viii) The Director of the Central Drug Research Institute, Lucknow, ex officio;

(ix) Two persons to be nominated by the Central Government from among persons who are in charge of drugs control in the States;

(x) 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 or the staff of an Indian University or a college affiliated thereto;

(xi) 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;

(xii) One person to be nominated by the Central Government from the pharmaceutical industry;

(xiii) One pharmacologist to be elected by the governing body of the Indian Council of Medical Research;

(xiv) One person to be elected by the Central Council of the Indian Medical Association;

(xv) One person to be elected by the Council of the Indian Pharmaceutical Association;

(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:

2[Provided that the person nominated or elected, as the case may be, under Cl. (ix) or Cl. (x) or Cl. (xi) or Cl. (xvi) of sub-section (2) shall hold office for so long as he holds the appointment of the office by virtue of which he was nominated or elected to the Board].

(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 function 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.

1. Subs. by Act 13 of 1964, Sec. 4,for sub-section (2) (w.e.f. 15th September, 1964).

2. Subs. by Sec. 4, ibid. for the proviso (w.e.f. 15th September, 1964).

6. The Central Drugs Laboratory. –

(l) The Central Government shall, as soon as may be, 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 or any rule made under this Chapter:

Provided that, if the Central Government so prescribes, the functions of the Central Drugs Laboratory in respect of any drug or class of drugs **1**[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 class of drugs **1**[or such 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-

(a) The functions of the Central Drugs Laboratory;

2[* * * * *]

(d) The procedure for the submission to the said Laboratory **3**[under Chapter IV or Chapter IV-A] of samples of drugs **4**[or cosmetics) for analysis or test, the forms of the Laboratory's reports thereon and the fees payable in

respect of such reports;

(e) Such other matters as may be necessary or expedient to enable the said Laboratory to carry out its functions;

(f) The matters necessary to be prescribed for the purposes of the proviso to sub-section (1).

STATE AMENDMENT

U.P.-In sub-section (i) of Sec. 6 of the principal Act, the following proviso after the existing proviso shall be added, namely: -

"Provided further that the State Government may, with the prior approval of the Central Government, direct that the functions of the Central Drugs Laboratory and of the Director may be carried out in Uttar Pradesh by such Authority and such officer respectively as may be specified by the State Government by notification in the Official Gazette and any reference in this Act to the Central Drugs Laboratory or the Director shall then be construed as a reference to such Authority or officer, as the case may be.**5**

West Bengal. -In sub-section (i) of Sec. 6 of the principal Act, the following proviso after the existing proviso shall be added, namely:

"Provided further that the State Government may, with the prior approval of the Central Government, direct that the functions of the Central Drugs Laboratory and the Director may be carried out in West Bengal by such Authority and such Officer respectively as may be specified by the State Government by notification in the Official Gazette and any reference in this Act to the Central Drugs Laboratory or the Director shall then be construed to mean such Authority or officer, as the case may be.**6**

1. Ins. by Act 21 1912, Sec. 5 (w.e.f. 27th July, 1964).

2. Clauses (b) and (c), omitted by Act 11 of 1955, Sec. 4.

3. Subs. by Act 13 of 1964, Sec. 5 for "under Chapter IV"

4. Ins. by Act 21 of 1962, Sec. 5 (w.e.f. 27th July, 1964).

5. Vide U.P. Acts No. 47 of 1975, Sec. 5. (w.e.f. 15th September 1964).

6. Vide West Bengal Act No. XLII of 19 73, Sec. 5.

7. The Drugs Consultative Committee. -

(l) The Central Government may constitute an Advisory Committee to be called “the Drugs Consultative Committee” to advise the Central Government, the State Governments and the Drugs Technical Advisory Board on any matter tending to secure uniformity throughout **1**[India in the administration of this Act.

(2) The Drugs Consultative Committee shall consist of two representatives of the Central Government to be nominated by that Government and one representative of each State Government to be nominated by the State Government concerned.

(3) The Drugs Consultative Committee shall meet when required to do so by the Central Government and shall have power to regulate its own procedure.

1. Subs. by Act 3 of 1951, Sec. 3 and Schedule for 'the States”.

1[7-A. Sections 5 and 7 not to apply to 2[Ayurvedic, Siddha or Unani] drugs. -Nothing contained in Secs. 5 and 7 shall apply to **2**[Ayurvedic, Siddha or Unani] drugs.

1. Ins. by Act 13 of 1964, Sec. 6 (w.e.f. 15th September, 1964).

2. Subs. by Act 68 of 1982, Sec. 2 (w.e.f. Ist February 1983).

CHAPTER III

[1][Import of Drugs and Cosmetics]

1. Subs. by Sec. 4, ibid. (w.e.f. lst February, 1983).

8. Standards of quality –

1[(1) For the purposes of this chapter, the expression “standard quality” means-

(a) In relation to a drug, that the drug complies with the standard set out in [the Second Schedule]; and

(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 three month's notice of its intention so to do, may by a like notification add to or otherwise

amend [the Second Schedule] for the purposes of this Chapter and thereupon **2**[the Second Schedule] shall be deemed to be amended accordingly.

1. Subs. by Act 21 of 1962, Sec. 2, for sub-section (1) (w.e.f. 27th July, 1964).

2. Subs. by Act 13 of 1964, Sec. 7, for "the Schedule" (w.e.f. 15th September, 1964).

1[9. Misbranded drugs. -For the purposes of this chapter, a drug shall be deemed to be misbranded-

(a) If it is so colored, 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; or

(b) If it is not lapelled in the prescribed manner; or

(c) If its label or container or anything accompanying the drug bears any statement, design or devices which makes any false claim for the drug or which is false or misleading in any particular.]

1. Subs. by Act 68 of 1982, Sec. 5, for Sec. 9 (w.e.f. Ist February 1983).

1[9-A. Adulterated drugs. -For the purposes of this chapter, a drug shall be deemed to be adulterated, -

(a) If it consists, in whole or in part, of any filthy, putrid or decomposed substance; or

(b) If it has been prepared, packed or stored under insanitary conditions where by it may have been contaminated with filth or whereby it may have been rendered injurious to health; or

(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; or

(d) If it bears or contains, for purposes of colouring only, a colour other than one which is prescribed; or

(e) If it contains any harmful or toxic substance which may render it injurious to health; or

(f) If any substance has been mixed therewith so as to reduce its quality or strength.

1. Subs. by Act 68 of 1982, Sec. 6 for Secs. 9-A and 9-B (w.e.f. Ist February, 1983).

9-B. Spurious drugs. -For the purposes of this chapter, a drug shall be deemed to be spurious-

(a) If it is imported under a name which belongs to another drug; or

(b) If it is an imitation of, or is 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; or

(c) If the label or 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; or

(d) If it has been substituted wholly or in part by another drug or substance; or

(e) If it purports to be the product of a manufacturer of whom it is not truly a product.

9-C. Misbranded cosmetics. -For the purposes of this chapter, a cosmetic shall be deemed to be misbranded-

(a) If it contains a colour which is not prescribed; or

(b) If it is not labelled in the prescribed manner; or

(c) If the label or container or anything accompanying the cosmetic bears any statement which is false or misleading in any particular.

9-D. Spurious cosmetics. -For the purposes of this chapter, a cosmetic shall be deemed to be spurious, -

(a) If it is imported under a name which belongs to another cosmetic; or

(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 and

conspicuously marked so as to reveal its true character and its lack of identity with such other cosmetic; or

(c) If the label or container bears the name of an individual or a company purporting to be the manufacturer of the cosmetic which individual or company is fictitious or does not exist; or

(d) If it purports to be the product of a manufacturer of whom it is not truly a product.]

10. Prohibition of import of certain drugs or cosmetics. -From such date **1** as may be fixed by the Central Government by notification in the Official Gazette in this behalf, no person shall import-

(a) Any drug **2**[or cosmetic], which is not of standard quality;

3[(b) Any misbranded drug **4**[or misbranded or spurious cosmetics];

5[(bb) Any **2**[adulterated or spurious] drug;]

(c) Any drug **2**[or cosmetic] for the import of which a licence is prescribed, otherwise than under, and in accordance with, such licence;

6[(d) Any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof **4**[the true formula or list of active ingredients contained in it together with quantities thereof.]

(e) 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[(ee) Any cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended;]

(f) Any drug **8**[or cosmetic] the import of which is prohibited by rule made under this chapter:

Provided that 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:

Provided further that 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 import of any drug or class of drugs not being of standard quality.

9[* * * *]

1. Ist April, 1947, for Cls. (a), (b), (c), (e) and (f) and 1st April, 1949, for Cl. (d). See Notification 18-12-46-D-1, dated the 11th February, 1947, Gazette of India, 1947, Pt. 1, p. 189. as amended by Notification No. F-1-2148-D (1) dated the 29th September, 1948. Ist April, 1953, for the States of Himachal Pradesh. Bilaspur, Kutch, Bhopal, Tripura, Vindhya Pradesh and Manipur: vide Notification No. S.R.O. 666, dated the 30th March, 1953, Gazette of India, 1953. Pt. II, Sec. 3, p. 451.

2. Ins. by Act 21 of 1952, Sec. 8 (w.e.f. 27th July, 1964).

3. Subs. by Sec. 8, ibid, for Cl. (b).

4. Subs. by Act 68 of 1982, Sec. 7 (w.e.f. lst February, 1983).

5. Ins. by Act 13 of 1964, Sec. 9 (w.e.f. 15th September, 1964).

6. Subs. by Act 11 of 1955, Sec. 5 for Cl. (d).

7. Ins. by Act 21 of 1962, Sec. 8 (w.e.f. 27th July, 1964).

8. Ibid.

9. Omitted by Act 68 of 1982, Sec. 7 (w.e.f. Ist February 1983).

1[10-A. Power of Central Government to prohibit import of drugs and cosmetics 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 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].

1. Ins. by Sec. 7, ibid.

11. Application of law relating to sea customs and powers of Customs Officers. –

(1) The law for the time being in force relating to sea, customs and to goods, the import of, which is prohibited by Sec. 18 of the Sea Customs Act, 1878 (8 of 1878) **1**, shall, subject to the provisions of Sec. 13 of this Act, apply in respect of drugs **2**[and cosmetics] the import of which is prohibited under this chapter, and officers of Customs and officers empowered under that Act to perform the duties imposed thereby on a, **3**[Commissioner of Customs] and other officers of Customs, shall have the same powers in respect of such drug **2**[and cosmetics] as they have for the time being in respect of such goods as aforesaid.

4[(2) Without prejudice to the provisions of sub-section (1) the **3**[Commissioner of Customs] or any officer of the Government authorized by the Central Government in this behalf, may detain any imported package which he suspects to contain any drug **2**[or cosmetic] the import of which is prohibited under this chapter and shall forthwith, report such detention to the Drugs Controller, India, and, if necessary, forward the package or sample of any suspected drug **2**[or cosmetic] found therein to the Central Drugs Laboratory.]

1. Now see the Customs Act, 1962.

2. Ins. by Act 21 of 1962, Sec. 9 (w.e.f. 27th July, 1964).

3. Subs. by Act 22 of 1995, Sec. 83.

4. Subs. by Act II of 1955, Sec. 6, for sub-section (2).

12. Power of Central Government to make rules. -

(l) The Central Government may; **1**[after consultation with or on the recommendation of the Board] and after previous publication by notification in the Official Gazette, make rules for the purpose of giving effect to the provisions of this chapter:

2[Provided that consultation with the Board may be dispensed with if the Central Government is of opinion that circumstances have arisen which render it necessary to make rules without such consultation, but in such a case the Board shall be consulted within six months of the making of the rules and the Central Government shall take into consideration any suggestions which the Board may make in relation to the amendment of the said rules.]

(2) Without prejudice to the generality of the foregoing power, such rules may, -

(a) Specify the drugs or classes of drugs **3**[or cosmetics or classes of cosmetics] for the import of which a licence is required, **4**[and prescribe the form and conditions of such licences, the authority empowered to issue the same, the fees payable therefor and provide for the cancellation, or suspension of such licence in any case where any provision of this chapter or the rules made thereunder is contravened or any of the conditions subject to which the licence is issued is not complied with;]

(b) Prescribe the methods of test or analysis to be employed in determining whether a drug **3**[or cosmetic] is of standard quality;

(c) Prescribe, in respect of biological and organometallic compounds, the units or methods of standardization;

5[(CC) Prescribe under Cl. (d) of **6**[Sec. 9-A] the colour or colours which a drug may bear or contain for purposes of colouring;]

(d) Specify the diseases or ailments, which an imported drug may not purport or claim **7**[to prevent, cure or mitigate] and such other effects, which such drug may not purport or claim to have;

(e) Prescribe the conditions subject to which small quantities of drugs, the import of which is otherwise prohibited under this chapter, may be imported for the purpose of examination, test or analysis or for personal use;

(f) Prescribe the place at which drugs **3**[or cosmetics] may be imported, and prohibit their import at any other place;

(g) Require the date of manufacture and the date of expiry of potency to be clearly and truly stated on the label or container of any specified imported drug or class of such drugs, and prohibit the import of the said drugs or class of drugs after the expiry of a specified period from the date of manufacture;

(h) Regulate the submission by importers, and the securing, of samples of drugs 'for cosmetics] for examination, test or analysis by the Central Drugs Laboratory, and prescribe the fees, if any, payable for such examination, test or analysis;

(i) Prescribe the evidence to be supplied, whether by accompanying documents or otherwise, of the quality of drugs **3**[or cosmetics] sought to be imported, the procedure of officers of customs in dealing with such evidence, and the manner of storage at places of import of drugs **3**[or cosmetics] detained pending admission,

(j) Provide for the exemption, conditionally or otherwise, from all or any of the provisions of this chapter and the rules made thereunder of drugs **3**[or cosmetics] imported for the purpose only of transport through and export from **8**[India];

(k) Prescribe the conditions to be observed in the packing in bottles, packages or other containers, of imported drugs **9**[or cosmetics] **10**[including the use of packing material which comes into direct contact with the drugs];

(1) Regulate the mode of labelling drugs **9**[or cosmetics] imported for sale in packages, and prescribe the matters which shall or shall not be included in such labels;

(m) Prescribe the maximum proportion of any poisonous substance which may be added to or contained in any imported drug, prohibit the import of any drug in which that proportion is exceeded, and specify substances which shall be deemed to be poisonous for the purposes of this chapter and the rules made thereunder;

(n) Required that the accepted scientific mane of any specified drug shall be displayed in the prescribed manner on the label or wrapper or any imported, patent or proprietary medicine containing such drug;

(o) Provide for the exemption, conditionally or otherwise, from all or any of the provisions of this chapter or the rules made thereunder, of any specified drug or class of drugs **9**[or cosmetic or class of cosmetics].

1. Subs. by Act 68 of 1982, Sec. 9 (w.e.f. Ist February, 1983).

2. Ins. by Act 11 of 1955, Sec. 7.

3. Ins. by Act 21 of 1962, Sec. 10 (w.e.f. 27th July, 1964).

4. Subs. by Act 68 of 1982, Sec. 9 (w.e.f. lst February, 1983).

5. Ins. by Act 13 of 1964, Sec. 10 (w.e.f. 15th September, 1964).

6. Subs. by Act 68 of 1982, Sec. 9, for "Sec. 9-B" (w.e.f. lst February, 1983).

7. Subs. by Act 11 of 1955, Sec. 7 for "to cure or mitigate'.

8. Subs. by Act 3 of 1951, Sec. 3 and Schedule for 'the States'.

9. Ins. by Act 21 of 1962, Sec. 10 (w.e.f. 27th July, 1964).

10. Ins. by Act 68 of 1982, Sec. 9 (w.e.f. 1st February, 1983).

1[13. Offences. -

(l) Whoever himself or by any other person on his behalf imports, -

(a) Any drug deemed to be adulterated under Sec. 9- A or deemed to be a spurious drug under Sec.9-B or any spurious cosmetic referred to in Sec. 9-D, or any cosmetic of the nature referred to in Cl. (ee) of Sec. 10 shall be punishable with imprisonment for a term which may extend to three years and a fine which may extend to five thousand rupees; -

(b) Any drug or cosmetic other than a drug or cosmetic referred to in Cl. (a), the import of which is prohibited under Sec. 10, or any rule made under this chapter, shall be punishable with imprisonment for a term which may extend to six months, or with fine which m ay extend to five hundred rupees, or with both;

(c) Any drug or cosmetic in contravention of the provisions of any notification issued under Sec. 10-A, shall be punishable with imprisonment for a term which may extend to three years, or with fine which may extend to five thousand rupees, or with both.

(2) Whoever having been convicted of an offence-

(a) Under Cl. (a) or Cl. (c) 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 five years, or with fine which may extend to ten thousand rupees, or with both;

(b) Under Cl. (b) 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 one year, or with fine which may extend to one thousand rupees, or with both.

(3) The punishment provided by this section, shall be in addition to any penalty to which the offender may be liable under the provisions of Sec. 11.]

1. Subs. by Sec. 10, ibid. for Sec. 13, (w.e.f. lst February, 1983).

14. Confiscation. -Where any offence punishable under Sec. 13 has been committed, the consignment of the drugs **1**[or cosmetics] in respect of which the offence has been committed shall be liable to confiscation.

1. Subs. by Act 21 of 1962 Sec. 11 (w.e.f. 27th July, 1964).

15. Jurisdiction. -No Court inferior to that **1**[of a Metropolitan Magistrate or of a judicial Magistrate of the first class] shall try an offence punishable under Sec. 13.

1. Subs. by Act 68 of 1982, Sec. 11 (w.e.f. Ist February 1983).

CHAPTER IV

Manufacture, Sale and Distribution of 1[Drugs and Cosmetics]

1. Subs. by Sec. 12, ibid. (w.e.f. lst February, 1983).

16. Standards of quality. -

1[(l) For the purposes of this chapter, the expression “standard quality” means-

(a) In relation to a drug, that the drug complies with the standard set out in **2**[the Second Schedule], and

(b) In relation to a cosmetic, which the cosmetic complies with such standard as maybe prescribed.]

(2) The **3**[Central Government], after consultation with the Board and after giving by notification in the Official Gazette not less than three months' notice of its intention so to do may by a like notification add to or otherwise amend **2**[the Second Schedule] for the purposes of this chapter, and thereupon **2**[the Second Schedule] shall be deemed to be amended accordingly.

1. Subs. by Act 21 of 1962, Sec. 12, for sub-section (1) (w.e.f. 27th July, 1964).

2. Subs. by Act 13 of 1964, Sec. 11, for "the Schedule" (w.e.f. 15th September, 1964).

3. Subs. by Act 11 of 1955, Sec. 8, for "State Government".

1[17. Misbranded drugs. -For the purposes of this chapter, a drug shall be deemed to be misbranded, -

(a) If it is so colored, 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; or

(b) If it is not lapelled in the prescribed manner; or

(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 particulars

1. Secs. 17, 17-A, 17-C for Subs. by Act 68 of 1982, Sec. 13 (w.e.f. lst February, 1983).

17-A. Adulterated drugs. -For the purposes of this chapter, a drug shall be deemed to be adulterated, -

(a) If it consists in whole or in part, of any filthy, putrid or decomposed substance; or

(b) If it has been prepared, packed or stored under insanitary conditions where by it may have been contaminated with filth or whereby it may have been rendered injurious to health; or

(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; or

(d) If it bears or contains, for purposes of colouring only, a colour other than one which is prescribed; or

(e) If it contains any harmful or toxic substance which may render it injurious to health; or

(f) If any substance has been mixed therewith so as to reduce its quality or strength.

17-B. Spurious drugs. -For the purposes of this chapter, a drug shall be deemed to be spurious, -

(a) If it is manufactured under a name which belongs to another drug; or

(b) If it is an imitation of, or is 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; or

(c) If the label or 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; or

(d) If it has been substituted wholly or in part by another drug or substance; or

(e) If it purports to be the product of a manufacturer of whom it is not truly a product.

17-C. Misbranded cosmetics. -For the purposes of this chapter, a cosmetic shall be deemed to be misbranded, -

(a) If it contains a colour which is not prescribed; or

(b) If it is not labelled in the prescribed manner; or

(c) If the label or container or anything accompanying the cosmetic bears any statement which is false or misleading in any particular.

17-D. Spurious cosmetics. -For the purposes of this chapter, a cosmetic shall be deemed to be spurious, -

(a) If it is manufactured under a name which belongs to another cosmetic; or

(b) If it is an imitation of, or a substitute for, another cosmetic or resembles another cosmetic in a manner likely to deceive or bears upon it or upon its label or contain or the name of another cosmetic unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other cosmetic; or

(c) if the label or container bears the name of an individual or a company purporting to be the manufacturer of the cosmetic which is individual or company is fictitious or does not exist; or

(d) If it purports to be the product of a manufacturer of whom it is not truly a product.]

18. Prohibition of manufacture and sale of certain drugs and cosmetics. - From such date **1**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-

(a) **2**[manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale], or distribute- -

3[(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;]

4(iii) Any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof the Subs. Sec. 9, ibid, for certain words [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, purports or claims **5**[to prevent cure or mitigate] any such disease or ailment, or to have any such other effect as may be prescribed;

6[(v) Any cosmetics 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;]

(b) **7**[sell or stock or exhibit or offer for sale] or distribute any drug **8**[or cosmetic] which has been imported or manufactured in contravention of any of the provisions of this Act or any rule made thereunder;

(c) **8**[manufacture for sale or for distribution, or sell or stock or exhibit or offer for sale,] or distribute any drug **9**[or cosmetic], except under, and in accordance with the conditions of, a licence issued for such purpose under this chapter:

Provided that nothing in this section shall apply to the manufacture, subject to prescribed conditions, of small quantities of any drug for the purpose of examination, test or analysis:

Provided further that the **9**[Central Government] may, after consultation with the Board, by notification in the Official Gazette, permit, subject to any conditions specified in the notification, the **10**[manufacture for sale or for distribution, sale, stocking or exhibiting or offering of sale] or distribution of any drug or class of drugs not being of standard quality.

11[* * * *]

1. Ist April, 1947, for sub-sections (i), (ii) and (iv) and (v) of Cl. (a) and and Cls. (b) and (c), Ist April, 1949,for sub-clause (iii) of Cl. (a) in so far as it takes effect in Delhi, Ajmer and Coorg, see Notification No. 18-12146-D (II), dated 11th February, 1947, Gazette of India, 1947. Pt. I, p. 189, as amended by Notification No. F.1-2148-D (II), dated 29th September, 1948; lst April, 1953,for the States of Himachal Pradesh, Bilaspur, Kutch, Bhopal, Tripura, Vindhya Pradesh and Manipur, vide Notification No. S.R.O. 664, dated the 30th March, 1953, Gazette of India, 1953, Pt. II, Sec. 3, p. 451.

2. Subs. by Act 68 of 1982, Sec. 14 (w.e.f lst February, 1983),

3. Subs. by Sec. 14, ibid, for Cls. (i), (ii) and (ii-a) (w.e.f. lst February, 1983).

4. Subs. By Act 11 of 1955, Sec. 9, for sub-clause (iii).

5. Subs. by Sec. 9, it, for "to cure or mitigate".

6. Subs. by Act 21 of 1962, Sec. 14, for sub-clause (v) (w.e.f. 27th July, 1964).

7. Subs. by Act 68 of 1982, Sec. 14 (w.e.f. lst February, 1983).

8. Ins. by Act 21 of 1962, Sec. 14 (w.e.f. 27th July, 1964).

9. Subs. by Act 11 of 1955, Sec. 9, for "State Government".

10. Subs. by Act 68 of 1982, Sec. 14, for "manufacture for sale, sale" (w.e.f. Ist February, 1983).

11. Explanation omitted by Sec. 14, ibid. (w.e.f. Ist February, 1983).

1[18-A. Disclosure of the name of the manufacturer etc.- 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 cosmetics.]

1. Ins. By Act 13 of 1964, Sec. 14 (w.e.f. 15th September, 1964).

1[18-B. Maintenance of records and furnishing of information. - Every person holding a licence under Cl. (c) of Sec. 18 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.]

1. Ins. by Act 68 of 1982, Sec. 15 (w.e.f. 1st February, 1983.

19. Pleas. –

(l) Save as hereinafter provided in this section, it shall be no defence in a prosecution under this chapter to prove mere by that the accused was ignorant of the nature, substance or quality of the drug **l** [or cosmetic] in respect of which the offence has been committed or of the circumstances of its manufacture or import, or that a purchaser, having bought only for the purpose of test or analysis, has not been prejudiced by the sale.

(2) **2**[For the purposes of Sec. 18, a drug shall not be deemed to be misbranded or **3**[adulterated or spurious] or to be below standard quality nor shall a cosmetic be deemed to be misbranded or to be below standard quality] only by reason of the fact that-

(a) There has been added thereto some innocuous substance or ingredient because the same is required for the manufacture or preparation of the drug **1**[or cosmetic] as an article of commerce in a state fit for carriage or consumption, and not to increase the bulk weight or measure of the drug **1**[or cosmetic] or to conceal its inferior quality or other defects; or

4[* * * * *]

(b) In the process of manufacture, preparation or conveyance some extraneous substance has unavoidably become intermixed with it: provided that this clause shall not apply it relation to any sale or distribution of the drug **1**[or cosmetic] occurring after the vendor or distributor became aware of such intermixture.

5[(3) A person not being the manufacturer of a drug or cosmetic or his agent for the distribution thereof, shall not be liable for a contravention of Sec. 18 if he proves-

(a) That he acquired the drug or cosmetic from a duly licensed manufacturer, distributor or dealer thereof;

(b) That he did not know and could not with reasonable diligence, have ascertained that the drug or cosmetic in any way contravened the provisions of that section; and

(c) That the drug or cosmetic, while in his possession, was properly stored and remained in the same state as when he acquired it.]

1. Ins. by Act 21 of 1962, Sec. 15 (w.e.f. 27th July, 1964).

2. Subs. by Act 13 of 1964, Sec. 15 for certain words and figures (w.e.f. 15th September, 1964).

3. Subs. by Act 68 of 1982, Sec. 16 for "adulterated" (w.e.f. Ist February, 1983).

4. Clause (aa) as inserted by Act 11 of 1955, Sec. 10 omitted by Act 13 of 1964, Sec. 15 (w.e.f. 15th September, 1964).

5. Subs. by Act 13 of 1964, Sec. 15, for sub-section (3) (w.e.f. 15th September, 1964).

STATE AMENDMENT

Uttar Pradesh. -After Sec. 19 of the principal Act, the following new section shall be inserted, namely: -

"19-A. Burden of proof. -When any drug or cosmetic is seized from any person under Cl. (c) of Sec. 22 by an Inspector in the reasonable belief that such drug or cosmetic is misbranded or adulterated, the burden of proving that such drug or cosmetic is not misbranded or adulterated shall be on the person from whose possession such drug or cosmetic was seized. **1**

West Bengal. -After Sec. 19 of the principal Act the following new section shall be inserted, namely: -

'19-A. Burden of proof. -When any drug or cosmetic is seized from any person in the reasonable belief that such drug or cosmetic is not misbranded or adulterated, the burden of proving that such drug or cosmetic is misbranded or adulterated shall be on the person from whose possession such drug or cosmetic was seized. **2**

1. Vide U.P. Act 47 of 1975, Sec. 5.

2. Vide West Bengal Act XLII of 1973, Sec. 5.

1[20. Government Analysts. –

(1) The State Government may, by notification in the official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Government Analysts for such areas in the State and in respect of such drugs or **2**[classes of drugs or such cosmetics or classes of cosmetics] as may be specified in the notification.

(2) The Central Government may also, by notification in the official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Government Analysts in respect of such drugs or **2**[classes of drugs or such cosmetics or classes of cosmetics] as may be specified in the notification.

(3) Notwithstanding anything contained in sub-section (1) or sub- section (2), neither the Central Government nor 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.

3[(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 sub-section (1) or sub-section (2) of this section.]

1. Subs. by Act 35 of 1960, Sec. 4, for Secs. 20 and 21 (w.e.f 16th March, 1961).

2. Subs. by Act 21 of 1962, Sec. 16, ' for 'class of drugs" (w.e.f. 27th July, 1964).

3. Ins. by Act 68 of 1982, Sec. 17 (w.e.f. lst February, 1983).

21. Inspectors. –

(l) The Central Government or a State Government may, by notification in the official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Inspectors for such areas as maybe assigned to them by the Central Government or the State Government, as the case may be.

(2) The powers which may be exercised by an Inspector and the duties which maybe performed by him, the drugs or **1**[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 **2**[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 Sec. 21 of the Indian Penal Code (45 of 1860), and shall be officially subordinate td such authority **3**[having the prescribed qualifications as the Government appointing him May specify in this behalf.]

1. Subs. by Act 21 of 1962, Sec. 16, ' for 'class of drugs" (w.e.f. 27th July, 1964).

2. Subs. by Act 21 of 1962, Sec. 17, for "in the manufacture of import or sale of drugs" (w.e.f. 27th July, 1964).

3. Ins. by Act 68 of 1982, Sec. 18 (w.e.f. Ist February, 1983).

1[22. Powers of Inspectors. –

(l) Subject to the provisions of Sec. 23 and of any rules made by the Central Government in this behalf, an Inspector may, within the local limits of the area for which he is appointed, -

2[(a) 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) Take samples of any drug or cosmetic, -

(i) Which is being manufactured or is being sold or is stocked or exhibited or offered for sale, or is being distributed

(ii) 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 such assistance, if any, as he considers necessary,-

(i) 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 chapter has been, or is being committed; or

(ii) Enter and search any place in which he has reason to believe that an offence under this chapter has been, or is being committed; or

(iii) Stop and search any vehicle, vessels 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 chapter 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 as 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;]

3[(cc) Examine any record, register, document or any other material object found **4**[with any person, or in any place, vehicle, vessel or other conveyance referred to in Cl. (c)], and seize the same if he has reason to believe that it may furnish evidence of the commission of an offence punishable under this Act or the rules made thereunder;],

5[(cca) 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 to which he has reason to believe that an offence under this chapter has been, or is being committed;]

(d) Exercise such other powers as may be necessary for carrying out the purposes of this chapter or any rules made thereunder.

(2) The provisions of **6**[the Code of Criminal Procedure, 1973 (2 of 1974)], shall so far as may be, apply to any search or seizure under this chapter as far may be, apply to any search or seizure under this chapter as they apply to any search or seizure made under the authority of a warrant issued under **7**[Secs. 94] of the said Code.

8[(2-.A) Every record, register or other document seized under Cl. (cc) or produced under Cl. (cca) shall be returned to the person, from whom they were seized or who produced 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 chapter **9**[or refuses to produce any record, register or other document when so required under Cl.(cca) of sub-section (1), he shall be punishable with imprisonment which may extend to three years or with fine, or with both

1. Subs. by Act 11 of 1955, Sec. 11 for Sec. 22. (h) and (c) (w.e.f. 1st February, 1983).

2. Subs. By Act 68 of 1982, Sec. 19 for Cls. (a), (b) and (C) (w.e.f. 1st February 1983).

3. Ins. by Act 35 of 1960, Sec, 5 (w.e.f. 16th March, 1961).

4. Subs. By Act 68 of 1982, Sec. 19 (w.e.f. 1st February, 1983).

5. Ins. by ibid.

6. Subs. by Act 68 of 1982, for "the Code of Criminal Procedure, 1898" (w.e.f. Ist February, 1983).

7. Subs. by ibid, for "Sec. 98" (w.e.f. Ist February, 1983).

8. Ins. by ibid, (w.e.f Ist February, 1983).

9. Ins. by ibid, Sec. 19 (w.e.f. Ist February, 1983).

23. Procedure of Inspectors. -

(l) Where an Inspector takes any sample of a drug **1**[or cosmetic] under this chapter, he shall tender the fair price thereof and may require a written acknowledgment therefor.

(2) Where the price tendered under sub-section (1) is refused, or where the Inspector seizes the stock of any drug **2**[or cosmetics under Cl. (c) of Sec. 22, he shall tender a receipt therefor in the prescribed form.

(3) Where an Inspector takes a sample of a drug **2**[or cosmetic] for the purpose of test or analysis, he shall intimate such purpose in waiting 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:

Provided that where the sample is taken from premises whereon the drug **3**[or cosmetic] is being manufacturer, it shall be necessary to divide the sample into three portions only:

Provided further that where the drug **3**[or cosmetics is made up in containers of small volume, instead of dividing a sample as aforesaid, the Inspector may, and if the drug **3**[or cosmetic] be such that it is likely to deteriorate or be otherwise damaged by exposure shall take three or four, as the case may be of the said containers after suitably marking the same and, where necessary, sealing them.

(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 proceeding, if any, are instituted in respect of the drug **3**[or cosmetics; and

4[(iii) The third, where taken, he shall send to the person, if any, whose name, address and other particulars have been disclosed under Sec. 18-A.]

(5) Where an Inspector takes any action under Cl. (c) of Sec. 22, -

(a) He shall use all dispatch in ascertaining whether or not the drug **5**[or cosmetic] contravenes any of the provisions of Sec. 18 and, if it is ascertained that the drug **5**[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;

(b) If he seizes the stock of the drug **5**[or cosmetic], he shall, as soon as may be, inform **6**[a Judicial Magistrate] and take his orders as to the custody thereof;

(c) 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 **5**[or cosmetic], he shall, on being satisfied that the defect has been so remedied, forthwith revoke his order under the said clause.

7[(6) Where an Inspector seizes any record, register, document or any other material object under Cl. (cc) of sub-section (1) Sec. 22, he shall as soon as may be, inform **6**[a Judicial Magistrate] and take his orders as to the custody thereof.]

1. Ins. by Act 21 of 1962, Sec. 15 (w.e.f. 27th July, 1964).

2. Subs. by ibid, for "Sec. 98" (w.e.f. Ist February, 1983).

3. Ins. by ibid, (w.e.f Ist February, 1983).

4. Subs. by Act 13 of 1964, Sec. 16, for Cl. (iii) (w.e.f. 15th September, 1964).

5. Ins. by Act 21 of 1962, Sec. 15 (w.e.f. 27 the July, 1964).

6. Subs. by Act 68 of 1982, Sec. 20 for "Magistrate" (w.e.f. lst February, 1983).

7. Ins. by Act 35 of 1960, Sec. 6 (w.e.f. 16th March, 1961).

24. 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 **1**[for 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 **1** [or cosmetic] is being manufactured or is kept as the case may be.

1. Ins. by Act 21 of 1962, Sec. 15 (w.e.f. 27 the July, 1964).

25. Reports of Government Analysts. -

(l) The Government Analyst to whom a sample of any drug **1**[or cosmetic] has been submitted for test or analysis under sub-section (4) of Sec. 23, 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 **2**[and another copy to the person, if any, whose name, address and other particulars have been disclosed under Sec-18-Al, 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 under this chapter shall be evidence of the facts stated therein, and such evidence shall be conclusive unless the person from whom the sample was taken **3**[or the person whose name, address and other particulars have been disclosed under Sec. 18-Al, has, twenty-eight 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 contravention of the report.

(4) Unless the sample has already been tested or analyzed in the Central Drugs Laboratory, where a person has under sub-section (3) notified his intention of adducing evidence in controversial 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, **4**[or cosmetics produced before the Magistrate under sub-section (4) of Sec. 23 to be sent for test 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 under sub-section (4) shall be paid by the complainant or accused as the Court shall direct.

1. Ins. by Act 21 of 1962, Sec. 15 (w.e.f. 27 the July, 1964).

2. Subs. by Act 13 of 1964, Sec. 17, for certain words, brackets and figures (w.e.f 15th September, 1964).

3. Subs. By Act 13 of Sec. 17, ibid., for "or the said warrantor" (w.e.f. 15th September, 1964).

4. Ins. by Act 21 of 19 2, Sec. 15 (w.e.f. 27th July, 1964).

26. Purchaser of drug or cosmetic enabled to obtain test or analysis. -Any person **1**[or any recognised consumer association, whether such person is a member of that association or not) shall, on application in the prescribed manner and on payment of the prescribed fee, be entitled to submit for test or analysis to a Government Analyst any drug **2**[or cosmetic] **3**[purchased by him or it] and to receive a report of such test or analysis signed by the Government Analyst.

4[Explanation. -For the purposes of this section and Sec. 32, "recognised consumer association" means a voluntary consumer association registered under the Companies Act, 1956 (1 of 1956), or any other law for the time being in force.]

1. Ins. by Act 71 of 1986, Sec. 2 (a) (w.e.f. 15th September, 1987).

2. Ins. by Act 21 of 1962, Sec. 15 (w.e.f. 27th July, 1964).

3. Subs. by Act 71 of 1986, Sec. 2 (b) (w.e.f. 15th September, 1987), for the words, "purchased by him'.

4. Ins. by ibid. Sec. 2 (c) (w.e.f. 15th September, 1987).

1[26-A. Powers of Central Government to prohibit manufacture, etc., 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.]

1. Ins. by Act 68 of 1982, Sec. 21 (w.e.f. Ist February 1983).

1[27. Penalty for manufacture, sale, etc. o drugs in contravention of this chapter. -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 under Sec. 17-A or spurious under Sec. 17-B 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 Sec. 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 five years but which may extend to a term of life and with fine which shall not be less than ten thousand rupees.

(b) Any drug, -

(i) Deemed to be adulterated under Sec. 17-Abut not being a drug referred to in Cl. (a), or

(ii) Without a valid licence as required under Cl. (c) of Sec. 18,

Shall be punishable with imprisonment for a term which shall not be less than one year but which may extend to three years and with fine, which shall not be less than five thousand 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 one year and of fine of less than five thousand rupees;

(c) Any drug deemed to be spurious under Sec. 17-B but not being a drug referred to in Cl. (a) shall be punishable with imprisonment for a term which shall not be less than three years but which may extend to five years and with fine which shall not be less than five thousand 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 three years but not less than one year;

(d) Any drug, other than a drug referred to in Cl. (a), or Cl. (b) or Cl. (c), in contravention of any other provision of this chapter or any rule ma thereunder, shall be punishable with imprisonment for a term which shall not be less than one year but which may extend to two years and with fine:

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 one year.]

STATE AMENDMENTS

Uttar Pradesh. -Section 27 of the principal Act, shall be substituted by the following section, namely: -

"27. Penalty for manufacture, sale, etc., of drugs in contravention of this Chapter. -"Whoever himself for by any other person on his behalf manufacturers for sale, sells, stocks or exhibits for sale or distributes-

(a) Any drug-

(i) Deemed to be misbranded under Cl. (a), Cl. (b), Cl. (c), Cl. (d), Cl. (f) or Cl. (g) of Sec. 17 or adulterated under Sec. 17-B, or

(ii) Without a valid licence as required under Cl. (c) of Sec. 18; or

(b) Any drug other than a drug referred to in Cl. (a) in contravention of any of the provisions of this Chapter or any rule made thereunder-

"Shall be punished with imprisonment for life:

Provided that the Court may, for any special reasons to be recorded in writing impose a sentence of imprisonment which is less than the imprisonment for life."**2**

West Bengal. -(a) In CZ. (a) of Sec. 27 of the Principal Act, -

(i) For the words 'for a term which shall not be less than one year but which may extend to ten years", the words 'for life" shall be substituted,

(ii) In the proviso, for the words "imprisonment of less than one year", the words "less than imprisonment for life" shall be substituted;

(b) In Cl. (b) of Sec. 27 of the principal Act, for the words "for a term which may extend to three years", the words 'for life" shall be substituted. **3**

1. Ins. by Act 68 of 1982, Sec. 22 (w.e.f. lst February, 1983).

2. Vide U.P. Act 47 of 1975, Sec. 5.

3. Vide West Bengal Act XLII of 1973, Sec. 5.

1[27-A. Penalty for manufacture, sale, etc. of cosmetics in contravention of this chapter: -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-

(i) Any cosmetic deemed to be spurious under Sec. 17-C should be punishable with imprisonment for a term, which may extend to three years and with fine;

(ii) Any cosmetic other than a cosmetic referred to in Cl. (i) above in contravention of any provisions of this chapter or any rule made thereunder shall be punishable with imprisonment for a term which may extend to one year or with fine which may extend to one thousand rupees or with both.]

STATE AMENDMENT

Uttar Pradesh. -For Sec. 27-A of the principal Act, the following section shall be substituted, namely: -

"**27-A. Penalty for manufacture, sale, etc., of cosmetics in contravention of this Chapter: -**Whoever himself for by any other persons on his behalf manufacture for sale, sells, stocks or exhibits for sale, or distributes any cosmetic in contravention of any provisions of this Chapter or any rule made thereunder, shall be punishable with imprisonment for life and shall also be liable to fine:

Provided that the Court may, for adequate and special reasons to be mentioned in the judgment, impose a sentence of imprisonment, which is less than in imprisonment for life, **2**

West Bengal. -In Sec. 27-A of the principal Act, for the words "a term which may extend to one year, or with fine which may extend to five which may extend to five hundred rupees ", the words "life or with fine" shall be substituted**3**

1. Subs. by Act 68 of 1982, Sec. 22 (w.e.f. Ist February 1983).

2. Vide U.P. Act 47 of 1975, Sec. 5.

3. Vide West Bengal Act XLII of 1973, Sec. 5.

1[28. Penalty for non-disclosure of the name of the manufacturer, etc.- Whoever contravenes the provisions of Sec. 18-A **2**[or Sec. 24] shall be punishable with imprisonment for a term which may extend to one year, or with fine which may extend to **3**[one thousand rupees] or with both.]

1. Subs. by Act 13 of 1964, Sec. 19, for Sec. 28 (w.e.f. 15th September, 1964).

2. Ins. by 68 of 1982, Sec. 23 (w.e.f. Ist February 1983).

3. Subs. by ibid. for 'five hundred rupees" (w.e.f. Ist February, 1983).

1[28-A. Penalty for not keeping documents, etc, and for non- disclosure of information: -Whoever without reasonable cause or excuse, contravenes the provisions of Sec. 18-B shall be punishable with imprisonment for a term, which may extend to one year or with fine, which may extend to one thousand rupees or with both.

1. Ins. by Sec. 24, ibid. (w.e.f. Ist February 1983).

28-B. Penalty for manufacture, etc. of drugs or cosmetics in contravention of Sec. 26-A. -Whoever himself or by any other person on his behalf manufactures or sells or distributes any drug or cosmetic in contravention of the

provisions of any notification issued under Sec. 26-A, shall be punishable with imprisonment for a term which may extend to three years and shall also be liable to fine which may extend to five thousand rupees.]

29. 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 **1**[or cosmetic], shall be punishable with fine, which may extend to five hundred rupees.

1. Ins. by Act 21 of 1962, Sec. 15 (w.e.f. 27th July, 1964).

1[30. Penalty for subsequent offences: –

2[(l) Whoever having been convicted of an offence, -

(a) Under Cl. (b) of Sec. 27 is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which shall not be less than two years but which may extend to six years and with fine which shall not be less than ten thousand 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 two years and of fine of less than ten thousand rupees;

(b) Under Cl. (c) of Sec. 27, is again convicted of an offence under that clause shall be punishable with imprisonment for a term which shall not be less than six years but which may extend to ten years and with fine which shall not be less than ten thousand rupees;

(c) Under Cl. (d) of Sec. 27, is again convicted of an offence under that clause shall be punishable with imprisonment for a term which shall not be less than two years but which may extend to four years or with fine which shall not be less than five thousand rupees, or with both.]

3[(l-A) Whoever, having been convicted of an offence under Sec. 27-A is again convicted under that section, shall be punishable with imprisonment for a term which may extend to two years, or with fine which may extend to **4**[two thousand rupees] or with both.]

(2) Whoever, having been convicted of an offence under **5[***]** Sec. 29 is again convicted of an offence under the same section shall be punishable with imprisonment which may extend to **6**[ten years] or with fine, or with both.]

STATE AMENDMENTS

Uttar Pradesh. -For Sec. 30 of the principal Act, the following section shall be substituted, namely: -

"30. All offences punishable under this chapter shall be cognizable and non-bailable. **7**

West Bengal. -In Sec. 30 of the principal Act, -

(a) In subsection (1), -

(i) In Cl. (a), for the words "ten years", the worlds "imprisonment for life " shall be substituted;

(ii) In Cl. (b), for the words "may extend to ten years or with fine, or with both", the words "shall not be less than two years but which may extend to imprisonment for life and shall also be liable to fine" shall be substituted;

(b) In subsection (I-A), for the words "may extend to two years, or with fine which may extend to one thousand rupees, or with both the words "shall not be less than two years but which may extend to imprisonment for life and shall also be liable to fine "shall be substituted **8**

1. Subs. by Act 11 of 1955, Sec. 14, for Sec. 30.

2. Subs. by Act 68 of 1982, Sec. 25 (w.e.f. Ist February, 1983).

3. Ins. by Act 21 of 1962, Sec. 20 (w.e.f. 27th July, 1964).

4. Subs. by Act 68 1982, Sec. 25,for "one thousand rupees" (w.e.f. lst February, 1983).

5. The words and figures 'Sec. 28 or" omitted by Act 13 of 1964, Sec. 20 (w.e.f. 15th September, 1964).

6. Subs. by Sec. 20, ibid. for "two years" (w.e.f. 15the September, l 964).

7. Vide U.P. Act 47 of 1975, Sec. 5.

8. Vide West Bengal Act XLII of 1973, Sec. 5.

31. Confiscation. -

1[(1) Where any person has been convicted under this chapter for contravening any such provision of this chapter or any rule made thereunder as may be specified by rule made in this behalf, the stock of the drug **2**[or

cosmetic] in respect of which the contravention has been made shall be liable to confiscation **3**[and if such contravention is in respect of, -

4[(i) Manufacture of any drug deemed to be misbranded under Sec.17, adulterated under Sec. 17-A or spurious under Se. 17-B, or]

(ii) **5**[Manufacture for sale, or for distribution, sale, or stocking or exhibiting or offering for sale] or distribution of any drug without a valid licence as required under Cl. (c,) of Sec. 18,

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.]

6[(2) Without prejudice to the provisions contained in sub-section (1), 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 **7**[or is a **8**[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.]

1. Re-numbered as sub-section (1) by Act 35 of 1960, Sec. 9 (w.e.f. 16th March, 1961).

2. Ins. by Act 21 of 1962, Sec. 21 (w.e.f. 27th July, 1964).

3. Added by Act 13 of 1964, Sec. 21 (w.e.f. 15th September, l 964).

4. Subs. by Act 68 of 1982, Sec. 26,for Cl. (i) (w.e.f. Ist February 1983).

5. Ibid.

6. Ins. by Act 35 of 1960, Sec. 9, subs. by Act 21 of 1962, Sec. 21 (w.e.f. 27th July, 1964).

7. Subs. by Act 13 of 1964, Sec. 21, for "or is a misbranded drug" (w.e.f. 15th September, 1964).

8. Subs. by Act 68 of 1982, Sec. 26 (w.e.f. Ist February 1983).

1[31-A. Application of provisions to Government departments: -The provisions of this chapter except those contained in Sec. 31 shall apply in relation to the manufacture, sale or distribution of drugs by any department of Government as they apply in relation to the manufacture, sale or distribution of drugs by any other person.]

1. Ins. by Act 13 of 1964, Sec. 22 (w.e.f. 15th September, 1964).

32. Cognizance of offences. –

(1) No prosecution under this chapter shall be instituted except by an Inspector];

(2) No Court inferior to that of **1**[a Metropolitan Magistrate or of a judicial Magistrate of the first class] shall try an offence punishable under this chapter.

(3) 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.

STATE AMENDMENT

West Bengal. -For Sec. 32 of the principal Act, the following section shall be substituted, namely: -

"32. Cognizance of offences and arrest without warrant)- (1) All offences punishable under this Act shall be cognizable and non-bailable.

(2) Any Police Officer not below the rank of a Sub-Inspector of Police may arrest without warrant any person against whom a reasonable complaint has been made or credible information has been received of his having been concerned in any of the offences punishable under this Act. **2**

1. Subs. by Act 68 of 1982, Sec. 27 (w.e.f. lst February, 1983).

2. Vide West Bengal Act XLII of 1973, Sec. 5.

1[32-A. Power of Court to implead the manufacturer, etc.-Where, at any time during the trial of any offence under this chapter alleged to have been committed by any person, not being the manufacturer of a drug or cosmetic or his agent for the distribution thereof, the Court is satisfied, on the evidence adduced before it, that such manufacturer or agent is also concerned in that offence, then the Court may, notwithstanding anything contained **2**[in sub-sections (1), (2) and (3) of Sec. 319 of the Code of Criminal Procedure, 1973 (2 of 1974) proceed against him as though a prosecution had been instituted against him under Sec. 32.]

1. Ins. by Act 13 of 1964, Sec. 23 (w.e.f. 15th September, 1964).

2. Subs. by Act 68 of 1982, Sec. 28 (w.e.f. Ist February 1983).

33. Power of Central Government to make rules. -

1[(l) The Central Government may, **2**[after consultation with, or on the recommendation of the Board] and after previous publication by notification in the Official Gazette, make rules for the purpose of giving effect to the provisions of this chapter:

Provided that consultation with the Board may be dispensed with if the Central Government is of opinion that circumstances have arisen which render it necessary to make rules without such consultation, but in such a case the Board shall be consulted within six months of the making of the rules and the Central Government shall take into consideration any suggestions which the Board may make in relation to the amendment of the said rules.]

(2) Without prejudice to the generality of the foregoing power, such Rules may

(a) Provide for the establishment of laboratories for testing and analyzing drugs **3**[or cosmetics];

(b) Prescribe the qualifications and duties of Government Analysts and the qualifications of Inspectors;

(c) Prescribe the methods of test or analysis to be employed in determining whether a drug **3**[or cosmetic] is of standard quality;

(d) Prescribe; in respect of biological and organometallic compounds the units or methods of standardization,

4[(dd) Prescribe under Cl. (d) of **5**[Sec. 17- A] the colour or colours which a drug may bear or contain for purposes of colouring;]

(e) Prescribe the forms of licences **6**[for the manufacture for sale, or for distribution], for the sale and for the distribution of drugs or any specified drug or class of drugs **3**[or of cosmetics or any specified cosmetic or class of cosmetics], the form of application for such licences, the conditions subject to which such licences may be issued, the authority empowered to issue the same **7**[[the qualifications of such authority], and the fees payable therefor, **6**[and provide for the cancellation or suspension of such licences in any case where any provision of this chapter or the rules made thereunder is contravened or any of the conditions subject to which they are issued is not complied with;]

[(ee) Prescribe the records, registers or other documents to be kept and maintained under Sec. 18-B;]

(eea) Prescribe the fees for inspection (for the purposes of grant or renewal of licences) of premises wherein any drug or cosmetic is being or is proposed to be manufactured;

(eeb) Prescribe the manner in which copies are to be certified under sub-section (2-A) of Sec. 22;]

(f) Specify the disease or ailments which a drug may not purport or claim **8**[to prevent, cure or mitigates] and such other effects which a drug may not purport or clime have;

(g) Prescribe the conditions subject to which small quantities of drug may be manufactured for the purpose of examination, test or analysis;

(h) Require the date of manufacture and the date of expiry of potency to be clearly and truly stated on the label or container of any specified period from the date of manufacture or after the expiry of the date of potency;

(i) Prescribe the conditions to be served in the packing in bottles, packages, and other containers of drugs **9**[or cosmetics] **10**[including the use of Packing material which comes into direct contact which the drugs], and prohibit the sale, stocking or exhibition for sale, or distribution of drugs **9**[or cosmetics packed in contravention of such condition;

(1) Require that the accepted scientific name of any specified drug shall be displayed in the prescribed manner on the label or wrapper of any patent or proprietary medicine containing such drug;

11[* ***** ***** ***** ***** ***]**

12[(n) Prescribe the powers and duties of Inspectors **10**[and the qualifications of the authority to which Inspectors shall be subordinate and **13**[specify drugs or classes of drugs or cosmetics or classes of cosmetics] in relation to which and the conditions, limitations or restrictions subject to which powers and duties may be exercised or performed;]

(o) Prescribe the forms of report to be given by Government Analysts, and the manner of application for test or analysis under Sec. 26 and the fees payable therefor to cure or mitigate".

14[(p) Specify the offences against this Chapter or any rule made there under in relation to which an order of confiscation may be made under Sec. 31;and]

(q) Provide for the exemption, conditionally or otherwise, from all or any of the provisions of this chapter or the rules made thereunder, of any specified drug or class of drugs **15**[or cosmetic or class of cosmetics]

16[* ***** ***** ***** ***]**

STATE AMENDMENT

17[Maharashtra. -In Sec. 33 o the Drugs and Cosmetics Act, 1940 (23 of 1940), in its application to the State of Maharashtra, in sub-section (2), -

(a) In Cl. (e), the words “and the fees payable therefor” shall be deleted;

(b) Clause (eea) shall be deleted; and

(c) In Cl. (o) the words “and the fees payable therefor” shall be deleted.

After Sec. 33 of the principal Act, the following sections shall be inserted, namely--

“33-A. -Power o State Government to make rules. - The State Government may, by notification in the Official Gazette and subject the condition of previous publication, make rules, to prescribe the fees payable for the following Purposes Of this chapter, namely. --

(a) Grant or renewal of a licence for the manufacture for sale or distribution for the sale and for the distribution of drugs or any specified drugs or class of drugs or of cosmetics or any specified cosmetics or class of cosmetics;

(b) Inspection (for the purposes of grant or renewal of licences) of premises, wherein any drug or cosmetics is being or is proposed to be manufactured,

(c) Test or analysis of any drug or cosmetic by Government Analyst; and

(d) Any other matter for which fees may be prescribed under this chapter.

1. Subs. by Act 11 of 1955, Sec. 15,for sub-section (1).

2. Subs, by Act 68 of 1982, Sec. 29 (w.e.f. lst February, 1983).

3. Ins. by Act 13 of 1964, Sec. 22 (w.e.f. 27th July, 1964).

4. Ins. by Sec. 24, ibid. (w.e.f. 15th September 1964).

5. Subs. by Act 68 of 1982, Sec. 29 for “Sec. 17-B” (w.e.f. Ist February 1983).

6. Subs. by ibid. For 'for the manufacturefor sale".

7. Ins. by Act 68 of 1982, Sec. 29 (w.e.f. lst February, 1983).

8. Subs. By Act 11 of 1955, sec 15, for "to cure or mitigate".

9. Ins. by Act 21of 1962, sec. 22 (w.e.f.27th july, 1964).

10. Ins. by Act 68 of 1982, sec.29 (w.e.f. Ist February, 1983).

11. Clause (m) omitted by act 13of 1964,Sec.24 (w.e. f 15th September, 1964).

12. Subs. by Act 35 of 1960, Sec.10 for Cl. (n) (w.e.f 16th March, 1961).

13. Subs. by Act 2 of 1962, Sec. 22,for "the drugs or class of drugs " (w.e.f. 27th July 1964).

14. Subs. By Act 13 of 1964,Sec. 24, for Cl. (p) (w.e.f. 15th September 1964).

15. Ins. by Act 21 of 1962, Sec. 22 (w.e.f. 27th July, 1964).

16. Omitted by Act 13 of 1964 for sub-section (3) w.e.f.

17. Vide Mah. Act 31 of 1989, sec. 2 and 3.

1[33-A. Chapter not to apply to 2[Ayurvedic, Siddha or Unani] drugs. - Save as otherwise provided in this Act, nothing contained in this chapter shall apply to **1**[Ayurvedic, Siddha or Unani drugs.]

1. Ins. by Act 13 of 1964, Sec. 25 (w.e.f. Ist February 1969).

2. Ins. by Act 13 of 1964, Sec. 26 (w.e.f. Ist February, 1969).

1[CHAPTER IV-A

Provisions relating to 2[Ayurvedic, Siddha and Unani] Drugs

1. Subs-by Act 68 of l982, Sec.-30 (w.e.f .Ist February, 1983).

2. Vide Mah. Act 31 of 1989, sec. 2 and 3.

33-B Application of Chapter IV-A. -This chapter shall apply only to **1**[Ayurvedic, Siddha or Unani] drugs

1. Vide Mah. Act 31 of 1989, sec. 2 and 3.

33-C. Ayurvedic and Unani Drugs Technical Advisory Board. -

(1) The Central Government shall by notification in the Official Gazette and with effect from such date as may be specified therein, constitute a Board to be called the **4**[Ayurvedic, Sidha and Unani Drugs Technical Advisory Board] to advise the Government on technical matters arising out of other functions assigned to it by this chapter.

(i) The Board shall consist of the following members, namely:

(ii) The Director-General of Health Services, ex officio;

1(iii) The principal officer, dealing with Indian systems of medicine in the Ministry of Health, ex officio:]

(iv) The Director of the Central Drugs Laboratory, Calcutta, ex officio;]

(v) One person holding the appointment of Government Analyst under Sec.33-F, to be nominated by the Central Government;

(vi) One Pharmacognocist to be nominated by the Central Government"

2(vii) One photo-chemist to be nominated by the Central Government two from amongst the member 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 nominated by the Central Government;

(x) One teacher in ILM-UL-ADVIA and TAKLIS-WA-DAWASAZI, to be nominated by the Central Government;

3[(xi) One teacher in Gunapadam to be nominated by the Central Government;

(xii) Three persons, one each to represent the Ayurvedic, Siddha and Unani dug industry, to be nominated by the Central Government;

(xiii) Three persons, one each from among the practitioners of Ayurvedic, Siddha and Unani Tibb systems 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, member of the Board shall hold office for three years, but shall be eligible for re-nomination.

(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 not with standing 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.

1. Subs. by Act 68 of 1982,Sec. 30, for Cl. (iii) (w.e.f. 1st February, 1983).

2. Subs. by ibid; Sec. 30, for Cl. (viii) (w.e.f. Ist February, 1983).

3. Subs. By Sec. 30, ibid; for Cls. (xi) and (xii) (w.e.f. Ist February 1983).

4. Ibid.

1[33-D. Ayurvedic, Siddha and Unani Drugs Consultative Committee. –

(l) The Central Government may constitute an Advisory Committee to be called 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.

1. Sub. By Act 68 of 1982, SEC. 31for Sec. 33- D and 33-E (w.e.f. lst February, 1983).

33-E. Misbranded drugs. -For the purposes of this chapter, an Ayurvedic, Siddha or Unani drug shall be deemed to be misbranded-

(a) If it is so coloured, coated, powdered or polished that damage is concealed, or it is made to appear of, better or greater therapeutic value than it really is; or

(b) If it is not labelled in the prescribed manner; or

(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.

33-EE. Adulterated drugs. -For the purposes of this chapter, an Ayurvedic, Siddha or Unani drug shall be deemed to be adulterated, -

(a) If it consists, in whole or in part, of any filthy, putrid or decomposed substance; or

(b) If its has been prepared, packed or stored under insanitary conditions where by it may have been contaminated with filth or whereby it may aye been rendered injurious to health; or

(c) `If its container is composed, whole or in part, of any deleterious substance which may render the contents injurious to health; or

(d) If it bears, or contains for purpose of colouring only, a colour other than one which is prescribed; or

(e) If it contains any harmful or toxic substance which may render it injurious to health; or

(f) If any substance has been mixed therewith so as to reduce its quality or strength.

Explanation. -For the purpose of Cl. (a), a drug shall not be deemed to consist, in whole or in part, of any decomposed substance only by reason of the fact that such decomposed substance is the result of any natural decomposition of the drug:

Provided that such decomposition is not due to any negligence on the part of the manufacturer of the drug or the

dealer thereof and that it does not render the drug injurious to health.

33-EEA. Spurious drugs. -For the purposes of this chapter, an Ayurvedic, Siddha or Unani drug shall be deemed to be spurious-

(a) If it is sold, or offered or exhibited for sale, under a name which belongs to another drug; or

(b) If it is an imitation of, or is 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; or

(c) If the label or 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; or

(d) If it has been substituted wholly or in part by any other drug or substance; or

(e) If it purports to be the product of a manufacturer of whom it is not truly a product.

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

33-EEC. Prohibition of manufacture and sale of certain Ayurvedic, Siddha and Unani drugs. -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 drug;

(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; and

(iii) Any Ayurvedic, Siddha or Unani drug in contravention of any of the provisions of this chapter or any rule made thereunder;

(b) Sell, stock or exhibit or offer for sale or distribute any Ayurvedic, Siddha or Unani drug which has been manufactured in contravention of any of the provisions of this Act, 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 licence issued for such purpose under this chapter by the prescribed authority:

Provided that nothing in this section shall 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.

33-EED. Power of Central Government to prohibit, manufacture, etc., of Ayurvedic, Siddha or Unani drugs in public interest. -Without prejudice to any other provisions contained in this chapter, 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.]

33-F. Government Analysts. –

(1) The Central Government or a State Government may, by notification in the Official Gazette, appoint such persons, as it thinks fit, having the prescribed qualifications, 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 sub-section (1), neither the Central Government nor 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.

1[(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.]

1. Ins. by Act 68, of 1982, Sec. 32 (w.e.f. lst February, 1983).

33-G. Inspectors. –

(l) The Central Government or a State Government may, by notification in the Official Gazette, appoint such persons, as it thinks fit, having the prescribed qualifications, to be Inspectors for such areas as may be assigned to them by the Central Government, or the State Government, as the case may be.

(2) The powers which may be exercised by an Inspector and 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.

(3) 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.

(4) Every Inspector shall be deemed to be a public servant within the meaning of Sec. 21 of the Indian Penal Code (45 of 1860), and shall be officially subordinate to such authority as the Government appointing him may specify in this behalf.

33-H. Application of provisions of Secs. 22, 23, 24 and 25: -The provisions of Secs. 22, 23, 24 and 25 and the rules, if any, made thereunder shall, so far as may be, apply in relation to an Inspector and a Government Analyst appointed under this chapter as they apply in relation to an Inspector and a Government Analyst appointed under Chapter IV, subject to the modification that the references to “drugs” in the said sections, shall be construed as references to 2[Ayurvedic, Siddha or Unani] drug.

1[33-I Penalty or manufacture, sale, etc., of Ayurvedic, Siddha or Unani drug in contravention of this chapter. -Whoever himself for by any other person on his behalf-

(1) Manufactures for sale or for distribution-

(a) Any Ayurvedic, Siddha or Unani drug-

(i) Deemed to be adulterated under Sec. 33-EE, or

(ii) Without a valid licence as required under Cl. (c) of Sec. 33-EEC,

Shall be punishable with imprisonment for a term which may extend to one year and with fine which shall not be less than two thousand rupees;

(b) Any Ayurvedic, Siddha or Unani drug deemed to be spurious under Sec. 33-EEA, shall be punishable with imprisonment for a term which shall not be less than one year but which may extend to three years and with fine which shall not be less than five thousand 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 one year and of fine of less than five thousand rupees; or

(2) Contravenes any other provisions of this chapter or of Sec. 24 as applied by Sec. 33-H or any rule made under this chapter, shall be punishable with imprisonment for a term which may extend to three months and with fine which shall not be less than five hundred rupees.

1. Subs. by Sec. 33, ibid. for Secs. 33-I and 33-J.

33-J. Penalty for subsequent offences. -Whoever having been convicted of an offence, -

(a) Under Cl. (a) of sub-section (1) of Sec. 33-1 is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which may extend to two years and with fine which shall not be less than two thousand rupees;

(b) Under Cl. (b) of sub-section (1) of Sec. 33-I is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which shall not be less than two years but which may extend to six years and with fine which shall not be less than five thousand 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 two years and of fine of less than five thousand rupees;

(c) Under sub-section (2) of Sec. 33-1 is again convicted of an offence under that sub-section, shall be punishable with imprisonment for a term which may extend to six months and with fine which shall not be less than one thousand rupees.]

33-K. Confiscation. -Where any person has been convicted under this chapter, the stock of the **1**[Ayurvedic, Siddha or Unani] drugs, in respect of which the contravention has been made, shall be liable to confiscation.

1. State of Himachal Pradesh v. Soran Singh, 1998 (2) E.F.R. 293 at p. 302 (H.P.).

33-L. Application of provisions to Government departments. -The provisions of this chapter except those contained in Sec. 33-K shall apply in relation to the manufacture for sale, sale, or distribution of any **1**[Ayurvedic, Siddha or Unani] drug by any department of Government as they apply in relation to the manufacture for sale, sale, or distribution of such drug by any other person.

1. Subs. by Act 68 of 1982, Sec. 2 (w.e.f. Ist February, 1983).

33-M. Cognizance of offences. –

(l) No prosecution under this chapter shall be instituted except by an Inspector **1**[with the previous sanction of the authority specified under sub-section (4) of Sec. 33-G].

(2) No Court inferior to that **2**[of a Metropolitan Magistrate or of a Judicial Magistrate of the first class] shall try an offence punishable under this chapter.

1. Ins. by Sec. 34, ibid. (w.e.f. Ist February, 1983).

2. Subs. by Sec. 34, ibid.

33-N. Power of Central Government to make rules. –

(1) The Central Government may, **5**[after consultation with, or on the recommendation of, the Board] and after previous publication by notification in the Official Gazette, makes rules of the purpose of giving effect to the provisions of this chapter:

Provided that consultation with the Board may be dispensed with if the Central Government is of opinion that circumstances have arisen which render it necessary to make rules without such consultation, but in such a case, the Board shall be consulted within six months of the making of the rules and the Central Government shall take into consideration any suggestions which the Board may make in relation to the amendment of the said rules.

(2) Without prejudice to the generality of the foregoing power, such rules may-

(a) Provide for the establishment of laboratories for testing and analysing **1**[Ayurvedic, Siddha or Unani] drugs;

(b) Prescribe the qualifications and duties of Government Analysts and the qualifications of Inspectors;

(c) Prescribe the methods of tests or analysis to be employed in determining whether any **1**[Ayurvedic, Siddha or Unani] drug is labelled with the true list of the ingredients, which it is purported to contain;

(d) Specify any substance as a poisonous substance;

(e) Prescribe the forms of licences for the manufacture for sale of **1**[Ayurvedic, Siddha or Unani] drugs **2**[and for sale of processed Ayurvedic, Siddha or Unani drugs,] the form of application for such licences, the conditions subject, to which such licences may be issued, the authority empowered to issue the same and the fees payable therefor **2**[and provide for the cancellation or suspension of such licences in any case where any provisions of this chapter or rules made thereunder is contravened or any of the conditions subject to which they are issued is not complied with];

3[(f) Prescribe the conditions to be observed in the packing of Ayurvedic, Siddha and Unani drugs including the use of packing material which comes into direct contact with the drugs, regulate the mode of labelling packed drugs and prescribe the matters which shall or shall not be included in such labels];

(g) Prescribe the conditions subject to which small quantities of **l**[Ayurvedic, Siddha or Unani] drugs may be manufactured for the purpose of examination, test or analysis; and

4[(gg) Prescribe under Cl. (d) of Sec. 33-EE the colour or colours which an Ayurvedic, Siddha or Unani drug may bear or contain for purposes of colouring;

(ga) Prescribe the standards for Ayurvedic, Siddha or Unani drugs under Sec. 33-EEB;]

(h) Any other matter which is to be or may be prescribed under this chapter.

1. Subs. by Act 68 of 1982, Sec. 2 (w.e.f. Ist February, 1983).

2. Ins. by Sec. 35, ibid.

3. Subs. by ibid. for Cl. (f).

4. Ins. by Sec. 35, ibid.

5. Subs. by Sec. 35, ibid.

STATE AMENDMENT

Maharashtra. -In Sec. 33-N of the Principal Act, in sub-section (2) in Cl. (e), the words "and the fees payable therefor" shall be deleted.

After Sec. 33-N of the principal Act, the following section shall be inserted, namely: -

"33-N-1. Power of State Government to make rules. -The State Government may, by notification in the Official Gazette and subject to the condition of previous publication, make rules to prescribe the fees payable for the following purposes of this chapter, namely:-

(a) Grant or renewal of a licence for the manufacturefor sale of Ayurvedic, Siddha or Unani drugs, and for sale of processed Ayurvedic, Siddha or Unani drugs;

(b) Inspection (for the purpose of grant or renewal of licences) of premises, wherein any Ayurvedic, Siddha or Unani drug is being or is proposed to be manufactured;

(c) Test or analysis of any Ayurvedic, Siddha or Unani drug by Government Analyst; and

(d) Any other matter for which fees may be prescribed under this chapter. **1**

1. Vide Mah. Act 31 of 1989, Secs. 4 and 5.

33-0. Power to amend First Schedule. -The Central Government, after consultation with the Board and after giving, by notification in the Official Gazette, not less than three months notice of its intention so to do, may, by a like notification, add to or otherwise amend the First Schedule for the purposes of this chapter and thereupon the said Schedule shall be deemed to be amended accordingly.]

1[CHAPTER V

Miscellaneous

1. Subs. by Act 11 of 1955, Sec. 16, for Sec. 34.

1[2[33-P.] 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.]

1. Ins. by Act 35 of 1960, Sec. 11 (w.e.f 16th March, 1961).

2. Sec. 33-A re-numbered as Sec. 33-P by Act 13 of 1964, Sec. 27 (w.ef 15th September, 1964).

34. Offences by companies. –

(l) 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 provided in this Act if he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence.

(2) Notwithstanding anything contained in sub-section (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.

Explanation. -For the purposes of this section-

(a) "Company" means a body corporate, and includes a firm or other association of individuals; and

(b) "Director" in relation to a firm means a partner in the firm.

1[34-A. Offences by Government departments. -Where an offence under Chapter IV or Chapter IV-A 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:

Provided that nothing contained in this section shall renter any such authority or person liable to any punishment provided in Chapter IV or Chapter IV-A, as the case may be, if such authority or person proves that the offence was committed without its or his knowledge or that such authority or person exercised all due diligence to prevent the commission of such offence.]

1. Ins. by Act 13 of 1964, Sec. 28 (w.e.f. 15th September, 1964).

1[34-AA. Penalty for vexatious search or seizure. -Any Inspector exercising powers under this Act or the rules made thereunder who, -

(a) Without reasonable grounds of suspicion searches any place, vehicle, vessel or other conveyance; or

(b) Vexatiously and unnecessarily searches any person, or

(c) Vexatiously and unnecessarily seizes any drug or cosmetic, or any substance or article or any record, register, document or other material object; or

(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.]

1. Ins. by Act 68 of 1982, Sec. 36 (w.e.f. Ist February, 1983).

35. Publication of sentences passed under this Act. –

(l) If any person is convicted of an offence under this Act **1**[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.

(2) The expenses of such application shall be deemed to form part of the costs relating to the conviction and shall be recoverable in the same manner as those costs are recoverable.

1. Subs. by ibid. Sec. 37 (w.e.f. Ist February, 1983).

36. Magistrate's power to impose enhanced penalties. -Notwithstanding anything contained in **1[* *] 2**[the Code of Criminal Procedure, 1973 (2 of 1974)], it shall be lawful for **2** [any Metropolitan or any Judicial

Magistrate of first class] to pass any sentence authorised by this Act in excess of his powers under **1[* *]** the said Code.

1. The words and figures "Sec. 32 of" omitted by Act 13 of 1964, Sec. 29 (w.ef. 15th September, 1964).

2. Subs. by Act 68 of 1982, Sec. 38 (w.e.f. Ist February 1983).

1[36-A. Certain offences to be tried summarily: -Notwithstanding anything contained in the Code of Criminal Procedure, 1973 (2 of 1974), all offences under this Act punishable with imprisonment for a term not exceeding three years, other than an offence under Cl. (b) of sub-section (1) of Sec. 33-1, shall be tried in a summary way by a Judicial Magistrate of the first class specially empowered in this behalf by the State Government or by a Metropolitan Magistrate and the provisions of Secs. 262 to 265 (both inclusive) of the said Code shall, as far as may be, apply to such trial:

Provided that in the case of any conviction in a summary trial under this section, it shall be lawful for the Magistrate to pass a sentence of imprisonment for a term not exceeding one year:

Provided further that where at the commencement of, or in the course of a summary trial under this section, it appears to the Magistrate that the nature of the case is such that a sentence of imprisonment for a term exceeding one year may have to be passed or that it is for any other reason, undesirable to try the case summarily, the Magistrate shall, after hearing the parties record an order to that effect and thereafter recall any witness who has been examined and proceed to hear or rehear the case in the manner provided by the said Code.]

1. Ins. by Act 68 of 1982, Sec. 39 (w.e.f. lst February, 1983).

37. Protection of action taken in good faith. -No suit, prosecution or other legal proceeding shall be against any person for anything which is in good faith done or intended to be done under this Act.

1[38. 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 thirty days which may be comprised in one session or in two or more successive sessions **2**[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.]

STATE AMENDMENT

Maharashtra. -In Sec. 38 of the principal Act, for the words "Every rule made" the words "Every rule made by the

Central Government" shall be substituted.

After Sec. 38 of the principal Act, the following section shall be inserted namely: -

"39. Rules to be laid before State Legislature. -Every rule made by the State Government under this Act shall be laid, as soon as may be after it is made, before each House of the State Legislature, 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 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 and notify such decision in the Official Gazette, the rule shall m the date of publication of such notification 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 or omitted to be done under that rule.**3**.

1. Ins. by Act 13 of 1964, Sec. 30 (w.e.f. 15th September, 1964).

2. Subs. by Act 68 of 1982, Sec. 40 (w.e.f. lst February, 1983).

3. Vide Mah. Act 31 of 1989, Secs. 6 and 7.

1[THE FIRST SCHEDULE

[See Sec. 3 (a)

2[A-Ayurvedic and Siddha Systems]

1. Subs. by Act 13, of 1964, Sec. 31, for the Schedule, First Schedule came into force w.e.f., lst February, 1969 and the Second Schedule came into force (w.e.f. 15th September, 1964).

2. Subs. by Act 68 of 1982, Sec. 41 (w.e.f. Ist February 1983).

S. No.	Name of book
	Ayurveda
1.	Arogya Kalpadruma
2.	Arka Prakasha
3.	Arya Bhishak
4.	Ashtanga Hridya
5.	Ashtanga Samgraha

6. Ayrveda Kalpadruma
7. Ayurveda Prakasha
8. Ayurveda Samgraha
9. Bhaishjya Ratnavali
10. Bharat Bhaishjya Ratnakara
11. Bhava Prakasha
12. Brihat Nighantu Ratnakara
13. Charka Samhita
14. Chakra Datta
15. Gada Nigraha
16. Kupi Pakva Rasayana
17. Nighantu Ratnakara
18. Rasa Chandashu
19. Rasa Raja Sundara
20. Rasaratna Samuchaya
21. [Rasatnatra Sara Siddha Prayoga Samgraha
22. Rasa Tarangini
23. Rasa Yoga Sagara
24. Rasa Yoga Ratnakara
25. Rasa Yoga Samgraha
26. Rasendra Sara Samgraha
27. Rasa Pradipika
28. Sahasrayoga
29. Sarvaroga Chikitsa Ratnam
30. Sarvayoga Chikitsa Ratnam
31. Sharangadhara SaniMta,
32. Siddha Bhaishajya Manimala
33. Siddha Yoga Samgraha
34. Sushruta Samhita
35. Vaidya Chintamani
36. Vaidyaka Shabda Sindu

37. Vaidyaka Chikitsa Sara

38. Vaidya Jiwan

39. Basava Rajeeyam

40. Yoga Ratnakara

41. Yogatarangini

42. Yoga Chintamani

43. Kashyapasamhita

44. Bhelasamhita

45. Vishwanathachikitsa

46. Vrindachikitsa

47. Ayurvedachintamani

48. Abhinavachintamani

49. Ayurveda-ratnakar

50. Yogaratnasangraha

51. Rasamrita

52. Dravyagunai-iighantu

53. Rasamanjari

54. Banga-sena

1[54-A. Ayurvedic Formulary of India (Part 1)

54-B. Ayurvedic Sara Samgraha]

55. Siddha Vidya Thirattu

56. Therayar Maha Karisal

57. Brahma Muni Karukkadai (300)

58. Bhogar (700)

59. Pulippani (500)

60. Agasthiyar Chenduram (300)

61. Therayar Yamagam

62. Agashtiyar Chenduram (300)

63. Agashtiyar (1,500)

64. Athmarkshamrutham

65. Agasthiyar Pin (80)

66. Agasthiyar Rathna Churkkam

67. Therayar Karisal (300)

68. Veeramamuni Nasa Kandam

69. Agasthiyar (600)

70. Agasthiyar Kanma Soothiram

71. 18 Siddhars Chillarai Kovai

72. Yogi Vatha Kaviyam

73. Therayar Tharu

74. Agasthiyar Vaidya a Kaviyam (1,500)

75. Bala Vagadam

76. Chimittu Rathna (Rathana) Churukkam

77. Nagamuni (200)

78. Agasthiyar Chillarai Kovai

79. Chikitsha Rathnam Deepam

80. Agasthiyar Nayana Vidhi

81. Yugi Karisal (151)

82. Agasthiyar Vallathi (600)

83. Therayar Thaila Varkam

84. **1**[84-A. Siddha Formulary of India (Part-I)

2[B-Unani (Tibb) System]

S.No. Name of book

1. Karabadin Qadri

2. Karabadin Kabir

3. Karabadin Azam

4. llaj-ul-Amraz

5. Al Karabadin

6. Biaz Kabir, Vol. II

7. Karabadin Jadid

8. Kitab-ul-Taklis

9. Sanat-ul-Taklis

10. Miffa-ul-Khazain

11. Madan-ul-Aksir

12. Makhazan-ul-Murbhat]

1[13. National Formulary of Unani Medicine (Part-11)

1. Ins. by G.S.R. 735 (E) dated 28th August 1987.

2. Subs. by Act 68 of 1982, Sec. 41(w.e.f. lst February, 1983).

THE SECOND SCHEDULE

(See Secs. 8 and 16)

Standards to be complied with by imported drugs and by drugs manufactured for sale, Sold, stocked or exhibited for sale or distributed

	Class of drug	Standard to be complied with
1.	Patent or proprietary medicines, **1**[other than Homeopathic medicines,]	The formula or list of ingredients displayed in the prescribed manner of the label or container and such other standard as may be prescribed. The standards maintained at the International Laboratory for Bioligical standards, stantans serum Institute, Copenhagen and at the central Veterinary Laboratory, Weybridge surrey, U.K. and such other laboratories recognized by the World Health Organisation from time to time, and such further standards of strength, quality and

[2][2.	Substances commonly known as vaccines, sera, toxine, toxoids, anti-toxine, and antigens and biological products of like nature for veterinary use.	purity as may be prescribed,] Such standards as may be prescribed.
3.	**[3][* * *]**	
4.	Substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects, which cause disease in human beings or animals.	Standards of identity, purity and strength specified in the edition of the Homeopathic Pharmacopoeia of India for the time being and such other standards as may be prescribed. Standards of identity 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 to be prescribed.
[4][4-A	Homeopathic Medicines:	
	(a) Drugs included in the Homeopathic Pharmacopoeia of India.	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.]
	(b) Drugs not included in the Homeopathic Pharmacopoeia of India but which are included in the Homeopathic Pharmacopoeia of United States of America or, the United Kingdom or the German Homeopathic Pharmacopoeia.	
		Standards of indentity, purity and strength specified in the edition of the Indian

	(c) Drugs not included in the Homeopathic Phrmacopoeia of India or the United States of America, or the United Kingdom or the German Homeopathic Pharmacopoeia.	Pharmacopoeia for the time being in force and such other standards as may be prescribed.
[5][5.	Other drugs:	In case the standards of indentity 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 indentity, purity, and strength shall be those occurring in such immediately preceding edition of the Indian Pharmacopoeia and such other standards as may be prescribed.
	(a) Drugs included in the Indian Pharmacopoeia.	Standards of indentity, purity and strength specified for drugs in the edition of such official Pharmacopoeia of any other country fir the time being in force and such other standards as may be prescribed.
	(b) Drugs not included in the Indian Pharmacopoeia but which are included on the official Pharmacopoeia of any other country.	In case the standards of indentity, purity and strength for drugs are not specified in the edition of such official Pharmacopoeia for the time being in force, but are specified in the edition immediately preceding, the standards of indentity purity and strength shall be those occurring in such immediately preceding edition of such official Pharmacopoeia and such other standards as may be prescribed.]

1. Ins. by S.O. 887, dated the 19th March, 1966.

2. Subs. By G.S.R. 299 (E0, dated 23rd April, 1986

3. Serial No. 3 and entries relating thereto ommited by ibid.

4. Subs. By G,S.R. 820, dated 6th June, 1978, for the entry ins. by S.O. 887 dated 19th March 1966.

5. Subs, by Noti. No. G.S.R. 885 of 1973 dated 4th August, 1973.