The Narcotic Drugs and Psychotropic Substances (NDPS) Act, 1985 and Rules, 1985

The earlier provisions of the Acts including the Opium act 1857 and Dangerous Drugs Act, 1930 were inadequate to prohibit illicit trade of NDPS. These drugs of abuse have played havoc with the society. It was to counter procurement, manufacture and trade of such harmful substances, a new Act was enacted, keeping in view there commendations of various International Conventions.Today, India is part of global strategy adopted to counter ill-effects of NDPS.

It is enacted by the parliament in the 36th year of the Republic day of India.

Objective

It is the Act

- To consolidate and amend the law relating to narcotic drugs;
- To make stringent provisions for the control and regulation of operations relating to narcotic drugs and psychotropic substances;
- To provide for the forfeiture (seizure) of property derived from or used in illicit traffic in narcotic drugs and psychotropic substances;
- To implement the recommendations of the International Conventions on narcotic drugs and psychotropic substances; and for matters connected therewith. The Act extends to whole of India.

The Act is divided in 6 Chapters and it has 83 Sections.

Chapter I - preliminary;

ChapterII - Authoritiesand officers.

Chapter II-A - National Fund for Control of Drug Abuse,

ChapterIII - Prohibition,ControlandRegulationofNDPS,

Chapter IV - Offences and Penalties,

Chapter V - Procedure

ChapterV-A - Forfeiture of Property derived from or used in Illicit Trafficking,

Chapter VI - miscellaneous.

Definitions

1. **"addict"** means a person who has dependence on any narcotic drug or psychotropic substance;]
2. **"board"**means the Central Board of Excise and Customs constituted under the CentralBoards of Revenue Act, 1963 (54 of 1963)
3. **"cannabis (hemp)"** means -

(a) charas, that is, the separated resin, in whatever form, whether crude or purified, obtained Fromthe cannabis plant and also includes concentrated preparation and resin known as hashish oil Or liquid hashish;

(b) ganja, that is, the flowering or fruiting tops of the cannabis plant (excluding the seeds and Leaves when not accompanied by the tops), by whatever name they may be known or designated;And

(c) any mixture, with or without any neutral material, of any of the above forms of cannabis Or any drink prepared there from

4.Coca-derivatives It includes:

(a) Crude cocaine is the extract of coca leaf which can be used Directly or indirectly for the manufacture of cocaine.

(b) Ecgonine and all the derivatives of ecgonine from which it can Be recovered.

(c) Cocaine-methyl ester of benzoyl ecgonine and its salts and

(d) All preparations containing more than 0.1 % of cocaine.

5. Coca Leaf

(a) It is the leaf of the coca plant Erythroxylon except, the leaf From which all ecgonine, cocaine and any other ecgonine Alkaloids have been removed.

(b) Any mixture thereof with or without any neutral material but, Doesnot include any preparation containing not more than 0.1 % Of cocaine.

6. Coca Plant

It is the plant of any species of the Genus Erythroxylon i.e. E. Coca, E. Truxillenceand other species of Erythroxylon.

In relation to narcotic drugs and psychotropic substances, it means:

(a) cultivating any coca plant or gathering any portion of coca Plant,

(b) cultivating the opium poppy or cannabis plant,

(c) engaging in the production, manufacture, possession, sale, Purchase, transportation, ware-housing, concealment, use or Consumption, import inter-state, export interstate, import into India, export from India or transhipment of narcotic drugs or Psychotropic substances,

(d) dealing in any activities in narcotic drugs or psychotropic Substances other than those referred to under subclauses (a) to (c) as above,

(e) handling or letting out any premises for carrying on any of the Activitie sreferred to in subclauses (a) to (d) given above.

7. Controlled Substances

Any substance which the Central Government may, having regard to Theavailable information as to its possible use in the production or Manufacturing of the narcotic drugs or psychotropic substances or to The provisions of any International Convention by notification in Official Gazette, declare to be a controlled substance.

8. Manufactured Drug

(a) It means all coca derivatives, medicinal cannabis, opium Derivatives and poppy straw concentrate,

(b) Any other narcotic substance or preparation which the Central Government may having regard to the available information as To its nature or to a decision if any under any International Convention by notification in Official Gazette declare to be a Manufactured drug but, does not include any narcotic substance Or preparation which the Central Government may, having Regard to the available information as to its nature by notification In Official Gazette declare not to be a manufactured drug.

9. Opium

It means:

(a) Medicinal opium-the opium in powder, granulated or any other Form which has undergone the processes necessary to adopt it Formedicinal use in accordance with the requirements of Indian Pharmacopoeia or any other Pharmacopoeia.

(b) Prepared opium-any product of opium obtained by series of Operations designed to transform opium into any extract suitable Forsmoking,

(c) Phenanthrene alkaloids namely, morphine, thebaine, codeine Andtheir salts,

(d) diacetyl morphine i.e., the alkaloid known as diamorphine or Heroine and its salts, and

(e) all prepatations containing more than 0.2% of morphine or Containing any diacetyl morphine.

10. Opium Poppy

It is the plant of the species of Papaver somniferumL.(Papaveraceae) And the plant of any other species of Papaver from which opium or Any phenanthrene alkaloid can be extracted and which the Central Government may by notification in the Official Gazette declare to be Opium poppy for the purposes of this Act.

11. Poppy Straw

It represents all parts except, the seeds of the opium poppy after Harvesting, whether in their original form or crushed or powdered Andwhether or not juice has been extracted therefrom.

12. Poppy Straw Concentrate

It means the material arising when poppy straw has entered into a Process for the concentration of its alkaloids.

13. Psychotropic Substance

It is a natural or synthetic substance or its salt or preparation or any Natural material included in the list of psychotropic substances Specified in the Schedule to the Act. The list of some of the psychotropic substances covered under the Schedule to the Act include, tetrahydrocannabinol, amphetamine, Etycyclidine, rolicyclidine, psilocybine, tenocyclidine, dexamphetamine, Camazepam, clonazepam, clotizepam, diazepam, cloxazolam, Ketozolam, alprazolam, estazolam, bromazepam, haloxazolam, Amobarbital, pentobarbital, secobarbital, barbital, allobarbital, LSD, LSD-25, mesocarb, cathine, tetrazepam, triazolam, prazepam, Oxazepam, loprazolam, lorazepam, mazindol, meprobamate and others.

14.“Central Government factories” means factories owned by the Central Government or Factories owned by any company in which the Central Government holds at least fifty-one per cent. Of The paid-up share capital;

15. “medicinal cannabis”, that is, medicinal hemp, means any extract or tincture of cannabis (hemp);

16. “Narcotics Commissioner” means the Narcotics Commissioner appointed under section 5;

17. “narcotic drug” means coca leaf, cannabis (hemp), opium, popy straw and includes all Manufactured drugs.

AUTHORITIES AND OFFICERS

Central Government to take measures for preventing and combating abuse of and illicit traffic in narcotic drugs etc.

1. Subject to the provisions of this act, the Central Government shall take all suchvisions of his deems necessary or expedient for the purpose of preventing and combating abuse of narcotic drugs and psychotropic substances and the illicit traffic therein [and for ensuring their medical and scientific use].

2. Officers of Central Government

I. Without prejudice to the provisions of sub-section (3) of section 4, under section 5, the Central Government shall appoint a Narcotics Commissioner and may also appoint such other officers with such designations as it thinks fit for the purposes of this Act.

II. The Narcotics Commissioner shall, either by himself or through officers subordinate to him, exercise all powers and perform all functions relating to the superintendence of the cultivation of the opium poppy and production of opium and shall also exercise and perform such other powers and functions as may be entrusted to him by the Central Government.

3. The officers appointed under sub-section (1) shall be subject to the general control and direction of the Central Government, or, if so directed by that Government, also of the Board or any other authority or officer.

4. **The Narcotic Drugs and Psychotropic Substances Consultative Committee**

I. The Central Government may constitute, by notification in the Official Gazette, an advisory committee to be called "The Narcotic Drugs and Psychotropic Substances Consultative Committee" (hereafter in this section referred to as the Committee) to advise the Central Government on such matters relating to the administration of this Act as are referred to it by that Government from time to time.

II. The Committee shall consist of a Chairman and such other members, not exceeding twenty, as may be appointed by the Central Government.

III. The Committee shall meet when required to do so by the Central Government and shall have the power to regulate its own procedure.

PROHIBITION, CONTROL AND REGULATION

The Government prohibits the various operations such as cultivation, manufacture, possession, sale, purchase, transport, import, export etc. In relation to all narcotic drugs and psychotropic substances except for medical and scientific purposes.

1. Operations totally prohibited
2. Operations are controlled and regulated by the Central Government.
3. Operations are controlled by the State Governments.

I. Operations totally prohibited

1. Cultivation of any coca plant or gathering any portion of the coca plant
2. Cultivation of the opium poppy or any cannabis plant.
3. Production manufacture, possession, sale, purchase, transport, warehouse, use, consume, import inter-State, export inter-State, import into India, export from India or tranship any narcotic drug or psychotropic substance except for a medical and scientific purpose.

II. Operations controlled and regulated by the Central Government

No person without the permission of the Central Government shall:

1. Cultivation and collection of any portion of the coca plant, production, possession, sale, purchase, transport, import, export, use or consumption of coca leaves.
2. Cultivation of opium poppy and cannabis plant.
3. Production and manufacture of opium and production of poppy straw.
4. Sale of opium and opium derivatives to the State Government or manufacturing chemist.
5. Manufacture or manufactured drugs.
6. Manufacture, possession, transport, purchase, and consumption of psychotropic substances.
7. Import and Export of narcotic drugs and psychotropic substances.
8. produce, manufacture, possess, sell, purchase, transport, Warehouse, consume, use, import and export any NDPS except, For medical and scientific purpose with Government appoval.

The Central Government may fix time frame for cultivation of opium Poppy, frame regulations for delivery of opium by cultivators, fix prices Tobe paid to cultivator, issue permits for manufacture, possession, export, Import and prescribe other conditions for regulation. The Central Government appoints officers for this purpose.

III. Operations controlled by the State Governments

The State Government may permit, control and regulate all activities pertaining to poppy straw, cannabis excluding, charas and only possession, Transport, sale, purchase, import and export of manufacturing drugs other than opium and coca leaves.

The State Government is empowered to declare a place as warehouse for poppy straw, define limits of license for cannabis, fix price to be paid for cultivation of cannabis and impose other conditions of licence and permit.

No external dealings of NDPS are permitted. There are special Provisions for coca plant and leaves which do not contain alkaloid cocaine and used as a flavouring agent. Special orders of State Government are required for cannabis cultivation for obtaining fibres for industrial use or seeds for horticultural purpose.

Operations controlled:

1. Cultivation of cannabis plant.
2. Possession, transport, import inter-state. Export inter-State, warehousing, sale, purchase, consumption and use of poppy straw, and opium. Cannabis, manufactured drugs other than prepared opium and coca leaf,
3. Manufacture of medicinal opium
4. Manufacture and possession of prepared opium from opium lawfully possessed by an addict registered with the state Government on medical advice for his personal consumption.

Factories

The manufacture of opium is done by the Central Government at two Government factories at

1. Neemuch in Madhya Pradesh
2. Ghazipur in Uttar Pradesh

The State Governments are allowed only to manufacture the damaged or confiscated opium and remodel it.

Production and supply of the opium

1. The Poppy plant can be cultivated only on behalf of the Central Government under the licence granted for the purpose. Conditions imposed on the licence are to the complied with.
2. The cultivation can be undertaken only in those areas, notified by the Government in Madhya Pradesh, Uttar Pradesh and Rajasthan.

3. The Licences are granted by District Opium Officers for cultivation. The District Opium Officer appoints one of the licensed cultivators as a Lambardar who performs duties as specified by Narcotic Commissioner

4. Cultivators during harvesting take each day's collection to the Lumbardar for weighing and entry in records which are signed by Lumbarder and cultivator. The records are checked by District Opium Officers.

5. All opium produced is delivered to the District Opium Officer. The district officer weighs, examines and classifies the opium in the prescribed manner.

6. The whole opium collected by the district officer is then delivered to the opium factory.

7. The cultivators are paid for the opium produced by them and delivered as per the price fixed by Central Government from time to time.

8. The opium produced by a cultivator should not be adulterated with any foreign substance. Any adulterated opium, if found delivered is liable for confiscation.

9. Cultivators should not illegally dispose off any part of the produce.

10. The cultivators should cultivate the full area of land for which they may have received an advance amount from the Government.

Cultivation of Poppy for poppy heads only

Following conditions shall be observed in the cultivation of poppy for poppy heads:

1. The licence holder should pay duty on the area in which he cultivates poppy, at the rates fixed by the State Government on this behalf.

2. The licensee should neither consume any part of the crop by himself nor should dispose it off to others.

3. If the licensee does not sow poppy seeds before the first of December in any year, he should surrender the licence to the officer in charge of the Tehsil, not later than the 15th of December.

4. The licensee should not extract any opium from the poppy heads.

5. The licensee can sell the poppy heads to any person holding a license for the retail or wholesale of opium or any other person authorised by the State Government.

6. The licensee should comply with all provisions of the Opium Act 1878, the Dangerous Drugs Act 1930 and the Narcotic Drugs and Psychotropic Substances Act 1985 and the Rules made thereunder.

SALE OF OPIUM

Sale of opium shall be made from the Government factories at Neemuch and Ghazipur with the permission of the Central or State Government as detailed below:

1. Sale to State Government by the order of Central Government.
2. Sale to manufacturing chemists or other institutions can be effected only under the permit of the State Government. The manufacturing chemists while applying to the State Governments for opium permits shall state the following particulars in their applications.
3. The permit in three copies shall be sent to the concerned factory.
4. The price of opium is fixed by the Central Government from time to time. The price shall be for one kilogram of standard consistency..
5. The amount sanctioned to purchase the opium shall be sent to the factory by bank draft along with the purchase order.
6. The sale of opium mixtures is prohibited except in accordance with the rules prescribed by the State Government in whose jurisdiction the sale takes place.

Offences and Penalties

1. Persons who are convicted outside India for a similar offence earlier will be liable to enhanced punishment for the subsequent offence of the same kind in India.
2. All narcotic drugs and psychotropic substances, materials, apparatus, utensils etc. By means of which an offence has been committed are liable for confiscation.
3. The offences under this Act can be tried only by the presidency or First Class Magistrates. Second-class Magistrates, specially empowered on this behalf can also try offences under this Act.
4. For giving false information about the offence in relation to NDPS to The concerned officer, an individual may be punished with two years Imprisonment or fine or both.
5. The officer refusing to perform duty or showing negligence in Discharge of his duties, imprisonment of one year or fine or both are Possible.
6. Any Authorised Officer can enter into and search building, conveyance Or transport of place and in case of resistance, break open the lock and Door, remove any obstacle to such entry, seize NDPS and other materials, Conveyance, animal used in illicit traffic, detain any person for Interrogation, provided he/she believes that a search warrant or Authorisation cannot be obtained for want of time and if action is delayed, The offender may escape or NDPS may disappear. This action can be taken only after sunset and before sunrise provided, the officer has Authentic information of the crime or a complaint in writing. If this authority is misused by the officer and proved so, he/she is punishable for imprisonment of 6 months or fine of Rs. 1000/- or both.

S. No	OFFENCE	PENALTIES
1.	• For offence in relation to poppy straw, coca plant and leaves, Prepared opium poppy or cannabis plant, • In relation to manufactured drugs and preparations, psychotropic Substances, external dealings • For allowing premises to be used for offence	First conviction - punishment of rigorous imprisonment of 10-20 years and fine of not less than Rupees 1 lakh Subsequent conviction - 15-30 years and fine of Rs 1.5 to 3 lakhs.
2.	For contravention or offence relating to ganja	Punishment is upto 5 years and fine upto Rs.50.000 or both.
3.	Illegal possession of NDPS by an individual in Small quantity for personal consumption	Punishable with 6 months - 1 year imprisonment or fine or both.
4.	For illegal traffic of ndps and also for harbouring offenders or Helping offenders,	imprisonment of 10-20 years And fine of Rs 1-2 lakhs. For subsequent conviction, rigorous Imprisonment is for 15-30 years and fine of rs 1.5-3 lakhs.
5.	Failure to keep accounts or submit returns as required by law,	imprisonment for six months and a fine.
6.	Failure to produce records, licences, permits, authorization etc on demand by authorised persons	punishable with imprisonment up to 5 years or a fine or both.
7.	For giving false information about the offence in relation to NDPS to The concerned officer	punished with two years Imprisonment or fine or both.
8.	The officer refusing to perform duty or showing negligence in discharge of his duties.	imprisonment of one year or fine or both are Possible

9.	For certain serious offences that are committed after previous conviction, If Any individual or firm is found to possess more than following Quantities of NDPS without permission, license,etc, if the Offence is repeated,	The death penalty may be awarded.

MEDICINAL AND TOILET PREPARATION ACT –1955

INTRODUCTION:

Alcohol has excellent solvent properties apart from its preservative mechanism and hence it has found a very important role in the manufacturing of drugs and medicines.

Drinking alcohol is an abuse whereas its usage in toilet preparations may be considered as a luxury. For this reason, alcohol, which is used either for drinking or for the manufacture of toilet preparations such as perfumes, is subject to a much higher rate of excise duty than that used for the manufacture of medicinal preparations which cannot be used as ordinary alcoholic beverages.

Prior to the enactment of this act, each state in India had an Excise manual and a set of rules of its own. Thus, differences existed in the rates of excise duty for the same item in different states, leading to large scale inter-state smuggling of such preparations.

The Act was passed mainly to curb this evil and repealed the laws in force in any state prior to the commencement of this Act. However, any state rules not inconsistent with this Act are still valid and have the same force as if they have been made by an authority in this behalf under this Act.

The Medicinal and Toilet preparations Act was passed in the year 1955 and the Rules were passed in 1956. The Act extends to the whole of India and came into force on 1st April 1957.

OBJECTIVES OF THE ACT:

This Act was passed with the following objectives:

- To provide the collection of levy and duties of excise on medicinal and toilet preparations containing alcohol, narcotic drugs or narcotics.
- To provide for uniformity in the rules and rates of Excise duties leviable on such preparations throughout the country.

DEFINITIONS:

- **Alcohol:** Alcohol means ethyl alcohol of any strength and purity having the chemical composition C_2H_5OH.

  Absolute alcohol means alcohol conforming to the British Pharmacopoeial specifications for dehydrated alcohol.

- **Dutiable goods:** Dutiable goods means the medicinal and toilet preparations specified in the Schedule as being subject to the duties of excise levied under the Act.
- **Medicinal preparation:** Medicinal preparation includes all drugs which are a remedy or prescription prepared for internal or external use of human being or animals and all substances intended to be used for or in the treatment, mitigation or prevention of disease in human beings or animals.
- **Toilet preparation:** Toilet preparation means any preparation which is intended for use in the toilet of the human or in perfuming apparel of any description, or any substance intended to cleanse, improve or alter complexion, hair, skin or teeth, and includes deodorants and perfumes.
- **Bonded manufactory:** Bonded manufactory means the premises approved and licensed for the manufacture and storage of medicinal and toilet preparations containing alcohol, opium, Indian hemp or any other narcotic drug or narcotics on which duty has not been paid.
- **Non-bonded manufactory:** Non-bonded manufactory means the premises approved and licensed for the manufacture and storage of medicinal and toilet preparations containing alcohol, opium, Indian hemp or any other narcotic drug or narcotics on which duty has been paid.

- **Patent or Proprietary medicines:** Patent or Proprietary medicines means any medicinal preparation which bears either on itself or on its container or both, a name which is not specified in a monograph in a Pharmacopoeia, formulary or other publications notified in this behalf by the Central Government in the Official Gazette, or which is a brand name or any other mark such as a symbol, monogram, label, signature or invented words or any writing which is used in relation to that medicinal preparation for the purpose of indicating or so as to indicate a connection in the course of trade between the preparation and some

  person having the right either as proprietor or otherwise to use the name or mark with or without any indication of the identity of that person.
- **Denatured alcohol or Denatured spirit:** Denatured alcohol or Denatured spirit means alcohol of any strength which has been made unfit for human consumption by the addition of substances approved by the Central Government or by the State Government with approval of the Central Government.
- **Rectified spirit:** Rectified spirit means plain denatured alcohol of strength not less than 50.0° over proof and includes absolute alcohol.
- **London proof spirit:** London proof spirit means that mixture of ethyl alcohol and distilled water which at the temperature of 51°F weighs exactly 12/13th parts of an equal measure of distilled water at the same temperature.

- **Restricted preparation:** Restricted preparation means every medicinal and toilet preparation specified in the Schedules and includes every preparation declared by the Central Government as restricted preparation.
- **Unrestricted preparation:** Unrestricted preparation means any medicinal or toilet preparation containing alcohol but other than restricted preparation or a spurious preparation.

LICENSING PROCEDURE:

Manufacturing of alcoholic and narcotic preparations can only be undertaken under the authority of a license granted for the purpose and such a license is issued only if the requisite license for manufacture of drugs under the Drugs and Cosmetics Act and Rules has been first obtained. Application for the license or for its renewal is to be made to Licensing authority who is the excise in the case of a bonded manufactory or ware house and in other cases, such officer as the State government may authorize in this behalf.

A separate application is to be made if more than one kind of license is desired. Where the applicant has more than one place of business, he should obtain a separate license in respect of each such place of business. The application for the license should be submitted in the prescribed form accompanied by the prescribed fee, at least two months before the proposed date of commencement of the manufacture.

The following particulars are required to be submitted in the application for obtaining a license to manufacture dutiable goods in or outside bond:

1) Name and address of the applicant and place and site on which the manufactory is situated or to be constructed. If the applicant is a firm, the name, and address of every partner of the firm, and if it is a company, its registered name, and address, and the names and addresses of its directors, managers, and managing agents.
2) The amount of capital proposed to be invested in the venture.
3) Approximate date from which the applicant desires to commence the manufactory and the statement whether the bonded laboratory will require the services of a whole-time or part time excise officer and whether quarters for the excise staff will be provided within the manufactory.
4) The number and full description of vatts, still and other permanent apparatus and the machinery which the applicant wishes to get up together with the maximum quantity of alcohol and alcohol content in the finished preparations and the maximum quantities by weight of opium, Indian hemp or other narcotic drugs or narcotic and their contents in finished and unfinished preparations.
5) The site and elevation plans of the manufactory/building and also similar plans for the quarter of the Excise Officer together with relevant records.
6) The amount in cash or Government Promissory Notes which the applicant is prepared to furnish for the due performance of the conditions on which the license may be granted.
7) The kind and number of each license under the Drugs and Cosmetics Act held by applicant.
8) A list of all preparations which the applicant proposes to manufacture and/or those manufactured during the preceding year showing the percentage or proportion of alcohol in alcoholic preparations or opium, Indian hemp or another narcotic drug in terms of weight in proportion containing those substances, quoting the pharmacopoeia under which such preparations were proposed to be manufactured.

On receipt of the application, the Licensing Authority may enquire into the following:

- The qualifications and previous experience of technical personnel engaged in the manufacturing operations.
- The equipment of the bonded and non-bonded laboratory.
- The soundness of the applicant's financial position.
- Suitability of the proposed building for the establishment of the manufacturing unit.

The license cannot be sold or transferred. It should be exhibited in a conspicuous part of the licensed premises. Where a licensee sells or transfers his business to another person, the purchaser or the transferee has to obtain a fresh license but for the residue of the period covered by the license, it is issued free of cost.

A licensee can enter into partnership after obtaining the prior sanction of the licensing authority and his license is then suitably amended. If a partnership is dissolved, every partner is required to send a report of dissolution to the licensing authority within ten days.

If a licensee desires to transfer his business to new premises he can do so by informing the licensing authority at least fifteen days in advance, specifying the address of the premises, and getting his license suitably amended.

A license can be revoked, or suspended by the licensing authority if the licensee or any other in his employment is found to have committed a breach of the prescribed conditions or any of provisions of the act or rules, or has been convicted of an offence; after giving him a reasonable opportunity of showing cause against the action proposed to be taken.

The license remains valid for a period of one year and should be renewed thereafter. The application for renewal should be submitted at least one month before the commencement of the year to which it relates.

The licensee also provides a Visit Book paged and stamped by any officer empowered by the Excise commissioner in this behalf, in which the visiting officers may record any remarks when inspecting the licensed premises.

On termination of the period of the license, the licensee has to deliver the Visit Book, the account and the license to such officer as directed by the licensing authority.

All invoices, cash memoranda, permits and other documents relating to the consignments received and dealt with licensee are to be preserved for a year after the year to which they relate.

BONDED MANUFACTORY (OR) BONDED LABORATORY:

Bonded manufactory or bonded laboratory is premises or part of premises approved and licensed for the manufacture and storage of the medicinal and toilet preparations containing alcohol, Indian hemp, narcotic drugs or other narcotics on which duty has not been paid. In this, alcohol is stored and used under supervision of excise officers.

REQUIREMENTS OF BONDED MANUFACTORY:

- Spirit store
- Separate room/rooms for the manufacture of medicinal and toilet preparations.
- Separate room/rooms for the storage of finished medicinal and toilet preparations.
- Accommodation near the entrance for officer-in-charge with necessary furniture.
- Every room should bear a board indicating the name of the room and serial number.
- The pipe of sink or wash basins should be connected to the common drainage pipe of laboratory.
- The gas and electric connection supply should be cut off at the end of day's work.
- Every room should provide specific arrangements of malleable rods of prescribed dimensions and windows should be covered outside with strong netting of mesh of less than 25 mm.
- There shall be only one entrance in the laboratory and one door to each of its compartments.
- The vessels which are intended to hold alcohol and other liquid preparations should bear a distinct serial number and full capacity.
- Vessels containing alcohol, narcotic and finished preparations should be secured with excise ticket locks.
- For any additions or alterations in bonded premises, the manufacturer should take the prior permission of Excise commissioner.

PROCEDURE FOR OBTAINING RECTIFIED SPIRIT FROM DISTILLERY OR WAREHOUSE:

The spirit required for the manufacture in bond shall be obtained on an indent in triplicate countersigned by the officer-in-charge of the laboratory of approved spirit store or distillery. On the receipt of such indent, distillery or warehouse officer shall issue the spirit under appropriate permit and send advise portion of such permit to officer-in-charge. Excise officer of bonded manufactory shall verify the strength and volume of rectified spirit. He shall make the entry of such supply in register. Rectified spirit shall be then verified in volume, strength, entered in the register and then store in spirit store. Spirit shall be stored in permanent vessels of spirit stores of bonded laboratory. The cost of rectified spirit shall be paid by the licensee to the respective distillery or warehouse officer.

ISSUE OF RECTIFIED SPIRIT FROM THE SPIRIT STORE:

Manufacturer shall calculate the quantity of spirit based on the label and shall hand it over to the officer-in-charge. Then the officer-in-charge shall issue the spirit to the manufacturer. The spirit issued shall be immediately added to other ingredients of preparations in presence of officer-in-charge. After completion of manufacture of medicinal reparation or toilet preparation, it shall be removed to finished goods store.

STORAGE OF FINISHED PRODUCTS:

When the medicinal reparation or toilet preparation so manufactured enters in finished store it should be measured and stored in vessels, jars or bottles after making entry in register. Each jar or bottle should contain not less than 2273 ml of finished preparation. Each container shall bear the label with following particulars

a) Name of preparation
b) Batch number
c) Alcoholic strength
d) Name of manufacturer
e) Actual contents in liters
f) Date of storage

The containers or vessels should be arranged so as to follow easy identification of each batch. The finished preparation should be stored for three years or more with the permission of Excise Commissioner.

ISSUE OF PREPARATIONS FROM BONDED LABORATORY:

For the issue of medicinal and toilet preparations licensee should make an application to Excise officer-in-charge. Excise officer-in-charge after checking the entries and ensuring the duty payable shall issue a permit and allow required quantities to be removed. Medicinal and toilet preparations should be issued in bottles or containers of not less than 57 ml capacity. However, in exceptional cases, such preparations may be filled in smaller capacity bottles or containers with the prior written order of Excise Commissioner. Dutiable goods are delivered from 6 a.m. to 6 p.m. except Sundays and holidays. Alcoholic preparations are issued on the payment of excise duty.

NON BONDED MANUFACTORY (OR) NON BONDED LABORATORY:

Non bonded manufactory or non bonded laboratory is premises or part of premises approved and licensed for the manufacture and storage of the medicinal and toilet preparations containing alcohol, Indian hemp, narcotic drugs or other narcotics on which duty has been paid. In this, manufacture and sale of preparations are allowed from sunrise to sunset and on such days hours are fixed by the Excise Commissioner. Alcohol is stored and used under supervision of excise officers.

REQUIREMENTS OF NON BONDED MANUFACTORY:

1) The premises of non bonded manufactory should be separated from the other portion.
2) There should be a separate 'spirit store', 'laboratory' and 'finished store' with windows fitted with malleable iron rods and windows should be covered on the inside with strong netting of mesh of less than 25 mm.
3) There should be only one entrance in the laboratory and one door to each of its compartments.
4) The pipes from sink or wash basins should be connected to the common drainage pipe of laboratory.
5) The gas and electric connection supply should be cut off at the end of day's work.
6) There should be a separate spirit stores for spirit purchased at different rates of duty.
7) There should be a separate finished stores for medicinal and toilet preparations.

In case of small scale manufacture where the consumption of alcohol is less than 500 liters and for those who dispense medicinal preparations to their patients only, above conditions will be relaxable.

MANUFACTURE AND STORAGE OF NON- BONDED PREPARATIONS:

Manufacture of non bonded preparations should be carried out only at the licensed premises. Each preparation should be given batch number and should be registered. Finished preparations should be stored at respective finished stores and arranged in such way that it can be easily checked from the accounts register. The entry regarding storage of bulk drugs should be made in stock register from time to time.

PROCEDURE FOR OBTAINING RECTIFIED SPIRIT IN NON BONDED LABORATORY:

The rectified spirit required for medicinal and toilet preparation is obtained from distillery or spirit warehouse approved by Excise Commissioner. The manufacturer shall calculate the required quantity of spirit based on formula of the preparations in pharmacopoeia or formula on the label and hand it over to the officer in charge. Then officer-in-charge shall issue spirit to the manufacturer. The spirit issued shall be immediately added to other ingredients of preparations in presence of officer-in-charge. After completion of manufacture of medicinal preparation or toilet preparation, it shall be removed to finished goods store.

EXEMPTION FROM EXCISE DUTY:

Government may in public interest exempt any dutiable goods form excise duty. The supply of medicinal preparations containing alcohol is exempted from excise duty to the following institutions

- Hospitals and dispensaries supervised by the Central Government or State Government.
- Charitable hospitals and dispensaries under local bodies.
- Medical stores of Central Government or State Government.
- Any institution certified by District Medical officer supplying medicines free to the poor patients.
- Medical store depot of Central Government or State Government.

WARE HOUSING OF ALCOHOLIC PREPARATIONS:

- Bonded warehouses can be established anywhere in India to deposit dutiable goods.
- Duty paid goods or other than dutiable goods cannot be deposited in bonded warehouses.
- Manufacturers or dealers should make an application to Excise Commissioner to get the license for bonded warehouse.
- They should furnish a bond in prescribed form along with security for payment of excise duty on the removal of medicinal and toilet preparations as per the terms and conditions of Act and rules.
- When the goods are to be removed from one warehouse to another the consigner should make an application in triplicate to the officer in-charge with necessary information at least 24 hours before the removal of medicinal and toilet preparations.
- The Officer in-charge should take the accounts of those preparations and send the duplicate copy to the Officer in-charge of the warehouse of destination and triplicate copy will be sent to the consignee.
- When such preparations are received to another warehouse, the consignee should present such preparations along with the triplicate application and transport it with the permission of Officer in-charge.
- Then he prepares rewarehousing certificate in duplicate and triplicate and returns the application to the Officer in-charge of warehouse and triplicate to the consigner.
- The consigner shall present such triplicate copy of application with warehousing certificate to the officer in-charge of warehouse within 90 days of the issue of transport permit to him.

MANUFACTURE OF AYURVEDIC, HOMEOPATHIC, PATENT & PROPRIETARY PREPARATIONS:

AYURVEDIC PREPARATIONS:

- 'Asavas' and 'Aristas' are the principal types of Ayurvedic preparations which contain self generated alcohol.

- The pharmacopoeias that are used in various States are presently recognized as Ayurvedic pharmacopeias.
- Ayurvedic preparations containing self-generated alcohol in which the alcohol content does not exceed 2% proof spirit are deemed to be non-alcoholic and hence are exempted from the payment of the excise duty.
- Preparations containing more than 2% alcohol but not capable of consumption as an ordinary alcoholic beverage are also exempted from excise duty.
- The preparations which can be consumed as alcoholic beverages are liable to a duty of Rs. 1 per L.P. liter.
- Registered Ayurvedic Practitioners of good standing may be allowed to manufacture and dispense such preparations free of duty, provided, they take license and use preparations only for their patients.
- Ayurvedic preparations made by distillation or to which alcohol is added at any stage of manufacture are treated as preparations capable of being used as ordinary alcoholic beverages and hence are liable to a duty of Rs. 30 per L.P. liter.

HOMEOPATHIC PREPARATIONS:

All homoeopathic preparations containing alcohol are classified as being consumed as ordinary alcoholic beverages and attract duties prescribed for such class of preparations falling under the category of restricted preparations.

For Homoepathic preparations capable of consumption as ordinary alcoholic beverages, the excise duty of 4% *ad valorem* is required to be paid.

PATENT AND PROPRIETARY PREPARATIONS:

All Allopathic preparations containing alcohol can be categorized into the following two types:

1) Official preparations made strictly according to the formulae given in the current editions of B.P., B.P.C., I.P., U.S.P., N.F.(U.S.), any other pharmacopoeia recognized under the Drugs and Cosmetics Act, 1940 by the Government of India, and Veterinary Codex recognized by the Government of India.

2) Non-official allopathic preparations referred to as proprietary preparations which are prepared according to the allopathic system of medicine and conform strictly to the formula displayed on the label.

Medicinal and toilet preparations capable of being consumed as ordinary alcoholic beverages are referred to as 'restricted preparations' and are enlisted in the Schedule.

All other standard preparations and proprietary preparations not being capable of being consumed as alcoholic beverages are referred to as 'unrestricted preparations.

Any of the unrestricted preparations, if misused widely, may be declared to be restricted preparations by the Central Government either on the request of the State Government or on its own; and on the advice of the Standing Committee. Any new proprietary preparation is presumed to be a restricted preparation unless declared to the contrary by the Central Government on the advice of the Standing Committee. Any manufacturer wanting to manufacture a proprietary preparation should submit two samples of the preparation together with its formula to the State Government. The State Government shall then forward the samples to the Central Government which seeking the advice of the Standing Committee, will declare whether the sample is to be categorized as a restricted or an unrestricted preparation.

The Standing Committee consists of the following members;

1) Drugs Controller of India.
2) Chief Chemist, Central Revenues Laboratory.
3) One pharmacologist nominated by the Central Government.
4) The adviser on Indigenous System of Medicine, Ministry of Heath, Family Planning and Urban Development.

The Committee advises the Central Government on all matters connected with the technical aspects of administration of the Act and the Rules and particularly whether (i) a particular preparation is to be treated as a genuine medicinal or toilet preparation for the purposes of the Act; and if so (ii) whether it should be treated or continue to be treated as a restricted or unrestricted preparation.

THE PHARMACY ACT 1948

The recommendations of Drugs Enquiry Committee and Health Survey and Development Committee, laid the foundation for the enactment of the Pharmacy Act, 1948. **On** 4th **march, 1948,** the Statutory control on the pharmacy education in the country was established with the enactment of the Pharmacy Act, 1948 with the following preamble. "An Act to regulate the profession of pharmacy". Whereas it is expedient to make letter provision for the regulation of the profession and practice of pharmacy and for that purpose to constitute Pharmacy Councils.

Short Title

(1) This Act may be called the Pharmacy Act, 1948.

(2) It extends to the whole of India.

(3) It shall come into force at once, but Chapters III, IV and V shall take effect in a particular State from such date provided that where on account of the territorial changes brought about by the reorganization of States on the 1st day of November, 1956, Chapters III, IV and V have effect only in a part of a State, the said Chapters shall take effect in the remaining part of that State from such date as the State Government may in like manner appoint.

OBJECTIVES OF PHARMACY ACT

The prime aim of pharmacy is to safeguard the health of the people by making available proper medicaments to the people. Hence Pharmacists should have a thorough knowledge of the medicines. The Pharmacy Act was enacted in 1948 with the following objects.

1. To provide uniform education and training to the persons who are willing to enter into the profession of pharmacy throughout our country.

2. To maintain control over the persons entering the profession of Pharmacy by registration of pharmacists in every state and maintaining records thereof (aforesaid).

3. Extensive amendments have been made to the Act to stream-line the functionary organs and to plug certain loopholes in the years 1956, 1959, 1960, 1972, 1976, 1981 and 1991. This Act consists of five chapters.

The Pharmacy Act enacted by Ministry of Health and Family Welfare, Government of India is covered under 5 Chapters which encompass 46 sections. The major amendment to the Act was made in 1976 to Section 42 of the Act wherein after cutoff date of 151 November, 1983, the drug stores in the country would be run under the supervision of registered pharmacists.

The Chapters covered under the Pharmacy Act are as follows:

Chapter I -Introductory

Chapter II -Pharmacy Council of India (PCI)

Chapter III- State Pharmacy Council (SPC)

Chapter IV- Registration of Pharmacists

Chapter V- Miscellaneous

The Chapters I and II came into force immediately on enactment of the Act. Chapters III, IV and V were to be implemented within the timeframe given by the Central Government to the State Government by publication into the Official Gazette or the respective Union Territory. First Pharmacy Council of India was constituted in 1949. First Education Regulations (E.R) were to be framed by 1952 and effectively implemented within 3 years of their framing.

Definitions

1. **"agreement"** means an agreement entered into under section 20;

2. **"approved"** means approved by the Central Council under section 12 or section 14.

3. **"Central Council"** means the Pharmacy Council of India constituted under section 3.

4. **"Central Register"** means the register of pharmacists maintained by the Central Council under section 15A.

5. **"Executive Committee"** means the Executive Committee of the Central Council or of the State Council, as the context may require.

6. **"Indian University"** means a University within the meaning of section 3 of the University Grants Commission Act, 1956 (3 of 1956), and includes such other institutions, being institutions established by or under a Central Act, as the Central Government may, by notification in the Official Gazette, specify in this behalf.

7. **"medical practitioner"** means a person--

(i) holding a qualification granted by an authority specified or notified under section 3 of the Indian Medical Degrees Act, 1916 (7 of 1916), or specified in the Schedules to the Indian Medical Council Act, 1956 (102 of 1956); or

(ii) registered or eligible for registration in a medical register of a State meant for the registration of persons practicing the modern scientific system of medicine; or

(iii) registered in a medical register of a State, who, although not falling within sub-clause *(i)* or sub-clause *(ii)* is declared by a general or special order made by the State Government in this behalf as a person practicing the modern scientific system of medicine for the purposes of this Act; or

(iv) registered or eligible for registration in the register of dentists for a State under the Dentists Act, 1948 (16 1948); or

(v) who is engaged in the practice of veterinary medicine and who possesses qualifications approved by the State Government;]

8. **"prescribed"** means in Chapter II prescribed by regulations made under section 18, and elsewhere prescribed by rules made under section 46;

9**. "register"** means a register of pharmacists prepared and maintained under Chapter IV;

10. **"registered pharmacist"** means a person whose name is for the time being entered in the register of the State in which he is for the time being residing or carrying on his profession or business of pharmacy;

11**. "State Council"** means a State Council of Pharmacy constituted under section 19, and includes a Joint State Council of Pharmacy constituted in accordance with an agreement under section 20;

12. **"University Grants Commission"** means the University Grants Commission established under section 4 of the University Grants Commission Act,1956 (3 of 1956).

The Pharmacy Council of India

On 9th March, 1949, the Pharmacy Council of India (PCI) was constituted to fulfil the objectives of the Pharmacy Act, 1948 by way of:

(i) Prescribing the minimum standard of education required for qualifying as a pharmacist i.e., framing of Education Regulations prescribing the conditions to be fulfilled by the institutions seeking approval of the PCI for imparting education in Pharmacy.

(ii) Ensuring uniform implementation of the educational standards throughout the country.

(iii) Approving the courses of study and examination for pharmacists i.e., approval of the academic training institutions providing pharmacy courses.

(iv) Withdrawing approval, if the course of study does not continue to be in conformity with the educational standards prescribed by the PCI.

(v) Approving qualifications granted outside the territories to which the Pharmacy Act, 1948 extends i.e., the approval of foreign qualification.

(vi) Maintaining Central Register of Pharmacists.

Composition of Central Council of PCI

Ex-Officio Members	Officio Members Elected Members	Nominated Members
(i) Director-General of Medical and Health Services, Government of India or his/her nominee.	(i) Six members of whom atleast one teacher of each of the subjects of Pharmacy, Pharmaceutical Chemistry, Pharmacology and Pharmacognosy elected by University Grants Commission from amongst teacher of Indian Universities or affiliated colleges imparting diploma or degree in pharmacy.	(i) Six members nominated by the Government of India, Ministry of Health and Family Welfare, of which at least 4 should possess degree or diploma in pharmacy qualification and should be practicing pharmacy or pharmaceutical chemistry.
(ii) Drugs Controller General of India or his/her nominee.	(ii) One member elected by from amongst its members of Medical Council of India.	(ii) One representative each of University Grants Commission (UGC) and All India Council for Technical Education (AICTE).
(iii) Director, Central Drugs Laboratory (CDL), Kolkatta.	(iii) One member each elected by the State Pharmacy Council of each State who should be a registered pharmacist.	(iii) One member representing each State Government or Union Territory who shall be a registered pharmacist nominated by the respective State Government or Union Territory.

The Central Council of PCI elects the President, Vice-President and five members of the Executive Committee CEC) from amongst its members by election conducted in accordance with the norms laid down in the Pharmacy Act.

Any dispute arising out of the election of Executive Committee of PCI is referred to the Ministry of Health and Family Welfare, Government of India, whose decision shall be final.

The President or in his absence Vice-President chairs the meetings of the Central Council and the Executive Committee.

The Central Council meets at least once in a year whereas, the Executive Committee meets more frequently depending on the quantum of work usually, 4 times in a year.

The term of the President, Vice-President and the Council Members is for 5 years unless otherwise, re-elected or renominated, as the case may be. Ex-officio members of PCI hold their membership by virtue of their designation and cease to be the members on retirement or replacement.

The Director General of Health Services, Government of India and the Drugs Controller General of India may send their nominees in writing for attending a specific meeting in case they are unable to attend the meeting. Any member of the Central Council or Executive Committee who remains absent continuously for 3 meetings without intimation or without any valid reason is eligible to be disqualified as a member of the Council.

The Council appoints the Secretary or Registrar of PCI, who can also act as Treasurer. The Council appoints the other staff including Deputy Secretary or Assistant Secretaries to run the office.

The Central Council elects Chairmen of Education Regulations, Professional Pharmacy and Law Committees. The President and Vice President of PCI are Ex-officio members of these sub-committees.

The Council is a corporate body, a statutory organization which can sue or be sued. The Council can hold movable and immovable property and maintain accounts and registers. The minutes of the meetings of Central Council are required to be sent to Ministry of Health and Family Welfare, Government of India and all the decisions of the approval or otherwise of the institutions or colleges are published in the Official Gazette.

FUNCTIONS OF PHARMACY COUNCIL OF INDIA

1. Frame the rules: The Pharmacy Council of India frame the rules for fixing duties and powers of the Executive Committee, President, Vice-president, Secretary and Inspectors.

2. Furnish annual activities summary: The Council has to furnish a summary of its annual activities and accounts to the Central Government.

3. Education Regulations: The Council is responsible for framing the rules and regulations for approving the institutions which conduct Pharmacy courses. These regulations are known as Education Regulations (ER).

4. Central Register: The PCI has to maintain a "Central Register" containing the names of all registered pharmacists of all States.

Education Regulations (ER)

Under section 10 of the Pharmacy Act, The Pharmacy Council of India makes regulations called "Education Regulations" (ER) which prescribe the minimum standards of education required for

Pharmacists. (i.e) minimum qualification for entry into the course, duration of the course, subjects to study, minimum marks for passing the exam, and practical and hospital training.

Education Regulation (ER) basically Prescribes-

(i) the standard of education for qualification as a pharmacist i.e. minimum qualification for admission to the course, duration of the course, the syllabus, mode of examination, minimum marks for passing the examination, nature and duration of practical training, etc.

(ii) minimum conditions which an institution has to provide for seeking approval of the PCI for conducting a course of study for pharmacists.

(iii) conditions to be fulfilled by the Examining Authority for approval for conduct of examinations.

(iv) conditions to be fulfilled by the institutions to be recognized for giving the practical training.

(v) Practical training contract forms for the pharmacists.

The following education regulations are revised in the pharmacy education

1. Education regulation 1991
2. Education regulation 2014
3. Education regulation 2017
4. B.Pharm course regulation 2020

EDUCATION REGULATIONS 1991 (ER 91)

The Education Regulation ER 1991 replaced the previous Education Regulation ER 1981. This lays down the following.

1. Minimum qualification for admission to the course.

2. Nature and period of study.

3. Nature and period of practical training to be undergone after completion of a regular course.

4. Equipment and facilities to be provided for students by the Institutions running approved courses of study.

5. Conditions to be fulfilled by Institutions giving practical training.

6. Conditions to be fulfilled by the authorities holding approved examinations and the minimum marks for passing the subjects.

7. PCI is assigned to inspect the physical facilities of the educational institution in terms of infrastructure, staff, conducted sessional examination etc.

8. The ER 91 covers 3 parts of the D.Pharm course. (Part I & II is academic education and Part III is Practical training)

Section 11. Application of Education Regulations to States.

At any time after the constitution of the State Council under Chapter III and after consultation with the State Council, the State Government may, by notification in the Official Gazette, declare that the Education Regulations shall take effect in the State: Provided that where no such declaration has been made, the Education Regulations shall take effect in the State on the expiry of three years from the date of the constitution of the State Council.

Section 12. Approved courses of study and examinations.

(1) Any authority in a State which conducts a course of study for pharmacists may apply to the Central Council for approval of the course, and the Central Council, if satisfied, after such enquiry as it thinks fit to make, that the said course of study is in conformity with the Education Regulations, shall declare the said course of study to be an approved course of study for the purpose of admission to an approved examination for pharmacists.

(2) Any authority in a State which holds an examination in pharmacy may apply to the Central Council for approval of the examination, and the Central Council, if satisfied, after such enquiry as it thinks fit to make, that the said examination is in conformity with the Education Regulations, shall declare the said examination to be an approved examination for the purpose of qualifying for registration as a pharmacist under this Act.

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

Section 13. Withdrawal of approval.

(1) Where the Executive Committee reports to the Central Council that an approved course of study or an approved examination does not continue to be in conformity with the Education Regulations, the Central Council shall give notice to the authority concerned of its intention to take into

consideration the question of withdrawing the declaration of approval accorded to the course of study or examination, as the case may be, and the said authority shall within three months from the receipt of such notice forward to the Central Council through the State Government such representation in the matter as it may wish to make.

(2) After considering any representation which may be received from the authority concerned and any observations thereon which the State Government may think fit to make, the Council may declare that the course of study or the examination shall be deemed to be approved only when completed or passed, as the case may be, before a specified date.

15A. The Central Register.

(1) The Central Council shall cause to be maintained in the prescribed manner a register of pharmacists to be known as the Central Register, which shall contain the names of all persons for the time being entered in the register for a State.

(2) Each State Council shall supply to the Central Council five copies of the register for the State as soon as may be after the first day of April of each year, and the Registrar of each State Council, shall inform the Central Council, without delay, all additions to, and other amendments in, the register for the State made from time to time.

(3) It shall be the duty of the Registrar of the Central Council to keep the Central Register in accordance with the orders made by the Central Council, and from time to time to revise the Central Register and publish it in the Gazette of India.

(4) The Central Register shall be deemed to be public document within the meaning of the Indian Evidence Act, 1872 (1 of 1872) and may be proved by the production of a copy of the Register as published in the Gazette of India.

Section 16. Inspection.

(1) The Executive Committee may appoint such number of Inspectors as it may deem requisite for purposes of this Chapter.

(2) An Inspector may--

(a) inspect any institution which provides an approved course of study;

(b) attend at any approved examination;

(c) inspect any institution whose authorities have applied for the approval of its course of study or examination under this Chapter, and attend at any examination of such institution.

(3) An Inspector attending at any examination under sub-section *(2)* shall not interfere with the conduct of the examination, but he shall report to Executive Committee on the sufficiency of every examination he attends and on any other matter in regard to which the Executive Committee may require him to report.

(4) The Executive Committee shall forward a copy of every such report to the authority or institution concerned, and shall also forward a copy together with any comments thereon which the said authority or institution may have made, to the Central Government and to the Government of the State in which the authority or institution is situated.

Section 17. Information to be furnished.

(1) The Central Council shall furnish copies of its minutes and of the minutes of the Executive Committee and an annual report of its activities [1]*** to the Central Government.

(2) The Central Government may publish in such manner as it may think fit any report, [2][or copy], furnished to it under this section or under section 16.

Section 19. Constitution and composition of State Pharmacy Council (SPC)

State Pharmacy Council is charged with the responsibility of maintaining an up-to-date register of the registered pharmacists within the State. With an amendment to Section 42 of the Pharmacy Act, no person other than registered pharmacists can compound, dispense or do the retail business pertaining to medicines.

The composition of State Pharmacy Council constituted by the State Government or the Joint State Pharmacy Council constituted by participating States is as follows:

State Pharmacy Council	Joint State Pharmacy Council (Section 21)
I Elected Members	
(i) Six members elected by registered pharmacists of the particular State. (ii) One member who is a registered medical practioner elected by the Medical Council of State	(i) 3-5 members elected from Registered pharmacists of each participating State. (ii) One registered Medical Practioner elected by the Medical Council of each participating State.

II Nominated Members	
(iii) Five members nominated by each State of which at least 3 should be Degree or diploma holders in pharmacy or pharmaceutical chemistry	(iii) 2-4 members nominated from each participating State of which more than 50% shall be the persons with degree or diploma qualification in pharmacy or pharmaceutical chemistry
III Ex-Officio Members	
(iv) (a) Chief Administrative Office or Incharge, Medical and Health Services of State or his/her nominee	(iv) (a) Chief Administrative Officer or Incharge, Medical and Health Services of each participating State or his/her nominee
(b) Officer Incharge for Drugs and Cosmetic Act, 1940 of each State, or his/her nominee	(b) Officer Incharge for Drugs and Cosmetics Act, 1940 of participating State or his/her nominee
(c) One Government Analyst under DCA, 1940 nominated by the State Government	(c) One Government Analyst under DCA, 1940 nominated by each participating State.

The term of State Pharmacy Council is for 5 years. The Council elects President and Vice-president of State Pharmacy Council who hold office for 5 years, provided he/she continues as a member of Council.

The Executive Committee of State Pharmacy Council (SPC) comprises of 5 members elected from amongst its members. The SPC appoints a Registrar who shall be the Secretary of the Council and he/she may also be the Treasurer.

The appointment of other officers, fixing of the salaries and payment of allowances to the members are also done by SPC. The SPC is Statutory Body with perpetual succession, can hold property with a common seal and sue or be sued.

State Pharmacy Council is custodian of the register of registered pharmacists in the State. The Council sends five copies of register to Pharmacy Council of India. State Pharmacy Council can fix the registration fee on annual basis or a long-term basis.

It has to send l/4th of its collection of registration fee every year before 1st of May to Pharmacy Council of India. State Pharmacy Council, from time to time, keeps informed the concerned State Government about its activities. The SPC also organizes continuing education programmes for registered pharmacists with a view to update their professional skill and knowledge. A State Pharmacy Council, with permission of the Government, may appoint Inspectors with prescribed qualification under section 26-A to inspect any premises where drugs are compounded or

dispensed, enquire in qualification of person engaged in professional activity, investigate complaint in writing and institute prosecution in consultation with SPC. The State Council shall before the end of June in each year pay to the Central Council a sum equivalent to one-fourth of the total fees realized by the State Council under this Act during the period of twelve months ending on the 31st day of March of that year under section 44.

Functions of state pharmacy council

1. The State Pharmacy Council may fix rates of remuneration to be paid to its officers, and allowances etc., to its members.

2. The Council has to furnish a summary of its annual activities and accounts to the State Government and to the Pharmacy Council of India.

3. The Council has to pay one-fourth of the fees collected by them during the period of I year to the Pharmacy Council of India.

4. The State Pharmacy Council can appoint Inspectors to inspect premises where drugs are dispensed or compounded and to investigate any complaints received. If the complaints are proven, the Executive Committee of the State Council can take action against those authorities.

5. According to the registration of Pharmacists and maintenance of the Register.

Section 20. Inter-State agreements.

(1) Two or more State Governments may enter into an agreement to be in force for such period and to be subject to renewal for such further periods, if any, as may be specified in the agreement, to provide--

(a) for the constitution of a Joint State Council for all the participating States, or

(b) that the State Council of one State shall serve the needs of the other participating States.

(2) In addition to such matters as are in this Act specified, an agreement under this section may--

(a) provide for the apportionment between the participating States of the expenditure in connection with the State Council or Joint State Council;

(b) determine which of the participating State Governments shall exercise the several functions of the State Government under this Act, and the references in this Act to the State Government shall be construed accordingly;

(c) provide for consultation between the participating State Governments either generally or with reference to particular matters arising under this Act;

(d) make such incidental and ancillary provisions, not inconsistent with this Act, as may be deemed necessary or expedient for giving effect to the agreement.

(3) An agreement under this section shall be published in the Official Gazettes of the participating States.

Functions of joint state pharmacy council

1. The State Pharmacy Council of one State is to serve the needs of the other State or state.

2. The Council has to Prepare annual accounts statements and the amount of expenditure is to be shared by all the States.

3. According to the registration of Pharmacists and maintenance of the Register.

REGISTRATION OF PHARMACIST

1. First Register of Pharmacist: Immediately after independence until SPC was constituted.
2. Subsequent Register: During the period of implementation of Pharmacy Act and framing of Educational Registrations.
3. Regular Register: After Education Regulations came into force.

1. First Register of Pharmacist

Immediately after independence, there was shortage of pharmacists to run the hospitals and drug stores. Due to chaotic condition prevailing then, the State Governments were asked to appoint Registration Tribunal of 3 members of which one shall act as Secretary-cum Treasurer. In many States, this Registration Tribunal consisted of professional and judiciary persons. Registration Tribunal fixed last date for submitting application for registration as pharmacists provided he/she fulfilled following qualifications.

1. Minimum age of 18 years on date of application and

(a) If he/she holds degree/diploma in pharmacy or pharmaceutical chemistry or an approved Chemist and Druggist diploma issued by any State Government or a prescribed qualification granted by an authority outside India.

Or

(b) A graduate in any discipline with a minimum of three years experience in compounding and dispensing in a hospital or dispensing at any other place where drugs are regularly dispensed on prescriptions of medical practitioners.

Or

(c) A person who has passed examination recognized as adequate by the State Government for compounders or dispensers.

Or

(d)A person with minimum of five years experience in compounding or dispensing in a hospital or dispensary on prescriptions of medical practitioners.

After receipt of applications, the Registration Tribunal scrutinized the same and directed Secretary to enter the names of eligible candidates in Register as pharmacists. Any person aggrieved or not satisfied with the decision of Registration Tribunal was given 60 days time to appeal to a Special Appelate Authority, constituted for this purpose by the State Government and the decision of Appelate Authority was final and binding. After the formation State Pharmacy Council, the register was handed over to it.

2. Subsequent Register

For the interim period until Education Regulations were enforced in the State, the names of eligible candidates were included in the register of pharmacists on fulfilling the following criteria.

1. Minimum age of 18 years

2. A person satisfying conditions prescribed with the prior approval of the Central Councilor conditions entitling a person to have his name entered on the first register, provided he is a matriculate.

Or

A person with matriculate qualification who is a registered pharmacist in another State.

3. Regular Register

After implementation of Education Regulations framed by the Pharmacy Council of India, only a diploma in pharmacy holder of an institution approved by PCI who has undergone practical training of 500 hours after completion of D. Pharm. course is only eligible for registration as pharmacist.

There were two major amendments to the Pharmacy Act, 1948 for the purpose of registration of pharmacists in 1959 and 1976.

According to the amendment to Act in 1959, the First Register was once again opened for consideration of following categories of people for the purpose of registration as pharmacists.

(a) The persons who were displaced as a result of partition of country from erstwhile territor; of India which is part of Pakistan and who were carrying on the business or profession of pharmacy

as their principal means of livelihood on or before 4th March, 1948, and satisfy the conditions for inclusion in the First Register of Pharmacists.

(b) The citizens of India who have been carrying on the business or profession of pharmacy in any country outside India, provided they are qualified for registration in First Register.

(c) The persons who resided in an area which has become a territory of India and they satisfy the conditions for registration in First Register.

(d) The persons belonging to an area which has become part of other State as a result of State Reorganization on 1st November, 1956. Even though, the First Registration in such a State was closed, the persons in this category were enrolled as pharmacists in First Register provided they have fulfilled the criteria laid down for enrollment in the First Register.

(e) A person who has not responded to the call of registration in First Register eventhough he/she was qualified to be registered, due to ignorance or any other reason was once again given one time opportunity for registration.

The amendment to the Pharmacy Act in 1976 had considered following categories of people for registration as pharmacists:

(a) The displaced persons as a result of Bangladesh war or from Sri Lanka, Burma and Uganda or any other country between 14th April, 1957 and 25th March, 1971 provided they were carrying on business or profession of pharmacy as their principal means of livelihood for a period of not less than five years. This clause was also applicable to the persons affected by Goa Liberation Movement who was practicing pharmacy as per requirement in First Register.

(b) The Persons identified in the provision for the Drugs and Cosmetic Act, 1940 as qualified persons until 31st December, 1969 who were professing pharmacy were also considered for registration as pharmacists. These amendments were necessitated on humanitarian grounds and to attend to genuine difficulties in preparing the First Register. However, as on today the registration of pharmacists is strictly for diploma or degree in pharmacy holders from an institution approved by PCI.

The State Pharmacy Council maintains up-to-date Register of pharmacists after collection of requisite fees including following information.

(i) Full Name of pharmacist and his/her residential address

(ii) The date of his/her first admission to the Register

(iii) Qualification, year of passing of qualifying examination

(iv) Professional address

(v) Date of Birth and any other particulars as prescribed.

The Registrar appointed by SPC makes necessary entries in the Register and issues the receipt for registration which is documentary evidence for registration. A certificate of registration is also issued by State Pharmacy Council on payment of fees. Anyone who is aggrieved by the decision of Registrar for non-inclusion of his/her name in Register may appeal to SPC within three months and the decision of SPC regarding registration shall be final. The Registrar, on payment of fees, may issue duplicate certificate only on confirmation that the original is lost or destroyed.

Removal of Name from Register

Subject to provisions of Section 36 of the Act, the Executive Committee may order for removal of name of a person from Register, after giving reasonable opportunity to person concerned, on following grounds:

(i) A person whose name has been entered in the Register by error or an account of misrepresentation or suppression of fact,

(ii) A person who gives false information about himself/herself,

(iii) A person who submits false certificate or false document in support of his/her registration,

(iv) A person who is convicted of an offence in connection with his/ her profession,

(v) A person who was indirectly involved in commitment of professional offence and if it is proved that the offence was instigated or connived at by the registered pharmacist.

A person aggrieved by order of State Pharmacy Council for removal of name from Register may appeal to the State Government within one month and the order of the State Government upon such appeal shall be final.

A person whose name has been removed from the Register shall surrender forthwith his/her certificate of registration to the Registrar of SPC and the name so removed shall be published in the Official Gazette.

Offences and Penalties

Dispensing by Unregistered Person: Under Section 42 of the Act, no person other than a registered pharmacist shall compound, prepare, mix, or dispense any medicine on the prescription of a medical practitioner. Whoever contravenes this provision is punishable with imprisonment of six months or fine of Rs. 1000.00 or both. This shall not apply to the dispensing by a practitioner for his own patients. The penalty for falsely claiming to be registered pharmacist is Rs. 500.00 for first conviction and imprisonment extending to six months or fine of Rs. 1000.00 or both for subsequent conviction.