DRUGS AND COSMETICS ACT, 1940 AND ITS RULES 1945

……

BP505T-UNIT-I **10 Hours**

Drugs and Cosmetics Act, 1940 and its rules 1945:

Objectives, Definitions, Legal definitions of schedules to the Act and Rules

Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties.

Manufacture of drugs – Prohibition of manufacture and sale of certain drugs, Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license.

……

Introduction

Drug is an essential commodity and is required to be regulated in terms of its import, manufacture, sale and distribution. The Central Government and State Government are charged with the responsibility of providing the drugs of desired quality to the needy patients and in order to ensure this primary obligation of the Government, the network is required to be developed to root out adulterated, misbranded and spurious drugs from the society.

Objectives

1. For preventing substandard in drugs, probably for treatment and preserving high medical standards.
2. For controlling the import, manufacture, distribution, and sale of drugs and cosmetics by licensing.
3. For ensuring that manufacture, distribution, and sale of drugs and cosmetics is done by qualified persons only.
4. For controlling the manufacture, and sale of Ayurvedic, Siddha, and Unani drugs.
5. Establishment of Drugs Technical Advisory Board (DTAB) and Drugs Consultive Committees (DCC) for Allopathic and Allied drugs and Cosmetics [1].

Important Definitions

1. **Drug**

It Includes:

(i) All medicines for internal or external use of human beings or animals and substances used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals including, preparations applied on human body for the purpose of repelling insects like mosquitoes.

(ii) The substances other than food which may affect the structure or any function of the human body or used for the destruction of insects or vermin which cause disease in human beings or animals as specified from time to time by the Central Government by notification in the Official Gazette.

(iii) The substances used as components of a drug including, empty gelatin capsules.

(iv) The devices used for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette after consultation with the Drugs Technical Advisory Board (DTAB).

2. Cosmetic

It means any article intended to be sprayed, poured, rubbed or sprinkled on, or introduced into, or applied to the human body or its any part for cleansing, beautifying, promoting attractiveness or altering the appearance. It also includes any articles intended for use as a component of cosmetic.

3. Ayurvedic, Siddha or Unani Drugs

These include all medicines used for internal or external purposes or used in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals and manufactured exclusively in accordance with the formulae described in the authoritative books of Ayurvedic, Siddha and Unani Tibby Systems of Medicines specified in the First Schedule to the Drugs and Cosmetics Act, 1940.

4. Gudakhu

It is a tobacco product used for rubbing against human teeth. It contains tobacco powder, lime and molasses along with red mineral matter. It is a cosmetic within the provisions of the Act.

5. Patent or Proprietary Medicine

It means:

(i) In relation to Ayurvedic, Siddha or Unani System of Medicine, all formulations containing only such ingredients mentioned in the formulae described in the authoritative books of

Ayurvedic, Siddha or Unani System of Medicine specified in First Schedule to the Act but does not include the medicine .administered by parenteral route.

(ii) In relation to any other system of medicine including, allopathic, a drug presented in a form ready for internal or external administration of human beings or animals and which is not included for the time being in the editions of Indian Pharmacopoeia or any other Pharmacopoeia.

6. Misbranded Drug

A drug is considered as a misbranded drug:

(i) if it is not labeled in the prescribed manner,

or

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

or

(iii) if the label or container or anything accompanying the drug bears any statement, design or device which makes any false claim for the drug or gives misleading information.

7. Adulterated Drug

A drug is considered to be adulterated:

(i) if it consists in whole or in part of any filthy, putrid, or decomposed substance,

or

(ii) if it has been prepared, packed or stored under poor sanitary conditions whereby, it may have been contaminated with filth and rendered injurious to health,

or

(iii) if container of the drug is composed in whole or in part of any poisonous substance which may render the contents injurious to health,

or

(iv) if it contains a colour other than one which is prescribed,

or

(v) if the drug contains any harmful or toxic substance which may render it injurious to health,

or

(vi) if the drug is admixed with any substance so as to reduce its quality or strength.

8. Manufacture in relation to Drug or Cosmetic

Any process fully or partly used for making, altering, ornamenting, finishing packing, labeling, breaking up or otherwise treating or adopting any drug/cosmetic with a view to its sale or distribution but, does not include the compounding or dispensing of any drug or the packing of any drug or cosmetic in the ordinary course of retail business.

9. Spurious Drug

A drug is deemed to be a spurious drug:

(i) if it is imported under a name which belongs to another drug,

or

(ii) if it is an imitation of or a substitute for another drug or if it resembles another drug in a manner likely to deceive or bears upon it or its label or container the name of another drug,

or

(iii) if it has been substituted wholely or in part by another drug substance,

or

(iv) if it claims to be the product of a manufacturer or company of whom it is not truly a product.

10. Misbranded Cosmetic

A cosmetic shall be deemed to be misbranded:

(i) if it contains a colour which is not prescribed,

or

(ii) if it is not labelled in prescribed manner, or

(iii) if the label or container or anything accompanying the cosmetic bears any statement which is false or misleading.

11. Spurious Cosmetic

A cosmetic shall be deemed to be spurious:

(i) if it is imported under a name which belongs to another cosmetic,

or

(ii) if it is an imitation of or a substitute for another cosmetic; resembles another cosmetic in a manner likely to deceive; or bears upon it or upon its label or container the name of another cosmetic,

or

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

or

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

Schedules to the Act and Rules [2]

There are two Schedules to the Act and 35 Schedules to the Rules.

The Schedules to the Act

1. First Schedule: It comprises the list of books of references for Ayurvedic, Siddha and Unani medicines. There are 57 books of Ayurveda, 30 books of Siddha and 13 of Unani Tibb systems listed in the Schedule which are used for different formulations in accordance with the provisions of the Act.

2. Second Schedule: It comprises of the standards to be complied with for imported drugs, manufacture of drugs, their sale, stocking and storage etc.

The Schedules to the Rules

Schedule A: Different Forms for application to procure licence, renewal of licence, and for all other activities.

Schedule B: Rates of fees charged for analysis by COL or State Drugs Laboratories.

Schedule C: List of biological and other special products governed by special provisions

Schedule C (I): List of other special products governed by special provisions

Schedule D: Class of drugs: extent and conditions of exemption

Schedule D (I): Undertaking of the manufacturer or his authorized agent required to be submitted along with application form for obtaining a registration certificate.

Schedule D (II): Undertaking of the manufacturer or his authorized agent required to be submitted along with application form for registration of a bulk drug or its formulation or its import into India

Schedule E (I): List of poisonous substance under Ayurvedic , Siddha and Unani medicines

Schedule F: Requirement for operation of blood bank and / or preparation of blood components

Schedule F(I): Provisions for bacterial vaccines, viral vaccines, antisera, diagnostic antigens, etc.

Schedule F (II): Standards for surgical dressings

Schedule F (III): Standards for Umbilical tapes

Schedule FF: Standards for ophthalmic preparations

Schedule G: Drugs required to be taken under medical supervision.

Schedule H: List of prescription drugs

Schedule J: List of diseases or ailments which a drug may not purport to prevent or cure.

Schedule K: Drugs exempted from certain provisions related to manufacturer.

Schedule M: GMP (Good Manufacturing Practices) comprising requirements of factory premises, plant and equipment

Schedule M-l: Homoeopathic preparations requirements of factory premises, plants and equipments

Schedules M-(II): Cosmetics - requirements of factory premises for manufacture

Schedules M-(III): Requirements of factory premises for manufacture of medical devices

Schedule N: List of minimum equipment of running a pharmacy

Schedule O: Standards for disinfectant fluids

Schedule P: Life period of drugs

Schedule P-l: Pack sizes of drugs

Schedule Q: List of colours, dyes and pigments permitted in cosmetics and soaps, list of colours permitted in soaps

Schedule R: Standards for condoms of rubber latex and other mechanical contraceptives

Schedule R-I: Standards for medical devices

Schedules S: Standards for Cosmetics

Schedules T: GMP (Good Manufacturing Practices) for manufacture of Ayurvedic, Siddha and Unani medicines, G.M.P., machinery, equipment minimum manufacturing premises, etc.

Schedules U: Particulars required to be shown in manufacturing records; raw material and analytical records

Schedules U (1): Particulars required to be shown in manufacturing records.

Schedules V: Standards for patent or proprietary medicines

Schedules X: Psychotropic substances

Schedules Y: Requirements and guidelines on clinical trials for import and manufacture of new drug

Import of drugs and cosmetics [3]

The import of drugs and cosmetics is regulated by the provisions of this Act.

Classes of drugs and cosmetics prohibited from import

The following categories of drugs and cosmetics are prohibited from import:

1. Drugs or cosmetics which are not of standard qualities.
2. Drugs or cosmetics which are misbranded, spurious and adulterated.
3. Drugs or cosmetics for import of which licence is required.
4. Any patent or proprietary medicine *without* true formula or list of active ingredients and their quantities.
5. Any drug or formulation which claims to prevent or cure diseases mentioned schedule J.
6. Any drug or cosmetic for which manufacture, sale or distribution is prohibited in country of its origin.
7. Any drug which is not packed or not labeled in conformity with the Rules of the Act.
8. Any cosmetic containing an ingredient which may render it unsafe or harmful.
9. Any drug or cosmetic the import of which is prohibited by Act.

Exemptions

The drugs exempted from provisions regulating the import of drugs are shown in Table 1.

Table 1: Drugs exempted from provisions regulating the import

Class of drugs	**Extent and conditions of Exemption**
1.Substances not intended for medicinal use	They can be imported without any restriction, provided imported in bulk and the importer certifies that they are imported for non medicinal uses.
2. Substances included in Schedule C1 required for manufacturing purposes but not intended for medicinal use.	Exempted from all provisions regulating import except that the importer should be holding license for manufacture of Schedule C and C1 drugs.
3.Substances used both as drugs as well as articles e.g. powdered milk, Farex, oats, lactose etc.	Exempted from all provisions regulating import.
4. Ginger, pepper, cumin, cinnamon, and all other similar spices and condiments other than those of official quality.	Exempted from all provisions regulating import.

Import of drugs under license

1. License is required for the import of drugs.
2. License is obtained on application to the proper licensing authority.

3. License is valid up to 31st December.
4. Licensee should inform to licensing authority if any changes.

Import under license or permit.

The licensing authority grants a license for the import of following classes of drugs

A. Drugs specified in schedule C and C1 excluding those specified in schedule X
B. Drugs specified in schedule X
C. Small quantities of drugs imported for examination, test or analysis
D. Drugs for personal use prescribed by a Registered Medical Practitioner
E. Any new drug

A. Drugs specified in schedule C and C1 excluding those specified in schedule X

Conditions to be fulfilled

1. Licensee must have adequate facilities for storage.
2. Licensee must maintain a record of the sale, showing the particulars of the names of drugs and of the persons to whom they have been sold.
3. Licensee must allow an inspector to inspect premises and to check the records.
4. Licensee must furnish the sample to the authority.
5. Licensee must comply with undertaking given in the Form No:09.

B. Drugs specified in schedule X

Conditions to be fulfilled

1. A license is necessary.
2. Licensee must have adequate facilities for storage.
3. Applicant must be reputable in the occupation, trade or business.
4. The license granted ever before should not be suspended or cancelled.

C. Small quantities of drugs imported for examination, test or analysis

Conditions to be fulfilled

1. A license is necessary.
2. Imported under license in Form-11.
3. The licensee must use the imported drug only for the said purpose and use at the place specified in the license.
4. The licensee must keep the record to the quantities, name of the manufacturer and date of import.

D. Drugs for personal use prescribed by a Registered Medical Practitioner

Conditions to be fulfilled

1. The drug must be bonified personal use.
2. The quantity should be reasonable and covered by RMP prescription.
3. The drug must be declared to the Custom Collector if so directed.
4. More than 100 doses are imported with license. Applying in Form No. 12A and 12B.

E. Any new drug

Conditions to be fulfilled

1. License is required.
2. The licensee is required to provide the documents of standards of quality, purity and strength.

Application and Duration of Import Licence and Registration Certificate

An application for import licence is made to licensing authority in Form 8 for drugs excluding Schedule X and in Form 8-A for schedule X drugs. The licence is issued in Form-l0 orl0-A as the case may be. The application for Registration Certificate is made to Licensing Authority in Form 40 and Registration Certificate is issued in Form 41. The application for both import licence and Registration Certificate may be made by manufacturer himself or his authorized agent in India having a valid licence. Both the import licence and Registration Certificate are valid for a period of *three* years from date of issue. If the application is made three months in advance before expiry of licence or certificate, it is valid until orders are passed on application.

Permitted Places for Import of Drugs

The import of drug into India is *permitted* only from following places:

(i) By rail: Ferozepur Cantonment and Amritsar railway stations for drugs from Pakistan. Ranaghat, Bongaon and Mohiassan railway stations for drugs from Bangladesh

(ii) By road: Raxual for drugs from Nepal

(iii) By sea: Chennai, Kolkatta, Mumbai, Nhava Sheva, Kandla, and Cochin

(iv) By air: Mumbai, Chennai, Kokatta, Delhi, Ahmedabad and Hyderabad.

Conditions of Import Licence [4]

The importer has to fulfil the conditions that are stipulated in the Rules and also comply with following conditions.

1. The manufacturer shall observe undertaking given in Form 9

2. The Licensee should maintain a proper record of imported drug wherein the entries should be made serially for the stock of imported material, its distribution, persons to whom the imported drug is issued, price charged, remaining and quantity of imported drugs. The drug imported for the purpose of test or analysis or the new drugs imported are not for general use.
3. The importer should maintain all proper storage facilities for drugs imported as required in accordance with the provisions of the Act.
4. The importer should permit the inspector or officer on behalf of the State Government or Central Government without notice to inspect the premises, stocking facilities, records, analytical details, and sale of imported substance.
5. The licensee should withdraw the substance from market if asked to do so by Authority, if found that the substance is substandard.

An import licence is for one category of drug from single manufacturer abroad, or it could be for more drugs from same manufacturer from one location. Separate licence is required for import of drugs from different manufacturers or from the same manufacturer located at different places.

Other Features of Import

1. No new homoeopathic medicine can be imported without permission in writing from the Licensing Authority
2. Small quantities of a new drug may be permitted for import by a Government hospital or Autonomous medical institution for the treatment of patient suffering from life threatening disease, subject to fulfillment of conditions laid down for the purpose.
3. Small quantities of drugs for examination, test or analysis may be imported subject to the conditions that the licensee shall use the drug exclusively, for the purpose for which it is imported; the licensee shall allow any inspector authorized by the licensing authority to inspect premises without prior notice and investigate the manner in which substances are being withdrawn and used. The licence is issued in Form 11. The licensee should maintain all the records and comply with conditions stipulated for licence.

Suspension and Cancellation of Import Licence or Registration Certificate

If the manufacturer or licensee fails to comply with any conditions of the Registration Certificate, the licensing authority may after giving him an opportunity to show cause may suspend or cancel the Registration Certificate for such period as it thinks fit. However, the

aggrieved person may appeal to the Central Government within thirty days against such order and the decision of the Government in this regard shall be final.

Offences and Penalties

The offences and penalties related to import of drugs is given in Table 2.

Table 2: Offences relating to import of drugs

Offences	**penalties**	
	First Conviction	**Subsequent Conviction**
1. An offence of any adulterated (section *9-A)* or spurious drug (section 9-B) or cosmetic (section 9-0) being imported into the country in violation of provisions of the Act	Imprisonment upto three years and a fine upto five thousand rupees.	Imprisonment upto 5 years or a fine upto ten thousand rupees or both.
2. Import of drugs or cosmetics other than those referred above the import of which is forbidden.	Imprisonment upto 6 months or a fine upto 500 rupees or both.	Imprisonment upto 12 months or a fine upto 1000 rupees or both.
3. Any drug or cosmetic imported in contravention with provisions of any notification issued under Section 10-A	Imprisonment upto three years or a fine upto five thousand rupees or both.	Imprisonment upto 5 years or a fine upto ten thousand rupees or both.

Manufacture of Drugs [5]

Manufacture in relation to any drug includes any process or part of a process for making, altering, finishing, packing, labelling, breaking up or otherwise treating or adopting any drug with a view to its sale and distribution, but does not include compounding or dispensing of any drug or packing of any drug in ordinary course of retail business. Manufacture of drugs is a blend of art and science, to be achieved strictly in accordance with the provisions of Good Manufacturing Practices (GMP).

Prohibition of manufacture and sale of certain drugs

The following categories of drugs and cosmetics are prohibited to be manufactured or sold in our country.

1. Any drug or cosmetic which is substandard, misbranded, adulterated or spurious.
2. Any patent or proprietory medicine without clear indication of ingredients.
3. Any drug claiming for accurate cure or prevention of diseases listed in Schedule J.
4. Any manufacturing of formulation containing drug or cosmetic which has been imported into our country in contravention to the provisions of the Act and Rules.
5. Manufacturing for sale of any drug or cosmetic containing any harmful ingredient.
6. Manufacturing for sale of any drug or cosmetic in contravention to the provisions of the Act and Rules, provided that manufacture of small quantities of any drug for the purpose of examination, test or analysis is permitted, subject to prescribed conditions. Separate applications for separate licences for more than one premises of manufacture are required to be made.

Conditions for grant of license and conditions of license for manufacture of drugs

A person who is interested in starting manufacturing of drugs is required to fulfill several conditions laid down in DCA and Rules. The conditions to be fulfilled before licence is granted are collectively called as "Conditions Precedent" and conditions that are required to be fulfilled after the licence is obtained for manufacturing are called "Conditions Subsequent". The Licensing Authority is both in States and at Central Government. The Central Government is empowered to prohibit manufacturing and sale of any drug formulation in public interest.

The types of licenses are granted are

1. Manufacturing of drugs for examination, test or analysis
2. Manufacture of new drug
3. Manufacturing under Loan licences
4. Licence for Repacking
5. Licence to Manufacture of drugs other than Schedule C, C(1), and Schedule X
6. Licence to Manufacture of Biologicals and Special Products in Schedules C and C (1)
7. Manufacturing of drugs belonging to Schedule X

Manufacture of drugs

Licences are required for the manufacturing of following categories of drugs.

1. Manufacturing of drugs for examination, test or analysis

2. Manufacture of new drug
3. Manufacturing under Loan licences
4. Licence for Repacking
5. Licence to Manufacture of drugs other than Schedule C, C(1), and Schedule X
6. Licence to Manufacture of Biologicals and Special Products in Schedules C and C (1)
7. Manufacturing of drugs belonging to Schedule X

1. Manufacturing of drugs for examination, test or analysis

If the manufacturer does not hold separate licence for test, analysis or examination, the licence is obtained in Form 29. The provisions relating prohibition of manufacturing of certain drugs do not apply for such manufacturing meant for test or analysis. The validity of the licence is for I year.

Conditions

1. The manufactured drugs should be kept in containers bearing appropriate label indicating the purpose of test or analysis.
2. The drugs should be used for the purpose for which they are manufactured.
3. When the material is supplied to other manufacturer, the label stating the name and address of manufacturer, scientific name of the drug, licence number, date of manufacture etc., should be provided.
4. The manufacturer should allow the Inspector to inspect the premises, manufacturing, and analytical records and withdraw the samples if required for analysis. The manufacturer should comply with the provisions of the Act and Rules.
5. The manufacturer should maintain an Inspection Book and the same be shown to the Inspector.
6. The licensee should comply with other requirements for which a notice has been given to him one month before by the Licensing Authority.

2. Manufacture of new drug

In addition to provisions for manufacture of drugs, there should be documentary evidence for quality, purity, therapeutic trials of new drugs and evidence for approval under schedule 'Y' (Clinical trials).

3. Manufacturing under Loan licences

Loan license is given to a person who does not have his own arrangements for manufacturing but wishes to avail the manufacturing facilities owned by another licensee. For drugs other than Schedules C, C(I) and X, loan licences can be given. Drugs specified in Schedules C/C(I),

Procedure

A licence is obtained from licensing authority on application in prescribed form No. 24 A, 27 A with prescribed fees. Application for grant or renewal of loan licence is made in Form 24-A. The licence is issued by Licensing Authority in Form 25-A, which is valid for 1 year.

Conditions

1. The general conditions applicable to other than Schedules C, C(I) and X.

Additional conditions

1. Application must be supported by the parent firm.
2. Drug inspector inspects the premises of parent firm and checks and assesses the spare capacity.
3. Loan license is required to test each batch of raw materials and finished products.
4. Records of testing should be maintained for 5 years or 2 years in case of expiry drugs from such data.
5. Patent medicines must be safe for use in the context of vehicle and additives.
6. The production must be supervised by competent person of loan licensee.

4. Licence for Repacking

Process of breaking up any drug from its bulk container [8] into small packages and labeling with a view to their sale and distribution is done under repacking licence. It is issued for drugs other than Schedules C, C1 and X, subject to fulfillment of conditions.

Procedure:

The application is made for grant or renewal of licence in Form 24-B. The licence is issued by Licensing Authority after inspection in Form 25-B.

Conditions

1. Adequate space and equipment should be provided. Hygienic conditions of working should always be maintained.
2. Repacking should be supervised by competent person.
3. There should be adequate arrangement for testing of samples.
4. The licence should always be displaced at premises of repacking.

5. The factory primises for repacking should comply with provisions of Schedule M.
6. 6.Adequate staff should be appointed and any change in staff structure should be immediately informed to Controlling Authority.
7. The container or package of repacked drug should bear on its label the words - "Rpg.Lic.No".
8. The licence is valid till31^{Ist} December every year and required to be renewed. There should be separate application for separate licence.

5. Licence to Manufacture of drugs other than Schedule C, C(1), and Schedule X

A license is obtained from licensing authority on application in prescribed Form No, 24 with prescribed fees. If conditions are fulfilled then license is issued in prescribed Form No. 25.

Conditions

1. The factory premises shall comply with conditions laid down in the Schedule M.
2. The manufacture shall be conducted under active supervision of Competent Technical Staff.
3. Adequate facilities for testing should be provided and it should be separate from manufacturing unit.
4. Adequate facilities for storage of drugs.
5. Licensee must allow an Inspector to inspect the premises, check the record and to take the sample.
6. Licensee must display the licence on the premises and produce it when asked for.
7. Licensee must pay fees and get endorsement on the licence if the licensee wishes to manufacture any additional product.
8. Record of testing and manufacture (Schedule U) should be maintained at least for 2 years from the date of expiry of drugs and for 5 years in case of other drugs.
9. Licensee must provide samples to the Authority.
10. Licensee must furnish the data of stability of drug if demanded.
11. Licensee must provide any additional requirement as directed by Authority.
12. Inspection book must be maintained.
13. The licensee shall comply with the requirements of GMP.

6. Licence to Manufacture of Biological and Special Products in Schedules C and C (1)

A licence is obtained from licensing authority on application in prescribed Form No. 27 with prescribed fees.

Conditions

1. The general conditions applicable to other than Schedules C, C(I) and X.

Special conditions for Biologicals

1. All Schedule C drugs must be issued in previously sterilized, sealed glass of other suitable containers.
2. All containers should comply with Schedule F/F1.
3. The drug must comply with standards specified in Schedule F.
4. Serum should be tested for freedom from abnormal toxicity.
5. Multidose containers for liquids should contain preservatives to prevent growth of microorganism.
6. Sterility testing should be done.
7. Some classes of substances should be tested for the absence of aerobic and anaerobic microorganisms like bacterial vaccines, dry preparation of insulin, sera etc.
8. Solution for parenteral administration in dose of 10 ml or more should be tested for freedom from pyrogens.
9. There should be separate laboratories culture and manipulation of spore bearing pathogens.

7. Manufacturing of drugs belonging to Schedule X

A licence is obtained from licensing authority on the application in prescribed Form No. 27B with prescribed fees. If conditions are fulfilled then licence is issued in prescribed Form No. 28B.

Conditions

1. The general conditions applicable to other than Schedules C, C(I) and X.

Special conditions

1. Account of all transactions regarding manufacture should be maintained in a serially bound and paged register as follows. This should be prescribed for 5 years.
   - ✓ **Accounts of drug used in manufacture** (Date of issue, Name of the drug, Opening balance, Quantity received, Quantity used, Balance quantity, Sign.)

- ✓ **Account of production** (Date of manufacturer, Name of drug, Batch No., Quantity of raw material, Wastage, Quantity of manufactured drug)
- ✓ **Amount of manufactured drug** (Date of manufacturer, Name of drug, Batch No., Opening balance, Quantity manufactured, Quantity sold, Name of purchaser, Balance quantity)

2. Manufacturer is required to send the copies of invoice of sale of drugs to licensing authority every 3 months.
3. Preparations should be labeled as X_{RX} (red ink).
4. No Schedule X drugs should be supplied by the way of physician sample.
5. Drugs specified in Schedule X drugs shall be marketed in packaging not exceeding 100 Units dose- Tablets/Capsule, 300 ml –Oral liquid and 5 ml –Injection**.**

REFERENCES

1. Nanjwade BK, Hiremath GM, editors. Pharmaceutical Jurisprudence, New Delhi: Ikon Book Publishers and Distributors; 2011.
2. Kar RK, Prabhu TP, Patel KN. editors. Pharmaceutical Jurisprudence, Lucknow: Thakur Publication; 2019.
3. Mithal BM. Text book of Forensic Pharmacy
4. Suresh B. Forensic Pharmacy
5. Mehra ML. Hand book of drug law

Unti II- **BP 505T. (Drug and cosmetic act 1940 and its rule 1945)**

Introduction:

The drugs and cometics act 1940 and rules 1945 have been passed to regulate the import, manufacture, distribution and sale of drugs and cosmetics. All the operations related to drugs should be done by qualified persons. To have a check, on search operation the central and state government are established the state and central drug control authorities. Drug and cosmetics rule have been divided into 18 parts, each belong with a particular subject. There are two schedules to the act and 25 schedules to the rules.

Schedule G

It contains the list of the drugs should be used under the medical supervision only.

List of drugs under schedule G:

Aminopterin
L-**A**sparaginase **B**leomycin
Busulphan; its salts
Carbutamide
Chlorambucil;its salts
Chlorothiazide and other derivatives of 1, 2, 4 benzothiadiazine
Chlorpropamide; its salts
Chlorthalidone and other derivatives of Chlorobenzene compound.
2[(**C**is-Platin)]
Cyclophosphamide; its salts
2[(**C**ytarabine)]
Daunorubicin
Di-Isopropyl Eluorophosphate **D**isodium Stilboestrol
Diphosphate
Doxorubicin Hydrochloride
Ethacrynic Acid, its salts
Ethosuximide
Glibenclamide
Hydantoin; its salts; its derivatives, their salts
Hydroxyurea
Insulin, all types
[(Lomustine Hydrochloride)]
Mannomustine; its salts
Mercaptopurine; its salts
Metformin; its salts
Methsuximide
Mustine, its salts
Paramethadione
Phenacemide
Phenformin; its salts
5-**P**henylhydantoin; its alkyl and aryl derivatives; its salts
Primadone
[(**P**rocarpazine Hydrochloride])
Quinthazone
Sarcolysine
[(**S**odium-2-Mercaptoethanesulfonate]
Tamoxiten Citrate
Testolactone
Thiotepa
Tolbutamide
Tretamine; its salts
Troxidone

Antihistaminic substances the following, their salts, their derivatives, salts of their derivatives
Antazoline
Bromodiphenhydramine
Buclizine
Chlorcyclizine
Chlorpheniramine
Clemizole Cyproheptadine
Diphenhydramine
Diphenylpyraline
Doxylamine Succinate
Isothipendyl
Mebhydrolin Napadisylate
Meclozine Phenindamine
Pheniramine Promethazine
Thenalidine Triprolidine
Substances being tetra-N-Subs. derivatives of Ethylene Diamine or Prophylenediamine

.

Schedule H :

This schedule contains the list of the drugs to be sold by retail only in the prescription of a registered medical practitioner (RMP)

List of drugs under schedule H:

Abacavir
Abciximab
Acamprosate calcium
Acebutol hydrochloride
Aclarubicin
Albendazole
Alclometasone dipropionate
Actilyse
Acyclovir
Adenosine
Adrenocorticotrophic hormone (acth)
Alendronate sodium
Alopurinol
Alphachymotrypsin
2[Alprazolam
Alprostadil
Amantadine hydrochloride
Amifostine
Amikacin sulphate
Amiloride hydrochloride 21.
Amineptine
Aminoglutethimide
Amino salicylic acid
Amiodarone hydrochloride
Amitriptyline
Amlodipine besylate
Amoscanate
Amoxopine
Amrinonelactate
Analgin
Androgenic anabolic, oestrogenic & progestational substances
Antibiotics
Apraclonidine
Aprotinin
Organic compound of arsenic
Arteether
Artemether
Artesunate
Articaine hydrochloride
Atenolol
Atracurium besylate injection
Atorvastatin
Auranofin
Azathioprine
Aztreonam
Bacampicillin
Baclofen
Balsalazide
Bambuterol
Barbituric acid
Basiliximab
Benazepril hydrochloride
Benidipine hydrochloride
Benserazide hydrochloride
Betahistine dihydrochloride
Bethanidine sulphate
Bezafibrate
Bicalutamide
Biclotymol monohydrate lactate
Bifonazole
Bimatoprost
Biperiden hydrochloride
Biphenyl acetic acid
Bitoscanate
Bleomycin
Primonidine tartrate
Bromhexine hydrocloride
Bromocriptine mesylate
Budesonide
Bulaquine
Bupivacaine hydrochloride
Bupropion
Buspirone
Butenafine hydrochloride
Butorphanol tartrate
Cabergoline
Calcium dobesilate
Candesartan
Capecitabine
Captopril
Carbidopa
Carbocisteine
Carboplatin
Carboquone
Carisoprodol
L-carnitine
Carteolol hydrochloride
Carvedilol
Cefadroxyl
Cefatoxime sodium
Cefazolin sodium 92.
2[Cefdinir
Cefepime hydrochloride
Cefetamet pivoxil
Cefpirome
Cefpodoximepoxetil
Ceftazidime pentahydrate
Ceftizoxime sodium]
Cefuroxime
Celecoxib
Centchroman
Centbutindole
Centpropazine
Cetirizine hydrochloride
2[Chlordiazepoxide
Chlormezanone
Chlorpromazine
Chlorzoxazone
Ciclopiroxolamine
Cimetidine
Cinnarizine
Ciprofloxacin hydrochloride
Cisplatin
Citalopram hydrobromide
Clarithromycin
Clavulanic acid
Clidiniumbromide
Clindamycin
Clobazam
Clobetasol propenate
Clobetasone 17-butyrate
2[Clofazimine]
Clofibrate
Clonazepam
Clonidine hydrochloride
Clopamide
Clopidogrel bisulphate
Clostebolacetate
Clotrimazole
Clozapine
2[Codeine]

Colchicine
Corticosteroids
Cotrimoxazole
Cyclandelate
Cyclosporins
Daclizumab
Danazole
Dapsone
Desloratadine
Desogestrol
Dexrazoxane
Dextranomer
Dextropropoxyphene
2[Diazepam]
Diazoxide
Diclofenac sodium/potassium
Dicyclomin hydrochloride
Didanosine
Digoxine
Dilazep hydrochloride
Diltiazem
Dinoprostone
2[Diphenoxylate, its salts]
Dipivefrin hydrochloride
Di-sodiumpamidronate
Disopyramide
Docetaxel
Domperidone
Donepezil hydrochloride
Dopamine hydrochloride
Dothiepin hydrochloride
Doxapram hydrochloride
Doxazosin mesylate
Doxepin hydrochloride
Doxorubicin hydrochloride
Drotrecogin-alpha
Ebastine
Econozole
Efavirenz
Enalapril meleate
Enfenamic acid
Epinephrine
Epirubicine
Eptifibatide
Ergot, alkaloids of whether hydrogenated or not, their homologoues, salts
Esomeprazole
Estradiol succinate
Estramustine phosphate 182.
Etanercept
Ethacridine lactate
2[Ethambutol hydrochloride]
Ethamsylate
Ethinyloestradiol
2[Ethionamide]
Etidronate disodium
Etodolac
Etomidate
Etoposide
Exemestane
Famciclovir
Famotidine
Fenbendazole
Fenofibrate
Fexofenadine
Finasteride
Flavoxate hydrochloride
5-fluorouracil
Fludarabine
Flufenamic acids
Flunarizine hydrochloride
Fluoxetine hydrochloride
Flupenthixol
Fluphenazine enanthate and decanoate
Flurazepam
Flurbiprofen
Flutamide
Fluticasone propionate
Fluvoxamine maleate
Formestane
Fosfestril sodium
Fosinopril sodium
Fossphenytoin sodium
Fotemustine
Gabapentin
Galanthamine hydrobromide
Galamine, its salts, its quaternary compound
Gancyclovir
Ganirelix
Gatifloxacin
Gemcitabine
Gemfibrozil
Gemtuzumab
Genodeoxycholic acid
Gliclazide
Glimepiride
Glucagon
Glycopyrrolate
Glydiazinamide
Goserelin acetate
Granisetron
Guanethidine
Gugulipid
Halogenated hydroxyquinolines
Haloperidol
Heparin
Hepatitis b. Vaccine
Hyaluronidase
Hydrocorisone 17-butyrate
Hydrotalcite
Hydroxizine
Ibuprofen
Idebenone
Indapamide
Imipramine
Indinavir sulphate
Indomethacin
Insulin human
Interferon
Intravenous fat emulsion
Iobitridol
Iohexol
Iopamidol
Iomeprol
Iopromide
Irbesartan
Irinotecan hydrochloride
Iron preparation for parenteral use
Isepamicine
Isocarboxside
Isoflurane
Isonicotnic acid hydrazine and other-hydragine derivatives of isonicotinic acid
Isosorbide dinitrate/ mononitrate
Isotretinoin
Isoxsuprine
Itopride
Ketoconazole
Ketoprofen
Ketorolactromethamine
Labetalol hydrochloride
Lacidipine
Lamivudine
Lamotrigine
Latanoprost
Lefunomide
Lercanidipine hydrochloride
Letrozole
Leuprolide acetate
Levamesole
Levarterenol
Levobunolol
Levocetirizine
Levodopa
2[Levofloxacin]
Levovist
Lidoflazine
Linezplid

Lithium carbonate
Lofepramine decanoate
Loperamide
Lorazepam
Losartan potassium
Loteprednol
Lovastatin
Loxapine
Mebendazole
Mebeverine hydrochloride
Medroxyprogesterone acetate
Mefenamic acid
Mefloquine hydrochloride
Megestrol acetate
Meglumine iocarmate
Melagenina
Elitracenhydrochloride
Meloxicam
Mephenesin, its esters
Mephentermine
2[Meropenam]
Mesterolone
Metaxalone
Methicillin sodium
Methocarbamol
Methotraxate
Metoclopramide
Metoprolol tartrate
Metrizamide
Metronidazole
Mexiletine hydrochloride
Mianserin hydrochloride
Miconazole
2[Midazolam]
Mifepristone
Milrinone lactate
Miltefosine
Minocycline
Minoxidil
Mirtazapine
Misoprostol
Mitoxantrone hydrochloride
Mizolastine
Moclobemide
Mometasone furoate
Montelukast sodium
Morphazinamide
hydrochloride
Mosapride
2[Moxifloxacin]
Mycophenolate mofetil
Nadifloxacin
Nadolol
Nafarelin acetate
Nalidixic acid
Naproxen
Narcotics drugs listed in
Narcotic Drugs &
Psychotropic Substances Act,
1985
Natamycin
Nateglinide
N-butyl-2-cyanoacrylate
Nebivolol
Nebumetone
Nelfinavir mesilate
Netilmicin sulphate
Nevirapine
Nicergoline
Nicorandil
Nifedipine
Nimesulide
Nimustine hydrochloride
2[Nitrazepam]
Nitroglycerin
Norethisterone enanthate
Norfloxacin
Octylonium bromide
Ofloxacin
Olanzapine
Omeprazole
Ornidazole
Orphenadrine
Orthoclone sterile
Oxazepam
Oxazolidine
Oxcarbazepine
Oxethazaine hydrochloride
Oxiconazole
Oxolinic acid
Oxprenolol hydrochloride
Oxybutynin chloride
Oxyfedrine
Oxymetazoline
Oxyphenbutazone
Oxytocin
Ozothine
Paclitaxel
Pancuronium bromide
Pantoprazole
Para-amino benzene
sulphonamide, its salts &
derivatives
Parp-amino salicylic acid, its
salts, its derivatives
Parecoxib
Paroxetine hydrochloride
D-penicilamine
2[Pentazocine]
Pentoxifylline
Pepleomycin
Phenelzineh sulphate
Phenobarbital
Phenothiazine, derivatives of
and salts of its derivatives
Phenylbutazine
Pimozide
Pindolol
Pioglitazone hydrochloride
Piracetam
Piroxicam
Pituitory gland, active
principles of, not otherwise
specified in this schedule and
their salts
Polidocanol
Polyestradiol phosphate
Poractant alfa
Praziquantel
Prednimustine iothalamates
Prednisolone stearoylglycolate
Prenoxdiazinhydro-chloride
Promazine hydrochloride
Promegestone
Propafenon hydrochloride
Propanolol hydrochloride 416.
Propofol
Protristyline hydrochloride
2[Pyrazinamide]
Pyrvinium
Quetiapine fumerate
Quinapril
Quinidine sulphate
Rabeprazole
Racecadotril
Raloxifene hydrochloride
Ramipril hydrochloride
Ranitidine
Rauwolfia, alkaloids of, their
salts, derivatives of the
alkaloids or rauwolfia
Reboxetine
Repaglinide
Reproterol hydrochloride
Rilmenidine
Riluzone
Risperidone
Ritonavir
Ritodrine hydrochloride
Rituximab
Rivastigmine
Rocuronium bromide
Ropinirole
Rosoxacin
Rosiglitazone meleate

Salbutamol sulphate
Salicyl-azo-sulphapyridine
Salmon calcitonin
Saquinavir
Satranidazole
Secnidazole
Septopal beads & chains
Serratiopeptidase
Sertraline hydrochloride
Sibutramine hydrochloride
Sildenafil citrate
Simvastatin
Sirolimus
Sisomicin sulphate
S-neominophagen
Sodiumpico sulphate
Sodium cromoglycate
Sodium hyaluronate
Sodium valproate
Sodium and maglumine iothalamates
Somatostatin
Somatotropin
Sotalol
2[Sparfloxacin]
Spectinomycin hydrochloride
Spironolactone
Stavudine
Sucralfate
Sulphadoxine
Sulphamethoxine
Sulphamethoxypyridazine
Sulphaphenazole
Sulpiride
Sulprostone hydrochloride
Sumatriptan
Tacrine hydrochloride
Tamsulosin hydrochloride
Trapidil
Tegaserod maleate
Teicoplanin
Telmisartan
Temozolamide
Terazosin
Terbutaline sulphate
Terfenadine
Terizidone
Terlipressin
Testosteroneun decoanoate
Teratolol hydrochloride
Thalidomide
2[Thiacetazone]
Thiocolchicoside
Thiopropazate, its salts
Thymogene
Thymosin-alpha1
Tiaprofenic acid
Tibolone
Timolol maleate
Tinidazole
Tizanidine
Tabramycin
Tolfenamic acid
Topiramate
Topotecan hydrochloride
2[Tramadolhydrochloride]
Tranexamic acid
Tranylcypromine, its salts
Trazodone
Tretinoin
Trifluperazine
Trifluperidol hydrochloride
Triflusal
Trimetazidine dihydrochloride
Trimipramine
Tripotassium dicitrate bismuthate
Tromantadine hydrochloride
Urokinase
Valsartan
Vasopressin
Vecuronium bromide
Venlafaxine hydrochloride
Verapamil hydrochloride
Verteporfin
Vincristine sulphate
Vinblastine sulphate
Vindesine sulphate
Vinorelbine tatrate
Xipamide
Zidovudine hydrochloride
Ziprasidone hydrochloride
Zoledronic acid
2[Zolpidem]
Zopiclone
Zuclopenthixol

Scheulde M

The requirements of good manufacturing practices (GMP) and factory premises and the requirements of plant and equipements.

GOOD MANUFACTURING PRACTICES FOR PREMISES AND MATERIALS

1 GENERAL REQUIREMENTS:

*1.1. **Location and surroundings***.- The factory building(s) for manufacture of drugs shall be so situated and shall have such measures as to avoid risk of contamination from external environment including open sewage, drain, public lavatory or any factory which produce disagreeable or obnoxious odour or fumes, excessive soot, dust, smoke, chemical or biological emissions.

*1.2. **Buildings and premises***.- The building(s) used for the factory shall be designed, constructed, adapted and maintained to suit the manufacturing operations so as to permit production of drugs under hygienic conditions. They shall conform to the conditions laid down in the Factories Act, 1948 (63 of 1948).

The premises used for manufacturing, processing, warehousing, packaging, labelling and testing purposes shall be –

(i) compatible with other drug manufacturing operations that may be carried out in the same or adjacent area / section;
(ii) adequately provided with working space to allow orderly and logical placement of equipment, materials and movement of personnel so as to:

(a) avoid the risk of mix-up between different categories of drugs or with raw materials, intermediates and in-process material;

(b) avoid the possibilities of contamination and cross- contamination by providing suitable mechanism;

(iii) designed / constructed / maintained to prevent entry of insects, pests, birds, vermins and rodents. Interior surface (walls, floors and ceilings) shall be smooth and free from cracks, and permit easy cleaning, painting and disinfection
(iv) air-conditioned, where prescribed for the operations and dosage forms under production. The production and dispensing areas shall be well lighted, effectively ventilated, with air control facilities and may have proper Air Handling Units (wherever applicable) to maintain conditions including temperature and, wherever necessary, humidity, as defined for the relevant product. These conditions shall be appropriate to the category of drugs and nature of the operation. These shall also be suitable to the comforts of the personnel working with protective clothing, products handled, operations undertaken within them in relation to the external environment. These areas shall be regularly monitored for compliance with required specifications;
(v) provided with drainage system, as specified for the various categories of products, which shall be of adequate size and so designed as to prevent back- flow and/or prevent insects and rodents entering the premises. Open channels shall be avoided in manufacturing areas and, where provided, these shall be shallow to facilitate cleaning and disinfection;
(vi) the walls and floors of the areas where manufacture of drugs is carried out shall be free from cracks and open joints to avoid accumulation of dust. These shall be smooth, washable, coved and shall permit easy and effective cleaning and disinfection. The interior surfaces shall not shed particles. A periodical record of cleaning and painting of the premises shall be maintained.
1.3 Water System. - There shall be validt. system for treatment of water drawn from own or any other source to render it potable in accordance with standards specified by the Bureau of Indian Standards or Local Municipality, as the case may be, so as to produce Purified Water conforming to Pharmacopoeial specification. Purified Water so produced shall only be used for all the operations except washing and cleaning operations where potable water may be used. Water shall be stored in tanks, which do not adversely affect quality of water and ensure freedom from microbiological growth. The tank shall be cleaned periodically and records maintained by the licensee in this behalf.
1.4. Disposal of waste. -
(i) The disposal of sewage and effluents (solid, liquid and gas) from the manufactory shall be in conformity with the requirements of Environment Pollution Control Board.
(ii) All bio-medical waste shall be destroyed as per the provisions of the Bio- Medical Waste (Management and Handling) Rules, 1996.
(iii) Additional precautions shall be taken for the storage and disposal of rejected drugs. Records shall be maintained for all disposal of waste.
(iv) Provisions shall be made for the proper and safe storage of waste materials awaiting disposal. Hazardous, toxic substances and flammable materials shall be stored in suitably designed and segregated, enclosed areas in conformity with Central and State Legislations.

2. Warehousing Area:
2.1 Adequate areas shall be designed to allow sufficient and orderly warehousing of various categories of materials and products like starting and packaging materials, intermediates, bulk and finished products, products in quarantine, released, rejected, returned or recalled, machine and equipment spare parts and change items.

2.2. Warehousing areas shall be designed and adapted to ensure good storage conditions. They shall be clean, dry and maintained with acceptable temperature limits. Where special storage conditions are required (e.g. temperature, humidity), these shall be provided, monitored and recorded. Storage areas shall have appropriate house-keeping and rodent, pests and vermin control procedures and records maintained. Proper racks, bins and platforms shall be provided for the storage of materials.
2.3. Receiving and dispatch bays shall protect materials and products from adverse weather conditions.
2.4. Where quarantine status is ensured by warehousing in separate earmarked areas in the same warehouse or store, these areas shall be clearly demarcated. Any system replacing the physical quarantine, shall give equivalent assurance of segregation. Access to these areas shall be restricted to authorized persons.

3. Production area:
3.1. The production area shall be designed to allow the production preferably in uni-flow and with logical sequence of operations.
3.2. In order to avoid the risk of corss-contamination, separate dedicated and self- contained facilities shall be made available for the production of sensitive pharmaceutical products like penicillin or biological preparations with live micro-organisms. Separate dedicated facilities shall be provided for the manufacture of contamination causing and potent products such as Beta-Lactum, Sex Hormones and Cytotoxic substances.
3.3. Working and in-process space shall be adequate to permit orderly and logical positioning of equipment and materials and movement of personnel to avoid cross- contamination and to minimize risk of omission or wrong application of any manufacturing and control measures.
3.4. Pipe-work, electrical fittings, ventilation openings and similar service lines shall be designed, fixed and constructed to avoid 1[accumulation of dust]. Service lines shall preferably be identified by colours and the nature of the supply and direction of the flow shall be marked/indicated.

4. Ancillary Areas:
4.1 Rest and refreshment rooms shall be separate from other areas. These areas shall not lead directly to the manufacturing and storage areas.
4.2 Facilities for changing, storing clothes and for washing and toilet purposes shall be easily accessible and adequate for the number of users. Toilets, separate for males and females, shall not be directly connected with production or storage areas. There shall be written instructions for cleaning and disinfection of such areas.

5. Quality Control Area.
5.1. Quality Control Laboratories shall be independent of the production areas. Separate areas shall be provided each for physico-chemical, biological, microbiological or radio-isotope analysis. Separate instrument room with adequate area shall be provided for sensitive and sophisticated instruments employed for analysis.
5.2 Quality Control Laboratories shall be designed appropriately for the operations to be carried out in them. Adequate space shall be provided to avoid mix-ups and cross-contamination. Sufficient and suitable storage space shall be provided for test samples, retained samples, reference standards, reagents and records.
5.3. The design of the laboratory shall take into account the suitability of construction materials and ventilation. Separate air handling units and other requirements shall be provided for biological, microbiological and radioisotopes testing areas. The laboratory shall be provided with regular supply of water of appropriate quality for cleaning and testing purposes.
5.4. Quality Control Laboratory shall be divided into separate sections i.e. for chemical, microbiological and wherever required, biological testing. These shall have adequate area for basic installation and for

ancillary purposes. The microbiology section shall have arrangements such as airlocks and laminar air flow work station, wherever considered necessary.

6. Personnel:

6.1. The manufacture shall be conducted under the direct supervision of competent technical staff with prescribed qualifications and practical experience in the relevant dosage form and / or active pharmaceutical products.

6.2 The head of the Quality Control Laboratory shall be independent of the manufacturing unit. The testing shall be conducted under the direct supervision of competent technical staff who shall be whole time employees of the licensee.

6.3. Personnel for Quality Assurance and Quality Control operations shall be suitably qualified and experienced.

7. Health, clothing and sanitation of workers:

7.1 The personnel handling Beta-lactum antibiotics shall be tested for Penicillin sensitivity before employment and those handling sex hormones, cytotoxic substances and other potent drugs shall be periodically examined for adverse effects. These personnel should be moved out of these sections (except in dedicated facilities), by rotation, as a health safeguard.

7.2 Prior to employment, all personnel, shall undergo medical examination including eye examination, and shall be free from Tuberculosis, skin and other communicable or contagious diseases. Thereafter, they should be medically examined periodically, at least once a year. Records shall be maintained thereof. The licensee shall provide the services of a qualified physician for assessing the health status of personnel involved in different activities.

7.3 All employees shall be instructed to report about their illness or abnormal health condition to their immediate supervisor so that appropriate action can be taken.

7.4 Direct contact shall be avoided between the unprotected hands of personnel and raw materials, intermediate or finished, unpacked products.

8. Manufacturing Operations and Control:

8.1 All manufacturing operations shall be carried out under the supervision of technical staff approved by the Licensing Authority. Each critical step in the process relating to the selection, weighing and measuring of raw material addition during various stages shall be performed by trained personnel under the direct personal supervision of approved technical staff.

8.2. Precautions against mix-up and cross-contamination:

8.2.1. The licensee shall prevent mix-up and cross-contamination of drug material and drug product (from environmental dust) by proper air-handling system, pressure differential, segregation, status labelling and cleaning. Proper records and Standard Operating Procedures thereof shall be maintained.

8.2.2 The licensee shall ensure processing of sensitive drugs like Beta-Lactum antibiotics, sex hormones and cytotoxic substances in segregated areas or isolated production areas within the building with independent air-handling unit and proper pressure differentials.

9. Sanitation in the Manufacturing Premises:

9.1 The manufacturing premises shall be cleaned and maintained in an orderly manner, so that it is free from accumulated waste, dust, debris and other similar material. A validt. cleaning procedure shall be maintained.

9.2 The manufacturing areas shall not be used for storage of materials, except for the material being processed. It shall not be used as a general thoroughfare.

9.3 A routine sanitation program shall be drawn up and observed, which shall be properly recorded and which shall indicate–

(a) specific areas to be cleaned and cleaning intervals;

(b) cleaning procedure to be followed, including equipment and materials to be used for cleaning; and

(c) personnel assigned to and responsible for the cleaning operation.
9.4 The adequacy of the working and in-process storage space shall permit the orderly and logical positioning of equipment and materials so as to minimize the risk of mix- up between different pharmaceutical products or their components to avoid cross contamination, and to minimise the risk of omission or wrong application of any of the manufacturing or control steps.
9.5 Production areas shall be well lit, particularly where visual on-line controls are carried out.

10. Raw Materials:
10.1 The licensee shall keep an inventory of all raw materials to be used at any stage of manufacture of drugs and maintain records as per Schedule U.
10.2 All incoming materials shall be quarantined immediately after receipt or processing. All materials shall be stored under appropriate conditions and in an orderly fashion to permit batch segregation and stock rotation by a "first in/first expiry'first-out" principle. All incoming materials shall be checked to ensure that the consignment corresponds to the order placed.
10.3 All incoming materials shall be purchased from approved sources under valid purchase vouchers. Wherever possible, raw materials should be purchased directly from the producers.

11. Equipment:
11.1 Equipment shall be located, designed, constructed, adapted and maintained to suit the operations to be carried out. The layout and design of the equipment shall aim to minimise the risk of errors and permit effective cleaning and maintenance in order to avoid cross-contamination, build-up of dust or dirt and, in general, any adverse effect on the quality of products. Each equipment shall be provided with a logbook, wherever necessary.
11.2 Balances and other measuring equipment of an appropriate range, accuracy and precision shall be available in the raw material stores, production and in-process control operations and these shall be calibrated and checked on a scheduled basis in accordance with Standard Operating Procedures and records maintained.
11.3 The parts of the production equipment that come into contact with the product shall not be reactive, additive or adsorptive to an extent that would affect the quality of the product.

12. Documentation and Records:– Documentation is an essential part of the Quality assurance system and, as such, shall be related to all aspects of Good Manufacturing Practices (GMP). Its aim is to define the specifications for all materials, method of manufacture and control, to ensure that all personnel concerned with manufacture know the information necessary to decide whether or not to release a batch of a drug for sale and to provide an audit trail that shall permit investigation of the history of any suspected defective batch.
12.1 Documents designed, prepared, reviewed and controlled, wherever applicable, shall comply with these rules.
12.2 Documents shall be approved, signed and dt. by appropriate and authorized persons.
12.3 Documents shall specify the title, nature and purpose. They shall be laid out in an orderly fashion and be easy to check. Reproduced documents shall be clear and legible. Documents shall be regularly reviewed and kept up to date. Any alteration made in the entry of a document shall be signed and dt.

13. Labels and other Printed Materials:– Labels are absolutely necessary for identification of the drugs and their use. The printing shall be done in bright colours and in a legible manner. The label shall carry all the prescribed details about the product.
14. Quality Assurance:–This is a wide-ranging concept concerning all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that products are of the quality required for their intended use.

15. Self Inspection and Quality audit:– It may be useful to constitute a self-inspection team supplemented with a quality audit procedure for assessment of all or part of a system with the specific purpose of improving it.

Written instructions for self-inspection shall be drawn up which shall include the following: -

(a) Personnel.
(b) Premises including personnel facilities.
(c) Maintenance of buildings and equipment
(d) Storage of starting materials and finished products.
(e) Equipment.
(f) Production and in-process controls.
(g) Quality control.
(h) Documentation.
(i) Sanitation and hygiene.
(j) Validation and revalidation programmes.
(k) Calibration of instruments or measurement systems.
(l) Recall procedures.
(m) Complaints management.
(n) Labels control.
(o) Results of previous self-inspections and any corrective steps take

17. Specification

17.1 For raw materials and packaging materials. - They shall include-

(a) the designated name and internal code reference;
(b) reference, if any, to a pharmacopoeial monograph;
(c) qualitative and quantitative requirements with acceptance limits;
(d) name and address of manufacturer or supplier and original manufacturer of the material;
(e) specimen of printed material;
(f) directions for sampling and testing or reference to procedures;
(g) storage conditions; and
(h) maximum period of storage before re-testing.

17.2 For product containers and closures:–

17.2.1 All containers and closures intended for use shall comply with the pharmacopoeial requirements. Suitable validt. test methods, sample sizes, specifications, cleaning procedure and sterilization procedure, wherever indicated, shall be strictly followed to ensure that these are not reactive, additive, absorptive, or leach to an extent that significantly affects the quality or purity of the drug. No second hand or used containers and closures shall be used.

18. Master Formula Records:

There shall be Master Formula records relating to all manufacturing procedures for each product and batch size to be manufactured. These shall be prepared and endorsed by the competent technical staff i.e. head of production and quality control.

The Master Formula shall include: -

(a) the name of the product together with product reference code relating to its specifications;
(b) the patent or proprietary name of the product along with the generic name, a description of the dosage form, strength, composition of the product and batch size;
(c) name, quantity, and reference number of all the starting materials to be used. Mention shall be made of any substance that may 'disappear‘ in the course of processing.
(d) a statement of the expected final yield with the acceptable limits, and of relevant intermediate yields, where applicable.
(e) a statement of the processing location and the principal equipment to be used.
(f) the methods, or reference to the methods, to be used for preparing the critical equipments including cleaning, assembling, calibrating, sterilizing;
(g) detailed stepwise processing instructions and the time taken for each step; (h) the instructions for in-process control with their limits;
(i) the requirements for storage conditions of the products, including the container, labelling and special storage conditions where applicable;
(j) any special precautions to be observed; (k) packing details and specimen labels.

SCHEDULE N

List of minimum equipment for the efficient running of a pharmacy

1. *Entrance.* - The front of a pharmacy shall bear an inscription ―Pharmacy in front.

2. *Premises.* - The premises of a pharmacy shall be separated from rooms for private use. The premises shall be well built, dry, well lit and ventilated and, of sufficient dimensions to allow the goods in stock, especially medicaments and poisons to be kept in a clearly visible and appropriate manner. The areas of the section to be used as dispensing department shall be not less than 6 square meters for one pharmacist working therein with additional 2 square meters for each additional pharmacist. The height of the premises shall be at least 2.5 meters.

The floor of the pharmacy shall be smooth and washable. The walls shall be plastered or tiled or oil painted so as to maintain smooth, durable and washable surface devoid of holes, cracks and crevices.

A pharmacy shall be provided with ample supply of good quality water.

The dispensing department shall be separated by a barrier to prevent the admission of the public.

3. *Furniture and apparatus.* - The furniture and apparatus of a pharmacy shall be adopted to the uses for which they are intended and correspond to the size and requirements of the establishment.

Drugs, chemicals, and medicaments shall be kept in a room appropriate to their properties and in such special containers as will prevent any deterioration of the contents or of contents of containers kept near them. Drawers, glasses and other containers used for keeping medicaments shall be of suitable size and capable of being closed tightly to prevent the entry of dust.

Every container shall bear a label of appropriate size, easily readable with names of medicaments as given in the Pharmacopoeias.

A pharmacy shall be provided with a dispensing bench, the top of which shall be covered with washable and impervious material like stainless steel, laminated or plastic, etc.

A pharmacy shall be provided with a cupboard with lock and key for the storage of poisons and shall be clearly marked with the work 'POISON' in red letters on a white background.

Containers of all concentrated solution shall bear special label or marked with the words ―To be dilute.

A Pharmacy shall be provided with the following minimum apparatus and books necessary for making of official preparations and prescriptions

SCHEDULE P

LIFE PERIOD OF DRUGS

Sl. No.	Name of the drug	Period between date of manufacture and date of expiry(months)	Condition of storage
1	Ampicillin	36	In a cool place
2	Ampicillin Capsules	24	
3	Bacitracin	18	In a cool place
4	Carbenicillin Sodium Injection	24	At temperature not Exceeding 5°C
5	Colistin Sulphate	60	Protected from light
6	Gentamycin Sulphate	60	In a cool place.
7	Thiamine Mononitrate	48	In a well closed container, protected from light, in a cool place.
8	Riboflavin	60	
9	Riboflavin-5-Phosphate	24	
10	Insulin Injection	24	At temperature between 2°C and 8°C, must not be allowed to freeze.
11	Dried Plasma	60	At a temperature not exceeding 25°C
12	Frozen Plasma	60	In deep freeze

SCHEDULE T

GOOD MANUFACTURING PRACTICES FOR AYURVEDIC, SIDDHA AND UNANI MEDICINES

The Good Manufacturing Practices (GMP) are prescribed as follows to ensure that:

(i) Raw materials used in the manufacture of drugs are authentic, of prescribed quality and are free from contamination.

(ii) The manufacturing process is as has been prescribed to maintain the standards.

(iii) Adequate quality control measures are adopted.

(iv) The manufactured drug which is released for sale is of acceptable quality.

(v) To achieve the objectives listed above, each licensee shall evolve methodology and procedures for following the prescribed process of manufacture of drugs which should be documented as a manual and kept for reference and inspection. However, under IMCC Act 1970 registered Vaidyas, Siddhas and Hakeems who prepare medicines on their own to dispense to their patients and not selling such drugs in the market are exempted from the purview of G.M.P.

SCHEDULE U

Particulars to be shown in various records of manufacturing of drug.

A. SUBSTANCES, OTHER THAN PARENTERAL PREPARATIONS IN GENERAL.

1. Serial number
2. Name of the product
3. Reference of Master Formula Records.
4. Lot/Batch Size.
5. Lot/Batch Number.
6. Date of commencement of manufacture and date of completion of manufacture and assigned date of expiry.
7. Name of all ingredients, specifications quantities required for the lot/Batch size and quantities actually used. All weighings and measurements shall be carried out by a responsible person and initialled by him and shall be counter-checked and signed by the competent technical staff under whose personal supervision the ingredients are used for manufacture.
8. Control Numbers of raw materials used in the formulation.
9. Date, time and duration of mixing.
10. Details of environmental controls like room temperature, relative humidity.
11. Date of granulation, wherever applicable.
12. Theoretical weight and actual weight of granules/powder blend.
13. Records of in-processes controls (Periodically whenever necessary):
    (a) Uniformity of mixing.
    (b) Moisture content of granules/powder in case of Tablet/Capsules.
    (c) pH of solution in case of liquid.
    (d) Weight variation.
    (e) Disintegration time.
    (f) Hardness
    (g) Friability test
    (h) Leak test in case of strip packing.
    (i) Filled volume of liquids.
    (j) Quantity of tablets/capsules in the final container.
    (k) Content of ointment in the filled containers.

B. PARENTERAL PREPARATIONS.

1. Serial number.
2. Name of the product.
3. Reference of the master formula record.
4. Batch /Lot size.
5. Batch No. and/or Lot No.
6. Date of commencement of manufacture and date of completion.
7. Names of all ingredients, specifications and quantity required for the Lot/Batch size and quantity actually used. All weighings and measurements shall be carried out by a responsible person and initialled by him and shall be countersigned by the technical staff under whose personal supervision the stock are issued and by another competent technical staff under whose supervision the ingredients are used for manufacture.
8. Control numbers of raw materials used in the formulation.
9. Date, time and duration of mixing.
10. Details of environmental controls like temperature, humidity, microbial count in the sterile working areas.
11. pH of the solution, wherever applicable.
12. Date and method of filtration.
13. Sterility test, reference on bulk batch wherever applicable.
14. Record of check on volume filled.
15. Date of filling.
16. Records of tests employed
    (a) To ensure that sealed ampoules are leak proof
    (b) To check the presence of foreign particles.
    (c) Pyrogen test, wherever applicable
    (d) Toxicity test, wherever applicable.
17. Records of checking of instruments and apparatus of sterilization (indicators).
18. Records of cleaning and sterilization of containers and closures, if necessary.
19. Records of sterilization in case of parenteral preparations which are heat sterilized including particulars of time, temperature and pressure employed. Such records should be marked to relate to the batch sterilized.

SCHEDULE V

STANDARDS FOR PATENT OR PROPRIETARY MEDICINES

Standards for patent or proprietary medicines, containing vitamins: Patent or proprietary medicines containing vitamins for prophylactic, therapeutic or paediatric use shall contain the vitamins in quantities not less than and not more than those specified.

General Standards for Different Categories of Patent or Proprietary Medicines. - In the case of pharmaceutical products containing several active ingredients, the selection shall be such that the ingredients do not interact with one another and do not affect the safety and therapeutic efficacy of the product.

Subject to the provisions of these rules, patent or proprietary medicines shall comply with the following standards, namely: -

1. Patent or proprietary medicines shall comply with the general requirements of the dosage form under which it falls as given in the Indian Pharmacopoeia. If the dosage form is not included in the Indian Pharmacopoeia, but is included in any other pharmacopoeia, prescribed for the purpose of the Second Schedule to the Act, it shall comply with the general requirements of the dosage of such pharmacopoeia. Without prejudice to the generality of the foregoing requirements, general requirements shall include compliance with colour consistency, clarity, stability, freedom from contamination with foreign matter

or fungal growth, defects like chipping and capping of tablets, cracking of the coating, mottled appearance and other characteristic defects that can be perceived by visual inspection.

2. Without prejudice to the generality of the following paras, dosage forms of patent or proprietary medicines shall comply with the following requirements, namely:-

(a) ***Tablets:*** Medicines shall comply with requirements for tablets as laid down in the Indian Pharmacopoeia. The nature of coating shall be indicated on the label. Permitted colours may, however, be added and declared on the label. Nature of tablets, such as uncoated, sugar coated or film coated, shall be declared on the label.

(b) ***Capsules*** : Medicines shall comply with the requirements for capsules laid down in the Indian Pharmacopoeia. However, the capsules shall be free from distortion or shape, dis-colouration and other physical defects like leakage of powder from joints, pinholes or cracks in the capsules;

(c) ***Liquid oral dosage forms***: Emulsions and suspensions shall disperse uniformly on shaking. Homogeneous solutions shall contain no sediments. The volume of the product (net content) in the container shall be not less than the labelled volume. The limit for ethanol content of pharmaceutical products shall be not less than 90 per cent and not more than 110 per cent of the labelled contents.

(d) ***Injections:*** Medicines shall comply with the requirements for injections as laid down in the Indian Pharmacopoeia.

(e) ***Ointments:*** Medicines shall comply with the requirements for injections as laid down in the Indian Pharmacopoeia.

3. The content of active ingredients, other than vitamins, enzymes and antibiotics, in patent or proprietary medicines shall be not less than 90 per cent and not more than 110 per cent of the labelled content; however, for enzymes and vitamins, only for lower limit of 90 per cent shall apply. In all dry formulations containing antibiotics, the limit shall be 90 to 130 per cent of the labelled contents and in case of liquid antibiotic formulations, the limit shall be 90 to 140 per cent of labelled contents.

Fiducial limits for error for microbiological assay of antibiotics may be estimated depending upon the design of assay procedure. Methods, used for assaying active ingredients shall employ the same basic principles and shall use same organisms as given in the latest edition of the Indian Pharmacopoeia or shall follow any other methods as approved by the authority competent to grant licence to manufacture.

4. All patent or proprietary medicines containing aspirin shall be subjected to ―Free Salicylic Acid Test¦ and the limit of such acid shall be 0.75 per cent. Except in case of soluble type aspirin in which case the limit of such acid shall be 3 per cent.

5. Patent or proprietary medicine to be tested under the provisions of rule 121-A for pyrogen shall be tested by injecting into rabbits not less than the human dose of the medicine based on body weight of a 60 kg. human being. Methodology and limits shall be based on the method recorded in the Indian Pharmacopoeia. Dose selected shall be indicated in the protocol but the dose shall be not greater than 5 times the human dose based on body weight of 60 kg for man.

6. In injectable patent or proprietary medicines, the test for freedom from toxicity, shall be performed as described in the Indian Pharmacopoeia. Dose selected shall be indicated in the protocol but the dose shall not be less than five times the human dose based on body weight of 60 kg. human being

SCHEDULE X

List of the drugs which are habit forming and are likely to be misused for addictive purposes.

Amphetamine
Meprobamate
Phencyclidine
Barbital
Methamphetamine
Phenometrazine

SCHEDULE Y

REQUIREMENTS AND GUIDELINES FOR PERMISSION TO IMPORT AND / OR MANUFACTURE OF NEW DRUGS FOR SALE OR TO UNDERTAKE CLINICAL TRIALS

DATA TO BE SUBMITTED ALONG WITH THE APPLICATION TO CONDUCT CLINICAL TRIALS/IMPORT/MANUFACTURE OF NEW DRUGS FOR MARKETING IN THE COUNTRY

1. Introduction

A brief description of the drug and the therapeutic class to which it belongs.

2. Chemical and pharmaceutical information2.1. Information on active ingredients

Drug information (Generic Name, Chemical Name or INN)

2.2. Physicochemical Data

(a) Chemical name and Structure

- Empirical formula
- Molecular weight

(b) Physical properties

- Description
- Solubility
- Rotation
- Partition coefficient
- Dissociation constant

2.3. Analytical Data

- Elemental analysis
- Mass spectrum
- NMR spectra
- IR spectra
- UV spectra
- Polymorphic identification

2.4. Complete monograph specification including

- Identification
- Identity/quantification of impurities
- Enantiomeric purity
- Assay

2.5. Validations

- Assay method
- Impurity estimation method
- Residual solvent/other volatile impurities (OVI) estimation method

2.6. Stability Studies (for details refer Appendix IX)

- Final release specification
- Reference standard characterization
- Material safety data sheet

2.7. Data on Formulation

- Dosage form
- Composition
- Master manufacturing formula
- Details of the formulation (including inactive ingredients)
- In process quality control check
- Finished product specification

- Excipient compatibility study
- Validation of the analytical method
- Comparative evaluation with international brand(s) or approved Indian brands, if applicable
- Pack presentation
- Dissolution
- Assay
- Impurities
- Content uniformity
- pH
- Force degradation study
- Stability evaluation in market intended pack at proposed storage conditions
- Packing specifications
- Process validation

When the application is for clinical trials only, the international non-proprietary name (INN) or generic name, drug category, dosage form and data supporting stability in the intended container-closure system for the duration of the clinical trial (information covered in item nos. 2.1, 2.3, 2.6, 2.7) are required.

3. Animal Pharmacology (for details refer Appendix IV)
    3.1. Summary
    3.2. Specific pharmacological actions
    3.3. General pharmacological actions
    3.4. Follow-up and Supplemental Safety Pharmacology Studies
    3.5. Pharmacokinetics: absorption, distribution; metabolism; excretion
4. Animal Toxicology (for details refer Appendix III)
    4.1. General Aspects
    4.2. Systemic Toxicity Studies
    4.3. Male Fertility Study
    4.4. Female Reproduction and Developmental Toxicity Studies
    4.5. Local toxicity
    4.6. Allergenicity/Hypersensitivity
    4.7. Genotoxicity
    4.8. Carcinogenicity

[Note.- Where the data on animal toxicity as per the specifications of Appendix III has been submitted and the same has been considered by the regulatory authority of the country which had earlier approved the drug, the animal toxicity studies shall not be required to be conducted in India except in cases where there are specific concerns recorded in writing.]

5. Human / Clinical pharmacology (Phase I)
    5.1. Summary
    5.2. Specific Pharmacological effects
    5.3. General Pharmacological effects
    5.4. Pharmacokinetics, absorption, distribution, metabolism, excretion
    5.5. Pharmacodynamics / early measurement of drug activity
6. Therapeutic exploratory trials (Phase II)
    6.1. Summary
    6.2. Study report(s) as given in Appendix II
7. Therapeutic confirmatory trials (Phase III)
    7.1. Summary
    7.2. Individual study reports with listing of sites and Investigators.
8. Special studies

8.1. Summary
8.2. Bio-availability / Bio-equivalence.
8.3. Other studies e.g. geriatrics, paediatrics, pregnant or nursing women

9. Regulatory status in other countries
9.1. Countries where the drug is
a) Marketed
b) Approved
c) Approved as IND
d) Withdrawn, if any, with reasons
9.2. Restrictions on use, if any, in countries where marketed /approved
9.3. Free sale certificate or certificate of analysis, as appropriate.
10. Prescribing information
10.1. Proposed full prescribing information
11. Samples and Testing Protocol/s
11.1. Samples of pure drug substance and finished product (an equivalent of 50 clinical doses, or more number of clinical doses if prescribed by the Licensing Authority), with testing protocol/s, full impurity profile and release specifications.
12. New Chemical Entity and Global Clinical Trial:
12.1 Assessment of risk versus benefit to the patients
12.2 Innovation vis-à-vis existing therapeutic option
12.3 Unmet medical need in the country.]

SCHEDULE F

PART XII B
REQUIREMENTS FOR THE FUNCTIONING AND OPERATION OF A BLOOD BANK AND / OR FOR PREPARATION OF BLOOD COMPONENTS.

BLOOD BANKS / BLOOD COMPONENTS

A. GENERAL
1. *Location and Surroundings* : The blood bank shall be located at a place which shall be away from open sewage, drain, public lavatory or similar unhygienic surroundings.
2. *Building* : The building (s) used for operation of a blood bank and/or preparation of blood components shall be constructed in such a manner so as to permit the operation of the blood bank and preparation of blood components under hygienic conditions and shall avoid the entry of insects, rodents and flies. It shall be well lighted, ventilated and screened (mesh), wherever necessary. The walls and floors of the rooms, where collection of blood or preparation of blood components or blood products is carried out shall be smooth, washable and capable of being kept clean. Drains shall be of adequate size and where connected directly to a sewer, shall be equipped with traps to prevent back siphonage.
Health, clothing and sanitation of staff: The employees shall be free from contagious or infectious diseases. They shall be provided with clean overalls, head-gears, foot-wears and gloves, wherever required. There shall be adequate, clean and convenient hand washing and toilet facilities.

B. ACCOMMODATION FOR A BLOOD BANK.
A blood bank shall have an area of 100 square meters for its operations and an additional area of 50 square meters for preparation of blood components. It shall be consisting of a room each for –
(1) registration and medical examination with adequate furniture and facilities for registration and selection of donors;

(2) blood collection (air-conditioned); (3) blood component preparation. (This shall be air-conditioned to maintain temperature between 20 degree centigrade to 25 degree centigrade);
(4) laboratory for blood group serology (air-conditioned);
(5) laboratory for blood transmissible diseases like Hepatitis, Syphilis, Malaria, HIV-antibodies (air-conditioned);
(6) sterilization-cum-washing;
(7) refreshment-cum-rest room (air-conditioned); (8) store-cum-records.

C PERSONNEL
staff:-
Every blood bank shall have following categories of whole time competent technical
(a) Medical Officer, possessing the qualifications specified in condition (i) of rule 122-G. (b) Blood Bank Technician(s) possessing –
(i) Degree in Medical Laboratory Technology (M.L.T) with six months'
experience in the testing of blood and/or its components; or
(ii) Diploma in Medical Laboratory Technology (M.L.T) with one year's experience in the testing of blood and / or its components, the degree or diploma being from a University / Institution recognized by the Central Government or State Government.
(c) Registered Nurse(s);
(d) Technical supervisor (where blood components are manufactured), possessing-
(i) Degree in Medical Laboratory Technology (M.L.T) with six months'
experience in the preparation of blood components; or
(ii) Diploma in Medical Laboratory Technology (M.L.T) with one year's experience in the preparation of blood components,
the degree or diploma being from a University / Institution recognized by the Central Government or State Government.

D. MAINTENANCE
The premises shall be maintained in a clean and proper manner to ensure adequate cleaning and maintenance of proper operations.

E. EQUIPMENT
Equipment used in the collection, processing, testing, storage and sale/distribution of blood and its components shall be maintained in a clean and proper manner and so placed as to facilitate cleaning and maintenance. The equipment shall be observed, standardized and calibrated on a regularly scheduled basis as described in the Standard Operating Procedures Manual and shall operate in the manner for which it was designed so as to ensure compliance with the official.

F. SUPPLIES AND REAGENTS:
All supplies and reagents used in the collection, processing, compatibility, testing, storage and distribution of blood and blood components shall be stored at proper temperature in a safe and hygienic place, in a proper manner and in particular.

Sale of drugs

Sale is defined as the seller transfers or agrees to transfer the property in goods to the buyer for a price. Wholesale means a dealer or an agent or a stockist appointed by the manufacturer for the sale of drugs to a retailer and a dealer means a dealer carrying on the retail business of sale of drugs of customers. For the sale of drugs a licence is required. For issuing the sale licence, the drugs are divided into following categories.

1. Drugs other than those specified in schedule C, C1 and X
2. Drugs specified in schedule C and C1 but excluding X
3. Drugs specified in schedule X.

Conditions of licence for retail sale of drugs

1. An application is made together with the prescribed fee to the licensing authorities for the retail sale of drugs in form19 for drugs other than those specified in schedule X and in form 19C for those specified in schedule X.

2. The licensing authority issues the licence for retail sale of drugs in form-20 for the application made for the drugs other than those specified in schedule C, C1 and X, in form-21 for those specified in schedule C and C1, in form 20-F for those specified in schedule X.
These are the following conditions.

a) The licence premises are adequate and equate with the facilities of proper storage of drugs.
b) The pharmacy shall comply the requirements of schedule N.
c) The licence shall be displayed in a prominent place.
d) All the compounding and dispensing of drugs shall be made under the direct supervision of qualified person.
e) The supply of drugs other than schedule X drugs on a prescription shall be recorded in register or credit memo book.
f) The supply of schedule C drug shall be recorded in register or credit memo book.
g) The drugs shall be purchased from a duly licensed dealer or a duly licensed manufacturer and purchase bill shall be numbered and maintained in a order.
h) All registers and records shall be produced for inspection by a inspector.
i) All registers and record shall be preserved for a period of 2years from the date of last entry.
j) Schedule H and X drugs shall be sold with the prescription of a registered medical practitioner.
k) The supply of schedule H and X drugs to the registered medical practitioner, hospital and nursing home shall be made only the signed order in writing. Such orders shall be preserved for a period of 2 years.
l) The schedule H and X drugs shall not be supplied more than once.
m) Only the prescribed schedules H and X drugs shall be dispensed but not the substitutes.
n) Schedule X drugs shall be stored in a cupboard undr lock and key separately undr the control of a responsible person.
o) An inspection book in form-35 shall be maintained.
p) The drugs after the expiry shall not be sold or stocked.
q) The physician sample drugs and the drugs meant for the government supply shall not be sold or stocked.
r) The supply of schedule X drugs shall be recorded in separate register and separate pages for each drug.
s) For the sale of additional categories of drugs listed in scheduleC and C1 excluding X, the licensee must take prior permission of the licensing authorities.

Wholesale of drugs

Application for the grant of wholesale of drug licence is made in form-19 for drugs other than specified in schedule X. And in form 19-C for drugs specified in schedule X.

On being satisfied with the condition fulfilled by the applicant the licensing authority issue the license in form 20-B for other than those schedule C, C1 and X and in Form 21-B for those specified in schedule C and C1 and in Form-20G for those specified in schedule X.

CONDITION OF WHOLESALE LICENSE.

1. The area of the proposed premises shall not be less than 10sq.mt.
2. It shall be in the charge of competent person who is a registered pharmacist or who has passed the matriculation examination or its equivalent with 4 years experience in dispensing of drugs.
3. The premises would have adequate facility for the storage of drugs.
4. The license shall be displayed in a prominent place.
5. The drugs shall be purchased from a duly licensed dealer or duly licensed manufacturer.
6. The supply of drug by wholesale shall be made against a case memo and it should be preserved for a period of 3 years from the date of last entry.
7. Records of purchase of drugs shall be maintained, purchase bills shall be serially numbered and maintained in an order.
8. All registers and records shall be produced for inspection by a inspector.
9. All registers and record shall be preserved for a period of 2years from the date of last entry.
10. An inspection book in form-35 shall be maintained.
11. The drugs after the expiry shall not be sold or stocked.
12. The physician sample drugs and the drugs meant for the government supply shall not be sold or stocked.
13. The supply of schedule X drugs shall be recorded in separate register and separate pages for each drug.
14. The copies of invoice of sale of schedule X drugs to the retailer shall be forwarded to the licensing authorities.
15. Any changes in the firm should be reported to the licensing authorities.

Restricted license

Restricted license are issued for the retail sale of drugs to

1. Dealers or persons in respect of drugs whose sale doesn't require the supervision of a qualified person.
2. Itinerant vendors in exceptional cases for bonafied travelling agents of firms dealing a drugs.
3. A vendor who purchases drugs from a licensed dealer for distribution in populated areas where other channels of distribution of drugs are not available.

Restricted license may also be issued to a travelling agent of a firm for the special purpose of distribution to the medical practitioner or dealers for supply of biological and other special products specified in schedule C.

Offence and penalties

offences	First conviction	Subsequent conviction
Manufacture, sale, distribution stocking of any adulterated or spurious drug or drug not of standard quality.	Imprisonment for a minimum of 5years extending upto life imprisonment and fine of not less than RS 10,000/-	Imprisonment upto 10 years and fine upto RS 20,000/- or both.
Manufacture, sale, distribution stocking of any adulterated drug but not containing any toxic or harmfull substances which may render injurious to health	Imprisonment from 1-3 years and fine not less than Rs 5000/-.	Imprisonment from 2-4 years and fine not less than Rs 10,000/-.
anufacture, sale, distribution cking of drug without a ense	e court may however for any equate at special reason to be orded in judgement impose a m of less than a year and ser fine	e court may however for any equate at special reason to be orded in judgement impose a term less than 2 years and fine less than . 10,000/-
ilure to keep records or close required information	prisonment upto 1 year and a e upto 1000/-	me as first conviction-
ing the report of a government alyst for advertising any drug.	ne upto 500/-	prisonment upto 10 years or with e or both

Labelling and packaging of drug

The containers of all the drugs and medicines are to be labelled in accordance with the Drugs and Cosmetic Rule 1945. Following particulars should be appeared on the label of the innermost container.
General labelling requirements and specimen level for drugs and cosmetics.

1. Labelling of drugs manufacture for sale

a) Proper name of the drug or for official product the name or synonyms specified in the pharmacopeia. Ex;- analgin tablets IP

b) For a new drug containing a single active ingredient or a preparation containing single active ingredients specified in schedule W. ex:- Ferrous Sulphate Tablets.

2. The net content

a. Weight in grams (solids, semisolids)
b. Volume in ml (Liquids).
c. Units in number (unit dosage form like tablets and capsules)

3. The content of active ingredients in a single dose or in 5ml or in 1ml or in 1 unit.
4. The name and the address of the manufacturer.
5. Batch number or lot number.
6. Manufacturing license number; Mfg.Lic.No. or M.L.
7. Date of manufacturing. Mfg.Date
8. Date of expiry for the preparation containing schedule P or schedule-C1 drugs.
9. Import License number for the imported preparation containing schedule-C1 drugs.
10. 'Physician's samples' not to be sold' for the free sample to distribute to the medical professionals.
11. The quantity of alcohol as aveage percentage by the volume of absolute alcohol, if the preparation contains more than 3% alcohol.
12. The words "For single use only" for mechanical contraceptives.

13. Retail price not to exceed Rs.____+Local tax Extra.
14. The drug for internal use, containing schedule-G substance labelled with the words.
    "CAUTION: It is dangerous to intake this preparation except under medical supervision.
15. The drug for internal use, containing schedule-H substance labelled the symbol Rx on the left top corner of the label and with the following words. "SCHEDULE-H DRUGS"
    WARNING: To be sold by retail on the prescription of a Registered medical Practitioner only.
16. The drugs for internal use containing schedule X substances labelled the symbol Rx on the left top corner of the label and with the following words.
    "SCHEDULE-X DRUGS"
    WARNING: To be sold by retail on the prescription of a Registered medical Practitioner only.
17. The preparation used as liniment, lotion, liquid antiseptic and other liquid medicine for external use shall be labelled with the words "FOR EXTERNAL USE ONLY"
18. The drugs for animal treatment shall be labelled with words "not for human use, for animal treatment only" and with a symbol of the head of the animal.
19. The drug containing industrial methylated spirit for human treatment shall be labelled with the word " for external use only".

List of permitted colors

Following colors may be permitted to be used in medicines.

1. Natural colours: annatto, carotene, chlorophyll, cochineal, curcumine, redoxide, iron oxide, yellow oxide, titanium oxide, black oxide of iron.
2. Artificial colours:

a. Caramel,

b. Riboflavin

3. Coal tar colours. The common coal tar colours are green, yellow, red, blue, orange, brown and black.
4. Lakes: the aluminium or calcium salts lakes are used.

Administration of the Act and Rules

Administration of the drugs and cosmetic act and rules are divided into 3 parts.

1) Admistrative part or advisory part.
   a) DTAB(Drug Technical Advisory Board)
   b) DCC (Drug Consultative Committee)
2) Analytical part.
   a) Central Drug Laboratory
   b) Drug testing laboratory of the state.
   c) Government analyst.
3) Executive Part
   a) Controlling authority
   b) Licensing authority
   c) Drug inspector.

DTAB(Drug Technical Advisory Board)

The following are the members of drugs technical advisory board.

1. Ex-officio members:
   i. Director General Health Services.(Chairman)
   ii. Drugs Controller of India
   iii. Director Central Drugs Laboratory, Kolkata
   iv. Director Central Research Institute, kasauli.
   v. Director Indian Veterinary Research Institute, Izatnagar.
   vi. President Pharmacy Council of India
   vii. President Medical Council of India.
   viii. Director Central Drug research Institute, Lucknow.
2. Nominted members:
   i. 2 persons nominated by central government who are incharge of drugs control in states.
   ii. 1 person from the pharmaceutical industry nominated by central government.
   iii. 2 government analysts nominated by central government.
3. Elected members.
   i. A teacher in Pharmacy or Pharmaceutical chemistry or Pharmacognosy of an Indian university or an affiliated college elected by the executive committee of the Pharmacy Council of India.
   ii. A teacher in medicine or therapeutics of an Indian University or an affiliated college elected by executive committee of Medical Council of India.
   ii.1 Pharmacologist elected by the governing body of the Indian Council of Medical Research.
   iv. 1 person elected by the central Counscil of Medical Association.
   v. 1 person to be elected by the council of Indian Pharmaceutical Association.

The nominated and elected members hold the office for 3 years. .They are eligible for re-nomination or re-election.

Function of DTAB

1. The board advises the central government and the state government on the technical matters arising out of the administration of the Act.
2. It advices the central government in framing and modifying the rules under the act related to import, manufacture, sale and distribution of drugs.

DCC (Drug Consultative Committee)

It is constituted under section 7 of the Drug and Cosmetics Act.

Constitution.

1. 2 representative nominated by central government.
2. 1 representative nominated by each state government.

The committee meets when required by the central government. It has the power to regulate its own procedure.

Function:

The committee advises the central government, the state government and the DTAB on any matter to secure uniformity throughout India in the administration of the act.

CDL(Central Drug laboratory)

The central government established a central drug laboratory under the Act. The director of central drug laboratory is appointed by central government. The different types of samples are tested in different laboratories, which are working on behalf of CDL Kolkata.

Types of sample to be tested	Laboratory where tested
Sera, Vaccines, toxins, antigens, antitoxins, sterilized surgical sutures and ligatures. bacteriophages	Central research Institute, kasauli
Antisera, vaccines, toxoids and diagnostic antigen. All for veterinary use	Veterinary Research Institute. Izatnagar
Samples of condoms	Central Pharmacopeal laboratory , Gaziabad
Samples for oral Polio vaccines	National Institute of Communicable diseases.
Samples of VDRL antigen	Laboratory of serology and chemical examiner to the government of India, Kolkata

Function

1. To analyze or test the sample of drugs and cosmetics sent it by the customs collectors.
2. To carry out other duties given by the central government or state government or DTAB.
3. All the test reports of the samples shall be sent under the register post in a sealed packet with a memorandum form-1.

Government analyst :

A Government Analyst appointed by the Central Government or a State Government under section 33F in case of Ayurvedic, Siddha and Unani drugs and; and under section 20 in relation to other drugs and cosmetics.
Qualifications of Government Analyst.
Government Analyst under the Act shall be a person who
(a) is a graduate in medicine or science or pharmacy or Pharmaceutical Chemistry of a 3[University established in India by law or has an equivalent qualification recognized and notified by the Central Government for such purpose] and has had not less than five years‘ post-graduate experience in the testing of drugs in a laboratory under control of *(i)* a Government Analyst appointed under the Act, or *(ii)* the head of an Institution or testing laboratory approved for the purpose by the appointing authority, 4[or has completed two years‘ training on testing of drugs, including items stated in Schedule C, in Central Drugs Laboratory], or
(b) possesses a post-graduate degree in medicine or science or pharmacy or Pharmaceutical chemistry of a 3[University established in India by law or has an equivalent qualification recognized and notified by the Central Government for such purpose] or possesses the Associateship Diploma of the Institution of

Chemists (India) obtained by passing the said examination with "Analysis of Drugs and Pharmaceuticals" as one of the subjects and has had after obtaining the said post-graduate degree or diploma not less than three years‘ experience in the testing of drugs in a laboratory under the control of *(i)* a Government Analyst appointed under the Act, or *(ii)* the head of an Institution or testing laboratory approved for the purpose by the appointing authority 4[or has completed training on testing of drugs, including items stated in Schedule C, in Central Drugs Laboratory]:

Function of Government Analysts.—
(1) The Government Analyst to whom a sample of any drug has been submitted for test or analysis under sub-section (4) of section 23, shall deliver to the Inspector submitting it a signed report in triplicate in the prescribed form.
(2) The Inspector on receipt thereof shall deliver one copy of the report to the person from whom the sample was taken, and shall retain the third copy for use in any prosecution in respect of the sample.
(3) Any document purporting to be a report signed by a Government Analyst under this Chapter shall be evidence to the facts stated therein, and such evidence shall be conclusive unless the person from whom the sample was taken has, within twenty-eight days of the receipt of a copy of the report, notified in writing the Inspector or the Court before which any proceedings in respect of the sample are pending that he intends to adduce evidence in controversion of the report.
(4) Unless the sample has already been tested or analysed in the Central Drugs Laboratory, where a person has under sub-section (3) notified his intention of adducing evidence in controversion of a Government Analyst‘s report, the Court may, of its own motion or in its discretion at the request either of the complainant or the accused, cause the sample of the drug produced before the Magistrate under sub-section (4) of section 23 to be sent for test or analysis to the said Laboratory, which shall make the test or analysis and report in writing signed by, or under the authority of, the Director of the Central Drugs Laboratory the result thereof, and such report shall be conclusive evidence of the facts stated therein.
(5) The cost of a test or analysis made by the Central Drugs Laboratory under sub-section (4) shall be paid by the complainant or accused as the Court shall direct.

Drugs Inspector :

Inspectors.—(*1*) The Central Government or a State Government may, by notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Inspectors for such areas as may be assigned to them by the Central Government or the State Government, as the case may be.
(2) The powers which may be exercised by an Inspector and the duties which may be performed by him and the conditions, limitations or restrictions subject to which such powers and duties may be exercised or performed shall be such as may be prescribed.
(3) No person who has any financial interest in the manufacture or sale of any drug shall be appointed to be an
Inspector under this section.
(4) Every Inspector shall be deemed to be a public servant within the meaning of section 21 of the Indian Penal Code (45 of 1860) and shall be officially subordinate to such authority as the Government appointing him may specify in this behalf.
Qualifications of Inspectors. —A person who is appointed an Inspector under the Act shall be a person who has a degree in Pharmacy or Pharmaceutical Sciences or Medicine with specialisation in Clinical Pharmacology or Microbiology from a University established in India by law:
Provided that only those Inspectors: –
i) Who have not less than 18 months‘ experience in the manufacture of at least one of the substances specified in Schedule C, or

(ii) Who have not less than 18 months‘ experience in testing of at least one of the substances in Schedule C in a laboratory approved for this purpose by the licensing authority, or
(iii) Who have gained experiences of not less than three years in the inspection of firms manufacturing any of the substances specified in Schedule C during the tenure of their services as Drugs Inspectors;
shall be authorised to inspect the manufacture of the substances mentioned in Schedule C:]

Duties of Inspectors of premises licensed for sale.

Subject to the instructions of the controlling authority, it shall be duty of an Inspector authorized to inspect premises licensed for the sale of drugs
(1) to inspect 3[not less than once a year] all establishments licensed for the sale of drugs within the area assigned to him;
(2) to satisfy himself that the conditions of the licences are being observed;
(3) to procure and send for test or analysis, if necessary, imported packages which he has reason to suspect contain drugs being sold or stocked or exhibited for sale in contravention of the provisions of the Act or Rules thereunder;
(4) to investigate any complaint in writing which may be made to him;
(5) to institute prosecutions in respect of breaches of the Act and Rules thereunder;
(6) to maintain a record of all inspections made and action taken by him in the performance of his duties, including the taking of samples and the seizure of stocks, and to submit copies of such record to the controlling authority;
(7) to make such enquiries and inspections as may be necessary to detect the sale of drugs in contravention of the Act;
(8) when so authorized by the State Government, to detain imported packages which he has reason to suspect contain drugs, the import of which is prohibited.

Duties of Inspectors specially authorized to inspect the manufacture of [drugs or cosmetics].

Subject to the instructions of the controlling authority it shall be the duty of an Inspector authorized to inspect the manufacture of drugs
(1) to inspect [not less than once a year], all premises licensed for manufacture of [drugs or cosmetics] within the area allotted to him to satisfy himself that the conditions of the licence and provisions of the Act and Rules thereunder are being observed;
(2) in the case of establishments licensed to manufacture products specified in Schedules C and C(1) to inspect the plant and the process of manufacture, the means employed for standardizing and testing the [drugs or cosmetics], the methods and place of storage, the technical qualifications of the staff employed and all details of location, construction and administration of the establishment likely to affect the potency or purity of the product;
(3) to send forthwith to the controlling authority after each inspection a detailed report indicating the conditions of the licence and provisions of the Act and rules thereunder which are being observed and the conditions and provisions, if any, which are not being observed;
(4) to take samples of the 1[drugs or cosmetics] manufactured on the premises and send them for test or analysis in accordance with these Rules;
(5) to institute prosecutions in respect of breaches of the Act and Rules thereunder.

Prohibition of sale.

No person in possession of a drug 2[or cosmetic] in respect of which an Inspector has made an order under clause *(c)* of sub-section *(1)* of section 22 of the Act shall in contravention of that order sell or otherwise dispose of any stock of such drug 2[or cosmetic].

Power of DI

Under the section 22 of DC Act. Drugs Inspectors have been assigned with following powers.
1. To inspect any premises where drug or cosmetic is being manufactured.

2. Inspection of premises where any drugs or cosmetics is being sold or stocked or offered for sale or distributed.
3. taking samples of any drug or cosmetics which is being manufactured or sold or stocked or offered for sale or distributed.
4. Taking samples of drugs or cosmetics from any person sent that sample for the test and analyses.
5. at all reasonable times with necessary assistance can search any person, enter and search any place where an offence under the act.
6. Examine any record , register document or any othjer materials related to manufacturing , sale or stock of drugs and cosmetics.

Licensing Authority.—No person shall be qualified to be a Licensing Authority under the Act unless:-
(i) he is a graduate in Pharmacy or Pharmaceutical Chemistry or in Medicine with specialization in clinical pharmacology or microbiology from a University established in India by law; and
(ii) he has experience in the manufacture or testing of drugs or enforcement of the provisions of the Act for a minimum period of five years:
3[Provided that the requirements as to the academic qualification shall not apply to those inspectors and the Government Analysts who were holding those positions on the 12th day of April,1989.]]

Controlling authority.

(1) All Inspectors appointed by the Central Government shall be under the control of an officer appointed in this behalf by the Central Government.
(2) All Inspectors appointed by the State Government shall be under the control of an officer appointed in this behalf by the State Government.
(3) For the purposes of these rules an officer appointed by the Central Government under sub-rule (1), or as the case may be, an officer appointed by the State Government under sub-rule (2), shall be a controlling authority.]

Qualification of a Controlling Authority.
To be a Controlling Authority under the Act
(1) No person shall be qualified unless
(i) he is a graduate in Pharmacy or Pharmaceutical Chemistry or in Medicine with specialization in Clinical Pharmacology or Microbiology from a University established in India by law; and
(ii) he has experience in the manufacture or testing of drugs or enforcement of the provisions of the Act for a minimum period of five years:
2[Provided that the requirements as to the academic qualifications shall not apply to those Inspectors and the Government Analysts who were holding those positions on the 12th day of April, 1989.]

References-

1. Drugs and Cosmetics Act ,1940 and Rules, 1945 As amended up to the 31st December, 2016
2. A text book of forensic pharmacy by B.M.Mithal
3. A text book of forensic pharmacy by Dr. B. Kuchhekar.
4. A text book of forensic pharmacy by N.K.Jain
5. A text book of forensic by B.Suresh.

BP 505 T (Pharmaceutical Jurisprudence) Theory

UNIT-III

- Pharmacy Act –1948: Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils; constitution and functions, Registration of Pharmacists, Offences and Penalties
- Medicinal and Toilet Preparation Act –1955: Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations. Offences and Penalties.
- Narcotic Drugs and Psychotropic substances Act-1985 and Rules: Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties.

Pharmacy Act –1948

Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils; constitution and functions, Registration of Pharmacists, Offences and Penalties

Definition

It is an act An Act to regulate the profession of pharmacy whereas it is expedient to make better provision for the regulation of the profession and practise of pharmacy and for that purpose to constitute Pharmacy Council. The Act was promulgated in the Year 1948 [1].

The PCI was first constituted in the year 1949 and reconstituted every 5 years.

In modern perspective, a pharmacist is a regarded as a member of health care team or an essential component of health system. The primary obligation of pharmacy is to safeguard the public health by making available the right medicaments. Medicines are of vital importance and hence their handling, compounding, dispensing and storage etc, need a thorough and specialized knowledge, skill and training of the personnel called pharmacists. The desired knowledge, skill and training are provided through the pharmacy courses [2].

Objectives

- Regulating and Raising the Status of the Profession of Pharmacy in India.

- Providing uniform education and training to the persons willing to enter the profession of Pharmacy.
- Maintaining control over the persons entering the profession of Pharmacy.
- To constituent 'Pharmacy Council of India' for setting new standards in 'Pharmacy Education'.
- To provide constitution and functions of 'State Pharmacy Council' for registration of pharmacists.
- To regulate the activities of pharmacists [3,4].

PHARMACY COUNCIL OF INDIA

In January 2015, the Pharmacy Council of India has published the new pharmacy practice regulations 2015 to regulate pharmacy in India [1]. The important provisions are:

a) The drugs can be dispensed only by a qualified registered pharmacist.
b) Registered pharmacists shall not give his registration certificate at more than one pharmacy.

c) Registered pharmacist shall also comply with the dress code by wearing white coat and apron with a badge displaying the name and registration number.
d) Every registered pharmacist shall dispense only those medicines as prescribed by the registered medical practitioner.
e) Every registered pharmacist shall maintain the medical or prescription records pertaining to the patients for a period of 5 years from the date of commencement of the treatment as per regulations.
f) Pharmacist should promote the rational use of drugs.
g) Other guidelines regarding ethical conduct of pharmacists.

The Central Government constitute a Central Council (Pharmacy Council of India). The PCI was constituted on 9th August, 1949 under section 3 of the Pharmacy Act. The council consisting of the following members:

A. *Elected members*:

a) Six members including at least one teacher each in pharmaceutical chemistry, pharmacology and pharmacognosy on the teaching staff of an Indian University or an affiliated college granting a degree or diploma in pharmacy. These members are elected by the University Grant Commission.
b) One member elected by the Medical Council of India from amongst its members.
c) One member who shall be registered pharmacist to represent each State elected by State Council from amongst its members.

B. *Nominated members*

a) Six members including at least four persons possessing degree or diploma in pharmacy and engaged in the practice of pharmacy or pharmaceutical chemistry, nominated by the Central Government.
b) A representative each of the University Grants Commission and All India Council for Technical Education.
c) One registered pharmacist to represent each State nominated by the State Government / Union Territory Administration.

C. *Ex-officio member*

a) The Director General of Health Services.
b) The Director of Central Drugs Laboratory.
c) The Drugs Controller of India.

If the ex-officio member under C (a) & (b) are unable to attend any meeting they can authorize a person each in writing to attend the meeting.

Function of Pharmacy Council of India (PCI)

The main functions of Pharmacy Council of India are:

a) To prescribe minimum standard of education required as a pharmacist.
b) Drafting of Education of Regulations to be fulfilled by the institutions for the approval, for imparting education in pharmacy.
c) To provide uniform implementation of the educational standards throughout the country.
d) Inspection of Pharmacy Institution to verify availability of the prescribed forms.
e) To recognize the course of study and examination for pharmacists.
f) To withdraw approval, if institution does not confirm educational standards prescribed by the PCI.
g) To approve qualifications granted outside the territories to which the Pharmacy Act extends i.e., the approval of foreign qualification.
h) To compile and maintain Central Register of Pharmacist.

President and Vice-president of Central Council

a) The President and Vice-President of the Central Council are elected by the members of the Council from amongst themselves. They hold office for a period not exceeding five years and not extending beyond the expiry of their term as the members of the Central Council, they are however eligible for re-election.
b) If the term of the President or Vice-President as member of the Central Council expires before the expire of the full term for which he is elected, he shall, if he is re-elected or re-nominated as a member of the Central Council, continue to hold office, as the president or Vice-President for the full term for which he is elected to such office.
c) Elections are to be conducted in the prescribed manner and in case of any dispute the same can be referred to the Central Government whose decision shall be final.

Terms of Office and casual vacancies.

a) Any nominated or elected member shall hold office for a term of five years from the date of his nomination or election or until his successor has been dully nominated or elected.

b) A nominated or elected member can resign his membership by writing under his hand to the President.

c) A nominated or elected member shall be deemed to have vacated his seat if he remains absent, without sufficient reason to the satisfaction of the Central Council, from three consecutive meetings of the Central Council.

d) A casual vacancy in the Central Council shall be filled by fresh nomination or election. The person so nominated or elected to fill the vacancy shall hold office only for the remaining term.

e) Members of the Central Council are eligible for re-nomination or re-election.

The Executive Committee:

The Pharmacy Act provides, constitution of Executive committee by the Central Council. The Executive committee consists of:

a) Ex. Officio members: (i) President who shall be the chairman of this committee and (ii) Vice-president.

b) Five other members elected by the Central Council from amongst its members.

The members of Executive committee holds the office until the expiry of his term as a member of Central Council, but if re-elected as a member of Central Council, he can hold office for residual term.

Powers of the Central Council to make regulations:

a) The council is authorized to lay down rules for its procedure, fix the rate of allowance payable to its members and members of other committee, which are previously sanctioned by Central Government and also decides modes of election.

b) It also lay down rules for the management of its property, and maintenance and auditing of accounts, holding of meetings, fixing functions, duties and powers of Executive Committee, president and vice-president and qualifications, terms of office, power and duties of secretary, inspectors and other officers of the council.

c) The council may constitute from amongst its members, such committees for general or other special purposes as deemed necessary.

d) The Council has to furnish copies of his minutes and those of Executive committee, together with a summary of annual activities and accounts to the Central Government. The Central Government may publish any reports or abstract in such manner as it thinks proper.

EDUCATION REGULATIONS 1991 (ED)

The Pharmacy Council of India make regulations which is known as Education Regulations 1991 [5]. It prescribe the

a) Minimum qualification for admission to the course.
b) Nature and period of course of study.
c) Nature and period of practical training to be undertaken after the completion of the regular course.
d) The subjects of examination and the standard attained therein.
e) The equipment and facilities to be provided by the institution for the students undergoing approved courses of study.
f) Conditions to be fulfilled by institutions giving practical training.
g) Conditions to be fulfilled by authorities holding approved examinations.

Central council before submitting the Education Regulation or any amendment thereof, as the case may be to the Central Government for approval, sends copies of draft of ER (Education Regulation) and all subsequent amendments to all State Governments and takes into consideration the comments of any State Government received within three months from the furnishing of the copies by Central Council. The ER then is published in Official Gazette by Central Governments as directed by Central Council. The Executive Committee from time to time reports to the Central Council on the efficacy of ER and may recommend to the Central Council such amendments thereof.

Application of Education Regulations to State

After the constitution of the state council under Chapter 3 and after consultation with State Council, the State Government may at any time, by notification in the Official Gazette declare that ER shall take effect in the State. If however, no such declaration has been made, the ER shall take effect in the State after three years from the date of the constitution of the State Council.

PHARM D. REGULATIONS 2008

Pharm D (Doctor of Pharmacy), qualification is considered for the purpose of registration as a pharmacist to practice the profession under the Pharmacy Act, 1948 [5]. There are two types of PharmD programmes:

i) Pharm D.

ii) Pharm D (Post Baccalareate)

Duration of the course:

Pharm. D: The course is full time of six academic years (5 years of study and one year of internship or residency). Each academic year shall spread overa period of not less than two hundred working days. Six academic years duration is divided into two phases.

a) Phase-I: Phase-I consists of first, second, third, fourth and fifth academic years.

b) Phase-II: Phase-II consists of internship or residency training during sixth year involving posting in speciality units in hospital. During this phase the student is exposed to actual pharmacy practice or clinical pharmacy services.

Pharm. D (Post Baccalaureate): The course is full time of three academic years (2 years of study and one year of internship or residency). Each academic year shall spread over a period of not less than two hundred working days. The period of three years duration is divided into two phases.

a) Phase-I: Phase-I consists of first and second academic years.

b) Phase-II: Phase-II consists of internship or residency training during third year involving posting in speciality units in hospital. During this phase the student is exposed to actual pharmacy practice or clinical pharmacy services.

Minimum qualification for admission:

Minimum qualification for admission to Pharm. D course is:

a) 10 + 2 examination with physics and chemistry as compulsory subjects with mathematics or biology or

b) D. Pharm, from PCI approved institution under section 12 of the Pharmacy Act or

c) Any other qualification approved by PCI as equivalent to any of the above examinations.

Pharm. D. (Post Baccalareate): Minimum qualification for admission to Pharm. D (Post Baccalareate) course is B. Pharm. from PCI approved institution under section 12 of the Pharmacy Act.

Reservation: There shall be reservation for SC, ST and OBC candidates as per the directives of Central Government / State Government / Union Territory Admission as the case may be from time to time.

Number of seats: PCI shall prescribe the number seats to be filled from time to time. Presently it is 30 for Pharm. D. and 10 for Pharm. D. (Post Baccalareate).
Permission: PCI approved institutions under section 12 of the Pharmacy Act running B. Pharm. course will only be permitted to run Pharm. D. programme and institutions running Pharm. D. courses will only be permitted to run Pharm. D. (Post Baccalaureate) programme with prior approval from PCI.

WITHDRAWAL OF APPROVAL

If the executive committee reports to the Central Council that an institution or authority holding an approved course of study or examination does not continue to be in conformity with the ER, the Central Council may give notice to the authority concerned of its intention withdrawing the declaration of approval accorded. The said authority then should make a representation within three months from the receipt of such notice and forward to the Central Council through the State Government.
Taking consideration, representation received from authority concerned, and any observation thereon which the State Government may think to make, the Council may declare that the course of study or examination shall be deemed to be approved only on fulfillment of specified conditions.

THE CENTRAL REGISTER OF PHARMACISTS

Under the provision of the section 15-A of the amendment Act1976, [5]:

a) Central Council has to maintain in a prescribed manner a register of pharmacist to be known as the Central Register which contains the names of all persons whose names are entered in the register for a state.
b) Every State Council has to supply five copies of a State to the Central Council as soon as after the first day of April every year, and Registrar of State Council should also inform all additions and other amendments in the register for a State, without delay to the Central Council.
c) Registrar of the Central Council has to keep the Central Register in accordance with the orders made by Central Council and should revise the Central Register from time to time and publish it in the Gazette of India.
d) The Central Register deemed to be public document within the meaning of the Indian Evidence Act 1872, and may be approved by the production of a copy of the register as published in the Gazette of India.

Registration in the Central Register: After receiving the report of registration of a person in the register for a State, the Registrar of Central Council enters the name of such person in the Central Register.

STATE AND JOINT STATE PHARMACY COUNCILS

State Council: Means, a State Council of Pharmacy constituted under the Act and includes a Joint State Council of Pharmacy in accordance with an agreement under section 20 of the Act [2].

State Government shall constitute a State Council consisting of the following members [1]:

a) Six members, elected from amongst themselves by registered pharmacists of the State.
b) Five members, of whom at least three shall be persons possessing a prescribed degree or diploma in pharmacy or pharmaceutical chemistry or registered pharmacists.
c) One member elected from amongst themselves by the members of each Medical Council or the Council of Medical Registration of the State.
d) Ex-officio members
   i) The chief administrative medical officer of the State.
   ii) The officer-in-charge of drugs control organization of the State.
   iii) The Government Analyst.

The joint State Pharmacy Council consists of following members

a) Not less than three members and not more than five members as the agreement shall provide elected from amongst themselves by the registered pharmacists of each of the participating States.
b) Not less than two members and not more than four members as the agreement shall provide, nominated by each participating State Government.
c) One member elected from amongst themselves by the members of each Medical Council or the Council of Medical Registration of each participating State.
d) Ex-officio members
   i) The chief administration medical officer of each participating State.
   ii) The officer-in-charge of drug control organization of each participating State.
   iii) The Government analyst.

Two or more State Government may agree to establish a joint State Council for all participating State or agree that the State Council of State must respond to the needs of

participating States. The membership of the State Pharmacy Council may be augmented by not more than two persons nominated by each of the State Governments of which at least one always have a degree or diploma in Pharmacy or pharmaceutical chemistry or registered pharmacist. The amount os expenditure to be shared between the State and may make other provisions for giving effect to the agreement. The inter-state agreement shall be published in the official Gazette of the participating States.

The President and Vice-President of the State Council are elected by the members from amongst themselves provided that for five years from the first constitution of the State Council, the President shall be a person nominated by the State Government who shall hold office for five years. The President and Vice-President shall hold office as such for a term not exceeding five years and not exceeding beyond the expiry of his term as a member of the State Council. He shall be eligible for re-election.

Terms of office and casual vacancies

a) Nominated or elected member hold office for a term of five years from the date of his nomination or election.
b) A nominated or elected member at any time resigns his membership by writing to the president and such seat thereupon become vacant.
c) If any member is absent, without excuse sufficient in the opinion of the State Council, for three consecutive meeting of the State Council, he shall be deemed to have vacated his seat.
d) The member who is elected from amongst themselves either by the registered pharmacist or by the members of Medical Council of the State or council of Medical Registration of the state as the case may be shall have to vacate his seat as a member of State council if he ceases to be a Registered Pharmacist or ceases to be a member of Medical Council or council of Medical Registration of the State as the case may be.
e) A casual vacancy in the State Council filled by fresh nomination or election as the case may be and the person nominated or elected to fill such vacancy, holds office only for the remainder of the term for whose place he takes.
f) Member of the State Council can be eligible for re-nomination or re-election.

Staff, remuneration and allowances

With previous sanction of the State Government, State Council may

a) Appoint Registrar, who also acts as a secretary and treasurer of the State Council, for a period of four years from the first constitution of State Council. Registrar is appointed by State Government.

b) Appointment of such other officers and servant may be required to enable State Council to carry out its functions.
c) Fix the remuneration and allowances to be paid to the President, Vice-president and other members of that Council.
d) Fix the pay and allowances and other conditions of service of officers and servants of that Council.

Inspector

A State Council with previous sanction of the State Government may appoint sufficient number of inspectors having prescribed qualifications.

Power of inspector: An inspector may

a) Inspect any premises where drugs are compounded and dispensed.
b) Enquire whether a person who is engaged in compounding or dispensing of drugs is a registered pharmacist or not
c) Inspect any complaint made in writing in respect of any contravention of this Act.
d) Institution prosecution under the order of the Executive Committee of the State Council.
e) Exercise such other power as may be necessary to give effect to some provisions of the Act.

Every inspector shall be deemed to be public servant within the meaning of section 21 of Indian Penal Code. Any person willfully obstructing an inspector in the exercise of the powers conferred on him by or under this Act or any rules made there under shall be punishable with imprisonment for a term which may extend to six months or fine of rupees thousand or both.

The State Council constitutes an Executive Committee consisting of the President (who shall be chairman of the Executive Committee) and Vice President and other members elected by the State Council from amongst them. The member of the Executive Committee shall hold office until the expiry of his term of office as member of the State Council. He shall br eligible for re-election.

REGISTRATION OF PHARMACISTS

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 [2].

The Pharmacy Act, 1948 under the chapter 4 provides for the registration of pharmacists in all the State in India. As soon as after this chapter has taken effect in the State, the first register of

pharmacist is required to be prepared by State Government concerned. The State Pharmacy Council is to be constituted soon after the preparation of first register and once State Council has been constituted the register is to be handed over to it. The State Council then has to be responsible for the maintenance of register. The register shall include the following particulars:

a) The full name and residential address of the registered persons.
b) The date of his first entry in the register.
c) His qualification for registration.
d) His professional address and if he is employed by any person the name of such person.
e) Such further particulars as may be prescribed.

Preparation of first register:

a) For the preparation of first register, State Government by notification in official Gazette constitute a Registration Tribunal consisting three persons, and also appoints Registrar who acts as a secretary of Registration Tribunal.
b) The State Government then by notification specify a date on or before which, application for registration accompanied with prescribed fee is made to the Registration Tribunal.
c) The Registration Tribunal examines every application received on or before the specified date and if satisfied that the applicant is qualified for registration, directs the entry of the name of the applicant on the register.
d) The first register so prepared is then published in a manner directed by State Government. Any person aggrieved by the decision of Registration Tribunal expressed on implied in the published register, may appeal within 60 days of publication to the authority appointed by State Government in this behalf.
e) The registrar amend the register accordingly with the decision of authority mentioned above and thereupon issues to every person a certificate of registration in prescribed form whose name is entered in the register.
f) After constitution of State Council, this register is to be given into its custody and Government directs to direct to credit application fee collected to State Council.

Qualification for entry on first register

A person who has attend age of 18 years, entitle to have his name in first register on pay ment of prescribed fee, if he resides or carries on the business or profession of pharmacy in the State and should have the following qualification:

a) A degree or diploma in pharmacy, or pharmaceutical chemistry or a chemist and druggist diploma of an Indian University, or a State Government or prescribed qualification granted by an authority outside India, or
b) A degree of an Indian University other than a degree in pharmacy or pharmaceutical chemistry and has been engaged in the compounding of drugs in a hospital or dispensary or other place in which drugs are regularly dispensed on prescription of Medical Practitioners for a total period of not less than three year.
c) Has passed an examination recognized as adequate by the State Government for compounders and dispensers.
d) Has not less than five years experience of compounding and dispensing in a hospital or dispensary or other place in which drugs are regularly dispensed on prescription of Medical Practitioners, prior to the date notified by the Registration. Tribunal for receipt of the application for entry of the names on first register.

Subsequent Register

After appointment of date to invite application for registration, to enter names in first register by State Government and before the Education Regulations have taken effect in the State, a person who has completed his 18 years of age shall on payment of prescribed fee, be entitle to have his name in the register, if he resides or carries on the business or profession of pharmacy in the State and if he has following qualifications:

a) Satisfies the conditions prescribed for registration and where no such conditions have been prescribed satisfies the conditions entitled to have his name enter on first register and are at least matriculate, or
b) Is a registered pharmacists in another State, or
c) Possesses qualification for registration granted outside the territories to which this Act extends and are at least matriculate.

After the Education Regulation have taken effect in the State, a person who has attained age of 18 years, shall on payment of prescribed fee, be entitled to have his name entered on the register and if he resides or carries on the business or profession of pharmacy in the State and if he –

a) Has passed an approved examination, or
b) Possesses a qualification granted outside the territories to which this Act extends, or
c) Is a registered pharmacist in another State.

Special provision for Registration of certain persons

The Pharmacy (Amendment) Act 1959, made certain special provisions for the registration of certain classes of persons besides the persons those who are eligible to register their name in subsequent register. This class of persons include particularly those who had been affected by the partition of the country in 1947 or by reorganization of States in 1956 or by transfer of certain foreign settlement to India or those who since passage of the Act migrated to India. By virtue of these provisions, a State Council may permit to enter on the register, the name of following classes of persons:

a) Displaced persons who had been carrying on the business or profession of pharmacy from a date prior to the 4th day of March 1948 and who satisfies the necessary conditions for registration in first register of a State.
b) Citizens of India who had been carrying on the business or profession of pharmacy in any country outside India and who satisfies the necessary conditions for registration in first register of a State.
c) Persons who resided in such area which at the time of the passage of Pharmacy Act not parts of India but which subsequently become a territory of India and who satisfies the necessary conditions to have their names in a first register of a State.
d) Person who carry on the business or profession of pharmacy in the State and who satisfy the conditions for registration in first register and had applied for registration on or before the date appointed, but did not get registered for some reasons.
e) Persons who carry on the business or profession of pharmacy in the State and who have been engaged in the compounding of drugs in a hospital or dispensary or other place in which drugs are regularly dispensed on prescription of medical practitioners for a total period not less than five years before the date appointed by State Government.
f) Persons who were qualified to be registered in a State existing before the 1st day of November 1956, but who, because of the transfer of the area in which they resided or carries on their business or profession of pharmacy, to another State on that day and are not qualified to be registered in the latter State only by the reason that they are not matriculates or do not possess a qualification obtained from outside India, which is recognized by the Pharmacy Council of India.
g) Persons who were registered in a State existing before 1st November 1956 and later it becomes part of another State and residing or carrying on the business or profession of pharmacy in later State.

h) Persons who resides or carry on their business or profession of pharmacy in an area in which the chapter relating to the registration applies after the commencement of the Pharmacy (Amendment) Act, 1959; and who satisfies condition for registration in first register.

Any person desiring to enter his name under special provisions in the register may apply in that behalf to the State Council. Such application should be accompanied with prescribed fee. These provisions remain in operation for a period of two years from the commencement of Pharmacy (Amendment) Act, 1959. The State Government however by notification, extend the period of operation of clause 1, 2 and 3, not exceeding two years in aggregate.

Scrutiny of applications for registration:

After the date appointed applications for registration accompanied by the prescribed fee shall be addressed to the Registrar of the State Pharmacy Council. If upon such application Registrar is of the opinion that the applicant has requisite qualifications for registration, he may direct to enter the name of the applicant in the register. Persons whose name has been removed from the register of any State shall not be entitled to have his name entered in the register except with the approval of State Council recorded at a meeting. Any persons whose application for registration is rejected by the Registrar, may appeal to the State Council within three months from the date of rejection. The decision of the State Council thereon is final. Upon entry of name in the register, registrar issues a certificate of registration in a prescribed form.

Renewal fees:

The retention of the name on the register after 31st December of the year following the year in which the name is first entered in the register, subject to the payment of prescribed fee annually before the 1st day of April. If a renewal fee is not paid by the due date, the Registrar shall remove the name of defaulter from the register. The name so removed however may be restored to the register on the prescribed conditions having satisfied. On payment of the renewal fee, the Registrar issues a receipt therefore, and such receipt deemed to be proof of renewal of registration. Any additional qualifications obtained by register pharmacist shall be entered in the register on payment of prescribed fee.

Removal of the names from the register:

The Executive Committee after giving an opportunity to a concerned to explain his conduct and on sufficient inquiry if satisfied, orders to remove the name of a registered pharmacist on following conditions:

a) If his name has been entered in the register by error or on account of misrepresentation or suppression of material fact or,
b) If he has been convicted of any offence or has been guilty of any infamous conduct in any professional respect, which in the opinion of the Executive Committee, renders him unfit to be kept in the register or,
c) That a person employed by him to work under him, in connection with any business of pharmacy has been convicted of an offence or held guilty of any such infamous conduct, if such person is a registered pharmacist, he is liable to remove his name from register.

Such order shall be made only if Executive Committee is satisfied that:

a) The offence or infamous conduct was instigated or conceived at by the registered pharmacist or,
b) The register pharmacist has any time during the period of twelve months immediately preceding the date on which the offence or infamous conduct took place, committed similar offence or guilty of infamous conduct or,
c) Any person employed by the registered pharmacist in connection with any business of pharmacy has been guilty of similar offence during the preceding twelve months and that the registered pharmacist had knowledge of such previous offence or infamous conduct or
d) The offence or infamous conduct continued over a long period and then to the registered pharmacist had or reasonable ought to have had knowledge of continuing offence or infamous conduct or,
e) The offence is an offence under the Drugs and Cosmetics Act, and the registered pharmacist did not use his intelligence to see that the provision of this Act were being observed at his place of business by persons under his control.

The removal of names from the register may either be permanent or only for a specified period of time. The order of Executive Committee directing removal of a name from the Register should be confirmed by the State Pharmacy Council and it takes effect only after three months of the date of such information. This period is probably given to allow the person to find an alternative means of livelihood. A person aggrieved by the order directing the removal of his

name, may appeal to the State Government within thirty days from the date on which he received such order and the decision of the State Government shall be final. A person whose name has been removed from the register is required to surrender his certificate of registration to the Registrar of the Pharmacy Council concerned and the name so removed shall be published in Official Gazette.

Restoration of the names to register:

The State Council may at any time for reasons appearing sufficiently to it, orders that upon payment of the prescribed fee, the name of a person removed from the register shall be restored to the register. Where an appeal against removal was made and rejected by State Government the name cannot be restored unless confirmed by State Government.

Issue of duplicate certificates of registration:

If it is shown to the satisfaction of the Registrar that a certificate of registration has been lost or destroyed, the Registrar may on payment of prescribed fee, issue a duplicate certificate in prescribed form.

OFFENCES AND PENALTIES

Falsely claiming to be Registered Pharmacist:

Any person whose name is not entered in the register, falsely claims to be a Registered Pharmacist or uses in connection with his name any words or letters to suggest that his name is so entered in the register, is punishable with fine up to five hundred rupees on first conviction and with imprisonment up to six months or fine up to thousand rupees or both on any subsequent conviction.

The use of description such as 'Pharmacist', 'Chemist', 'Druggist', 'Pharmaceutist', 'Dispenser', 'Dispensing Chemist' or any combination of such words by a person indicates that his name is entered in the register of a state.

If a person who is registered pharmacist in another state and who at the time of making claims to registration in the State has filed an application for registration shall not be deemed to be guilty of the offence. Cognizance of an offence punishable under this section shall not be taken except upon complaint made by order of the State Government or the Executive Committee of the State Council.

Dispensing by unregistered persons:

The persons other than registered pharmacists, dispensing any medicine for patients is liable for punishment with imprisonment up to six months or with fine up to six months or with fine up to one thousand rupees or with both.

References

1. Shalini Sharma, Jgdeep Singh Dua. Pharmaceutical Jurisprudence. S. Vikash and Company, 1st Edition, 2019.
2. N K Jain. A Text Book of Forensic Pharmacy. Vallabh Prakashan, 6th Edition, 2003.
3. Shyam Chandak. Pharmaceutical Jurisprudence. Nirali prakashan, 4th Edition, 2016.
4. Neerja Gandhi and Harvinder Popli. Pharmaceutical Jurisprudence. CBS Publisher & Distributors Pvt. LtD, 1st Edition, 1997.
5. B. S Kuchekar. Pharmaceutical Jurisprudence. Nirali prakashan, 25th Edition, 2016.

Medicinal and Toilet Preparations (excise duties) Act, 1955 and Rules thereunder 1976

The present Act prescribes uniform rules for whole of the country regarding duty leviable on such preparations. Alcohol may be used in the manufacture of medicines and toilet preparations. The alcohol required for this purpose can be obtained at lower rate of duty than required for drinking as ordinary alcoholic beverages.

This Act extends to the whole of India and provides legal binding on the use of alcohol.

A. Objective

It provides for the levy and collection of duties of excise on medicinal and toilet preparations containing alcohol, opium, Indian hemp, or other narcotic drugs and narcotics.

B. Definations

Alcohol: Alcohol means ethyl alcohol of any strength and purity having chemical composition C_2H_6OH.

Dutiable goods: It includes the medicinal and toilet preparations specified in the schedule as being subject to the duties of excise levied under this Act.

Medicinal Preparation: It includes the drugs used as a remedy or prescription prepared for internal or external use of human beings or animals and all substances intended to be used for or in treatment, mitigation or prevention of disease in human being or animals.

Toilet Preparation: The preparation intended to be used in the toilet of human body or in perfuming apparel of any description, or any substance intended to cleanse, improve or alter the complexion, skin, hair or teeth, and includes deodorants and perfumes.

Bonded Manufactory: It means the premises or any part of the premises approved and licensed for the manufacture and storage of medicinal and toilet preparations containing alcohol, opium, Indian hemp and other narcotic drugs or narcotics on which duty has not been paid.

Non-bonded manufactory: It means the premises or any part of the premises approved and licensed for the manufacture and storage of medicinal and toilet preparations containing alcohol opium, Indian hemp and other narcotic drugs or narcotics on which duty been paid.

Denatured Spirit or Denatured alcohol: It means alcohol of any strength which has been rendered unfit for human consumption by the addition of substances approved by the Central Government or by the State Government with the approval of the Central Government.

Spirit Store: It is the part of the bonded or non-bonded manufactory used for the storage of alcohol, opium, Indian hemp and other narcotic drugs or narcotics purchased free of duty or at prescribed rates of duty specified in the Schedule to the Act.

Restricted Preparation: These are medicinal preparations which are considered as capable of being misused as ordinary alcoholic beverages.

Unrestricted Preparation: These are medicinal preparations which are considered to be not capable of being, misused as ordinary alcoholic beverages.

Substandard Preparations: It includes:

(a) A pharmacopoeial preparation in which the amount of any of the various ingredients is below the minimum i.e. requirement.

(b) A proprietary medicine, not conforming to the formula displayed on the label.

C. Manufacture

Manufacturer gets the rectified spirit required for manufacture of medicinal and toilet preparations from a distillery or a spirit warehouse of the state. If there is a loss of rectified spirit due to the wastage in transit, and if the Excise Commissioner satisfies that the loss is bonafide and due to negligence by the manufacturer, the duty payable in respect of such loss may be waived in full or in part depending on the circumstances.

Permission of State Government is necessary to claim the concessions in duty in case of the issues of rectified spirit made to non-bonded manufactories.

There are two modes of manufacture of medicinal and toilet preparation containing alcohol,

(i) Manufacture in bond; and
(ii) Manufacture outside bond.

In the first case, alcohol on which duty has not been paid shall be used under the excise supervision and in case of manufacturer outside bond, only the alcohol on which duty has already been paid shall be used.

Procedure for license:

Every person, desiring to manufacture Medicinal and Toilet preparation containing alcohol or other narcotic substances is required to obtain a license,

(1) From the Excise Commissioner in case of a Manufacture in Bond; and

(2) From the officer as the State Government may authorise in this behalf in case of manufacture outside bond.

The application for grant of license should be submitted in the prescribed form together with prescribed fee (treasury chalan) so as to reach the licensing authority at least two months before the proposed date of the commencement of the manufacture.

Such application should contain the following particulars:

(1) The name or names and address or addresses of the applicant or applicants.

In case of a firm, the name and address of every partner. In case of a company, its registered name and address, the names and addresses of it's Directors, Managers and Managing agents.

(2) Name and address of the place and the site on which the Bonded or Non-bonded Laboratory is situated or to be constructed.

(3) The amount of capital proposed to be invested.

(4) Approximate date from which the applicant desires to start the manufacture if the required license is granted.

(5) The number and full description of the vats, stills and other permanent apparatus and machinery which the applicant wishes to set up.

(6) The maximum quantities in L.P. Liters of alcohol and alcoholic content in unfinished and finished preparations are likely to remain in the laboratory at any one time; and Maximum quantities by weight of opium, Indian hemp or other narcotic drug and their content in unfinished and finished preparations are likely to remain in the laboratory at one time.

(7) In case of Bonded laboratory, whether the proposed bonded manufactory will require the services of a whole-time or part-time excise officer.

(8) A list of all preparations, that the licensee proposes to manufacture showing,

(i) The percentage or proportion of alcohol in such preparation containing alcohol.

(ii) The quantities of opium, Indian hemp or other narcotic drugs in terms of weight in preparations containing these substances.

(9) The kind and number of licences held by the applicant under the Drugs and Cosmetics Act, 1940.

(10) Site and elevation plans of the manufactory building or buildings showing the location of the different rooms with doors and windows therein.

(11) In case of a firm, a true copy of the partnership deed. And in case of a company, the list of the Directors and Managers together with copies of Memorandum of Association and Articles of Association.

On receipt of such application the licensing authority makes the following enquiries:

(a) The qualifications and experience of the technical persons.

(b) The equipment of the bonded or non-bonded laboratories,

(c) Suitability of the proposed building for the establishment of a laboratory.

After satisfying that the applicant is eligible for the issue of a license, the licensing authority (the Excise Commissioner) shall issue a license and approve the plans of buildings submitted along with the application by the applicant. After constructing the buildings and establishing the laboratory as per the approved plans, the planning authority shall verify the plans to ascertain whether the construction is as per the approved plan or not.

In some cases where security is required to be furnished the licensing authority shall fix the amount of such security before granting the license. The security shall be either in cash or in interest bearing securities like Government Promissory Notes, National Savings Certificates, etc.

I. Bonded Laboratory or Bonded Manufactory

Following are the requirements of the bonded laboratory:

1. A spirit store, (if a distillery or a rectified spirit warehouse from which rectified spirit is made available, is not attached with the laboratory).
2. Room or rooms for the manufacture of medicinal preparations.
3. One or more rooms for the storage of the finished medicinal preparations.
4. A separate room or arrangement for the manufacture of toilet preparations.

5. The storage room for the finished toilet preparations.
6. Accommodation near the entrance for the officer-in-charge with necessary furniture.
7. Every room in the bonded laboratory should bear a board indicating the name of the room and serial number.
8. The pipes from sinks or wash basins in the laboratory should be connected with the general drainage of the laboratory.
9. The arrangements of gas and electric connections should be such that their supply can be cut off at the end of the day's work.
10. Every window in the bonded laboratory would be provided with specific arrangement of malleable iron rods of prescribed dimensions and the window should be covered on the inside with strong wire netting of a mesh not exceeding 25 mm.
11. There shall be-only one entrance to the bonded laboratory and one door to each of it's compartments. All the doors shall be secured with excise ticket locks in the absence of the officer-in-charge. No alterations in the bonded premises shall be made without the previous orders of the Excise Commissioner.
12. All vessels intended to hold alcohol and other liquid preparations should bear a distinctive serial number and full capacity.
13. The vessels for the storage of alcohol, opium, Indian hemp and other narcotic drugs and all the finished preparations on which duty has not been paid should bear excise ticket locks.

For the manufacture in bonded laboratory, the rectified spirit shall be issued without previous payment of duty subject to the condition that the manufacturer enters into a bond in prescribed form with sufficient security.

Obtaining the rectified spirit from the Distillery or spirit warehouse approved the Excise Commissioner:

The spirit required for the manufacture in bond shall be obtained on an in prescribed form countersigned by the officer in-charge of the laboratory from the approved spirit store or distillery. After receiving the duplicate of indent from the officer in-charge of the bonded laboratory, the distillery or warehouse officer shall issue the spirit under the appropriate permit, and send the advice portion of such permit to the officer-in-charge. The cost price of such rectified spirit shall be paid by the licensee to the distiller warehouse officer.

Verification and Storage of rectified spirit received:

After receiving the rectified spirit, it is verified in volume and strength and entered in the register. Then the spirit is stored in the spirit store.

Issue of the rectified spirit from the spirit store for manufacture:

The licensee should calculate the requirement of spirit on the basis of the formula of the preparation in pharmacopoeia or formula displayed on the label and hand it over to the officer-in-charge. Officer-in-charge shall then issue the spirit to the manufacturer. All rectified spirit issued shall be added immediately to the other ingredients of the preparation in presence of the officer-in charge.

The manufacturing vessels like percolators charged with alcohol should bear a label indicating

(a) The name and batch number of the preparation.

(b) Description and quantity of alcohol placed in it.

(e) Date of removal of the preparation and the quantity of such preparation removed.

On completion of the manufacture of a medicinal and toilet preparation, it should be removed to the finished goods store. With the permission of officer-in-charge, the licensee shall take specified quantity of the free sample for analysis in his laboratory.

Storage of finished products:

1. Finished preparations should be stored in bulk in jars or bottles each containing not less than 2,273 ml.
2. The preparations ready for issue may be filled in the containers of not less than 57 ml capacity. In some cases the Excise Officer may authorize issue in smaller containers.
3. Every container should be labeled and the label should contain:

(a) Name of the preparation.

(b) Batch number.

(e) Alcoholic strength; and

(d) Name of the manufacture.

4. The label on the container in which the preparation is stored in bulk should in preparation is stored in bulk should in addition indicate alcoholic content in liters, alcoholic strength and the date of storage.

5. The containers are so arranged on the rack so as to allow ready identifications of each batch.

6. The finished preparations may be stored in a store room for a period of three years or more with the permission of Excise Commissioner.

Issue of preparations from bonded laboratory:

For taking out the preparations from a bonded laboratory, the licensee should apply in prescribed form to Excise Officer-in-charge. After checking the entries and realizing the duty payable, the officer-in-charge shall issue a permit and allow the required quantities to be removed. However, the issue to another bonded warehouse may be made without payment of duty under proper security governed by the rules under this Act.

II. Non-Bonded Laboratory or Non- Bonded Manufactory

The manufacture and sale in the non-bonded laboratory should be conducted between sunrise and sunset only and on such days and hours as may be fixed by the Excise Commissioner.

Building Arrangements:

1. The portion of the non-bonded laboratory should be separated from the other portion used for other business.
2. There should be separate 'spirit store', laboratory' and finished store' and these should have the windows fitted with malleable iron bars of specific dimensions and the windows should be covered on the inside with strong wire netting of mesh not exceeding 25 mm.
3. There should be only one entrance to the non-bonded manufactory and one door to each of the above-mentioned departments.
4. All the pipes from sinks and wash-basins inside the non-bonded laboratory should be connected with the general drainage system of the premises.
5. The arrangements of gas and electric supply should be such that their supply can be cut off at the end of day's work.
6. There should be separate spirit store for the rectified spirit purchased at different rates of duty.
7. There should be separate finished stores for medicinal and toilet preparations falling under each item of the schedule to the act e.g., pharmacopoeial preparations with the items like, Aquas, Elixirs, Lotions, spirits etc., and Non-phamacopoeial preparations.

The State Government may relax the provisions in case of small manufacturers whose annual consumption of alcohol is not more than 500 litres and in the case of those who prepare medicinal preparations for dispensing to their patients only and not for sale.

Obtaining the rectified spirit-duty paid:

To obtain the spirit for manufacturing medicinal and toilet preparations from approved distiller or a spirit warehouse, the licensee should send the indent along with treasury chalan (evidence of duty payable) to the officer-in-charge of the distillery. The cost of such rectified spirit shall be paid by the licensee to the distillery or spirit-warehouse-keeper.

The officer-in-charge of the distillery, after satisfying himself that the correct amount of duty has been paid shall order the issue of rectified spirit required together with a permit covering the issue. After entering in the proper register, the spirit so obtained should be transferred to the respective spirit store.

Manufacture and storage of the preparations:

1. The manufacture of preparations from duty paid spirit should be carried out only at the licensed premises.
2. Each preparation should be registered after its manufacture and given a distinctive batch number.
3. All finished preparations should be transferred from the laboratory to the finished store and so arranged that they can be easily checked from the account register.
4. Finished preparations prepared from rectified spirit obtained at different rates of duties should be stored separately in the finished store.
5. The finished preparation stored in bulk should be measured in the storage vessel to the nearest fluid ounce (28.350 ml) and sealed.
6. The quantities from the bulk storage taken out by the manufacturer from time to time should be entered in the stock-card attached thereto. The Excise Officer, without any previous notice to the manufacturer may take samples at least once a month for analysis.

D. Exemption from Duty

The followings are exempted from duty on medicinal preparations containing alcohol manufactured in India and supplied direct from a bonded manufactory or warehouse.

1. Hospitals and dispensaries under Government or subsidized by the Government (State or Central).
2. Charitable hospitals and dispensaries under local bodies,
3. Medical Stores of Government.
4. Any institution certified by District Medical Officer supplying medicines free to the poor.

The Government has power to exempt any dutiable goods from the levy of the duty in the interest of the trade or in public interest.

E. Classification of Medicinal and Toilet Preparations Containing Alcohol

(A) Allopathic Preparations:

(a) Official allopathic preparations.

(b) Non-official allopathic preparations (Patent and Proprietary Preparations).

(B) Homoeopathic Preparations.

(C)Ayurvedic Preparations.

Medicinal and Toilet preparations are also classified as

(i) Restricted preparations.

(ii) Un-restricted preparations.

Allopathic Preparations:

Official preparations are made according to the formulae given in official books like I.P, B.P, B.P.C., U.S.P., N.F., Veterinary Codex (Government of India) etc.

Non-official allopathic preparations are prepared according to the allopathic system of medicine and confirm strictly to the formula displayed on the label. The official and non-official preparations, capable of being consumed as ordinary alcoholic beverages are known as 'Restricted Preparations'. Central Government may declare the unrestricted preparations as restricted preparations if they are widely misused.

Proprietary preparation which is newly put in the market is presumed to be a restricted preparation unless declared to be otherwise by the Central Government on the advice of the Standing Committee.

Any manufacturer intending to manufacture a new non-official alcoholic preparation should submit two samples of such preparations with the recipe to the State Government. The State Government, on advice of the Standing Committee, shall declare the class of such preparation, whether restricted or unrestricted.

Homoeopathic Preparations:

American, British and general pharmacopoeias shall be recognized as standard pharmacopoeia for Homoeopathic preparations.

Ayurvedic Preparations:

Ayurvedic preparations containing alcohol may be of two types:

(1) Those containing self-generated alcohol e.g. Asavas and Aristas.

(2) Those prepared by distillation or to which alcohol is added at any stage of manufacture.

Duty shall not be levied on Ayurvedic preparation containing self generated alcohol in which the alcoholic content is less than 2 per cent. In case of the preparation, the alcoholic content of which is more than 2% and if it is capable of being consumed as ordinary alcoholic beverages, the duty shall be paid, otherwise not.

Registered Ayurvedic Practitioners are allowed to manufacture and dispense (except by distillation or by addition of alcohol during the process) such preparations are free of duty, provided:

(a) They take a license.

(b) Use such preparations only for the patients of the practitioners and not for sale to the general public.

(c)They should allow Excise Officer to draw samples of such preparations to ensure that the preparations contain only self-generated alcohol; and

(d) They should maintain accounts of the preparations manufactured or dispensed to the patients together with the names and addresses of the patients. The Ayurvedie preparations may be manufactured in bond or without bond.

F. Warehousing of Alcoholic Preparations

The manufacturers or dealers in dutiable goods are allowed to establish bonded warehouses anywhere in India to deposit dutiable goods. The persons who intend to establish a warehouse should apply in prescribed form along with prescribed fees to Excise Commissioner of State and obtain a license for the purpose from him. The Excise Commissioner may require the licensee to furnish a bond in prescribed form with surety or security, binding him to pay duty on the goods deposited or for removal of such goods to another warehouse or for the due observance of the terms, conditions and requirements of the Act. All such goods brought for warehousing should be produced to the officer-in-charge of the warehouse with the relative transport permit. Before the entry in the warehouse, the goods should be weighed, gauged and assessed to duty and the particulars should be recorded in the register maintained for the purpose. The bonded warehouse should be locked and secured as per the directions of Excise Commissioner.

Goods shall not be removed from any warehouse without payment of duty. Duty shall not be paid for the removal of goods to other warehouse or for export. Goods shall remain in the warehouse in which they are deposited for three years or more as the Excise Commissioner allow.

G. Export of Medicinal and Toilet

Preparations (Alcoholic Preparations):

No duty shall be paid on alcoholic preparations which are exported from India. The preparations can be exported by two methods:

(1) Duty paid goods shall be exported under claim for rebate of duty.

(2) Goods (without payment of duty) shall be exported under bond.

I. Export of Duty Paid Goods:

Export of Duty paid goods shall be made under claim for rebate of duty. The owner of the non-bonded manufactory or a wholesale dealer who wants to export duty paid goods should give minimum 48 hours' notice to the concerning Excise-Officer to supervise the packing of the goods which are to be exported. The manufacturer or dealer should present the consignment to be exported to the concerning officer who shall send the samples of such dutiable goods to the Chemical Examiner for analysis to confirm the alcoholic contents of these goods. From the report of Chemical Examiner, the officer shall enter the alcoholic contents (strength) in the

duplicate copy of the application which shall be presented to Excise Commissioner by the exporter for claiming rebate of excise duty.

After verifying the application, the officer-in-charge or concerning officer shall get the following particulars noted on the packages:

(1) Name and address of the consignee.

(2) Total quantity of the goods packed.

(3) Description of the goods packed.

(4) Alcoholic strength of the goods in London-proof (L.P.) liters.

(5) A Gross weight of each package.

The Officer-in-charge shall then seal each package with his official seal and endorse all the copies of the application specifying the period within which the goods shall be actually exported. The Officer shall return the duplicate to the consignor, who has to enter the number and date of the railway receipt or bill of landing in duplicate copy, after dispatching the goods. The consignor should inform these particulars to the concerning officer for entry in the other copies. On arrival of the goods at the consignee's place (place of export) the goods should be presented to the Customs Collector, Border Examiner etc. for examination, along with duplicate application. After such examination the Customs Collector, Border Examiner such officers of customs may allow export. For obtaining the payment of rebate the exporter should produce to the Excise Commissioner, the duplicate application along with the certificate of the officer who examined the goods. The Excise Commissioner if satisfied from the comparison of duplicate and original application that the claim is in order, he shall sanction the rebate claimed by the exporter.

II. Export under Bond:

The owners of the bonded manufactory or bonded warehouse can export the alcoholic preparations under bond. The exporter should present an application in triplicate to the Excise Officer-in-charge of the bonded laboratory or warehouse, giving the statements that the goods are to be exported by sea or air or by parcel post. The packages of the goods to be exported should be marked in ink or oil color with the particulars like serial number, owners name and special mark if any and total quantity of the dutiable goods with their alcoholic strength in L.P. liters.

On verification of the particulars in the application, the Officer-in-charge also note the following particulars on the packages,

(1) Name and address of the consignee (to whom the goods are to be exported).

(2) Description of goods.

(3) Total quantity of the goods packed.

(4) Gross weight of the package.

The officer may seal each package with his official seal. The packages can be exported in the same way as that of duty-paid goods.

Inter-State movement of Medicinal and Toilet Preparations under the Act:

Medicinal and Toilet preparation under this Act can be moved from one State to another after payment of duty as per the rules. Such dutiable goods can also be transferred from a bonded warehouse of one State to the bonded warehouse of the other State. The procedure for the same is described in the further paragraph.

Movement of dutiable goods from one Bonded Warehouse to another Bonded warehouse:

When the goods are to be removed from one warehouse to another, the consignor or the consignee should enter into a bond with surety or sufficient (prescribed) security. Such bond shall be furnished to the officer-in-charge of the warehouse of removal or of the warehouse of destination as the case may be. Such bond shall remain valid until the Officer-in-charge of the warehouse of removal has received a re-warehousing certificate (stating that the goods have been re-warehoused) from the Officer-in-charge of warehouse of destination. The consignor should make an application in triplicate for removal of goods from one warehouse to another warehouse to the officer-in-charge of the warehouse together with other necessary information as the Excise Commissioner may require at least 24 hours before the removal of goods.

The officer-in-charge shall take the account of goods and send the duplicate copy after giving remark for removal to the officer-in-charge of the warehouse of destination. And the triplicate copy shall be given to the consignor to send to the consignee.

On arrival of the goods at the destination, the consignee should present such goods along with the triplicate application and the transport permit to the officer-in-charge. Then he shall take account of goods and complete the re-warehousing certificate on the duplicate and triplicate

and return the duplicate to the officer-in-charge of the warehouse of removal and the triplicate to the consignee for dispatch to the consignor. The consignor shall then present such triplicate copy of the application together with the warehousing certificate to the officer in-charge of his warehouse within 90 days of the issue of the transport permit to him.

G. Entry, Search and Seizure

An officer authorized by Excise Commissioner shall have free access at reasonable time to any premises, equipment, stocks and accounts of manufacturers and dealers in dutiable goods. Any excise officer authorized in this behalf by the State Government may stop and detain any person carrying or removing any dutiable goods without transport permit or other relevant document required.

Excise Officers, not below the rank of sub-inspectors has power to stop search and seize the vessel or vehicle carrying the dutiable goods. He has also power to enter and search at any time, any premises or land in which he has reason to believe that dutiable goods are stored, manufactured in contravention of the Act and Rules there under. In case of any resistance to entry or search or; seizure he has power to break open any door and remove any other obstacle and open and search into such land or premises.

Such officer may also seize and remove or detain any receptacle, packages or coverings of such goods and animals, vehicles or vessels involved in carrying the goods and the machinery used in the manufacture of such goods. All such searches, seizures etc., made under the Act are in accordance with Criminal Procedure Code.

I. Offences and Penalties

1. (a) Contravention of any of the provisions relating to the terms and conditions of a license granted under this Act; or

(b) Failure to pay any duty of excise payable under this Act; or

(c) Failure to supply required information or supplying false information; or

(d) Attempt to commit or abet any of the above offences.

Punishable with imprisonment up to six months or with fine up to Rs. 2,000/-or with both.

2. Connivance by any owner or occupier of land or by any agent of such owner occupier for any offence against the provisions of this Act, or any rules there under.

Punishable with imprisonment up to six months or with fine up to Rs. 500 or both for every offence.

3. Vexations search, seizure by any officer exercising powers under this Act or under the rules made there under.

Punishable with fine up to Rs. 2,000/-.

4. Refusal to perform or withdrawal of one-self from the duty by the Excise Officer without permission of the superior officer.

Punishable with imprisonment up to three months or with fine up to three months pay.

5. Failure to furnish proof of export, within the prescribed period to the satisfaction of Excise Commissioner, by any persons authorized to export dutiable goods in bond.

Punishable with a fine up-to Ra. 2,000/- extent to twice the amount of duty.

6. Of all the offences committed with respect to warehousing.

Punishable with a fine up to Rs. 2,000/- and the goods related to the offences are liable to confiscation.

7. Obstruction to the officers while exercising their powers regarding Entry, Search and Seizure.

Punishable with a fine up to Rs. 500/-.

8. Prosecution: Only the sub-inspector or officer above his rank can institute the prosecution under this Act.
9. Arrests: Only the sub-inspector or officer above his rank can make arrest under this Act.
10. A breach of the rules, where no punishment is provided.

Punishable with a fine up to Rs. 1,000/- and confiscation of the goods.

11. Keeping of stocks of dutiable goods in disorderly manner (not in accordance with the provisions of this Act).

Punishable with a fine up to Rs. 1,000/-

12. Maintaining false accounts of stock of goods in a manufactory or warehouse or not following the provision of this Act while maintaining such accounts.

Punishable with a fine up to Rs. 2,000/-.

13. Sale of dutiable good except in prescribed containers bearing a label.

Punishable with a fine up to Rs. 1,000/- and confiscation of the goods related with this offence.

14. Disclosure of information by Excise officers learned by him in his official capacity.

Punishable with a fine up to Rs. 1,000/-.

Reference

B. S Kuchekar. Pharmaceutical Jurisprudence. Nirali prakashan, 25th Edition, 2016.

The Narcotic Drugs and Psychotropic Substances Act, 1985, with rules, 1985

Definition:

The Narcotic Drugs and Psychotropic Substances Act, 1985, commonly referred to as the NDPS Act, is an Act of the Parliament of India that prohibits a person to produce/manufacture/cultivate, possess, sell, purchase, transport, store, and/or consume any narcotic drug or psychotropic substance.

Objectives:

- The main object of this Act is to consolidate and amend the law relating to narcotic drugs, to make stringent provision for the control and regulation of operations relating to narcotic drugs and psychotropic substances.
- It also provides licensing system for both Central and State Governments to regulate the manufacture, cultivation, import, export inter-state traffic, transportation, sale and possession etc, of the Narcotic Drugs and Psychotropic substances.

Definition:

"*Addict*": Means a person who has dependence or habitual to regular use of any narcotic drug or psychotropic substances.

"*Cannabis*": (hemp): It means

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

(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;

"*Cannabis plant*": means any plant of the genus cannabis.

"*Coca derivative*": means—

(a) crude cocaine, that is, any 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, that is, methyl ester of benzoyl-ecgonine and its salts; and

(d) All preparations containing more than 0.1 per cent. of cocaine;

"*Coca leaf*": means—

(a) The leaf of the coca plant except a 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 does not include any preparation containing not more than 0.1 percentage of cocaine;

(vii) "Coca plant" means the plant of any species of the genus Erythroxylon;

"*Manufacture*": in relation to narcotic drugs or psychotropic substances, includes—

(1) All processes other than production by which such drugs or substances may be obtained;

(2) Refining of such drugs or substances;

(3) Transformation of such drugs or substances; and

(4) Making of preparation (otherwise than in a pharmacy on prescription) with or containing such drugs or substances;

"*Manufactured drug*": means—

(a) All coca derivatives, medicinal cannabis, opium derivatives and poppy straw concentrate;

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

"***Narcotic drug***" means coca leaf, cannabis (hemp), opium, popy straw and includes all manufactured drugs;

"*Opium*": means—

(a) The coagulated juice of the opium poppy; and

(b) Any mixture, with or without any neutral material, of the coagulated juice of the opium poppy, but does not include any preparation containing not more than 0.2 percentage of morphine;

"*Opium derivative*": means—

(a) Medicinal opium, that is, opium which has undergone the processes necessary to adapt it for medicinal use in accordance with the requirements of the Indian Pharmacopoeia or any other pharmacopoeia notified in this behalf by the Central Government, whether in powder form or granulated or otherwise or mixed with neutral materials;

(b) Prepared opium, that is, any product of opium obtained by any series of operations designed to transform opium into an extract suitable for smoking and the dross or other residue remaining after opium is smoked;

(c) Phenanthrene alkaloids, namely, morphine, codeine, thebaine and their salts;

(d) Diacetylmorphine, that is, the alkaloid also known as dia-morphine or heroin and its salts; and

(e) All preparations containing more than 0.2 per cent. of morphine or containing any diacetylmorphine;

"*Opium poppy*": means—

(a) The plant of the species *Papaver somniferum* L; and

(b) The plant of any other species of *Papaver* from which opium or any phenanthrene alkaloid can be extracted and which the Central Government may, by notification in the Official Gazette, declare to be opium poppy for the purposes of this Act;

"*Poppy straw*": means all parts (except the seeds) of the opium poppy after harvesting whether in their original form or cut, crushed or powdered and whether or not juice has been extracted there from;

"*Poppy straw concentrate*": means the material arising when poppy straw has entered into a process for the concentration of its alkaloids;

"*Preparation*": in relation to a narcotic drug or psychotropic substance, means any one or more such drugs or substances in dosage form or any solution or mixture, in whatever physical state, containing one or more such drugs or substances;

"*Prescribed*": means prescribed by rules made under this Act;

'*Production*" means separation of opium, poppy straw, coca leaves or cannabis from the plants from which they are obtained;

"*Psychotropic substance*": means any substance, natural or synthetic, or any natural material or any salt or preparation of such substance or material included in the list of psychotropic substances specified in the Schedule;

"*Small quantity*": in relation to narcotic drugs and psychotropic substances, means any quantity lesser than the quantity specified by the Central Government by notification in the Official Gazette;]

"*To import inter-State*": means to bring into a State or Union territory in India from another State or Union territory in India;

"*To import into India*": with its grammatical variations and cognate expressions, means to bring into India from a place outside India and includes the bringing into any port or airport or place in India of a narcotic drug or a psychotropic substance intended to be taken out of India without being removed from the vessel, aircraft, vehicle or any other conveyance in which it is being carried.

"*To export from India*": with its grammatical variations and cognate expressions, means to take out of India to a place outside India;

"*To export inter-State*": means to take out of a State or Union territory in India to another State or Union territory in India;

"*To transport*": means to take from one place to another within the same State or Union territory;

"*Illicit traffic*": in relation to narcotic drugs and psychotropic substances, means—

(i) Cultivating any coca plant or gathering any portion of coca plant;

(ii) Cultivating the opium poppy or any cannabis plant;

(iii) Engaging in the production, manufacture, possession, sale, purchase, transportation, warehousing, concealment, use or consumption, import inter-State, export inter-State, import into India, export from India or transshipment, of narcotic drugs or psychotropic substances;

(iv)Dealing in any activities in narcotic drugs or psychotropic substances other than those referred to in sub-clauses (*i*) to (*iii*); or

(v) Handling or letting out any premises for the carrying on of any of the activities referred to in sub-clauses (*i*) to (*iv*),

"*Essential narcotic drug*": means a narcotic drug notified by the Central Government for medical and scientific use;

"*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.

AUTHORITIES AND OFFICERS

Measure for preventing and combating abuse of narcotic drugs and illicit traffic therein:

Central Government under the provisions of this Act, may take the measures with respect to all or any of the following matters.

1. Co-ordination of actions by various officers, State Governments and other authorities under this Act, or under any other law for the time being in force relating to the enforcement of the provisions of this Act.

2. Obligations under the International Conventions.

3. Assistance to the concerned authorities in foreign countries and concerned international organizations regarding prevention and suppression of illicit traffic in narcotic drugs and psychotropic substances.

4. Identification, treatment, education, aftercare, rehabilitation and social re-interaction of addicts.

5. Such other matters for effective implementation of this Act and preventing and combating the abuse of narcotic drugs and psychotropic substances and illicit traffic therein.

Officers of Central Government:

Under the provisions of this Act, the Central Government may appoint Narcotic Commissioner and such other officer as it thinks fit.

Narcotic Commissioner himself or with the help of other officers shall perform the functions relating to:

(i) The supervision of the cultivation of the opium poppy, and

(ii) Production of opium; and

(iii) Other functions as may be entrusted to him by the Central Government.

The State Government may appoint such officers as deemed fit for the purposes of this Acts.

The Narcotic Drugs and Psychotropic Substances Consultative Committee:

For efficient administration of this Act, the Central Government may constitute an advisory committee known as: 'The Narcotic Drugs and Psychotropic Substances Consultative Committee".

This committee consists of a Chairman and such other members not exceeding 20, as may be appointed by the Central Government. For efficient discharge of it's functions the Committee may constitute and appoint one or more sub-committees.

The committee shall advice the Central Government on the matters relating to the administration of this Act.

Prohibition, Control and Regulation:

Section 8, of this Act prohibits certain operations such as cultivation of coca plant, opium and cannabis plant, manufacture, possession, sale, purchase, transport, import, export, etc. relating to the narcotic drugs and psychotropic substances except for medical and scientific purposes. However, section 9, of this Act empowers the Central Government to permit, control und regulate by rules, certain operations relating to certain narcotic drugs and psychotropic substances.

(a) Prohibition of certain operations as per sec. 8: No person shall:

(i) Cultivate any coca plant or gather any portion of coca plant or,

(ii) Cultivate the opium poppy or any cannabis plant; or

(iii) Produce, manufacture, possess, sell, purchase, transport, ware-house, use, consume, import inter-state, export inter-state, import into India, export from India or transship any narcotic drug or psychotropic substance except for medical and scientific purposes and to the extent and in the manner provided by other provisions of this Act, or the rules or orders made there under.

(b) Power of Central Government to Permit, Control, and Regulate:

(1) Permission and Regulation of certain operations by Central Government: Central Government may, by rules permit and regulate:

(i) The cultivation, or gathering of any portion of coca plant (only on account of the Central Government), or the production, sale, purchase, transport, import inter-state, export inter-state, use or consumption of coca leaves.

(ii) The cultivation of the opium poppy; (only on account of Central Government).

(iii) The production and manufacture of opium and production of opium and production of poppy straw.

(iii) The sale of opium and opium derivatives from the Central Government factories for export from India or sale to State Government or to manufacturing chemists.

(iv) The manufacture of manufactured drugs (Other than prepared opium) but not including manufacture of medicinal opium or any preparation containing any manufactured drug from materials which the maker is lawfully entitled to possess.

(v) The manufacture, possession, transport, imports inter-state, export inter-state, sale, purchase, consumption or use of psychotropic substances.

(vi) The import into India and export from India and trans-shipment of narcotic drugs and psychotropic substances.

Control on Certain Operations by Central government: According to the rules:

(i) Government shall fix from time to time the limits within which licenses may be given for the cultivation of opium poppy.

(ii) All Opium, the product of land cultivated with the opium poppy shall be delivered by the cultivators to the officers authorized on behalf of Central Government.

(iii) The Central Government may from time to time fix the price to be paid to the cultivators for the opium delivered.

(iv) The rules may prescribe the forms and conditions of licenses or permits for the manufacture, possession, transport, import-inter-state, export inter-state, sale, purchase, consumption or use of psychotropic substances. The rules may also prescribe the authorities granted and the fees that may be charged therefore.

(v) The rules may prescribe the forms and conditions of licenses for cultivation of the opium poppy and for the production and manufacture of opium. The rules may also prescribe the fees that may be charged therefore, the authorities by which such licenses may be granted, withheld, refused or cancelled and the authorities before which appeals against the orders of withholding, refusal or cancellation of licenses shall lie.

(vi) The rules may provide for the weighed, examined, classified according to the quality and consistence by the officers authorized in this behalf by the Central Government in the presence of the cultivator at the time of delivery by the cultivator.

(vii) The rules may provide for the weighment, examination and classification, according to the quality and consistence of the opium received at the factory and the deduction from or addition to the standard price to be made in accordance with the result of such examination.

(viii) The rules may prescribe the forms and conditions of licenses for the manufacture of manufactured drugs, the authorities by which such licenses may be granted and the fees that may be charged therefore.

(ix) The rules may require that opium delivered by cultivator, if found as a result of examination in the Central Government factory to be adulterated, may be confiscated by the officers authorized in this behalf.

Power of State Government to permit, control and regulate:

Permission and Regulation of certain operations by State Government: State Government may by rules permit and regulate:

(i) The possession, transport, inter-state import, inter-state export, warehousing, sale, purchase, consumption and use of poppy straw.

(ii) The possession, transport, inter-state import, inter-state export, sale, purchase, consumption and use of opium.

(iii) Cultivation of any cannabis plant production, manufacture, possession, transport, inter-state import, inter-state export, sale purchase, consumption or use of cannabis (excluding charas).

(iv) Manufacture of medicinal opium or any preparation containing any manufactured drug from materials which the maker is lawfully entitled to possess.

(v) Possession, transport, purchase, sale, inter-state import, inter-state export, use or consumption of manufactured drugs other than prepared opium and of coca-leaf and any preparation containing an manufactured drug.

(vi) The manufacture and possession of prepared opium from opium lawfully possessed by an addict registered with the State Government on medical advice for his personal consumption.

Control of certain operations by State Government: The rules under this Act may

(i) Provide that the State Government shall fix from time to time the limits within which licenses may be given for the cultivation of any cannabis plant.

(ii) Make provision that, only the cultivators licensed by the prescribed authority of the State Government shall be authorized to engage in cultivation of any cannabis plant.

(iii) Require that all cannabis, the produce of land cultivated with cannabis plant, shall be delivered by the cultivators to the officers of the State Government authorized on this behalf.

(iv) Empower the State Government to fix from time to time, the price to be paid to the cultivators for the cannabis delivered.

(v) Prescribe the forms and conditions of licenses or permits licenses or permits for some or all of the followings: possession, transport, import inter-state, export inter-state, warehousing, sale, purchase, consumption and use of poppy straw, opium, cannabis (excluding charas).

National Fund for Control of Drug Abuse

1. The Central Government may, by notification in the Official Gazette, constitute a Fund to be called the National Fund for Control of Drug Abuse (hereafter in this Chapter referred to as the Fund) and there shall be credited thereto:
    - An amount which the Central Government may, after due appropriation made by Parliament by law in this behalf, provide.
    - The sale proceeds of any property forfeited under Chapter VA.
    - Any grants that may be made by any person or institution.
    - Any income from investment of the amounts credited to the Fund under the aforesaid provisions.
2. The Governing Body shall consist of a Chairman (not below the rank of an Additional Secretary to the Central Government) and such other members not exceeding six as the Central Government may appoint.
3. The Governing Body shall have the power to regulate its own procedure.
4. Annual report of activities financed under the Fund-
    - The Central Government shall, as soon as may be, after the end of each financial year, cause to be published in the Official Gazette, a report giving an account of the activities financed under the previous section during the financial year, together with a statement of accounts.

5. The Fund shall be applied by the Central Government to meet the expenditure incurred in connection with the measures taken for

- Combating illicite traffic of narcotic and psychotropic substances.
- Controlling abuse
- Identifying, treating, rehabilitating addicts.
- Preventing drug abuse.

- Supply of drugs to addicts.

OFFENCES AND PENALTIES

1. **Punishment for contravention in relation to poppy straw:**
2. **Punishment for contravention in relation to coca plant and leaves:**
3. **Punishment for contravention in relation to prepared opium:**
4. **Punishment for contravention in relation to opium poppy and opium:**
5. **Punishment for embezzlement (illegal disposal) of opium by cultivator:**
6. **Punishment for contravention in relation to cannabis plant and cannabis:**
   (a) Where such contravention relates to ganja or the cultivation of cannabis plant: Rigorous imprisonment upto five years with a fine upto fifty thousand rupees.
   (b) Where such contravention relates to cannabis other than ganja: Rigorous imprisonment for not less than ten years which may extend to twenty years with fine not less than one lakh rupees which may extend to two lakh rupees.
7. **Punishment for contravention in relation to manufactured drugs and preparations:**
8. **Punishment for contravention in relation to psychotropic substances:**
9. **Punishment for illegal import into India, export from India or transhipment of narcotic drugs and psychotropic substances:**
10. **Punishment for external dealings in narcotic drugs and psychotropic substances in contravention of the provisions of this Act:** Rigorous imprisonment for not less than ten years which may extend to twenty years with a fine not less than one lakh rupees which may extend to two lakh rupees.
11. **Punishment for allowing premises, etc. to be used for commencement of an offence:** Rigorous imprisonment for not less than ten years which may extend to twenty years with fine not less than one lakh rupees which may extend to two lakh rupees.
12. **Punishment for certain acts by licensee or his servants:** The acts are:

(a) Omitting to maintain accounts in accordance with the provisions of this Act.
(b) Failure of producing license, permit or authorization on demand of any authorized officer.
(c) Keeping any false account or making false statement.
(d) Knowingly doing any act in breach of any of the conditions of license, permit or authorization for which a penalty is not prescribed elsewhere in this Act: Imprisonment up-to three years or fine or both.

13. **Punishment for illegal possession in small quantity for personal consumption of any narcotic drug or psychotropic substance or consumption such drug or substance:**

(a) Where the narcotic drug or psychotropie substance possessed or consumed is cocaine, morphine, diacetyl-morphine or any other narcotic drug or any psychotropic substance. Imprisonment up-to one year or fine or both.

(b) Where the narcotic drug or psychotropic substance possessed or consumed is other than those mentioned in (a) above: Imprisonment up-to six months or fine or both.

14. **Punishment for abetment and criminal conspiracy:** Punishment provided for the offences.
15. **Enhanced punishment for certain offences after previous conviction: On second and every subsequent conviction of offences:**
16. **Punishment for offence for which no punishment is provided under this act:** Imprisonment up-to six months or fine or both.

Opium Poppy Cultivation and Production of Poppy Straw

The NDPS Act empowers the Central Government to permit and regulate cultivation of opium poppy for medical and scientific purposes. The Government of India notifies the tracts where opium cultivation can be licensed as well as the General Conditions for issuance of license every year.

Opium and poppy straw are the raw materials obtained from the opium poppy plant (Papaver somniferum), from which alkaloids such as morphine, thebaine and codeine are extracted. Concentrate of poppy straw is a product obtained in the process of extracting alkaloids from poppy straw.

Production and supply of the opium

- Opium (also called "raw opium") is the latex obtained by making incisions on the green capsules of opium poppy plants.
- Cultivation can be done only in those areas, notified by the govt.
- Licences are granted by district opium officers for cultivation. He appoints one licenced cultivator who performs duties as specified by narcotic commissioner with help of small cultivators under him.
- Harvest of each day's collection is weighed and entered in records which is signed by cultivator. The records are checked by the dist opium officer.
- The whole opium collected by the dist. Officer is then delivered to opium factory.

- The cultivators are paid and they should not dispose off any part of the procedure and adulteration is liable for confiscation.
- Cultivator should cultivate full area of land for which he may have received advance amount from the govt.
- Opium shall not be cultivated in any part of the India except UP and MP (as per central opium rules, 1934).

Manufacture-

Poppy straw is first pulverized, then washed as many as six to ten or more times in water which may have an acid added to increase solubility, to produce **poppy straw concentrate** (**PSC**, also known as **concentrate of poppy straw**, **CPS**). Dried, the concentrate is a beige to brown powder. It contains salts of various alkaloids, and can range from nine to 30 times the morphine concentration of poppy straw. Opium concentrates using solvents other than acidifed or plain water are often but not necessarily called PSC.

Fee for grant of licence.

The licence of cultivation of opium poppy may be granted by the District Opium Officer on payment of a fee of [rupees twenty-five].

Form of licence for cultivation of the opium poppy-

The licence for cultivation of opium poppy for the production of opium or poppy straw shall be issued in Form No. 1 appended to these rules.

Issue of licence-Subject to the general conditions relating to grant of licence notified by the Central Government*, the District Opium Officer may issue licence to any person for a crop year for cultivation of the opium poppy for production of opium or poppy straw on receipt of an application made by that person in Form No.2 appended to these rules.

Licence to specify the area, etc.-The licence for cultivation of opium poppy issued under rule 8 shall specify the area aid designate the Plots to be cultivated with opium poppy.

Procedure with regard to measurement of land cultivated with opium poppy.-

1. All plots of land cultivated with opium poppy in accordance with the licence issued under these rules, shall be measured in metres by the proper officer in the presence of the cultivator.

2. The measurement conducted by the proper officer shall be subject to such further checks bv such officers as may be specified by the Narcotics Commissioner in this behalf.

Delivery of opium produced-

All opium, the produce of land cultivated opium poppy, shall be delivered by the cultivators to the district Opium Officer or any other officer duly authorised in this behalf, by the Narcotics Commissioner at a place as may be specified by such officer.

Manufacture Sale and Export of Opium

Manufacture of opium- Opium shall not be manufactured save by the Central Government Opium Factories at Ghazipur and Neemuch: Provided that opium mixtures may be manufactured from opium lawfully possessed by a person authorised under the rules made by the State Government for the said purpose.

Export of opium-The export of opium is prohibited save when the export is on behalf of the Central Government.

Sale to State Governments or manufacturing chemist.-

1) The sale of opium to the State Governments or manufacturing chemists or the person or entity who has been granted licence under sub-section (2A) of rule 36, as the case may be, shall be only from the Government Opium Factories, located at Neemuch and Ghazipur
2) The sale of opium from the Government Opium Factory at Neemuch and Ghazipur to manufacturing chemists or the person or entity who has been granted licence under sub-rule (2A) of rule 35, as the case may be, shall be only under a permit granted by or under the orders of the State Government within whose jurisdiction the chemist or the person or entity resides or has his place of business in the forms prescribed by that Government.

Manufacture of Manufactured drugs

- Morphine, thebaine, dihydro-morphine, codeine, dihydro codeine and salts are manufactured at govt factory, Ghazipur.
- Manufacture of crude cocaine, cocaine salts, ecgonine, diacetylmorphine and its salt is prohibited.
- Manufacturing of cocaine and its salt is prohibited, except cocaine hydrochloride which can be prepared from confiscated cocaine only.
- Medicinal hemp manufacture shall be under licence issued by chief excise authority of the state govt.
- Manufacture of synthetic drugs is prohibited, except it is under the authorized license granted by narcotic commissioner on govt behalf.
- Licensee

- Should have drug manufacturing license granted to him under drugs and cosmetics act 1940.
- Should deposit 5000 as security and shouldn't manufacture excess than requirements of the country for a year according to international narcotics board.
- Notice of commencement of drug manufacture must be given 15 days prior to licensing authority and also one month's notice before he ceases to manufacture.
- Security arrangements are made around manufacturing premises.

Offences and penalties

- For contravening any provisions of the act or rules imprisonment for 10 to 20 yrs and fine from one lakh to two lakh rupees can be imposed. In certain cases rigorous imprisonment will be 15 to 30 yrs and fine from 1.5 lakh to 3 lakh.
- ・ Illegal possession of cocaine, morphine punishable with imprisonment upto one yr or fine or both.
- ・ Failure to keep accounts or submit returns as required by law, punishable law imprisonment for 6 months and fine.
- ・ Failure to produce records, license, permit, authorization etc., on demand by the authorized persons, punishable with imprisonment upto 5 yrs or fine or both.

Reference

1. B. S Kuchekar. Pharmaceutical Jurisprudence. Nirali prakashan, 25th Edition, 2016.

2. S.P. Agrawal, Rajesh Khanna. Pharmaceutical Jurisprudence & Ethics (Forensic Pharmacy). 3rd edition Birla Publication Pvt. Ltd. 2004 p. No. 169-191

PHARMACEUTICAL JURISPRUDENCE
(Theory)

Subject code: BP 505 T.

B. Pharm – 5th Sem

Preference Unit - IV

Contents

Study of Salient Features of Drugs and Magic Remedies Act and its rules:

Objectives:

- Under competition of marketing of any product, advertising has become a part of our life.
- Modern age is called 'advertisement' era.
- It has occupied special position in our life.
- Media (TV, Internet) and newer method for advertisement has brought massive progress.
- About fifty years ago, advertising was not appreciated but now the position is quite different. Modern methods of advertising in TV and internet have proved effective.
- Drugs and cosmetic manufactures are spending money in advertising. So, the products are reasonable high.
- Ethical advertising is never objectionable, while unethical or misuse of advertisement (for promoting sale of drugs) cause harm to the user of the advertised goods. (e.g pen or a drug for curing disease condition – lead to worse). Hence, advertisement of drugs is not directly public rather persons like physician, pharmacist and nurses.
- A common practice in India might be selling of magic remedies such as Kavachas, mantras, talishmans etc. which are claimed to be universal cure of any disease.
- Advertisement in the magazines, newspapers and on the premises of doctors, hakims or vaids claiming cure of disease.
- Innocent peoples are often trapped of such unsocial activity which leads waste of time, money, spoil their health and prematurely leave the world.
- Recent years there has been great increase in the objectionable advertisements (sexual content and muscle improving) published in newspaper and magazine and internet. This leads to self-medication with harmful drugs which cause a great harm. To stop such practice, The Drugs and Magic Remedies Act 1954, was passed.
- The act as well as rule came into force in 1st April, 1955 and amended in 1963 and extends all over India except Jammu and Kashmir.

Definitions:

Advertisement - Any notice, circular, label, wrapper, any announcement in orally of by means of producing transmitting sound and light.

Drug – any chemical substances or medicines are used for internal or external treatment of human beings or animals or used for diagnosis, cure, mitigation, treatment or prevention of disease or other than food that influence in structure or organic function of the body

Magic remedy – This includes a talisman (a ring or stone that bring luck), mantra, kavacha have miraculous power or in the cure, diagnosis, treatment or influencing any structure or organic function of the body.

Registered medical practitioner - any person who holds a qualification granted by an authority specified in, or notified under section 3 of the Indian Medical Degrees Act, 1916 (7 of 1916) specified in the Schedules to the Indian Medical Council Act, 1956.

Prohibition of advertisements:

a) Certain drugs for treatment of certain diseases and disorders:

No person shall not take part in the publication of any advertisement relating to any drug in terms which suggest

i) Miscarriage or prevention of conception in women or
ii) Maintenance or improvement of the sexual pleasure of human beings or
iii) Rectification of menstrual disorder in women or
iv) Diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition specified in the Schedule.

b) Misleading advertisements relating to drugs:

Any person shall not take any part in the publication of any advertisement relating to a drug if the advertisement contains any matters which—

i) directly or indirectly gives a false brand regarding the true character of the drug; or
ii) makes a false claim for the drug; or

c) Magic remedies for treatment of certain diseases and disorders.

Any person shall not take any part in the publication of advertisement related to any magic remedy which directly or indirectly claims to efficient for purposes of specified in section (a).

d) Import into, and export from, India of certain advertisements.

Any person shall not import into, or export from, the territories to which this Act extends any documents containing an advertisement under in section a or in section b or section c, and any document containing any such advertisements shall be deemed to be goods of which the import or export has been prohibited under section 19 of the Sea Customs Act, 1878.

Classes of Exempted advertisements:

- Any registered medical practitioner has displayed advertisement on sign board or notice his buildings showing that treatment of any disease or disorder.
- Any matter related to the disease or disorder showing on the book or treatise.
- Any advertisement relating to any drug sent confidentially (by posting) to the registered medical practitioner or whole seller or retail chemist and showing the specification "For the use only of registered medical practitioner or a hospital or a laboratory".
- Any advertisement relating to a drug printed or published by the state or central govt.
- Any advertisement, labels or sets of instruction are permitted under the Drugs and Cosmetics Act and Rules.

Classification of Advertisement:

Class	Condition
1. Leaf let or literature on packing of drugs	1. Only such information shall be shown on advertisement that required for the guidance of registered medical practitioner. The contents of the matter as follows
2. Drug advertisement in medical, pharmaceutical, scientific and technical journals	A. Therapeutic use of drugs B. Route of administration C. Dosage form D. Side effects

	E. Any precaution observed during treatment 2. Any claim made in the advertisement in respect of the drug shall not false or misleading
3. Price lists or therapeutic indexes published by manufacturers, importers or distributers of drugs under Drugs and Cosmetics Act & Rules 1940 4. Medical literature distributed by medical retailers appointed by manufacturers, importers under Drugs and Cosmetics Act & Rules 1940	1. Only such information shall be shown on advertisement that required for the guidance of registered medical practitioner. The contents of the matter as follows A. Therapeutic use of drugs B. Route of administration C. Dosage form D. Side effects E. Any precaution observed during treatment 2. The distribution of such literature is confined only to the physician, hospital, dispensaries, medical and research institution, chemist and druggists under Drugs and Cosmetics Act & Rules 1940 3. Any claim made in the advertisement in respect of the drug shall not false or misleading

Offences and Penalties:

Whoever breaks any of the provisions of this Act shall, on conviction, be punishable—

Offences	**Penalties (Imprisonment/fine)**
A. Under the Act & Rules	6 months or fine or both
1. First conviction	1 year or fine or both
2. Second conviction	As per rule
B. Offence by company	Not applicable
1. In-charge person as well as compony (with knowledge)	Forfeiture of any document, article or thing, includes its content
2. Guilty without knowledge	
C. Convict under the act	
1. Court may direct	

Powers of entry, search, etc.:

Any Gazetted Officer authorised by the State Government may, within the local limits of the area for which he/she is so authorised,—

(a) Enter and search at all reasonable times, with such assistants, if any, as he/she considers necessary, any place in which he has reason to believe that an offence under this Act has been or is being committed;

(b) seize any advertisement which he has reason to believe contravenes any of the provisions of this Act: Provided that the power of seizure under this clause may be exercised in respect of any document, article or thing which contains any such advertisement, including the contents, if any, of such document, article or thing, if the advertisement cannot be separated by reason of its being embossed or otherwise, from such document, article or thing without affecting the integrity, utility or saleable value thereof; examine any record, register, document or any other material object found in any place mentioned in clause (a) and seize the same if he has reason to believe that it may furnish evidence of the commission of any offence punishable under this Act.

(c) Where any person seizes anything under clause (b), he shall, as soon as may be, inform a Magistrate and take his orders as to the custody.

References:

Text book of Forensic Pharmacy by B.M. Mithal

A text book of Forensic Pharmacy by N.K. Jain

The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 by Govt. of India publications

Prevention of Cruelty to animals Act-1960:

Objectives:

- Animals are considered as important experimental subjects in modern days of research. Why???
- Although humans and animals (technically "non-human animals") may look different, at a physiological and anatomical level they are remarkably similar (**Fig.1**). Animals, from mice to monkeys, have the same organs (heart, lungs, brain etc.) and organ systems (respiratory, cardiovascular, nervous systems etc.) which perform the same functions in pretty much the same way.

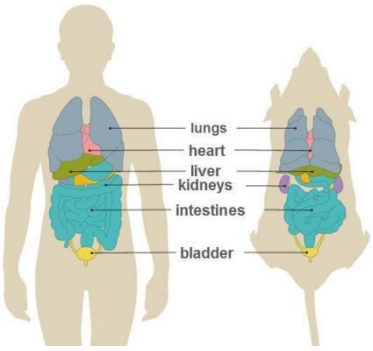

Fig 1. Physiological and anatomical level, humans and other animals are remarkably similar

- The similarity means that nearly 90% of the veterinary medicines that are used to treat animals are the same as, or very similar to, those developed to treat human patients.
- approximately 99% of our DNA is similarity with DNA of mice.
- 108 Nobel Prizes awarded for Physiology or Medicine, 96 were directly dependent on animal research.
- Addiction (monkeys), Alzheimer's Disease (mice), Diabetes – Type I (mice), Heart Damage (rats), HIV/AIDS (monkeys, mice) are Current examples of animal research in medicine for establishing for safety and therapeutic efficacy of drugs.
- Data generation on animal toxicology and animal pharmacology that clinical trials under taken the drugs and cosmetic rules are come first.
- Above facts indicates that animals may be subjected to injury, pain or suffering and even death. It explains unethical practice.
- 1890 – the first animal act was implicated to stop the cruelty towards animals.
- 1960 – The Prevention of Cruelty to animal's act was passed. This act was solely for protection of animals from unnecessary pain and suffering.
- 1998 – Control and supervision Rules were implemented. The purpose is general awareness about animal welfare, the breeding, and experiments on animals. This Act and rule was extended whole country except Jammu and Kashmir.

Definitions:

Animal- Any leaving creature other than human being

Board – Animal welfare board established under sec- 4 of the act.

Breeder – Breeds animals for the purpose of transfer to the authorized institution for performing experiments.

Committee – Control and supervision on animals under section 15 of the act.

Establishment – Any individual, company, firm, corporation, institution except college (upto PG label) performing experiments on animals.

Experiment – Use of an animal for the purpose of acquiring knowledge of a biological, psychological, ethological, physical or chemical nature.

Institutional Animals Ethics Committee- A body/committee comprising a group of persons to control and supervision on experimented animals.

Contract Research – Any research undertaken by an individual, company, firm, corporation or institution on behalf of a foreign individual, corporation or institution.

Collaborative Research – Any research undertaken between two or more research institution without any financial consideration and is meant for advancement of scientific research and human welfare.

Institutional Animal Ethics Committee (IAEC):

IAEC consist of

a) A biological scientist
b) Two scientists from different biological dept.
c) A veterinarian physician
d) A scientist from animal facility of the establishmentconcern
e) A scientist from outside of the institution
f) A social person
g) A representative of the Committee for the Purpose ofControl and Supervision of Experiments on Animals (CPCSEA)
h) A specialist (radioactive substance or deadly microorganisms) may be co-opted.

- An eight-member IAEC is constituted in every registered institute. All research project proposals using small animals, such as rats, mice, rabbits or guinea-pigs, have to be approved by the IAEC before initiation.
- Every member of the IAEC has the right to question/reject of a project; unapproved proposals are referred to a subcommittee of experts for scrutiny and possible approval. The IAEC cannot approve research projects on large animals, such as dogs, cats, nonhuman primates, cattle, goats and sheep.

CPCSEA

- Article 51A(g) of the Constitution of India reads that it is the fundamental duty of every citizen of India "to protect and improve the natural environment including forests, lakes, rivers and wildlife and to have compassion for living creatures".
- In 1960, the Prevention of Cruelty to Animals (Fig. 2) Act was formally made public by an act of the Indian Parliament.
- Section 15 of the Act provides for constitution, by

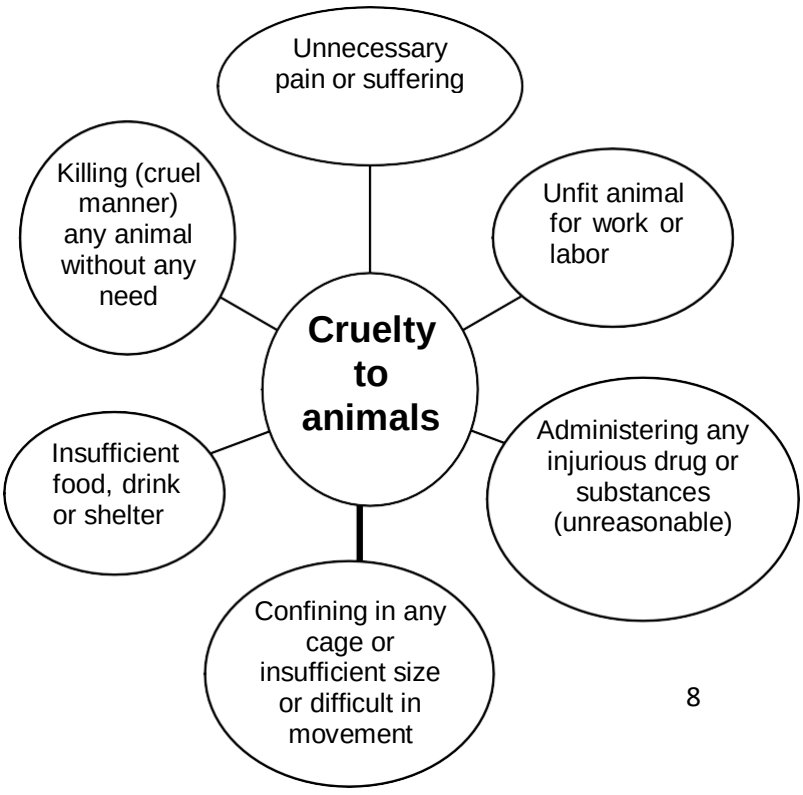

Fig.2 Cruelty to Animals

the Central Government of India, CPCSEA to supervise and control experiments on animals.

Guidelines for Breeding and Stocking of Animals

A. Breeding for business organization (Establishment):

1. Applicant must have registered and trade of animals for the purpose of experiments.
2. For registration, the applicant shall have filled in a specified format and submitted to Member- secretary or authorized person appointed by the committee.
3. They shall apply for registration within sixty days from the date of commencement of the breeding and experiments on animals under the Rules 1998.
4. Stop of breeding animals in case committee refuses to give registration.

B. Breeders for university and colleges:

1. Govt. of India has set up the "Committee" for the purpose of control and supervision of experiments on animals under the Minister of Social Justice and Empowerment, Shastri Bhavan, New Delhi. This committee shall look over registration process.
2. The applicant shall apply in prescribed format for registration to the Secretary or the authorized officer of the committee.
3. The application shall have verified information relating to premises where the experiments are to be conducted, animal housing facilities, details of breeding of animals and its trade, availability of trained manpower in handling of animals.
4. After verification, if the committee satisfied, the registration is approved for such breeder.
5. Every registered breeder shall comply all the condition at the time of registration.
6. They shall maintain a day to day register of particular animals used for conducting experiments with number of animals, the species, the age, gender, and any other related information.
7. The committee or authorized person shall examine the register during their inspection.
8. If the committee or authorized person is not satisfied during examination, they will give the opportunity to improve or may take appropriate action against breeder.

C. Guidelines for stock of the animals (by the breederand the establishment):

1. Animal houses shall be located in a quite atmosphere
2. The premises shall keep in clean and hygienic condition.
3. Animals shall have protected from drought and extremeweather.

4. Animal cage for small and stable (firmly fixed or not likely to move or change) for large animals. So that they can live in comfort and not to be over crowded.
5. Proper care should be maintained during off-hours and on holidays.
6. The registered establishment shall stick to the detailed specification laid by the committed for housing, feeding and maintenance of various species used in animal experiment.
7. The cages and stable shall maintain the standard laid down by the Indian Standards Institution (ISI)
8. Animal attendants must be suitably trained andexperienced in their duties.

Performance of Experiments:

Purpose:

- Discovery of new knowledge or chemical (or biological) active compound
- Useful for saving or establish prolonging life
- Less sever suffering of any disorder or disease
- Combating any disease in human, plant and animals.

Guidelines for performing the experiment as follows

1. The experiment shall not have performed in public demonstration except in school, college and recognized training institution for attaining purpose of manual skills.
2. Person-in-charge of the institution should take responsibility to perform on animal experiment. In case outside of the institution, the experiment should be carried out by qualified person.
3. All experiment shall be performed by or under the supervision of a duly qualified person (Diploma/Degree/PG in Pharmacy/ Medicine/ Veterinary/ Life Sciences or certificate in Laboratory animal techniques sciences).
4. Experiment performed with due care and humanity.
5. During or after experiment, the animals are not suffering unnecessary pain.
6. Before and after experiment, the animals should be under proper care or looked properly.
7. During operational procedure, anesthetic should be administered to animal by a trained person, so that, animals are not suffer pain or feeling of pain throughout the experiment.
8. Under influence of anesthesia, if animals are recovered abnormal or sever pain at any stage of continuing experiment, it shall be painlessly destroyed and discontinued the experiment.
9. Experiment with animals shall not be repeated, if experiment is already established or justified or conclusively known.
10. Pain on eye of animal by any chemical agent that should not be applied.
11. Dogs shall not have debarked (This is a surgical procedure to reduce tissue in the vocal chords) during experiment purpose.

Transfer and acquisition of animals for experiment:

Acquiring animal for conducting any experiment:

1. Every breeder has a register and shall apply for experimental activity permission directly to the Secretary or authorized person of Committee/ Institutional Animal Ethics Committee by stating name of the species and the number of animals acquired.
2. The committee shall scrutiny the application, if satisfied, may grant the permission for conducting experiments.
3. While granting permission, a condition is applied that animals are not suffering unnecessary pain during or after experiments on them.
4. Person carrying on experiments on animals should inform authority about completion of experiment for which the permission has been granted.

Contract animal experiments:

1. Contract animal experiment or research shall not permit to any establishments or educational institutional except with prior permission of the committee.
2. Collaborative research between two academic institution may be permitted for such purpose.

Transfer of animals for experiment:

1. Transfer of any animal for sale purpose to an unregistered breeder is not permitted.
2. A breeder can't acquire any animal by sale except from a registered breeder.
3. Acquired animal can't be sale except from registered breeder.
4. Experiment in production/ breed improvement programme, animals may be given out by breeder institution for domestic use.
5. Genetic experiment on rat and mice not available in India, if such, the breeder shall take the permission from Institutional Animal Ethics Committee (IAEC).
6. Import of any animal available in the country is also not allowed.

Records:

1. Every registered breeder\IAEC should maintain record of the animals and furnish them to the committee from time to time.
2. All laboratory shall inform exact number of animals used in a specified format to the Secretary or authorized person.

Power to suspend or revoke registration:

1. Rules made by the committee are not followed or not satisfied by the committee.
2. The Committee giving a reasonable opportunity for rectification, after that the registration may revoke for a specific period or indefinitely or grant the license on a special condition.
3. Failure of compliance of rule and regulation, the committee may impose pending or suspend the registration.

4. During suspension period, the breeder shall take care of animals, cease to perform any experiment or acquire or transfer of any animal is prohibited.

Offences and Penalties

If any person-

1. Breaks any order made by the Committee under section 19; or commits a break of any condition imposed by the Committee under that section: he shall be punishable with fine which may extend to two hundred rupees
2. The person in-charge of the institution has breached the condition imposed by the Committee under that section: he shall be deemed to be guilty of the offence and shall be punishable accordingly.
3. The penalty under this Act is, the offender (in the case of a first offence) will have to pay fine which shall extend to fifty rupees and if it is the case of second offence or subsequent offence committed within three years of the previous offence, he will be fined with not less than twenty-five rupees but which may extend to one hundred rupees or with the imprisonment for a term which may extend to three months or with both. Also, in the case of second offence, the offender's vehicle is seized, and he will never be allowed to keep an animal again.

Reference:

Text book of Forensic Pharmacy by B.M. Mithal

A text book of Forensic Pharmacy by N.K. Jain

Pereira S, Veeraraghavan P, Ghosh S, Gandhi M. Animal experimentation and ethics in India: the CPCSEA makes a difference. Altern Lab Anim. 2004;32 Suppl 1B:411-415. doi:10.1177/026119290403201s67

The Prevention of Cruelty Animals Act,1960 by Govt. of India publications

National Pharmaceutical Pricing Authority:

Drugs Price Control Order (DPCO)- 2013

- Drugs Price Control Order (DPCO), 1995 was introduced in India on date 6th January 1995
- This Act has abolished under sec.3 of the Essential Commodities Act 1955.
- The Central Government has changed the Drug (Prices Control) Order, 1995 and was introduce the Drugs (Prices Control) Order, 2013 on dated 15.05.2013 and this Act came into force in India on the date 22.03.2016.

Objectives:

- This Act will provide govt. control over the prices of bulk drugs as well as drug formulations.

Definitions:

"***Active pharmaceutical ingredients or bulk drug***" means any pharmaceutical, chemical, biological or plant product including its salts, esters, isomers, analogues and derivatives, conforming to standards specified in the Drugs and Cosmetics Act, 1940 and which is used as such or as an ingredient in any formulation.

"***Brand***" means a name, term, design, symbol, trademark or any other feature that identifies one seller's drug as different from those of other sellers.

"Ceiling price" means a price fixed by the Government for Scheduled formulations in accordance with the provisions of this order.

"Dealer" means a person carrying on the business of purchase or sale of drugs, whether as a wholesaler or retailer.

"Distributor" means a person engaged in the work of distribution of drugs and includes an agent or a stockist for stocking drugs for sale to a dealer;

"Existing manufacturer" means manufacturer existing on the date of publication of this order in the Official Gazette.

"Form" means a form specified in the Second Schedule of the Act

"Formulation" means a medicine processed out of or containing one or more drugs with or without use of any pharmaceutical aids, for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease and, but shall not include –

i) any medicine included in any genuine Ayurvedic (including Sidha) or Unani (Tibb) systems of medicines;
ii) any medicine included in the Homeopathic system of medicine; and
iii) any substance to which the provisions of the Drugs and Cosmetics Act

"Generic version of a medicine" means a formulation sold in pharmacopeial name or the name of the active pharmaceutical ingredient contained in the formulation, without any brand name

"Import" means bringing a drug into India from a place outside India for its sale.

"Local taxes" means any tax or levy (except excise or import duty included in retail price) paid or payable to the Government or the State Government or any local body under any law for the time being in force by the manufacturer or his agent or dealer

"Manufacturer" for the purpose of this Order means any person who manufactures or imports or markets drugs for distribution or sale in the country
"Market share" means the ratio of domestic sales value (on the basis of moving annual turnover) of a brand or a generic version of a medicine and the sum of total domestic sales value of the all brands and generic versions of that medicine sold in the domestic market having same strength and dosage form
"Margin to retailer" mean a percentage of price to retailer
"Market-based data" means the data of sales related to a drug collected or obtained by the Government as deemed fit, from time to time
"Maximum retail price" means the ceiling price or the retail price plus local taxes and duties as applicable, at which the drug shall be sold to the ultimate consumer and where such price is mentioned on the pack
"Moving annual turnover" in a particular month means cumulative sales value for twelve months in domestic market, where the sales value of that month is added and the corresponding sales of the same month in the previous year are subtracted
"National List of Essential Medicines" means National List of Essential Medicines, 2011 published by the Ministry of Health and Family Welfare as updated or revised from time to time and included in the first schedule of this order by the Government through a notification in the Official Gazette
"New drug" mean a formulation launched by an existing manufacturer of a drug of specified dosages and strengths as listed in the National List of Essential Medicines by combining the drug with another drug either listed or not listed in the National List of Essential Medicines or a formulation launched by changing the strength or dosages or both
"Pharmacoeconomics" means a scientific discipline that compares the therapeutic value of one pharmaceutical drug or drug therapy to another
"Price list" means a price list referred to in paragraphs 24 and 25 and includes a supplementary price list
"Price to retailer" means the price of a drug at which it is sold to a retailer which includes duties and does not include local taxes
"Retail price" means the price fixed by the Government for a new drug under paragraph 5 of the Act
"Retailer" means a dealer carrying on the retail business of sale of drugs to customers
"Scheduled formulation" means any formulation, included in the First Schedule whether referred to by generic versions or brand name
"schedule" means a Schedule added to this Order (Drugs Price Control Order (DPCO)-2013)
"wholesaler" means a dealer or his agent or a stockist engaged in the sale of drugs to a retailer, hospital, dispensary, medical, educational or research institution or any other agency;
"wholesale price index" means annual wholesale price index of all commodities as announced by the Department of Industrial Policy and Promotion, Government of India, from time to time.

Sale prices of bulk drugs:

A. Prices of Drugs in First or Second Schedule:

- **First Schedule:** it contains the list of 74 bulk drugs
- **Second Schedule:** it contains various forms for approval or revision of prices of Scheduled formulations

- **Third Schedule:** it specifies the maximum pre-tax (of income or profits) considered or calculated before the deduction of taxes) return on sales turnover of manufacturer/importers of formulations under A, B & C categories
- The ultimate object of first & second schedule of the act to regulate the fair prices from different manufactures. Central govt. has authorized to fix the maximum sale prices of bulk drugs manufactured in the country. They have fixes more than sale price and average price in the fixation of prices in drug formulations.
- 31st January and 30th June each year, the manufacture of bulk drugs have furnished details on specified in form I. Govt. shall take into consideration, while fixing the maximum sale price of bulk drugs.
- A post tax return (An **after-tax return** is any profit made on an investment after subtracting the amount due for taxes) of 14% on net value or a return of 22% on capital employed or a new plant an internal rate of return of 12% on long term marginal costing (The increase or decrease in the total cost of a production for making one an item) depending upon the option for any of the specified rates of return that may be exercised by the manufacture of bulk drugs.
- For basic stage of production, govt. shall take consideration of a post-tax return 18% on net value or return of 26% on capital employed.
- Any person cannot sell at a price exceeding the fixed maximum price plus local taxes.
- Price option once exercised will be final and any change of price will not possible without prior approval of the govt.
- For revision of bulk drug price, the manufacture can apply the application with showing complete information to the govt. at least four months from date of receipt. The govt. may fix a revised the price or reject the application

B. Price of bulk drugs other than those specified in First or Second Schedule:

- The manufacturer can apply will all required information to the govt. within 30 days of the commencement of order, so, govt. can fix their prices.
- The manufacturer can apply for price revision to the govt. within 14 days of the commencement of manufacturer. In this case, the manufacturer/ distributor can refuse sale of drug to any dealer
- The govt. can direct the manufacturer to manufacturer formulation; as per consumption and planed growth of pharmaceutical industry
- Importer of bulk drug shall furnish price list to govt. each year, within 30 days of introduction of finance Bill. If importer fails to furnish, then govt. can fix the price based on available information.

Retail price of formulations:

Formula of retail price of any drug formulation, RP = $(M.C + C.C + P.M. + P.C) \times 1 + \frac{MAPE}{100} + E.D$

R.P = Retail Price; M.C = Materials Cost (inclusive of processing losses); C.C = Conversion Cost (combination of direct labor costs and manufacturing overhead costs) as per notified from time to time; P.M = packing material costs; P.C = Packing Charges; MAPE = maximum allowable post manufacturing expenses inclusive of trade margins (good purchased for resale (either wholesale or retail)); E.D = Excise duty

- In case of category I formulation, the MAPE shall not exceeds 70%, 100% for category II which specified in Third Schedule. If a formulation contains in both I & II category, the formulation would be deemed to be a category I formulation

- For imported formulation, the retail price may be fixed on the basis of landed costs (The landed cost includes the original price of the product, transportation fees (both inland and ocean), customs, duties, taxes, tariffs, insurance,
- currency conversion, crating (a slatted wooden box or framework for packing), handling and payment fees). The price shall not exceed 50% of the landed cost.
- Prices of category I formulation shall fix or revised by the govt. Retail prices of formulations specified in Third Schedule can also fix or revise by the govt. if, govt. cannot fix the retail prices of formulation the same cannot be sold at a price higher than that prevailing.
- New formulations in category I or II or their new packs cannot be marketed prior approval of their retail prices by the government. If, the govt does not fix the price within 4 months of their application of manufacturer or importer, he may sell them at prices not exceeding those claimed in their application to the government.
- Any formulation, not listed in the schedule, the manufacturer shall submit the detail information including fix or revise retail price to the govt. in the January and June each year. The govt. may fix or revise the retail price of nonscheduled formulation.
- The manufacturer, importer or distributor shall sell a formulation to a wholesaler at retail price not exceeding minus 20% (for ethical), 18% (for non-ethical), to a retailer at a retail price minus 15% (non-ethical)
- Display on labels of the contains with the words "Retail price not to exceed Rs……" local taxes extra.
- Every dealer shall display price lists of the product in their business house.
- Dealer can not sell loose quantity of a formulation from a container and also refuse to sale of any drug to a customer.

Retail price and ceiling price of scheduled formulations:

1. **Calculation of ceiling price of a scheduled formulation.– (1)**

The ceiling price of a scheduled formulation of specified strengths and dosages as specified under the first schedule shall be calculated as under:

Step1. First the Average Price to Retailer of the scheduled formulation i.e. P(s) shall be calculated as below:
Average Price to Retailer, P(s) = (Sum of prices to retailer of all the brands and generic versions of the medicine having market share more than or equal to one percent of the total market turnover on the basis of moving annual turnover of that medicine) / (Total number of such brands and generic versions of the medicine having market share more than or equal to one percent of total market turnover on the basis of moving annual turnover for that medicine.)

Step2. Thereafter, the ceiling price of the scheduled formulation i.e. P(c) shall be calculated as below:

$$P(c) = P(s). (1+M/100),$$

where P(s) = Average Price to Retailer for the same strength and dosage of the medicine as calculated in step1 above.
M = % Margin to retailer and its value =16
(2) The ceiling price calculated as per sub-paragraph (1) and notified by the Government shall be applicable to scheduled imported formulations also.

2. **Calculation of retail price of a new drug for existing manufacturers of scheduled formulations.–**

- The price to retailer of a new drug, not available in domestic market, shall be fixed by the Government on the principles of "Pharmacoeconomics" of the new drug, on the recommendation of a Standing Committee of Experts formed under paragraph 15.
- The retail price of such new drug shall be fixed by adding sixteen percent margin to retailer on the price to retailer as fixed.

3. Ceiling price of a scheduled formulation in case of no reduction in price due to absence of competition.–

- No reduction in average price to retailer with respect to the prices to retailer of the schedule formulation; and
- There are less than five manufacturers for that formulation having one percent or more market share, the ceiling price shall be calculated as under:-
- In the event of other strengths or dosage forms of the same scheduled formulation is available in the list of scheduled formulation, the average price to retailer shall be calculated as under:

Step1: First the Average Price to Retailer of such scheduled formulation i.e. P(s) shall be calculated as under:

P(s) = Pm{1-(Pi1+Pi2+…)/(N*100)} Where,

Pm = Price to Retailer of highest priced scheduled formulation under consideration.

Pi = % reduction in Average Price to Retailer of other strengths and dosage forms (calculated as in step1 of sub-paragraph (1) of paragraph 4) in the list of schedule formulations w.r.t the highest priced formulation taken for calculating the average price to retailer of such strengths and dosage forms.

N = Number of such other strengths or dosage forms or both in the list of schedule formulations

Step2. Thereafter, the ceiling price of the scheduled formulation i.e. P(c) shall be calculated as under:

P(c) = P(s).(1+M/100), where

P(s) = Average Price to Retailer of the scheduled formulation as calculated in step1 here in above and

M = % Margin to retailer and its value=16

(ii) in the event of other strengths or dosage forms of the scheduled formulation is not available in the schedule but there are other scheduled formulations in same sub-therapeutic category as that of the scheduled formulation, then the Ceiling Price shall be calculated as under:

Step1: First the Average Price to Retailer of such scheduled formulation i.e. P(s) shall be calculated as under:

P(s) = Pm{1-(Pi1+Pi2+…)/(N*100)}, Where,

Pm = Price of highest priced formulation taken for calculating the average price to retailer of the formulation under consideration.

Pi = % reduction in Average Price to Retailer of other schedule formulations (calculated as in step1 of sub-paragraph (1) of paragraph 4) in same sub-therapeutic category as that of the scheduled formulation under consideration w.r.t the highest priced formulation taken for calculating the average price to retailer.

N = Number of such other schedule formulations in same subtherapeutic category as that of the scheduled formulation under consideration.

Step2. Thereafter, the ceiling price of the scheduled formulation i.e. P(c) shall be calculated as under:

P(c) = P(s)*(1+M/100), where

P(s) = Average Price to Retailer of the scheduled formulation as calculated in step1 above and
M = % Margin to retailer and its value=16

4. **Margin to retailer.–** While fixing a ceiling price of scheduled formulations and retail prices of new drugs, sixteen percent of price to retailer as a margin to retailer shall be allowed.

5. **Maximum retail price.–**
The maximum retail price of scheduled formulations shall be fixed by the manufacturers on the basis of ceiling price notified by the Government plus local taxes wherever applicable, as under:
Maximum Retail Price = Ceiling price + Local Taxes as applicable
The maximum retail price of a new drug shall be fixed by the manufacturers on the basis of retail price determined by the Government plus local taxes wherever applicable, as under:
Maximum Retail Price = Retail Price + Local Taxes as applicable

6. **Fixation of ceiling price of scheduled formulations.–**
- The Government shall fix and notify the ceiling prices of the scheduled formulations in accordance with the provisions of the paragraphs 4 and 6, as the case may be, and no manufacturer shall sell the scheduled formulations at a price higher than the ceiling price (plus local taxes as applicable) so fixed and notified by the Government.
- Where any manufacturer sells a scheduled formulation at a price higher than the ceiling price (plus local taxes as applicable) fixed and notified by the Government, such manufacturers shall be liable to deposit the overcharged amount along with interest thereon from the date of such overcharging.

7. **Fixation of retail price of a new drug for existing manufacturers of scheduled formulations.–**
- The Government shall form a Standing Committee of such Experts, as it may deem fit, within sixty days of notification of this order with a view to recommend the retail prices of new drugs on the principles of "Pharmacoeconomics".
- Where an existing manufacturer of a drug with dosages and strengths as specified in National List of Essential Medicines launches a new drug, such existing manufacturers shall apply for prior price approval of such new drug from the Government in Form-I specified under Schedule-II of this Order.
- On receipt of the application under sub-paragraph (2), in the event of the new drug available in domestic market, the Government shall fix the retail price of the new drug in accordance with the provision of sub-paragraph(1) of paragraph 5 and in the event of the new drug not available in domestic market, the Government shall forward the same to the Standing Committee of Experts who shall examine the application on the principles of "Pharmacoeconomics" and make recommendations of retail price of the new drug to the Government within thirty days of the receipt of application.
- The Government shall, on receipt of recommendation under subparagraph (3), within thirty days, fix the retail price of such new drug and such price shall be applicable to such applicant of such new drug.
- Where existing manufacturer of scheduled formulation fails to apply for prior approval of the price of the new drug in Form-I, such manufacturer shall be liable to deposit the overcharged amount over and above such price fixed and notified by the

Government, if any, along with interest thereon from the date of launch of the new drug, in addition to the penalty.

- No existing manufacturer of a scheduled formulation shall sell such a new drug at a price higher than the retail price (plus local taxes as applicable) fixed by the Government for such new drug and in case such a manufacturer is found to sell such a new drug at a price higher than the retail price (plus local taxes as applicable) fixed by the Government, such manufacturer of the new drug shall be liable to deposit the overcharged amount along with interest from the date of overcharge, in addition to the penalty.

8. Revision of ceiling price of scheduled formulations.–

- The Government shall revise the ceiling prices of scheduled formulations as per the annual wholesale price index (WPI) for preceding calendar year on or before 1st April of every year and notify the same on the 1st day of April every year.
- The manufacturers may increase the maximum retail price (MRP) of scheduled formulations once in a year, in the month of April, on the basis of the wholesale price index with respect to previous calendar year and no prior approval of the Government in this regard shall be required.
- Information about the revision, if carried out, shall be forwarded to the Government in either electronic or physical form in Form-II within a period of fifteen days of such revision and non-submission of information under this sub-paragraph shall be construed as non revision of maximum retail price (MRP) and the concerned manufacturer shall be liable to deposit the amount charged over and above the pre-revised maximum retail price (MRP), along with interest thereon from the date of overcharging.
- In case of decline in wholesale price index, there shall be a corresponding reduction in the maximum retail price and in case of scheduled formulations produced or available in the market before the date of notification of revised ceiling price, the manufacturers shall ensure within a period of forty-five days of the date of such notification that the maximum retail price (MRP) of such scheduled formulation does not exceed the revised ceiling price (plus local taxes as applicable) and information about the revision shall be sent to the Government in either electronic or physical form in Form-II within a period of fifteen days of such revision.
- Non-submission of information under the sub-paragraph (4) shall be construed as non reduction in maximum retail price (MRP) and the concerned manufacturer shall be liable to deposit the amount charged over and above the maximum retail price revised based on decline in wholesale price index, along with interest thereon as overcharged amount from the date of overcharging.

National List of Essential Medicines 2015

(Symbols P, S and T appearing in this Schedule denote essentiality at Primary, Secondary and Tertiary levels respectively)			
Section 1-Anesthetic agents			
1.1-General Anesthetics and oxygen			
	Medicine	**Level of Healthcare**	**Dosage form and strength**
1.1.1	Halothane	S, T	Inhalation
1.1.2	Isoflurane		
1.1.3	Ketamine	P, S, T	Injection 10 mg/ml, 50 mg/ml

1.1.4	Nitrous oxide		Inhalation
1.1.5	Oxygen		Inhalation (Medicinal gas)
1.1.6	Propofol		Injection 10 mg/ml
1.1.7	Sevoflurane	T	Inhalation
1.1.8	Thiopentone	P, S, T	Powder for Injection 0.5 g & 1 g
1.2-Local anesthetics			
1.2.1	Bupivacaine	S, T	Injection 0.25% & 0.5% & Injection 0.5% with 7.5% glucose
1.2.2	Lignocaine	P, S, T	Topical forms 2-5% Injection 1% & 2% Injection 5% with 7.5% Glucose
1.2.3	Lignocaine (A) + Adrenaline (B)	P, S, T	Injection 1% (A) + 1 :200000 (5 mcg/ml) (B) Injection 2% (A) + 1 :200000 (5
1.2.4	Prilocaine (A) + Lignocaine (B)	T	Cream 2.5% (A) + 2.5% (B)
1.3-Preoperative medication and sedation for short term procedures			
1.3.1	Atropine	P, S, T	Injection 0.6 mg/ml
1.3.2	Glycopyrrolate	S, T	Injection 0.2 mg/ml
1.3.3	Midazolam	P, S, T	Tablet 7.5, 15 mg Oral liquid 2 mg/ml Injection 1 mg/ml & 5 mg/ml
1.3.4	Morphine		Injection 10 mg/ml & 15 mg/ml
Section 2- Analgesics, antipyretics, non-steroidal anti-inflammatory medicines, medicines used to treat gout and disease modifying agents used in rheumatoid disorders			
2.1- Non-opioid analgesics, antipyretics and no steroidal anti -inflammatory medicines			
2.1.1	Acetylsalicylicacid	P, S, T	Tablet 300 mg to 500 mg Effervescent/ Dispersible/ Enteric coated Tablet 300 mg to 500 mg
2.1.2	Diclofenac		Tablet 50 mg Injection 25 mg/ml
2.1.3	Ibuprofen		Tablet 200 mg & 400 mg Oral liquid 100 mg/5 ml
2.1.4	Mefenamic acid		Capsule 250 mg Capsule 500 mg Oral liquid 100 mg/5 ml
2.1.5	Paracetamol		Tablet 500 mg & 650 mg All licensed oral liquid dosage forms and strengths Injection 150 mg/ml Suppository 80 mg & 170 mg
2.2-Opioid analgesics			
2.2.1	Fentanyl	S, T	Injection 50 mcg/ml
2.2.2	Morphine	P, S, T	Tablet 10 mg Injection 10 mg/ml Injection 15 mg/ml
2.2.3	Tramadol	S, T	Capsule 50 mg Capsule 100 mg Injection 50 mg/ml
2.3-Medicines used to treat gout			

2.3.1	Allopurinol	P, S, T	Tablet 100 mg & 300 mg
2.3.2	Colchicine		Tablet 0.5 mg
2.4-Disease modifying agents used in rheumatoid disorders			
2.4.1	Azathioprine	S, T	Tablet 50 mg
2.4.2	Hydroxychloroquine		Tablet 200 mg & 400 mg
2.4.3	Leflunomide		Tablet 10 mg Tablet 20 mg
2.4.4	Methotrexate		Tablet 5 mg, 7.5 mg & 10 mg Injection 25 mg/ ml
2.4.5	Sulfasalazine		Tablet 500 mg
Section 3-Antiallergics and medicines used in anaphylaxis			
3.1	Adrenaline	P, S, T	Injection 1 mg/ml
3.2	Cetirizine		Tablet 10 mg Oral liquid 5 mg/5ml
3.3	Chlorpheniramine		Tablet 4 mg Oral liquid 2 mg/5 ml
3.4	Dexamethasone		Tablet 0.5 mg
3.5	Hydrocortisone		Powder for Injection 100 mg
3.6	Pheniramine		Injection 22.75 mg/ml
3.7	Prednisolone		Tablet 5 mg, 10 mg & 20 mg Oral liquid 5 mg/5 ml & 15 mg/5 ml
Section 4-Antidotes and other substances used in poisoning			
4.1- Nonspecific			
4.1.1	Activated charcoal	P, S, T	Powder (as licensed)
4.2-Specific			
4.2.1	Atropine	P, S, T	Injection 1 mg/ml
4.2.2	Calcium gluconate		Injection 100 mg/ml
4.2.3	Desferrioxamine	S, T	Powder for Injection 500 mg
4.2.4	Dimercaprol		Injection 50 mg/ml
4.2.5	Methylthioninium chloride (Methylene blue)		Injection 10 mg/ml
4.2.6	N-acetylcysteine	P, S, T	Sachet 200 mg Injection 200 mg/ml
4.2.7	Naloxone		Injection 0.4 mg/ml
4.2.8	Neostigmine		Injection 0.5 mg/ml
4.2.9	Penicillamine	S, T	Capsule 250 mg
4.2.10	Pralidoxime chloride (2- PAM)	P, S, T	Injection 25 mg/ml
4.2.11	Snake venom antiserum a) Soluble/ liquid polyvalent	P, S, T	Injection Powder for Injection
4.2.12	Sodium nitrite	S, T	Injection 30 mg/ml
4.2.13	Sodium	S, T	Injection 100 mg/ml
Section 5-Anticonvulsants/Antiepileptics			
5.1	Carbamazepine	P, S, T	Tablet 100 mg, 200 mg & 400 mg CR Tablet 200 mg & 400 mg Oral liquid 100 mg/5 ml & 200 mg/5 ml
5.2	Clobazam	S, T	Tablet 5 mg & 10 mg
5.3	Diazepam	P, S, T	Oral liquid 2 mg/5 ml Injection 5 mg/ml Suppository 5 mg
5.4	Levetiracetam	S, T	Tablet 250 mg, 500 mg & 750

			mg ER Tablet 750 mg Oral liquid 100 mg/ml Injection 100 mg/ml
5.5	Lorazepam	P, S, T	Tablet 1 mg, 2 mg Injection 2 mg/ml
5.6	Magnesium sulphate	S, T	Injection 500 mg/ml
5.7	Phenobarbitone	P, S, T	Tablet 30 mg, 60 mg Oral liquid 20 mg/5 ml
		S, T	Injection 200 mg/ml
5.8	Phenytoin	P, S, T	Tablet 50 mg, 100 mg & 300 mg ER Tablet 300 mg Oral liquid 20 mg/5 ml, 125mg/5ml Injection 50 mg/ml
5.9	Sodium valproate	P, S, T	Tablet 200 mg, 300 mg, 500 mg CR Tablet 300 mg, 500 mg Oral liquid 200 mg/5ml
		T	Injection 100 mg/ml
Section 6-Anti-infective medicines			
6.1-Anthelminthics			
6.1.1-Intestinal anthelminthic			
6.1.1.1	Albendazole	P, S, T	Tablet 400 mg Oral liquid 200 mg/5 ml
6.1.1.2	Mebendazole	P, S, T	Tablet 100 mg Oral liquid 100 mg/5 ml
6.1.2- Antifilarial			
6.1.2.1	Diethy lcarbamazine	P, S, T	Tablet 50 mg & 100 mg Oral liquid 120 mg/5 ml
6.1.3-Anti-schistosomal & anti-trematodal medicine			
6.1.3.1	Praziquantel	S, T	Tablet 600 mg
6.2-Antibacterials			
6.2.1-Beta lactam medicines			
6.2.1.1	Amoxicillin	P, S, T	Capsule 250 mg & 500 mg Oral liquid 250 mg/5 ml
6.2.1.2	Amoxicillin (A) + Clavulanic acid (B)		Tablet 500 mg (A) + 125 mg (B) Oral liquid 200 mg (A) + 28.5 mg (B)/5 ml Dry Syrup 125 mg (A) + 31.25 (B)/5 ml
		S, T	Powder for Injection 500 mg (A) + 100 mg (B) Powder for Injection 1 g (A) + 200 mg (B)
6.2.1.3	Ampicillin	P, S, T	Powder for Injection 500 mg Powder for Injection 1 g
6.2.1.4	Benzathine benzylpenicillin		Powder for Injection 6 lac units Powder for Injection 12 lac units
6.2.1.5	Benzyl penicillin		Powder for Injection 10 lac units
6.2.1.6	Cefadroxil		Tablet 500 mg, 1 g Oral liquid 125 mg/5 ml
6.2.1.7	Cefazolin		Powder for Injection 500 mg Powder for Injection 1 g
6.2.1.8	Cefixime	S, T	Tablet 200 mg, 400 mg Oral liquid 50 mg/5 ml Oral liquid 100 mg/5 ml

6.2.1.9	Cefotaxime		Powder for Injection 250 mg, 500 mg & 1 g
6.2.1.10	Ceftazidime		Powder for Injection 250 mg Powder for Injection 1 g
6.2.1.11	Ceftriaxone		Powder for Injection 250 mg, 500 mg, 1 g & 2 g
6.2.1.12	Cloxacillin	P, S, T	Capsule 250 mg, 500 mg Oral Liquid 125 mg/5 ml Powder for Injection 250 mg
6.2.1.13	Piperacillin (A) + Tazobactam (B)	T	Powder for Injection 1 g (A) + 125 mg (B) Powder for Injection 2 g (A) + 250 mg (B) Powder for Injection 4 g (A) + 500 mg (B)
6.2.2-Other antibacterials			
6.2.2.1	Azithromycin	P, S, T	Tablet 250 mg, 500 mg Oral liquid 200 mg/5 ml Powder for Injection 500mg
6.2.2.2	Ciprofioxacin		Tablet 250 mg, 500 mg Oral liquid 250mg/5ml Injection 200 mg/100ml
6.2.2.3	Clarithromycin	S, T	Tablet 250 mg, 500 mg Oral liquid 125mg/5ml
6.2.2.4	Co-trimoxazole [Sulphamethoxazole (A) + Trimethoprim (B)]	P, S, T	Tablet 400 mg (A) + 80 mg (B) Tablet 800 mg (A) + 160 mg (B) Oral liquid 200 mg (A) + 40 mg (B)/5 ml
6.2.2.5	Doxycycline		Capsule 100 mg Dry Syrup 50 mg/5 ml
6.2.2.6	Gentamicin		Injection 10 mg/ml, 40 mg/ml
6.2.2.7	Metronidazole		Tablet 200 mg, 400 mg Oral liquid 200 mg/5 ml Injection 500mg/100 ml
6.2.2.8	Nitrofurantoin		Tablet 100 mg Oral liquid 25 mg/5 ml
6.2.2.9	Vancomycin	T	Powder for Injection 250 mg, 500 mg & 1 g
6.2.3-Antileprosy medicines			
6.2.3.1	Clofazimine	P, S, T	Capsule 50 mg, 100 mg
6.2.3.2	Dapsone		Tablet 25 mg, 50 mg & 100 m
6.2.3.3	Rifampicin		Capsule 150 mg, 300 mg
6.2.4-Antituberculosis medicines			
6.2.4.1	Capreomycin	P, S, T	Powder for Injection 1 g
6.2.4.2	Cycloserine		Capsule 125 mg, 250 mg
6.2.4.3	Ethambutol		Tablet 200 mg. 400 mg. 600 mg & Tablet 800 mg
6.2.4.4	Ethionamide		Tablet 125 mg, 250 mg
6.2.4.5	Isoniazid		Tablet 50 mg, 100 mg, 300 mg Oral liquid 100 mg/5 ml
6.2.4.6	Kanamycin		Powder for Injection 500 mg, 750 mg & 1 g
6.2.4.7	Levofloxacin		Tablet 250 mg, 500 mg & 750 mg
6.2.4.8	Linezolid		Tablet 600 mg
6.2.4.9	Moxifloxacin		Tablet 200 mg, 400 mg
6.2.4.10	Para-amino salicylic acid		Tablet 500 mg Granules (As licensed)
6.2.4.11	Pyrazinamide		Tablet 500 mg, 750 mg, 1000 mg

			& 500 mg Oral liquid 250 mg/5 ml
6.2.4.12	Rifabutin	S, T	Capsule 150 mg
6.2.4.13	Rifampicin	P, S, T	Capsule 150 mg, 300 mg, 450 mg & Capsule 600 mg Oral liquid 100 mg/5 ml
6.2.4.14	Streptomycin	P, S, T	Powder for Injection 750 mg Powder for Injection 1 g
6.3-Antifungal medicines			
6.3.1	Amphotericin B a) Amphotericin B (conventional) b) Lipid, Liposomal Amphotericin B	S, T	Powder for Injection 50 mg

The detail list of national list of essential medicines 2015 will found in the drugs (prices control) order, 2013 which is published by Govt. of India.

References:

Text book of Forensic Pharmacy by B.M. Mithal
A text book of Forensic Pharmacy by N.K. Jain
The drugs (prices control) order, 2013 by Govt. of India publications

UNIT-V

5.1. Pharmaceutical Legislations-A brief review, Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee

5.2. Code of Pharmaceutical ethics: Definition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath

5.3. Medical Termination of Pregnancy Act

5.4. Right to Information Act

5.5. Introduction to Intellectual Property Rights (IPR)

5.1. Pharmaceutical Legislations

History

In the early part of the 20th century, there was practically no legislative control on drugs as well as on the profession of pharmacy. Although the Opium Act-1878, the poison act-1919 and the dangerous drugs act-1930 were inforce, these were specific in nature and grossly inadequate in controlling the chaotic conditions prevailing at that time. In 1927, a resolution was passed by the council of states to recommend to the Governor General in Council to usage all Provisional Governments to take immediate steps to control indiscriminate use of drugs and to legislate for the standardization of the preparation and sale of drugs. The government of India in pursuance to the resolution appointed a committee known as the Drugs Enquiry Committee in 1928.

Government of India on 11th August 1930, appointed a committee under the chairmanship of Late Col. R.N. Chopra to see into the problems of Pharmacy in India and recommend the measures to be taken. This committee published its report in 1931. It was reported that there was no recognized specialized profession of Pharmacy. A set of people known as compounders were filling the gap. Just after the publication of the report Prof. M. L. Schroff (Prof. Mahadeva Lal Schroff) initiated pharmaceutical education at the university level in the Banaras Hindu University. In 1935 United Province Pharmaceutical Association was established which later converted into Indian Pharmaceutical Association. The Indian Journal of Pharmacy was started by Prof. M.L. Schroff in 1939. All India Pharmaceutical Congress Association was established in 1940.

The Pharmaceutical Conference held its sessions at different places to publicize Pharmacy as a whole. Govt. brought 'Drugs Bill' to regulate the import, manufacture, sale and distribution of drugs in British India. This Bill was finally adopted as 'Drugs Act of 1940. The first Drugs Technical Advisory Board (DTAB) under this act was constituted. Central Drugs Laboratory was established in Calcutta 1945 and 'Drugs Rule under the Drugs Act of 1940' was established. The Drugs Act has been modified from time to time and at presents the provisions of the Act cover Cosmetics and Ayurvedic, Unani and Homeopathic medicines in some respects.

Introduction

pharmaceutical Legislations generally includes provisions relating to the manufacturing, importing, distribution, marketing, prescribing, labeling, dispensing, and sometimes pricing of pharmaceutical products, as well as the licensing, inspection, and control of personnel and facilities. A regulatory authority is usually established for administrative control. Medicine

registration is often a major element in legislation, to ensure that individual products meet the criteria of efficacy, safety, and quality. Countries that need to introduce comprehensive legislation can seek guidance from WHO guidelines.

5.1.1. Drugs enquiry committee

The government of India appointed a committee styled as the Drug Enquiry Committee under the Chairmanship of Col. R.N. Chopra on 11th August 1930 to study the issues related to the profession of pharmacy and its various aspects in India. This Drug Enquiry Committee was later known by the name 'Chopra Committee'. The important terms of reference for the Committee were:

i) To study the details regarding the extent to which drugs and chemicals of impure quality or defective strength, particularly those recognized by the British Pharmacopoeia are imported, manufactured or sold in British India and to make necessary recommendation for controlling such activities in the interest of the public.
ii) To report how far and to what extent the above recommendations should be extended to medicinal preparations used in the indigenous systems of medicines.
iii) To study and examine the necessity of legislation for restricting the profession of pharmacy to duly qualified persons and make recommendations to that effect.

The Chopra Committee took up the challenge of studying the problems and making recommendations with all its seriousness and professional significance. They travelled various centers of the country and studied the situations. The committee submitted its report in 1931.

The committee report made it clear that till that time there was no organized and self contained profession of pharmacy in India as compared to other parts of the world. The profession is represented by a group of people known as compounders whose status, functions and duties are ill defined and improperly understood. They handle drugs and poisons with utmost ease and freedom and in many cases in ignorance of their properties. The committee also observed that no stress is laid down on the basic qualification except in the revised compounders course in Bengal and the Chemists and Druggists course in Madras made in the late 1920s. The mere ability to read the prescriptions written in English was considered sufficient to practice pharmacy.

The Drugs Enquiry Committee also recommended for the compilation of the Indian Pharmacopoeia with monographs on drugs and pharmaceuticals in common use including those of the indigenous origin.

5.1.2. Health survey and development committee

In 1946, the Health Survey and Development Committee under the chairmanship of Sir Joseph Bhore (Bhore Committee) published its report. An important recommendation of the Bhore Committee was to have an enactment (Act) with the objective of raising the interests of qualified pharmacists and thereby protect the interests of public. It was made as the committee found that incompetent people were handling drugs and doing harm to the society. The Bhore Committee also suggested that the profession of pharmacy should be reserved for the pharmacists and the pharmacists should restrict their work to the professional activities of their profession. It was also suggested that the pharmacists should not be permitted to undertake functions like prescription of medicines and administration of anaesthetics. The committee also recommended for a revision of the pharmacy education in the country as the standard of training for those entering into the practice of pharmacy was unsatisfactory. Based on the recommendations of the Chopra Committee and the interim findings of the Bhore Committee the Government of India brought forth the Pharmacy Bill in 1945 and after three years continuous efforts and discussions at various levels, it took the shape of Pharmacy Act 1948. The first Pharmacy Council of India was constituted in 1949 under the provisions of the Pharmacy Act.

It was provided in the Pharmacy Act that within three years of its coming into force, the States should constitute their Pharmacy Councils and within three years of that the Education Regulations would take effect. Hence, the first Education Regulations under the Pharmacy Act should have come in force in all states in India by 1954 and those who are not qualified to enter the profession of pharmacy as per the Education Regulations should not have been allow to enter. However the situation was different. Many states took their own time to constitute the Pharmacy Councils. Even after the Pharmacy Act the profession of pharmacy has not been able to make much headway in the country.

In 1944, a committee was appointed once again under the chairmanship of Col. R.N. Chopra to prepare the material for the list of drugs in use in India irrespective of whether or not such items are included in the British Pharmacopoeia. The Indian Pharmacopoeial list, a prelude to the Indian Pharmacopoeia, was published in 1946 under the auspices of the above committee. In 1948 a full fledged Indian Pharmacopoeia Committee was constituted under the chairmanship of Dr. B.N. Ghosh of Calcutta and several sub-committees were also set up. The committee took seven years to complete the task and in 1955 the first edition of Indian Pharmacopoeia was published.

5.1.3. Hathi committee

In the context of large-scale expansion of the drugs and pharmaceuticals industry, with a view to ensuring the regulated and rapid growth of drug manufacture and further with a view to ensuring that all essential drugs are made available to the consumers at reasonable prices, Government constituted a Committee in February, 1974. This committee consists of 15 members under the chairmanship of Mr. Jaisukhlal Hathi, which had Members of Parliament along with officials and non-officials as members, to enquire into various facets of the drugs industry in India.

The terms of reference included progress made and status achieved by the industry, role of public sector, growth of indigenous industry, including the small scale, technological requirements, quality control measures, pricing of drugs etc. Almost all the aspects of the drugs and pharmaceutical industry were critically examined by Hathi Committee with a view to achieve self-sufficiency and to serve the national interest.

After conducting various meetings, the committee had submitted its report in the year 1975. The report contained 224 recommendations spread over 8 chapters on various aspects of pharmaceutical Industry. The thrust of recommendations related to re-emphasizing the leading role for the public sector, setting up of National Drug Authority, preference to Indian Sector over the foreign sector, indigenous production of raw materials, selective price control on prices of drugs etc.

5.1.3. Mudaliar committee

This committee known as the “Health Survey and Planning Committee”, headed by Dr. A.L. Mudaliar, was set up in 1959.

Objectives

1. To assess the performance in health sector since the submission of Bhore Committee report.
2. To evaluate the progress made in the first 2 plans and
3. To make recommendation for the future path of development of health services.

The report of the committee recorded that the disease control programmes had some substantial achievements in controlling certain virulent epidemic diseases. This committee found the conditions in PHCs to be unsatisfactory. Most of the PHC's were understaffed, large numbers of them were being run by ANM's or public health nurses in-charge.

Recommendations

1. Consolidation of advances made in the first two five years plans.
2. Strengthening of the district hospitals with specialist services to serve as central base of regional services.
3. Regional organizations in each state between the headquarters organization and the district in charge of a Regional Deputy or Assistant Directors-each to supervise 2 or 3 district medical or health officers.
4. Each PHC not to serve more than 40000 populations.
5. To improve the quality of health care provided by PHC.
6. Integration of medical and health services.
7. Constitution of an All India Health service on the pattern of Indian Administrative Services.

5.2. Code of Pharmaceutical ethics

The profession of pharmacy is noble in its ideals and pious in its character. Apart from being a career for earning livelihood, it has inherent in it the attitude of service and sacrifice in the interests of the suffering humanity. In handling, selling, distributing, compounding and dispensing medical substances including poisons and potent drugs, a pharmacist is, in collaboration with medical perssonel and others, charged with the onerous responsibility of safeguarding the health of people. As such he has to uphold the interests of his patrons above all things. The lofty ideals set up by Charaka, the ancient Philosopher Physician and Pharmacist in his erunciation: “Even if your own life be in danger you should not betray or neglect the interests of your patients” should be fondly cherished by all pharmacists.

Government restricts the practice of Pharmacy to those who qualify under regulatory requirements and grant them privileges necessarily denied to others. In return, Government expects the Pharmacist to recognize his responsibilities and to fulfil his professional obligations honourably and with due regard for the well being of Society.

Standards of professional conduct for pharmacy are necessary in the public interest to ensure an efficient pharmaceutical service. Every pharmacist should not only be willing to play his part in giving such a service but should also avoid any act or omission which would prejudice the giving of the services or impair confidence in any respect for pharmacists as a body.

The nature of pharmaceutical practice is such that its demands may be beyond the capacity of the individual to carry out or to carry out as quickly or as efficiently as the needs of the public require. There should, therefore at all times, be a readiness to assist colleagues with information or advice. A Pharmacist must, above all be a good citizen and must uphold and defend the laws of the state and the Nation.

5.2.1. Pharmacist in relation to his job

When premises are registered under statutory requirements and opened as a pharmacy, a reasonably comprehensive pharmaceutical service should be provided. This involves the supply of commonly required medicines of this nature without undue delay. It also involves willingness to furnish emergency supplies at all times.

5.2.1.1. Conduct of the Pharmacy:

1. The conditions in a pharmacy should be such as to preclude avoidable risk or error or of accidental contamination in the preparation, dispensing and supply of medicines.
2. The appearance of the premises should reflect the professional character of the pharmacy.
3. It should be clear to the public that the practice of pharmacy is carried out in the establishment.
4. Signs, notices, descriptions, wording on business, stationary and related indications should be restrained in size, design and terms.
5. In every pharmacy, there should be a pharmacist in personal control of the pharmacy who will be regarded as primarily responsible for the observance of proper standards of conduct in connection with it.

5.2.1.2. Handling of Prescriptions:

1. When a prescription is presented for dispensing, it should be received by a pharmacist without any discussion or comment over it regarding the merits and demerits of its therapeutic efficiency.
2. The Pharmacist should not even show any physiognomic expression of alarm or astonishment upon the receipt of a prescription; as such things may cause anxiety in patients or their agents and may even shake their faith in their physician.
3. Any question on a prescription should be answered with caution and care.
4. It is not within the privilege of a Pharmacist to add, omit or substitute any ingredient or alter the composition of a prescription without the consent of the prescriber, unless the change is emergent or is demanded purely by the technique of the pharmaceutical art and does not cause any alteration in the therapeutic action of the recipe.

5. In case of any obvious error in it due to any ommission, incompatibility or overdosage, the prescription should be referred back to the prescriber for correction or approval of the change suggested.

5.2.1.3. Handling of Drugs:

1. All possible care should be taken to dispense a prescription correctly by weighing and measuring all ingredients in correct proportions by the help of scale and measures: visual estimations must be avoided.
2. Further, a Pharmacist should always use drugs and medicinal preparations of standard quality available.
3. He should never fill his prescriptions with spurious, sub-standard and unethical preparations.
4. A Pharmacist should be very judicious in dealing with drugs and medicinal preparations known to be poisonous or to be used for addiction or any other abusive purposes.

5.2.1.4. Apprentice Pharmacist:

1. While in-charge of a dispensary, drug store or hospital pharmacy where apprentice pharmacists are admitted for practical training, a pharmacist should see that the trainees are given full facilities for their work so that on the completion of their training, they have acquired sufficient technique and skill to make themselves dependable pharmacists.
2. No certificate or credentials should be granted unless the above criterion is attained and the recipient has proved himself worthy of the same.

5.2.2. Pharmacist in relation to his trade

Prices charged from customers should be fair and in keeping with the quality and quantity of commodity supplied and the labour and skill required in making it ready for use, so as to ensure an adequate remuneration to the pharmacist taking into consideration his knowledge, skill, the time consumed and the great responsibility involved, but at the same time without unduly taxing the purchaser.

5.2.2.1. Fair Trade Practice:

1. No attempt should be made to capture the business of a contemporary by cut-throat competition, that is, by offering any sort of prizes or gifts or any kind of allurement to patronizers or by knowingly charging lower prices for medical commodities than those charged by a fellow pharmacist if they be reasonable.
2. In case any order or prescription genuinely intended to be served by some dispensary is brought by mistake to another, the latter should be refuse to accept it and should direct the customer to the right place.
3. Labels, trademarks and other signs and symbols of contemporaries should not be imitated or copied.

5.2.2.2. Purchase of Drugs:

1. Drugs should always be purchased from genuine and reputable sources.
2. Pharmacist should always be on his guard not to aid or abet, directly or indirectly the manufacture, possession, distribution and sale of spurious or sub-standard drugs.

5.2.2.3. Hawking of Drugs:

1. Hawking of drugs and medicinals should not be encouraged nor should any attempt be made to solicit orders for such substances from door to door.
2. Self-service method of operating pharmacies and drug-stores should not be used as this practice may lead to the distribution of therapeutic substances without an expert supervision and thus would encourage self-medication, which is highly undesirable.

5.2.2.4. Advertising and Displays:

No display material either on the premises, in the press or elsewhere should be used by a pharmacist in connection with the sale to the public of medicines or medical appliances which is undignified in style or which contains:

a) Any wording design or illustration reflecting unfavorably on pharmacist collectively or upon any group or individual.
b) A disparaging reference, direct of by implication to other suppliers, products, remedies or treatments.
c) Misleading, or exaggerated statements or claims.
d) The word “Cure” in reference to an ailment or symptoms of ill-health.
e) A guarantee of therapeutic efficacy.
f) An appeal to fear,
g) An offer to refund money paid.

h) A prize**,** competition or similar scheme.

5.2.3. Pharmacist in relation to medical profession

It is expected that medical practitioners in general would not take to the practice of pharmacy by owning drug stores, as this ultimately leads to coded prescriptions and monopolistic practices detrimental to the pharmaceutical profession and also to the interest of patients. It should be made a general rule that pharmacists under no circumstances take to medical practice that is to diagnosing diseases and prescribing remedies therefore even if requested by patrons to do so. In cases of accidents and emergencies a pharmacist may, however, render First Aid to the victim. No pharmacist should recommend particular medical practitioner unless specifically asked to do so.

5.2.3.1. Clandstine Arrangements:

No pharmacist should enter into any secret arrangements or contract with a physician to offer him any commission or any advantage of any description in return for his favour of patronage by recommending his dispensary or drugstore or even his self to patients.

5.2.3.2. Liaison with public:

A pharmacist should never disclose any information which he has acquired during his professional activities to any third party or person unless required by law to do so. He should never betray the confidence which his patrons repose in him or which he has won by virtue of his eminent character and conduct.

5.2.4. Pharmacist in relation to his profession

It is not only sufficient for a pharmacist to be law-abiding and to deter from doing things detrogatory to Society and his profession, but it should be his bounden duty to make others also fulfil the provisions of the pharmaceutical and other laws and regulations. He should not be afraid of bringing or causing a miscreant to be brought to book, may be a member of his own profession. Whereas it is obligatory for a pharmacist to extend help and cooperation to a fellow member in his legitimate needs, scientific, technical or otherwise, he is to be, at the same time, vigilant to weed the undesirable out of the profession and thus help to maintain its fair name and traditions.

5.2.4. Pharmacist's oath

I swear by the code of ethics of Pharmacy Council of India, in relation to the community and shall act as an integral part of health care team.

I shall uphold the laws and standards governing my profession.

I shall strive to perfect and enlarge my knowledge to contribute to the advancement of pharmacy and public health.

I shall follow the system which I consider best for Pharmaceutical care and counseling of patients.

I shall endeavor to discover and manufacture drugs of quality to alleviate sufferings of humanity.

I shall hold in confidence the knowledge gained about the patients in connection with my professional practice and never divulge unless compelled to do so by the law.

I shall associate with organizations having their objectives for betterment of the profession of Pharmacy and make contribution to carry out the work of those organizations.

While I continue to keep this oath unviolated, May it be granted to me to enjoy life and the practice of pharmacy respected by all, at all times!

Should I trespass and violate this oath, may the reverse be my lot!

5.3. Medical Termination of Pregnancy Act

The MTP Act, 1971 preamble states "an Act to provide for the termination of certain pregnancies by registered medical practitioners and for matters connected therewith or incidental thereto".

1. **Short title, extent and commencement.-**
   i) This Act may be called the Medical Termination of Pregnancy Act, 1971.
   ii) It extends to the whole of India except the State of Jammu and Kashmir.
   iii) It shall come into force on such date1 as the Central Government may, by notification in the Official Gazette, appoint.

2. **Definitions.-**in this Act, unless the context otherwise requires,—
   a) "guardian" means a person having the care of the person of a minor.
   b) "minor" means a person who, under the provisions of the Indian Majority Act, 1875 (9 of 1875), is to be deemed not to have attained his majority.
   c) "registered medical practitioner" means a medical practitioner who possesses any recognised medical qualification as defined in clause (*h*) of section 2 of the Indian Medical Council Act, 1956 (102 of 1956), whose name has been entered in a State Medical Register and who has such experience or training in gynaecology and obstetrics as may be prescribed by rules made under this Act.

3. **Place where pregnancy may be terminated.—**No termination of pregnancy shall be made in accordance with this Act at any place other than—

a) a hospital established or maintained by Government, or

b) a place for the time being approved for the purpose of this Act by Government or a District Level Committee constituted by that Government with the Chief Medical Officer or District Health Officer as the Chairperson of the said Committee: Provided that the District Level Committee shall consist of not less than three and not more than five members including the Chairperson, as the Government may specify from time to time.

4. Power to make rules.-

1) The Central Government may, by notification in the Official Gazette, make rules to carry out the provisions of this Act.

2) In particular, and without prejudice to the generality of the foregoing power, such rules may provide for all or any of the following matters, namely:—

   a. the experience or training, or both, which a registered medical practitioner shall have if he intends to terminate any pregnancy under this Act; and

   b. Such other matters as are required to be or may be, provided by rules made under this Act.

3) Every rule made by the Central Government under this Act shall be laid, as soon as may be after it is made, before each House of Parliament while it is in session for a total period of thirty days which may be comprised in one session or in two successive sessions, and if, before the expiry of the session in which it is so laid or the session immediately following, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.

5. Power to make regulations.

1) The State Government may, by regulations,—

(a) require any such opinion as is referred to in sub-section (*2*) of section 3 to be certified by a registered medical practitioner or practitioners concerned, in such form and at such time as may be specified in such regulations, and the preservation or disposal of such certificates;

(b) require any registered medical practitioner, who terminates a pregnancy, to give intimation of such termination and such other information relating to the termination as may be specified in such regulations;

(c) prohibit the disclosure, except to such persons and for such purposes as may be specified in such regulations, of intimations given or information furnished in pursuance of such regulations.

2) The intimation given and the information furnished in pursuance of regulations made by virtue of clause (*b*) of sub-section (*1*) shall be given or furnished, as the case may be, to the Chief Medical Officer of the State.

3) Any person who will fully contravenes or wilfully fails to comply with the requirements of any regulation made under sub-section (1) shall be liable to be punished with fine which may extend to one thousand rupees.

6. **Protection of action taken in good faith.—**No suit or other legal proceeding shall lie against any registered medical practitioner for any damage caused or likely to be caused by anything which is in good faith done or intended to be done under this Act.

5.4. Right to Information Act

An Act to provide for setting out the practical regime of right to information for citizens to secure access to information under the control of public authorities, in order to promote transparency and accountability in the working of every public authority, the constitution of a Central Information Commission and State Information Commissions and for matters connected therewith or incidental thereto.

1. Short title, extent and commencement.—*(1)* This Act may be called the Right to Information Act, 2005. *(2)* It extends to the whole of India. *(3)* The provisions of sub-section (1) of section 4, sub-sections *(1)* and *(2)* of section 5, sections 12, 13, 15,16, 24, 27 and 28 shall come into force at once, and the remaining provisions of this Act shall come into force on the one hundred and twentieth day of its enactment.

2. Definitions.—In this Act, unless the context otherwise requires,—

(a) "appropriate Government" means in relation to a public authority which is established, constituted, owned, controlled or substantially financed by funds provided directly or indirectly— (i) by the Central Government or the Union territory administration, the Central Government; (ii) by the State Government, the State Government;

(b) "Central Information Commission" means the Central Information Commission constituted under sub-section (1) of section 12;

(c) "Central Public Information Officer" means the Central Public Information Officer designated under sub-section (1) and includes a Central Assistant Public Information Officer designated as such under sub-section (2) of section 5;

(d) "Chief Information Commissioner" and "Information Commissioner" mean the Chief Information Commissioner and Information Commissioner appointed under sub-section (3) of section 12;

(e) "competent authority" means— (i) the Speaker in the case of the House of the People or the Legislative Assembly of a State or a Union territory having such Assembly and the Chairman in the case of the Council of States or Legislative Council of a State; (ii) the Chief Justice of India in the case of the Supreme Court; (iii) the Chief Justice of the High Court in the case of a High Court; (iv) the President or the Governor, as the case may be, in the case of other authorities established or constituted by or under the Constitution; (v) the administrator appointed under article 239 of the Constitution;

(f) "information" means any material in any form, including records, documents, memos, e-mails, opinions, advices, press releases, circulars, orders, logbooks, contracts, reports, papers, samples, models, data material held in any electronic form and information relating to any private body which can be accessed by a public authority under any other law for the time being in force;

(g) "prescribed" means prescribed by rules made under this Act by the appropriate Government or the competent authority, as the case may be;

(h) "public authority" means any authority or body or institution of self- government established or constituted— (a) by or under the Constitution; (b) by any other law made by Parliament; (c) by any other law made by State Legislature; (d) by notification issued or order made by the appropriate Government.

(i) "record" includes— (a) any document, manuscript and file; (b) any microfilm, microfiche and facsimile copy of a document; (c) any reproduction of image or images embodied in such microfilm (whether enlarged or not); and (d) any other material produced by a computer or any other device;

(j) "right to information" means the right to information accessible under this Act which is held by or under the control of any public authority and includes the right to— (i) inspection of work, documents, records; (ii) taking notes, extracts or certified copies of documents or records; (iii) taking certified samples of material; (iv) obtaining information in the form of diskettes, floppies,

tapes, video cassettes or in any other electronic mode or through printouts where such information is stored in a computer or in any other device;

(k) "State Information Commission" means the State Information Commission constituted under sub-section (1) of section 15;

(l) "State Chief Information Commissioner" and "State Information Commissioner" mean the State Chief Information Commissioner and the State Information Commissioner appointed under subsection (3) of section 15;

(m) "State Public Information Officer" means the State Public Information Officer designated under sub-section (1) and includes a State Assistant Public Information Officer designated as such under sub-section (2) of section 5;

(n) "third party" means a person other than the citizen making a request for information and includes a public authority.

3. Right to information.—Subject to the provisions of this Act, all citizens shall have the right to information.

4. Obligations of public authorities.—(1) Every public authority shall—

(a) maintain all its records duly catalogued and indexed in a manner and the form which facilitates the right to information under this Act and ensure that all records that are appropriate to be computerised are, within a reasonable time and subject to availability of resources, computerised and connected through a network all over the country on different systems so that access to such records is facilitated;

(b) Publish within one hundred and twenty days from the enactment of this Act,—

(i) the particulars of its organisation, functions and duties;

(ii) the powers and duties of its officers and employees;

(iii) the procedure followed in the decision making process, including channels of supervision and accountability;

(iv) the norms set by it for the discharge of its functions;

(v) the rules, regulations, instructions, manuals and records, held by it or under its control or used by its employees for discharging its functions;

(vi) a statement of the categories of documents that are held by it or under its control;

(vii) the particulars of any arrangement that exists for consultation with, or representation by, the members of the public in relation to the formulation of its policy or implementation thereof; (viii) a statement of the boards, councils, committees and other bodies consisting of two or more persons constituted as its part or for the purpose of its

advice, and as to whether meetings of those boards, councils, committees and other bodies are open to the public, or the minutes of such meetings are accessible for public;

(ix) a directory of its officers and employees;

(x) the monthly remuneration received by each of its officers and employees, including the system of compensation as provided in its regulations;

(xi) the budget allocated to each of its agency, indicating the particulars of all plans, proposed expenditures and reports on disbursements made;

(xii) the manner of execution of subsidy programmes, including the amounts allocated and the details of beneficiaries of such programmes;

(xiii) particulars of recipients of concessions, permits or authorisations granted by it;

(xiv) details in respect of the information, available to or held by it, reduced in an electronic form;

(xv) the particulars of facilities available to citizens for obtaining information, including the working hours of a library or reading room, if maintained for public use;

(xvi) the names, designations and other particulars of the Public Information Officers;

(xvii) such other information as may be prescribed; and thereafter update these publications every year;

(c) publish all relevant facts while formulating important policies or announcing the decisions which affect public;

(d) provide reasons for its administrative or quasi-judicial decisions to affected persons.

5. Designation of Public Information Officers.—

(1) Every public authority shall, within one hundred days of the enactment of this Act, designate as many officers as the Central Public Information Officers or State Public Information Officers, as the case may be, in all administrative units or offices under it as may be necessary to provide information to persons requesting for the information under this Act.

(2) Without prejudice to the provisions of sub-section (1), every public authority shall designate an officer, within one hundred days of the enactment of this Act, at each sub-divisional level or other subdistrict level as a Central Assistant Public Information Officer or a State Assistant Public Information Officer, as the case may be, to receive the applications for information or appeals under this Act for forwarding the same forthwith to the Central Public Information Officer or the State Public Information Officer or senior officer specified under sub-section (1) of section 19 or the Central Information Commission or the State Information Commission, as

the case may be: Provided that where an application for information or appeal is given to a Central Assistant Public Information Officer or a State Assistant Public Information Officer, as the case may be, a period of five days shall be added in computing the period for response specified under sub-section (1) of section 7.

(3) Every Central Public Information Officer or State Public Information Officer, as the case may be, shall deal with requests from persons seeking information and render reasonable assistance to the persons seeking such information.

(4) The Central Public Information Officer or State Public Information Officer, as the case may be, may seek the assistance of any other officer as he or she considers it necessary for the proper discharge of his or her duties.

(5) Any officer, whose assistance has been sought under sub-section *(4)*, shall render all assistance to the Central Public Information Officer or State Public Information Officer, as the case may be, seeking his or her assistance and for the purposes of any contravention of the provisions of this Act, such other officer shall be treated as a Central Public Information Officer or State Public Information Officer, as the case may be.

6. Request for obtaining information.—

(1) A person, who desires to obtain any information under this Act, shall make a request in writing or through electronic means in English or Hindi or in the official language of the area in which the application is being made, accompanying such fee as may be prescribed, to

(a) the Central Public Information Officer or State Public Information Officer, as the case may be, of the concerned public authority;

(b) the Central Assistant Public Information Officer or State Assistant Public Information Officer, as the case may be, specifying the particulars of the information sought by him or her: Provided that where such request cannot be made in writing, the Central Public Information Officer or State Public Information Officer, as the case may be, shall render all reasonable assistance to the person making the request orally to reduce the same in writing.

(2) An applicant making request for information shall not be required to give any reason for requesting the information or any other personal details except those that may be necessary for contacting him.

(3) Where an application is made to a public authority requesting for an information,—

(i) which is held by another public authority; or

(ii) the subject matter of which is more closely connected with the functions of another public authority,

the public authority, to which such application is made, shall transfer the application or such part of it as may be appropriate to that other public authority and inform the applicant immediately about such transfer:

Provided that the transfer of an application pursuant to this sub-section shall be made as soon as practicable but in no case later than five days from the date of receipt of the application

7. Disposal of request.—

(1) Subject to the proviso to sub-section (*2*) of section 5 or the proviso to sub-section (*3*) of section 6, the Central Public Information Officer or State Public Information Officer, as the case may be, on receipt of a request under section 6 shall, as expeditiously as possible, and in any case within thirty days of the receipt of the request, either provide the information on payment of such fee as may be prescribed or reject the request for any of the reasons specified in sections 8 and 9: Provided that where the information sought for concerns the life or liberty of a person, the same shall be provided within forty-eight hours of the receipt of the request.

(2) If the Central Public Information Officer or State Public Information Officer, as the case may be, fails to give decision on the request for information within the period specified under sub-section (1), the Central Public Information Officer or State Public Information Officer, as the case may be, shall be deemed to have refused the request.

(3) Where a decision is taken to provide the information on payment of any further fee representing the cost of providing the information, the Central Public Information Officer or State Public Information Officer, as the case may be, shall send an intimation to the person making the request, giving—

(a) the details of further fees representing the cost of providing the information as determined by him, together with the calculations made to arrive at the amount in accordance with fee prescribed under sub-section (1), requesting him to deposit that fees, and the period intervening between the despatch of the said intimation and payment of fees shall be excluded for the purpose of calculating the period of thirty days referred to in that sub-section;

(b) information concerning his or her right with respect to review the decision as to the amount of fees charged or the form of access provided, including the particulars of the appellate authority, time limit, process and any other forms.

(4) Where access to the record or a part thereof is required to be provided under this Act and the person to whom access is to be provided is sensorily disabled, the Central Public Information Officer or State Public Information Officer, as the case may be, shall provide assistance to enable access to the information, including providing such assistance as may be appropriate for the inspection.

(5) Where access to information is to be provided in the printed or in any electronic format, the applicant shall, subject to the provisions of sub-section (*6*), pay such fee as may be prescribed: Provided that the fee prescribed under sub-section (*1*) of section 6 and sub-sections (*1*) and (*5*) of section 7 shall be reasonable and no such fee shall be charged from the persons who are of below poverty line as may be determined by the appropriate Government.

(6) Notwithstanding anything contained in sub-section (*5*), the person making request for the information shall be provided the information free of charge where a public authority fails to comply with the time limits specified in sub-section (*1*).

(7) Before taking any decision under sub-section (*1*), the Central Public Information Officer or State Public Information Officer, as the case may be, shall take into consideration the representation made by a third party under section 11.

(8) Where a request has been rejected under sub-section (1), the Central Public Information Officer or State Public Information Officer, as the case may be, shall communicate to the person making the request,—

(i) the reasons for such rejection;

(ii) the period within which an appeal against such rejection may be preferred; and

(iii) the particulars of the appellate authority

(9) An information shall ordinarily be provided in the form in which it is sought unless it would disproportionately divert the resources of the public authority or would be detrimental to the safety or preservation of the record in question.

8. Exemption from disclosure of information—(*1*) Notwithstanding anything contained in this Act, there shall be no obligation to give any citizen,—

(a) information, disclosure of which would prejudicially affect the sovereignty and integrity of India, the security, strategic, scientific or economic interests of the State, relation with foreign State or lead to incitement of an offence;

(b) information which has been expressly forbidden to be published by any court of law or tribunal or the disclosure of which may constitute contempt of court;

(c) information, the disclosure of which would cause a breach of privilege of Parliament or the State Legislature;

(d) information including commercial confidence, trade secrets or intellectual property, the disclosure of which would harm the competitive position of a third party, unless the competent authority is satisfied that larger public interest warrants the disclosure of such information;

(e) information available to a person in his fiduciary relationship, unless the competent authority is satisfied that the larger public interest warrants the disclosure of such information;

(f) information received in confidence from foreign Government;

(g) information, the disclosure of which would endanger the life or physical safety of any person or identify the source of information or assistance given in confidence for law enforcement or security purposes;

(h) information which would impede the process of investigation or apprehension or prosecution of offenders;

(i) cabinet papers including records of deliberations of the Council of Ministers, Secretaries and other officers:

Provided that the decisions of Council of Ministers, the reasons thereof, and the material on the basis of which the decisions were taken shall be made public after the decision has been taken, and the matter is complete, or over: Provided further that those matters which come under the exemptions specified in this section shall not be disclosed;

9. Grounds for rejection to access in certain cases.—

Without prejudice to the provisions of section 8, a Central Public Information Officer or a State Public Information Officer, as the case may be, may reject a request for information where such a request for providing access would involve an infringement of copyright subsisting in a person other than the State.

10. Severability.—(*1*) Where a request for access to information is rejected on the ground that it is in relation to information which is exempt from disclosure, then, notwithstanding anything contained in this Act, access may be provided to that part of the record which does not contain any information which is exempt from disclosure under this Act and which can reasonably be severed from any part that contains exempt information.

11. Third party information.—(*1*) Where a Central Public Information Officer or a State Public Information Officer, as the case may be, intends to disclose any information or record, or part thereof on a request made under this Act, which relates to or has been supplied by a third party and has been treated as confidential by that third party, the Central Public Information Officer or

State Public Information Officer, as the case may be, shall, within five days from the receipt of the request, give a written notice to such third party of the request and of the fact that the Central Public Information Officer or State Public Information Officer, as the case may be, intends to disclose the information or record, or part thereof, and invite the third party to make a submission in writing or orally, regarding whether the information should be disclosed, and such submission of the third party shall be kept in view while taking a decision about disclosure of information.

12. Constitution of Central Information commissions—

(1) The Central Government shall, by notification in the Official Gazette, constitute a body to be known as the Central Information Commission to exercise the powers conferred on, and to perform the functions assigned to, it under this Act.

(2) The Central Information Commission shall consist of—

(a) the Chief Information Commissioner; and

(b) such number of Central Information Commissioners, not exceeding ten, as may be deemed necessary.

(3) The Chief Information Commissioner and Information Commissioners shall be appointed by the President on the recommendation of a committee consisting of—

(i) the Prime Minister, who shall be the Chairperson of the committee;

(ii) the Leader of Opposition in the LokSabha; and

(iii) a Union Cabinet Minister to be nominated by the Prime Minister.

(4) The general superintendence, direction and management of the affairs of the Central Information Commission shall vest in the Chief Information Commissioner who shall be assisted by the Information Commissioners and may exercise all such powers and do all such acts and things which may be exercised or done by the Central Information Commission autonomously without being subjected to directions by any other authority under this Act.

(5) The Chief Information Commissioner and Information Commissioners shall be persons of eminence in public life with wide knowledge and experience in law, science and technology, social service, management, journalism, mass media or administration and governance.

(6) The Chief Information Commissioner or an Information Commissioner shall not be a Member of Parliament or Member of the Legislature of any State or Union territory, as the case may be, or hold any other office of profit or connected with any political party or carrying on any business or pursuing any profession.

(7) The headquarters of the Central Information Commission shall be at Delhi and the Central Information Commission may, with the previous approval of the Central Government, establish offices at other places in India.

13. Term of office and conditions of service.—

(1) The Chief Information Commissioner shall hold office 2 [for such term as may be prescribed by the Central Government] and shall not be eligible for reappointment: Provided that no Chief Information Commissioner shall hold office as such after he has attained the age of sixty-five years.

(2) Every Information Commissioner shall hold office 1 [for such term as may be prescribed by the Central Government] or till he attains the age of sixty-five years, whichever is earlier, and shall not be eligible for reappointment as such Information Commissioner: Provided that every Information Commissioner shall, on vacating his office under this sub-section be eligible for appointment as the Chief Information Commissioner in the manner specified in sub-section.

(3) of section 12: Provided further that where the Information Commissioner is appointed as the Chief Information Commissioner, his term of office shall not be more than five years in aggregate as the Information Commissioner and the Chief Information Commissioner.

5.5. Introduction to Intellectual Property Rights (IPR)

Intellectual Property Right is exclusive right which is granted by government of India for protecting originality of work of inventor. Simple intellectual property right is intangible creation of human mind. Intellectual Property right includes Patent, Trademark, Trades crates, Industrial design, Layout design and Copyright oriented rights. Intellectual right is important for maintaining the quality, safety, efficacy of any Pharmaceutical product and services. It is certification authority and standard authority for certification and identification of product in would wide market. This intellectual property right is the rights given to people over the creation of their minds. They usually give the creator an exclusive right over the use of his/her creations for a certain period of time. Intellectual property refers to creations of the mind, inventions in artistic, literary, scientific and industrial field. It is important application for Protection of invention of inventor and maintaining the quality as well as standard of work of inventor.

5.5.1. Objectives of IPR

1. Intellectual property Right (IPR) is a term used for various legal entitlements which attach to certain types of information, ideas, or other intangibles in their expressed form.
2. The holder of this legal entitlement is generally entitled to exercise various exclusive rights in relation to the subject matter of the Intellectual Property.
3. The term intellectual property reflects the idea that this subject matter is the product of the mind or the intellect, and that Intellectual Property rights may be protected at law in the same way as any other form of property.
4. Intellectual property laws vary from jurisdiction to jurisdiction, such that the acquisition, registration or enforcement of IP rights must be pursued or obtained separately in each territory of interest.

5.5.2. Types of IPR

- Patents
- Trademarks
- Copyrights and related rights
- Geographical indications
- Industrial designs
- Trade secrets
- Layout design for integrated circuits

5.5.2.1. Patents

1. A patent is an exclusive right granted for an invention, which is a product or a process that provides a new way of doing something, or offers a new technical solution to a problem.
2. It provides protection for the invention to the owner of the patent.
3. The protection is granted for a limited period, i.e. 20 years. Patent protection means that the invention cannot be commercially made, used, distributed or sold without the patent owner's consent.
4. A patent owner has the right to decide who may or may not use the patented invention for the period in which the invention is protected. The patent owner may give permission to, or license, other parties to use the invention on mutually agreed terms.
5. The owner may also sell the right to the invention to someone else, who will then become the new owner of the patent. Once a patent expires, the protection ends, and an invention enters the

public domain, that is the owner no longer holds exclusive rights to the invention, which becomes available to commercial exploitation by others.

6. All patent owners are obliged, in return for patent protection, to publicly disclose information on their invention in order to enrich the total body of technical knowledge in the world. Such an ever-increasing body of public knowledge promotes further creativity and innovation in others.
7. In this way, patents provide not only protection for the owner but valuable information and inspiration for future generations of researchers and inventors.

Indian Patent Act

The history of Patent law in India starts from 1911 when the Indian Patents and Designs Act, 1911 was enacted. The present Patents Act, 1970 came into force in the year 1972, amending and consolidating the existing law relating to Patents in India. The Patents Act, 1970 was again amended by the Patents (Amendment) Act, 2005, wherein product patent was extended to all fields of technology including food, drugs, chemicals and micro-organisms. After the amendment, the provisions relating to Exclusive Marketing Rights (EMRs) have been repealed, and a provision for enabling grant of compulsory license has been introduced.

An invention relating to a product or a process that is new, involving inventive step and capable of industrial application can be patented in India. However, it must not fall into the category of inventions that are non-patentable as provided under sections 3 and 4 of the (Indian) Patents Act, 1970. In India, a patent application can be filed, either alone or jointly, by true and first inventor or his assignee.

Procedure for Grant of a Patent in India

1. After filing the application for the grant of patent, a request for examination is required to be made for examination of the application in the Indian Patent Office within 48 months from the date of priority of the application or from the date of filing of the application.
2. After the first examination report is issued, the applicant is given an opportunity to meet the objections raised in the report.
3. The applicant has to comply with the requirements within 6 months from the issuance of the first examination report which may be extended for further 3 months on the request of the applicant.
4. If the requirements of the first examination report are not complied with within the prescribed period of 9 months, then the application is treated to have been abandoned by the applicant.

5. After the removal of objections and compliance of requirements, the patent is granted and notified in the Patent Office Journal. The process of the grant of patent in India can also be understood from the following flow chart (**Fig.1**).

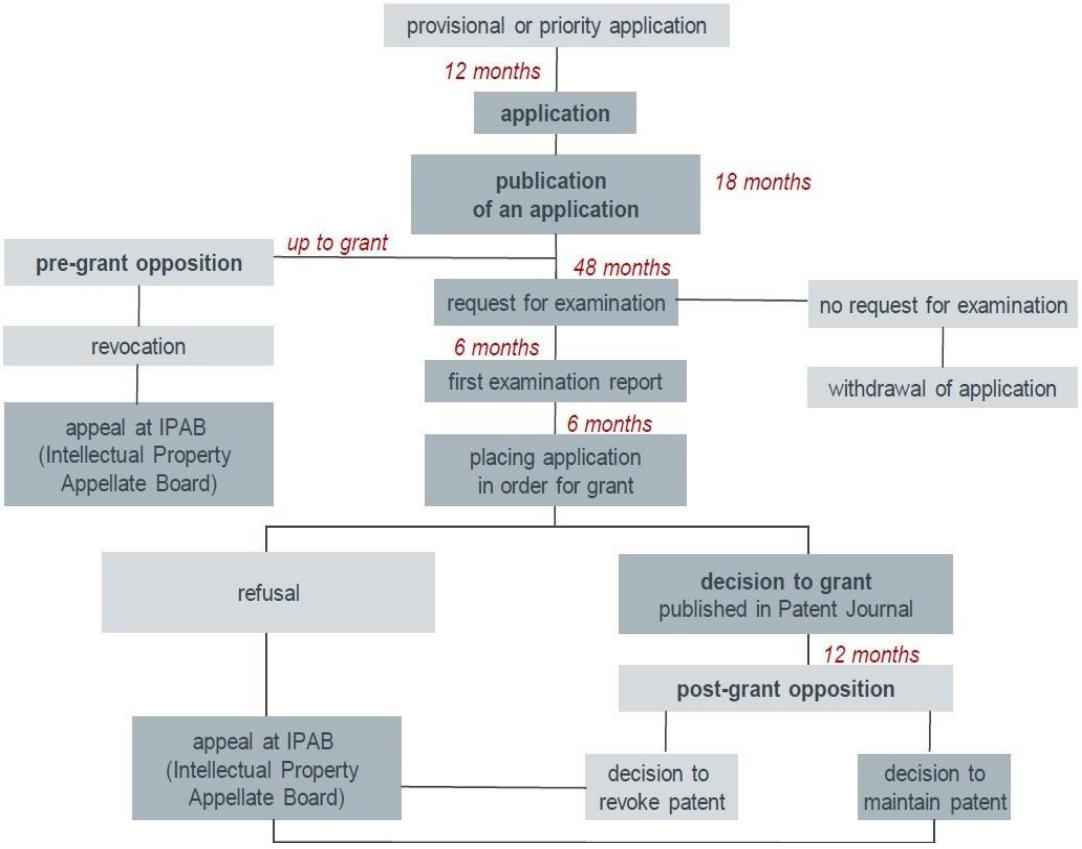

Fig.1. Patent granting procedure in India (from May 2016 onwards).

5.5.2.2. Trademarks

1. A trademark is a distinctive sign that identifies certain goods or services as those produced or provided by a specific person or enterprise.
2. It may be one or a combination of words, letters, and numerals.
3. They may consist of drawings, symbols, three- dimensional signs such as the shape and packaging of goods, audible signs such as music or vocal sounds, fragrances, or colours used as distinguishing features.
4. It provides protection to the owner of the mark by ensuring the exclusive right to use it to identify goods or services, or to authorize another to use it in return for payment.

5. It helps consumers identify and purchase a product or service because its nature and quality, indicated by its unique trademark, meets their needs.
6. Registration of trademark is prima facie proof of its ownership giving statutory right to the proprietor. Trademark rights may be held in perpetuity.
7. The initial term of registration is for 10 years; thereafter it may be renewed from time to time.

5.5.2.3. Copyrights and related rights

1. Copyright is a legal term describing rights given to creators for their literary and artistic works. The kinds of works covered by copyright include: literary works such as novels, poems, plays, reference works, newspapers and computer programs; databases; films, musical compositions, and choreography; artistic works such as paintings, drawings, photographs and sculpture; architecture; and advertisements, maps and technical drawings.
2. Copyright subsists in a work by virtue of creation; hence it‘s not mandatory to register. However, registering a copyright provides evidence that copyright subsists in the work & creator is the owner of the work. Creators often sell the rights to their works to individuals or companies best able to market the works in return for payment.
3. These payments are often made dependent on the actual use of the work, and are then referred to as royalties.
4. These economic rights have a time limit, (other than photographs) is for life of author plus sixty years after creator‘s death.

5.5.2.4. Industrial designs

1. Industrial designs refer to creative activity, which result in the ornamental or formal appearance of a product, and design right refers to a novel or original design that is accorded to the proprietor of a validly registered design. Industrial designs are an element of intellectual property.
2. Under the TRIPS Agreement, minimum standards of protection of industrial designs have been provided for. As a developing country, India has already amended its national legislation to provide for these minimal standards.
3. The essential purpose of design law it to promote and protect the design element of industrial production. It is also intended to promote innovative activity in the field of industries.

4. The existing legislation on industrial designs in India is contained in the New Designs Act, 2000 and this Act will serve its purpose well in the rapid changes in technology and international developments.
5. India has also achieved a mature status in the field of industrial designs and in view of globalization of the economy, the present legislation is aligned with the changed technical and commercial scenario and made to conform to international trends in design administration.
6. This replacement Act is also aimed to enact a more detailed classification of design to conform to the international system and to take care of the proliferation of design related activities in various fields.

5.5.2.5. Trade secrets

1. It may be confidential business information that provides an enterprise a competitive edge may be considered a trade secret. Usually these are manufacturing or industrial secrets and commercial secrets.
2. These include sales methods, distribution methods, consumer profiles, and advertising strategies, lists of suppliers and clients, and manufacturing processes. Contrary to patents, trade secrets are protected without registration.
3. A trade secret can be protected for an unlimited period of time but a substantial element of secrecy must exist, so that, except by the use of improper means, there would be difficulty in acquiring the information.
4. Considering the vast availability of traditional knowledge in the country the protection under this will be very crucial in reaping benefits from such type of knowledge.

References

1. Kuchekar BS, Khadatare AM, Itkar SC, Forensic Pharmacy, 7th ed., Pune: Nirali Prakashan, 2007.
2. N.K. Jain, Text Book of Forensic Pharmacy‖, (6th Ed.), Vallabh Prakashan Delhi, 2003, 302-312.
3. Loyd V. Allen Jr, Nicholas G. Popovich, Howard C. Ansel's Pharmaceutical Dosage Forms and delivers systems-New Drug Development and Approval Process-8th edition-B.I. publication, 25-65.

4. WHO, Quality Assurance of Pharmaceuticals, Vol-1, and Indian ed., Delhi: A.I.T.B.S. Publishers & Distributors, 2007; 86-96.
5. Douglas J. Pisano, David S. Manlus–FDA Regulatory Affairs, A guide for Prescription Drugs, Medical Devices and Biologics-New drug Application–Second edition-Marcel Dekker, Inc, 69-108.
6. Samaddar S G & Chaudhary B D, Practical insights into intellectual property strategy for technical institute, *Journal of Intellectual Property Rights*, 2008, 13, 590-600.
7. International Bureau of WIPO, What Is Intellectual Property, WIPO Pub No.450, June 2003.
8. Sharma D.K, Intellectual property and the need to protect it, *Indian Journal of Science and Reearch.*, 2014, 9, 84-87.