

Objectives :-

- To restore the position of pharmacy profession in various health services.
- To raise pharmacy profession in India.
- It has a control over person entering pharmacy profession.

- To provide uniform education & training throughout India.

- To regulate pharmacy practice in India.

→ To work over this objectives CPCI & provisions

pharmacy councils (CPC) were constituted.

Definitions :-

Agreement :- "Agreement" means an agreement entered into under sec. 20

Approved :- Approved means approved by central council under section 12(14).

Pharmacy Council of India (CPC)

Central Register :- "Central Register" means the registers of pharmacists maintained by the central council under sec. 15 A.

Business of Pharmacy.

Registers :- Means a register of pharmacists prepared by mentioned by chapter IV.

Registered pharmacist :- Means a person whose name is for the time being entered in Registers of state in which he is for the time being residing or carrying on his profession or

State council :- State council means a state council of pharmacy constituted under section

e, Joint state council constituted under sec 20

central council :- Means the pharmacy council of India constituted under sec 3 shall a body corporate by name of PCI.

→ 3 types of members → (1) elected member
 (2) Nominated Member
 (3) ex-officio

(1) elected members :- 6 members are elected from professors at Pharmacy colleges & universities by NRC.

- one member elected by MCI
 - one member is elected from each state of Pharmacy council.

(2) Nominated members :- 6 members are nominated by central govt & they are registered pharmacist.

- one member is nominated by each state govt.
 - 1st representative of DSC & 1st representative of ACTE.

(3) ex-officio
 - Directors general of Health Services, DMS
 - directors of central drug laboratory
 - drugs controller of India.

They can also appoint any other officers or servants required.
 - If any Nominated/Elected members does not attend 3 constitutive meetings, he/she is debarred.

functions of PCI

(1) Education Regulation (ER)

- PCI has set some min. conditions for education that is referred as 'Education Regulation'.

These condition are

1. minimum qualification required to get admission in B.pharm & D.pharm course.
2. minimum qualification required to become a registered pharmacist.

3. conditions to be fulfilled by Institute for Academic purpose
4. conditions to be fulfilled by Institute for practical purpose.
5. conditions to be fulfilled by examination authority.

- Among all people members of PCI, 1st is elected as president & 1st vice president.
- PCI can appoint a register that can work as treasurer or secretary.

(e) Type & duration of course (syllabus) 15.

(f) also selected by PCI

(g) examination subject & passing criteria is also selected by PCI

(h) nature & duration of practical training after the regular course is also decided by PCI

Application of education regulations of states:-

- The application of education regulation is done after the constitution of the state council under chapter III of this act

- After consultation with state council, the state govt may, by notification in official gazette, declare that education regulation

shall take effect in state:-

(II) Approval / withdrawal of Institute

- Institute have a apply to PCI / AICTE

→ PCI / AICTE sends an inspectors for a visit to Institute

- Inspectors checks all the conditions & criteria regarding ER are followed or not.

- Inspectors reports to the PCI, & if the report is found to be sufficient, institute is granted permission by PCI

(III) Recognition of qualification &

- any qualification of person from foreign Authority is recognized by PCI whether it is sufficient for registration of pharmacist or not.

(IV) Prosecution & maintenance of certified pharmacist registers :-

- A register is prepared by PCI having all the names of registered pharmacist from each state.

⇒ The main functions of Pharmacy Council is described in section 10 & 12.

⇒ To ensure the implementation of educational standards throughout pharmacy.

⇒ To maintain central Register of pharmacists.

diff b/w state pharmacy council & joint state pharmacy council

state pharmacy council is constituted under pharmacy act by each state of government.

Joint state pharmacy council :- When 2 or more state enters into an agreement by state, the needs of others participating

**SPC
Constitution**
(1) Elected members

- 3-5 members from each participating state elected thru one elected thd or registered pharmacist by state govt.
- 3-5 members from each participating state nominated by state govt.
- 3-5 members from registered pharmacist by each state govt.

(2) Nominated members

- 3 members from Nominated by state govt.
- 2-4 members are nominated by state govt.
- More than 3 should have half should have diploma certificate of degree or diploma degree certificate of pharmacists.

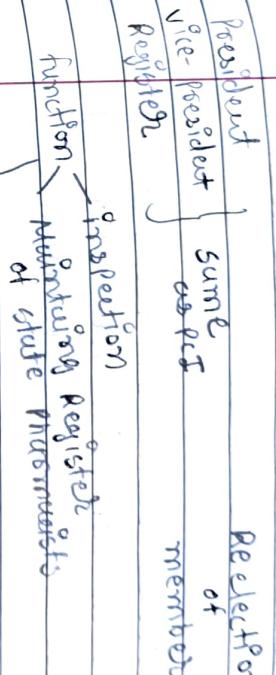
(3) ex-officio

- Chief Administrative Medical officer of each participating state.
- In charge of drug control of each state.

Registration of pharmacist:-

- Govt. drug analyst

- Govt drug analyst nominated by each state govt.


functions of SPC | JSPC

- (1) Registration of pharmacist within state
- (2) Preparation & Maintenance of pharmacist registers.

- (3) Appoints an inspector to inspect premises where drugs are sold as manufac.

States.

- Registered pharmacist is a pharmacist whose name is included in

- Registers of pharmacist of state He besides in as undergoes his pharmacy profession.

Two types of Registers based on whom they were indicated

(1) 1st Register :- Immediately after independence until state pharmacy council was constituted.

(2) subsequent Registers :- During the period of implementation of Pharmacy Act and forming of education Regulation.

(1) first Register :- The state pharmacy council was constituted from registered pharmacist of 1st Register.

Procedure for 1st Register :-

State govt constitutes a registered tribunal.

Registration tribunal fixes a date before which all the applications with prescribed form & fees are accepted.

Registration tribunal examines the application and if fulfills the criteria, disclosed the name of Register.

(3) educational Regulation :-

- (i) applicant must be 18 yrs of age.
- (ii) he should be residing or undergoing profession at the state he is applying.
- (iii) degree/diploma in Pharmacy
- (iv) chemist, druggist diploma
- (v) degree from any Indian University, i.e. Hons. experience of min 3 years in compounding or dispensing drugs at any Hospital or dispensary
- (vi) min. experience of 5 yrs in compounding or dispensing.

(4) passed the examination for chemist or dispensers as per state govt.

- (5) The final register is declared by state government.
- (6) Any person who is dissatisfied can appeal
- (7) decision of state govt is considered as final.

Registration tribunal examines the application and if fulfills the criteria, disclosed the name of Register.

Procedure :-

Registers of state council sets a fix date until which the applications are reviewed.

Applications are examined by register if found satisfactory name is inserted to register.

Requirement of qualification for subsequent registration

- (1) Applicant must be of 18 yrs.
- (2) He/She must be residing undergoing pharmacy profession in concerned state.
- (3) Qualification :- different types of qualification are discussed to 3 condition

(III) Special Provisions

- Special provisions are provided to people belonging to class of
 - (1) Affected by partition of IMA
 - (2) due to reorganization of states 1956
 - (3) migrated to India with required qualification similar to 1st register.
- (2) After preparation of 1st register & before ER take effect
 - degree diploma in Pharmacy
 - chemist & druggist in diploma
 - passed examination for compounder & dispenser approved by state govt.
 - Any displaced person involved in Pharmacy profession for 5 yrs prior to date of application.
- Qualifications Required for 1st Register
- Registered pharmacist of any other state.

offences & penalties for Pharmacy Act - 1955

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Medicinal & Toilet Prep' act - 1955.

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Penalty

offences

Imprisonment

fine

- If any person whose name is not for being exposed in conviction of the state falsely ~~and~~ registers that His name is subsequent to his name in connection with His name or titles any word
- Imprisonment for 500/-
- Subsequent conviction for 100/-
- 6th month

Definitions :-

- The use of description "pharmacist" conviction for chemist, druggist, pharmacist, dispenser, or any combination of such words.
- 1st month
- 500/-
- Subsequent conviction for 100/-
- 6th month

Toilet Preparation :- Any preparation intended for use in toilet of human body or perfume or apparel or cutaneous skin, hair, or teeth complex.

Alcohol :- Means ethylalcohol of any strength and purity having the chemical composition $\text{C}_2\text{H}_5\text{OH}$

Coca derivative :- Means -

- crude cocaine, that is, any extract of coca leaf which can be used directly or indirectly for manufacturing of cocaine.

collecting government :- means the central government or, as the case may be, state government or, as entitled to collect the govt which is entitled to collect the duties under this Act.

Excise officer :- means an officer of excise department of any states includes any person empowered by the collecting govt to exercise all or any of powers of an excise officer under this Act.

Bonded Manufacturing :- means the premises or any part of premises approved & licensed for manufacture & storage of medicinal & toilet prep containing alcohol, opium & other narcotic drugs on which duty not paid been levied.

Non-Bonded Manufacturing :- means the premises any part of premises approved & licensed for manufacture & storage of medicinal & toilet prep containing alcohol, opium, Indian Hemp & other narcotic drugs on which duty has been paid.

duty :- means the duty on excise payable under sec. 3 of Act.

The Licensing procedure for alcoholic & non-alcoholic preparation under Madrasal & toilet preparation Act.

Define :- mention prep & toilet prod:

- Application must be given before 2 months of commencement of manufacture using with prescribed form & fees

- Application must be given before 2 months of commencement of manufacture using with prescribed form & fees

Details to be mentioned in Application :-

- (1) Name, address of Applicant
- (2) " " of Partnership involved
- (3) Address of Bonded lab to be built
- (4) If it is a company, registered name, address also name & address of Manager & Director
- (5) Total Amount of Capital invested
- (6) No & description of apparatus & equipment
- (7) List of prep & % alcohol present in it

- (8) Amount of alcohol present at time of finished & unfinished product

(a) Approximate date of start Manufacture

(b) plan of elevation of laboratory & premises for excise officers.

(c) A statement whether part time excise officers is required or whole time.

(d) On receipt of application, the licensing authority would verify the following:

- financial position of applicant.
- suitability of building for production equipments
- qualification & experience of technical staff members

- if all the conditions are fulfilled licensed is issued in prescribed form.

form of application.

\Rightarrow every application for licence under this act shall be in proper forms of application that mentions.

Ideal properties.

- (1) describable premises.
- (2) proper date of commencement of work.

If application for grant of license is made it shall pay prescribed fee in challan.

grant of license:

- after granting such measures for licensing for the verification of details.
- the fixed quantity of alcohol while issuing the license.

X - to any manufacturer, licensing authority shall satisfy itself about the requirements of whole of that manufacturer.

Manufacture in Bond and outbond -

Manufacture in Bonded Laboratory :-

A Bonded laboratory is a laboratory having special bond with the govt. It is a premises that is approved by licensed for manufacture of medicinal & toilet preparation of alcohol & narcotic drugs for which duty is not paid.

- A separate room for manu & storage of toilet prep.

- A separate room for manu & storage of medicinal prep.

- An accommodation with all necessary furniture for excise officer.

imported raw materials & capital goods

machinery, vehicles etc.

without payment of duty

with payment of duty

Bonded manufacturing

Non-Bonded Manufacturing

Manufacturing Room

Storage Room

Export of finished goods

on Raw Materials (capital goods & finished cell duty waived off).

good

Domestic consumption
of finished goods

manufacturing on a Bonded Laboratory
(1) obtaining spirit :-

spirit can be obtained from spirit warehouse on distilleries.

an application needs to be given for this with the sign of officer in charge.

spirit is received in sealed containers by

No loss of spirit should occur in transit.

- such vessel to store alcoholic prep' should have distinct no & capacity mentioned.

- The pipes from sink should be connected to common drainage system.

- the gas & electrical connecting gas should be such that supply can be cut off at day end.

- There should be a bond over such com displayed serial no & purpose.

2) Notification & Storage of Spirit

- The excise officers on receiving spirit would verify the volume & strength of spirit.
- spirit is then stored in spirit store.

(3) Issue of spirit to Manufacturer:-

- Time to time required quantity of spirit is issued by manufacturer if Huss to give calculation of spirit issued to officer in charge.

(4) He has to keep all ingredients ready,

- in which spirit has to be mixed, and will mix spirit only in presence of officer in charge.

(5) wastage of spirit in Manufacture:-

- % of wastage can be fixed. But too excess loss of spirit manufacturing has to pay penalty.

(6) storage of manufactured product :-

- Product is stored in bulk container, not less than 2.25 litres.

(7) consumer should have label of :-

- Name of product, content, date of storage, Batch No, Strength.

=> details should be recorded with sign of incharge officer.

3) Issue of product from bonded laboratory

- for this purpose, Manc. has to give Application to excise officer.
- After checking all entries & releasing duties will allow the removal of product.

Manufacturing in out-Bonded / Non-Bonded lab.

- dutiable products are not delivered from Bonded lab before 6 am & after 6 pm on Holidays.
- A laboratory without special Bond with government. A premises approved by licensed for manufacturing of medicinal & toilet prep. Having alcohol & nutritive drugs for which excise duty is paid.

Manufacturing in Non-Bonded :-

- The license is issued from excise officer of the state for which.

Application should include

- A separate spirit store.
- Room for manufacture of medicinal preparation.
- Room for storage of finished medicinal prep.

- storage Room for Toilet Posy
- Non-Bonded Lab

- every Room in Non-Bonded indicates Name of
- should bears Bonded
- Room & serial no.

The pipe of sink or wash basin in

lub should be connected with general discharge of laboratory.

- Windows should be covered from inside with strong wire netting, the aperture of which should not exceed 2mm

all gas regulators or switches should be securely locked & cut off at the end of day's work

- is general procedure as Bonded lub
- obtained duty paid rectified spirit

A distillery or spirit warehouse approved by excise officer supplies the spirit for manufacture of medicinal or toilet posy

- excise officer supplies the spirit for manufacture of medicinal or toilet posy

The spirit can be obtained from spirit warehouse by sending prepared triplicate original copy to → spirit warehouse keeper

- spirit warehouse keeper

↓

The duplicate copy of Indent is sent to officer-in-charge of spirit warehouse along with challan showing payment of duty due on quantity to be purchased

↓

The treasury offices also sends an advice to officer in charge of warehouse who shall issue the spirit.

diff Between Bonded & Non-Bonded Laboratory

Bonded Lub Non-Bonded Lub

- Lub with special Bond with Bond with Govt. A promise with Govt. Bond with Govt. Licensed for Manufacturing Medicinal & Toilet Posy and Licensed for Manufacturing Medicinal & Toilet Posy without paying excise duty.

Posy after payment of duty.

- excise duty payable on removal of goods from Lub
- Bonded Lub to function at the time of spirit purchase

- NO excise stuff is Required.

Suitable for large scale
 Suitable for small scale manuf.

of manufacture

alcohol on which duty already been paid
has not been paid, it must be used under supervision.
Duty shall be used.

construction has 4 compartments

- Manufacturing Room
- Excise office
- Storage
- Spirit store
- Excise office
- Manufacturing Room
- Automation
- Storage.

So considered as non-alcoholic & thus, use released from payment of excise duty.

Homeopathics :-

- Amritan, Balsam, & general pharmaceuticals use considered as standard for Homeopathic prep.

- Homeopathic prep. Having alcohol use used as ordinary alcoholic beverages, and thus use liable to pay duty prescribed for prep.

Patent & Proprietary prep :-

- allopathic prep. use used as prepared according to modern medicine system, and use classified as :-

Manufacturing of Ayurvedic, Homeopathic, Patent & Proprietary preparations :-

Ayurvedic preparations :-

- Asafoetida & Asopus are major Ayurvedic formulation types that generate self generated alcohol.
- Recently, pharmaeopoeia used many states like known as standard Ayurvedic pharmaeopoeia.

Ayurvedic prep having self generated alcohol in content not more than 2% proof spirit.

- ① official prep. Prepared According to formulae in the current edition of B.P., B.P.C., I.P., O.S.P., N.O.F (O.S.) any other pharmaeopoeia recognized under the drug & cosmetic act, 1940.
- ② Non-official allopathic prep. (Patent prep.) Prepared according to the allopathic system of medicine & buying the formula on the label.

Excise Officer :- An officer of the excise department of any state and include
any person empowered by the collecting
agent to collect excise duty.

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Powers :-

① Inspection in the excise office will
inspect the premises of
manufacturing
dutiable goods.

e.g. storage

② entry, search & seizure - excise officer
(can) enter the premises
at any reasonable time & even if
doors are closed, can break & open

He can seize, the manufacturing, vessels
vehicle & even the whole tank & in
unappropriate condition also searched.

Responsibilities

- ③ detection of person or If a person is
found carrying dutiable goods
for which permission is required,
excise officer can detain the person.
- ④ dispose of seized articles & arrested
persons :-
- The articles seized i.e., vehicles, vessels,
or animals etc. are disposed by
the excise officer, if owner doesn't
pay penalties.

Duties :-

- It can also arrest the person
- To check the financial conditions of the applicant.
- Suitability of Building
- Equipment
- Qualification & experience of technical staff.

Offences & Penalties of Medicinal & Tolent Poisons Act

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- The narcotic & psychotropic substances Act - 1971
- Objectives :-

Penalties	Fines
Impersonation	₹ 200
Ag. months	₹ 200
up to	
Failure to supply information	₹ 200
up to 6 months	₹ 200
asked or supplying false	
information	
attempting to commit	₹ 2000
or help commission of	
any offence	
failure of excuse	₹ 100
3months	₹ 100
offices on duty	
-	
Stocks or documents	₹ 100

Non-compliance with conditions of license & failure to pay duty

Failure to supply information up to 6 months

Failure to supply false information

attempting to commit or help commission of any offence

failure of excuse 3months

stocks or documents

Definitions :-

- Cannabis (Hemp)
 - The dried leaves & flowering top of the cannabis sativa plant
 - cannabis contains active chemicals called cannabinoids that cause drug like effect on body
 - diff. forms known as Bhang, ganja etc.
 - Resin obtained from plant-chances

② opium :- obtained from opium poppy seeds.

- dried latex obtained from opium seeds.
- i.e. opium is made of analgesic.
- alkaloid morphine.

③ opium derivatives

- substance made by making changes in opium or mixing with opium like.

called opium derivatives.

④ medicated opium :- By making some changes in opium it is set as per pharmaceutical standards & can be used for therapeutic purpose.

⑤ prepared opium :- changes made in opium making it suitable for smoking.

⑥ Mesoin :- derivative of morphine i.e. diurethylmorphine.

⑦ opium poppy :- plant belonging to species "Papaver somniferum"

- plant of any other species of papaver from which opium is obtained.

⑧ poppy straw :- All parts of opium poppy except seeds, whether in original form or cut.

⑨ leaves :- leaf of plant *Crotonus agaves* from which cocaine is not removed.

(1) coca derivative :-

coca cocaine \rightarrow extract of coca leaf

need to manufacture cocaine

- cocaine & its salt.

- all prepns having 0.1% of cocaine.

Provisions

① administration of Act \leftarrow Advisory \leftarrow executive

② various operations \leftarrow totally prohibited \leftarrow controlled operation of controlled operation of central govt.

③ specail provisions \leftarrow regarding opium \leftarrow regarding manufacture of N.E.P. drugs \leftarrow regarding import / export of N.E.P. drugs

④ offences & penalties.

⑤ Administration of act \leftarrow consultative committee

(I) Advisory \leftarrow consultative committee

- The consultative committee for N.E.P. drug list is constituted by central govt.

- Has chairman & not more than 20 members.
- It advises regarding Administration of N & P drugs.

- for effective functioning the committee may from time to time have 2 subcommittees.

- (II) Executive: Narcotic Commission or executive committee

- He is appointed by central govt under N & P act.

- He makes the objectives of N & P act

- cultivation & gathering of coca - import, export & sale of it.
- He also supervises production & cultivation of opium.

(2) Various operations:

(I) Prohibition or totally prohibited:-

- cultivation & gathering of opium, cannabis & its derivatives
- He also supervises production & cultivation of opium.

→ manufacturing, sale import & export of

N & P drugs

- use of property derived by offence of N & P drugs.

- transfer / convert of property derived by offence of N & P drugs.

- digging of property derived by offence of N & P drugs.

(III) controlled operations

L They are 2 types

- (i) By central govt controlled operation

- (ii) Controlled operation by state govt.

(1) controlled operation by central government

- cultivation & gathering of opium; import, export & sale of it
- cultivation & gathering of cannabis & its derivatives
- manufacture, import, export & sale of N & P drugs.

- use of certain controlled substances for manufacture of N & P drugs.

- Manufacture, export, import & sale of certain controlled substances.

(2) Controlled operation by state govt.

- inter-state import, inter-state export, warehousing & use of cannabis, coca & opium & other manufactured N & P drugs.

- Sale of opium to state govt. is done under orders of central govt.
- Sale of opium to manufacturing chemist is done under permit application to manufacturing chemist.
- Propose stock in hand on date
- Quality required.

(B) Regarding Manufacturing of NEP drugs

- Code cocaine & its salt manufacturing is prohibited.
- Cocaine Hydrochloride can be prepared by chemical staff of govt from inappropriate cocaine.
- Morphine, codeine like alkaloids are only manufactured at govt opium factory.
- Narcotic substances can be manufactured under license issued by Narcotic Commissioner.
- Psychotropic substances can be manufactured under license of drugs & cosmetics act.
- Import & export of opium, cannabis, heroin is prohibited.
- Import & export of NEP drugs require license.
- Export of opium can be done only on behalf of central govt.
- Transhipment of NEP drugs at any port can be done by permission of custom collector.
- Functions of N.C.C. consultative committee:-
 - for administration of Narcotic & Psychotropic drug act, central govt has constituted a N.E.P. consultative committee.
 - This committee consists of a chairman & members not more than 20.

- for this purpose the money is generated from,

- 1) grant approved by parliament
- 2) sale of property obtained during Rups by officers.
- 3) financial support from Income tax department.

⇒ fund controlling is done by governing Body constituted by central govt.

- after the end of financial year. A report of activities financed is given to control govt.

functions of committees :-

1. controlling illegal selling of narcotic, Psychotropic drug or controlled substances.
2. controlling the abuse of Narcotic & Psychotropic drug.
3. Identify, treating, addicted person.
4. preventing drug abuse.
5. Educate public against drug abuse.