# Chapter - 1

# General Principles of Law, history and various Acts related to Drugs and Pharmacy profession

## Law:

- Law are the sets of rules and regulation to control, conduct of human individual in society.
- Law are the statutory binding on every person in the state or nation. Law are mandatory violation of which may result in punishment in term of incriment or fine or both.

**The purpose of introducing this subject in the curriculum of pharmacy students is twofold-**

1. To aid practicing pharmacist to understand their legal and ethical responsibility and there to avoid the pitfalls that leads to legislation
2. To serve as a text providing the students with some insight into the legal aspects of the practice of his profession.

## History:

- The **first time in India a chemist shop was opened in about 1811 by Mr. Bathgate** who come in India with East India company **in Calcutta**.
- After one hundred years this firm started manufacture of tincture and spirits.
- Another firm **Smith stanistreet and Co. Started abothecar by shop in 1821** and commenced the manufacturing in 1918.

- Bengal chemical and pharmaceutical works a small factory was started in Calcutta in **1901 by Achary Prafulla Chandra Ray**.

- In 1903 under the leadership of **prof. TK. Gajjar** a small factory at **Parel** was started which led to the development of other pharmaceutical units the alembic chemical wark Ltd at Baroda.
- These units were not sufficient to fulfill the requirements of Indian public in those days most of the medicines were being imported from abroad mainly from U.K, France and Germany.
- Then the situation was changed with the First World War cheaper drugs were imported from abroad. There were also increasing demands for indigenous drugs. The Indian and Foreign concern entered in competition grew up and the Indian market got flooded with inferior substandard and even harmful drugs.
- With this issue the public made the government to take notice of such situations of drug trade and industry and to think of introducing effective legislation to control the import manufacture, distribution and sale of the drugs.
- In those day **opium Act 1878 poison Act 1919 and Dangerous Act 1930** where in existence.
- Thus as such there was no legal control on Pharmacy profession at the beginning of this century with rapid expansion in pharmaceutical industries and market more comprehensive legislation was required Hence to have a comprehensive legislation the Indian Government appointed a **"Drug enquiry committee" (DEC)** under the **chairmanship of Lt. Col R.N. Chopra in 1931.**
- The committee was asked to make enquiries in the said matter and then to make recommendations for smooth control of manufacture import distribution and sell of drugs in the interest of public health.

## Various Acts related to Drugs and Pharmacy Profession:

- **There are also some act which are directly or indirectly related to drugs and pharmacy.**

1. Prevention of Food adulteration Act 1954
2. Development and regulation Act 1951
3. Industrial employment (Standing order) Act 1946
4. Industrial dispute Act 1947
5. Factory Act 1948
6. Indian patent design Act 1970.
7. Trade and merchandise mark Act 1958
8. Epidermic disease Act 1897.
9. Shops establishments, Act of respective State.

# Chapter 2 Pharmacy Law & Ethics

# Pharmacy Act 1948 & Rules

## Introduction Pharmacy Act 1948:-

Before independence there were no regulations for the profession and practice of pharmacy. The drug enquiry committee recommended that the person practicing pharmacy that is the person responsible for compounding and dispensing of medicines should have a proper education background.

Health survey and development committee also made a similar type of recommendation consequently the Pharmacy Act come into force in March 1948.

## Objectives of Pharmacy Act, 1948

The pharmacy act 1948 is passed with the main objects to regulate the profession and practice of pharmacy are as follows-

- To make better provisions for requlating profession and practicing of pharmacy.
- To rise the status of "Profession of Pharmacy" in India.
- To constitute "Pharmacy Council of India" For setting new standards in pharmacy education.
- To regulate pharmacy institution specially "Diploma in Pharmacy" through education requlations with registration of pharmacist.

## Definitions:-

The pharmacy act was passed in March 1948 there were following components to followed by pharmacy act.

***1. Registered Pharmacist*** :- Registered pharmacist means a person whose name is for the time being entered in the register of state in which he is for a time being residing or carrying on his profession or business of pharmacy.

***2. Central council :-*** Central council means ""PCI constituted under section-3 of pharmacy Act 1948.

***3. Executive committee: -*** Executive committee means executive committee of control council or state council as the context may require.

***4. State council: -*** State council means a "State Council of Pharmacy" constituted under section-19 and includes "Joint state council of Pharmacy" constituted in accordance with an agreement under section-20of Pharmacy Act 1948.

***5. Displaced person: -*** Any person who has left or has been displaced from place of is residence in Pakistan on or after 1march 1947 on account of setting upto dominions of India and Pakistan or an account of civil disturbance or fear there of and since than residing in India.

***6. Central Register: -*** Central Register means the register of pharmacist maintain by the pharmacy council of India under section-15A.

***7. Repatriates :-*** Repatriates means any person of Indian origin who has left or has been displaced from place of his residence in Burma, Srilanka, Uganda or any other countries, after 14 th April 1957 on account of civil disturbance or fear there of and since than residing in India.

***8. Medicinal practitioner: -*** A person registered for medicinal practitioner of state who is decleared by the state government of India.

A person registered or eligible for registration in the Register of dentist for a state under the dentist act 1948.

# Pharmacy Council of India :-

The first pharmacy council was constituted in 1949. It is reconstructed every five year. The pharmacy council of India is constituted under section-3 of pharmacy Act 1948 and consist of following members.

A. **Elected members**
B. **Nominated Members**
C. **Ex-official members**

### *A. Elected members :-*

- Six member elected by "***University Grand Commition***" from among teachers working in Indian University or college affiliated to Indian University which grands degree or diploma in Pharmacy.Among these only one teacher of each the subject pharmaceutical chemistry, pharmacology, Pharmacognosy.
- One members elected from themselves by member of "***Medical council of India***"
- One registered Pharmacist to represent each state, selected from themselves by member of eachstate council.

### *B. Nominated Members:-*

- Six members are nominated by the central government of whom at least four shall be processingdegree or D.Pharma and are in practice of pharmacy or pharmaceutical chemistry.
- A representative of University Grand Commition.
- A representative of "***All India council for technical education" (A.I.C.T.E.)***

### *C.* Ex-officio members:-

- The director general, health service, ex-officio.
- The drug controller of India.
- The director of central drug laboratory.

## Function of PCI:-

1. To regulate pharmacy institution specially Diploma in Pharmacy through education regulation.
2. To frame periodically "Education Regulation" with approval of central government for setting new standard for pharmacy education.
3. To approve or disapprove course of study and examination in pharmacy.
4. To recognise foreign qualification in pharmacy for purpose of registration.
5. To maintain central register of pharmacist.

### Power of PCI to regulation.

- Under section-10 of pharmacy Act, The pci is empowered to frame education regulations after approval of central government.
- Under section-18 a pharmacy act with approval of central government PCI is empowered to make regulations for the following purpose.
- Management of property of central council

- Manner of conducting elections.
- Holding meetings to fix time, place, and conduct, of business in such meeting.
- Function of executive committee, holding meetings to fix time and place.
- Power and duties of president and vice president.
- Qualifications, terms, power and degree of registered, inspectors and other officers.

### *Educations and Regulations:-*

Under section-10 of pharmacy Act 1948 the PCI is impowered to frame education regulation after approval of central government. The education regulations prescribed minimum standards of educations for Pharmacists which includes-

1. Qualification of Pharmacist
2. Minimum qualification for addmission to 1st year D.pharma.
3. Approval of institute conduction course of study.
4. Approval of examination
5. Eligible for appearing in examination at d.pharma part 1st and part 2nd.
6. Periods and other conditions of practical training.
7. Equipment and facilities to be provided by institutions.
8. Condition to fulfill by the examination authority.

# Procedure of framing

## Education regulation (ER) and Amendments.

- Under section-10 of pharmacy Act 1948 there is provision for framing education regulations for regulations and control of pharmacy institution. The central with approval of central govt. Make regulations called education regulations.
- Education regulation prescribe minimum standards of educations required for qualification as Pharmacists.
- Befor submitting the education regulations for approval of central forward copies of draft of education requlation to all state government.
- The state government of required to send comment to copy to draft.
- After considering the comments on the draft education regulation, The central council shall be submit the draft of education regulation to the central government for eight approval.
- After approval of central government education regulations are published in the official gazettes.

The efficacy of education regulation shall be reported to central council by the executive counciland may propose amendments. Some procedure also forward for efficiently amendments of statecouncil.

- Application of education regulation to the state.
- Any time after constitution of state council with due consultation of state council state government may apply education regulation to the state by notification in the official gazettes.

# State Pharmacy Council.

Section-19 of pharmacy Act 1948 provides for constitution and composition of state council. Every state government has to constitute state council accordingly which consists of following members.

1. Elected members

2. Nominated Members

3. Ex-officio members

***1. Elected members:*** **-** Six members elected from among themselves by registered Pharmacist of state.

One member elected by the state Medical council from amongst its member.

***2. Nominated Members:*** **-** Five members are nominated by the state government of whom atleast three should be degree are D.Pharma or pharmaceutical chemistry or should be registered Pharmacist.

***3. Ex-officio members:*** **-** The chief administrative medical officer of the state ex-officio.

- The officer incharge of drug controller department of State.
- The government analyst deputed by the state government.
- President and Vice President of shall be elected by the members from amongst themselves.
- Subject to membership they hold office for the five years and are also eligible for re-election.

Elected and nominated Members hold office for five years however they may in written resign at any time. If any nominated or elected member remain absent without sufficient reason for three constitutive meetings. He is deemed to have vacated his seat casual vacancies filled only for the reminder term by fresh nomination or elections as the case may be.

# Registration of pharmacist:-

The pharmacy act provides for registration of the pharmacist to regulate the entry of person in "Pharmacy professions" only person having requisite, qualifications, training, and experience are allowed to enter the professions. Name of registered Pharmacist are entered in the Register maintain by state council and central council.

***The register include particulars:-***

- Full name and resisdental address of registered Pharmacist.
- Date of first addmission to register.
- Qualification for registration
- Professional address, Name of employer if employed.
- Such other particulars are may be prescribed.

**First register:-**

- For preparation of 1st register the state government constitutes a "Registration Tribunal" by notification in the official gazette.
- The tribunal consists of three person and a register. The registered act as secretary of tribunal.
- The state government by notification specify the date for submission of applications for registration. The applications for registration along with prescribed fee should be made on or before this date registration tribunal.
- The state government by notification specify the date for submission of applications for registration. The applications for registration along with prescribed fee should be made on or before this date registration tribunal.

## Qualification for entry on 1st register:-

- A person above 18 years of age who resides or carries business or professions of pharmacy in the state on patient of prescribe fee is entitled for entry of the name in the 1st Register.
- Hold degree or diploma in Pharmacy of pharmaceutical chemistry or a "chemist" and "druggist" "Diploma of Indian University or state government". A qualification granted outside of India approved under section-14.
- Hold degree of and Indian University other than degree in pharmacy or pharmaceutical chemistry and has been engaged for a total period of time is more than than 3 years in compounding of drug in hospital or dispensary in other place.
- Passed an examination recognised as adequate by the state government for compounding or dispensing.

## Procedure for Registration of Pharmacist:-

- Under provisions for section-33 of act state pharmacy council register name, Address, and, Qualifications of the Pharmacist in the state register an application in prescribed pro-forma is to be submitted to the register of respective State pharmacy council.
- The application should be accomplished by the prescribed fee and following document.

***Document required for Registration of Pharmacist (P.C.I. Registration):-***

1. 5 recent passport size photo
2. ID proof
3. Address proof
4. Hospital training certificate
5. Mark sheet of 1st year and 2nd year D.Pharma, If you want to get the registration of B.Pharma then its complete mark sheet all year.
6. Provision certificate
7. 10+2 marksheet

## Renewal of Registration:-

- First registration continued till 31 December of year following the year in which it is granted there after registered Pharmacist should annually renew registration by the due date to retain his name on register of pharmacist.
- On failure to remit renewal fee before due date 1April of subsequent year.
- The name defalter pharmacist is remove from the registered on payment of renewal fee the register issues receipt therefore.
- This stand as a proof of renewal of Registration in order to avoid such situation, pharmacist may voluntarily remit advance renewal fee in Lump Sum (ARFL).

## Offences and Penalties:-

- Falsely claiming to be a registered Pharmacist.
- Dispensing by unregistered person.
- Will full obstruction to an inspector
- Failure to surrender certificate of registration.

# Chapter-3 | Pharmacy Law & Ethics (Pharmaceutical Jurisprudence)

## Drugs and Cosmetics Act 1940 and Rules 1945 and New Amendments

- Drugs and Cosmetics Act 1940 and Rules 1945 and New Amendments 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.
- 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. (Not Available in this Notes )
- Study of schedule C and C1, G, H, H1, K, P, M, N, X and Y. Sale of Drugs – Wholesale, Retail sale and Restricted license, Records to be kept in a pharmacy Drugs Prohibited for manufacture and sale in India
- Administration of the Act and Rules – Drugs Technical Advisory Board, Central Drugs Laboratory, Drugs Consultative Committee, Government analysts, licensing authorities, controlling authorities, Drug Inspectors.

# Drugs and Cosmetics Act 1940 and Rules 1945 and New Amendments Objectives, Definitions, Legal definitions of schedules to the Act and Rules

## Drugs and Cosmetics Act 1940 and Rules 1945 and New Amendments:

### Introduction:

- Drugs are vital to the health of an individual but cosmetics do not play any role in our health.
- Drugs have been classified as essential commodity under Essential Commodities Act.
- The Drugs and Cosmetics Act, 1940 and Rules, 1945 have been passed with the objective of regulating the import, manufacture, distribution and sale of drugs and cosmetics.
- Act regulates the manufacture and sale of drugs and cosmetics through licensing so that these are manufactured, distributed and sold only by qualified persons.
- Act covers the drugs under allopathic, ayurvedic, homoeopathic and Unani Tibb systems as well as drugs for veterinary use.
- The main object of the Act is to prevent substandard in drugs. It is a lifesaving statute and extends to whole of India.
- The Drugs and Cosmetics (Amendment) Act, 2008 was brought into force with effect from 10 August, 2009. Main features of the Amendment Act include

i. Insertion of new Section 17-E i.e. adulterated cosmetics,

ii. Insertion of Sections 36-AB (Special courts for trial of offences relating to adulterated drugs or spurious drugs, and

iii. Insertion of Section 36-AC (offences relating to adulterated drugs or spurious drugs to be cognizable and non-boilable in certain cases.

- Drugs and Cosmetics (Third Amendment) Rules, 2008 came into force with effect from 1 November, 2010 and introduced the requirements of "Good Laboratory Practices" as laid down in Schedule L-I.

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

## Import of drugs:

**Import of drugs without license**

- Substances not used for medicinal pupose
- Drugs in Sch-C1 required for manufacturing and not for medicinal use.
- Substances which are both drugs and foods such as: Condensed/Powdered Milk Malt Lactose Farex/Cereal
- Oats Predigested foods
- Ginger, Pepper, Cumin, Cinnamon

### Classes of drugs prohibited to import

Import of drug under license:

1) Specified in Schedule-C/C1
2) Specified in Schedule-X
3) Imported for Test/Analysis
4) Imported for personal use
5) Any new drugs
6) Drugs exempted from provisions of import

### Classes of Cosmetics prohibited to import

- Misbranded cosmetics
- Spurious cosmetics
- Cosmetic containing harmful ingredients
- Cosmetics not of standard quality
- Which contains more than-2 ppm Arsenic, 20 ppm lead, 100 ppm heavy metals SJTPC.

### Import of Drugs in India

- The Central Government exercises regulatory control over these drugs and cosmetics imported into country through (CDSCO) Central Drugs Standard Control Organisation headed by the (DCG) Drugs Controller General of India.

- The manufacture, sale, and distribution of drugs are primarily regulated by the State Drug Control Authorities appointed by the State Government.
- The objective of the drug regulatory system in the country is to ensure availability of safe, effective, and quality drugs, cosmetics, and medical devices based on scientific excellence and best possible regulatory practices.
- Drug is defined in Section 3 of the Drugs and Cosmetics Act 1940. The Central Government has the power to declare any drugs, cosmetics, or medical devices as useful Drugs by giving notification in the official gazette.
- By virtue of the said power the Central Government has Notified Disposable Hypodermic Syringe, Disposable Hypodermic Needle, and Orthopedic Implant, Catheter, as drugs in 1989.

**There are three types of import that are:**

1) Registered Drugs (Import under license or permit)
2) Unregistered Drugs
3) Import of Excipient

**1) Import of the Registered Drugs (Import under license or permit)**

- When any drug registered in India a Certificate of Registration in the prescribed Form 41 is issued by the appropriate authority of the Central Government. When any person wants to import the registered drug, it is required to have import licenses by the appropriate authorities of the Central Government.
- As per Rules 24 and 27 of the Drugs and Cosmetics Rules 1945, the import license to import drugs that are not specified in Schedule X to these Rules will be issued in the prescribed Form 10.
- It will also apply to import of drugs which are specified in Schedule X to the Drugs and Cosmetics Rules, 1945. The import license will be issued in the prescribed Form 10A.
- In India the drugs which are specified in Schedule X to the Drugs and Cosmetics Rules cannot be purchased over the counter without the prescription of a qualified doctor. Not only that the retailer also has to preserve the prescription for a period of two years.

**Labeling on the Imported Consignment**

- On every import consignment of the registered drugs a label should be affixed showing the name and address of the manufacturer, date of manufacturing, batch number, date of expiry of the drug, name and address of the importer, import license number and date. (Form 10 or 10A)

### Testing on Imported Drugs

- As a safeguard, the Drug Controller office is at the Nominated Port where the import consignment arrives draws sample from the imported drug for testing to verify. It is checked that the drug which is being imported in India as a registered drug is the same drug that is actually registered in India or not.
- The samples are sent for testing at the Central Drug Testing Laboratory of the Government of India. If the result of the testing comes to the satisfaction of the Drug Controller office the import consignment is given to the importer.
- Import of any drug for the purpose of examination, test, or analysis in India is allowed subject to the import should be made against Test License issued by the appropriate authorities in the prescribed Form 11.

**2) Import of the Unregistered Drugs**

- Unregistered drug means the drug which is not registered in India hence, no import license is issued consequently. The import of unregistered drug in India is not possible. However, there are various Drug Manufacturers Associations which have granted exemption from registration requirement under the Drugs and Cosmetics Act.
- The import of unregistered drug made under Advance Authorisation (Advance License). The Government of India Ministry of Commerce and Industries has by Policy Circulars made a provision that no registration is required if the unregistered drug imported under the Advance Authorisation.

**3) Import of Excipient**

- Import of any drug some substance is used for coloring or as preservative or as filler or diluter. The substance is not active in the drug in which it is used but works as vehicle or medium for the drug or other active substances. This substance which is so used it is called excipient.
- Excipient can be imported in India without any import license issued under the Drug and Cosmetics Act 1940. However, no objection certificate (NOC) issued by the Drug Controller Office in India is required for import of such excipient. A copy of the NOC is sent to the Drug Controller Office at the port where the imported cargo is to have arrived.
- No testing is required of the material imported as an excipient. The NOC issuing authority will mention in the NOC name and address of the manufacturer, name and quantity of the item to be imported and an instruction that Not for Medicinal use.

# Study of schedule C and C1, G, H, H1, K, P, M, N, X and Y. Sale of Drugs – Wholesale, Retail sale and Restricted license, Records to be kept in a pharmacy Drugs Prohibited for manufacture and sale in India

**Schedule C& C1:** It prescribes the list of the biological and other special products.

**Schedule G:** List of drugs for which caution should be written on the lable that it is dangerous to take preparations except under medical supervision.

List of substances that are required to be used only medical supervision and which are to be labeled accordingly.

**Schedule H:** List of prescription drugs.

**Schedule P:** Life periods of drugs.

**Schedule M:** Good manufacturing practices (GMP) requirements of factory premises, plant and equipment for pharmaceutical products.

**Schedule N:** List of minimum equipment for efficient running of a Pharmacy.

**Schedule X:** List of drugs whose impart, manufacture and sale, labeling and packing are governed by special provisions.

**Schedule Y:** Requirement and guidelines on clinical trials for impart and manufacture of new drugs.

## Sale of Drugs:

- The drug reach the consumer from the manufacturers by retail through shopkeepers.
- Manufactures generally sell their goods to the wholesaler (stockists) who in turn, sell the same to the retailers.

## Wholesale of Drugs

- Wholesale means a dealer or his agent or stockiest engaged in the sale of drugs to a retailer, hospital, dispensary, medical, educational or research institution or any other agency.

**Drugs other than these specified in schedule C, C1 and X:**

- Issued in form 20B licensee
- Drug should be purchased only form a dully Licensesd dealer or manufacture.
- Schedule X drugs — Licenses issued in Form 20G

**Drug specified in schedule C & C1 but not included in schedule X:—**

- License issued in the form 21B.

**Drugs specified in schedule C & C1 from motor vehicle:**

- License issued in the form 21BB.

## Retail Sale:

**For retail Sale two types of Licensess are issued,**

1. General
2. Restricted

**General licenses** are granted to persons who have premises for the business and who engage the services of a qualified person to supervise the sale of drugs and do the Compounding and dispensing.

**Conditions:**

- Licenses should be displayed in a prominent place in a part of the premises open to public.
- License should comply with provisions of Drugs and Cosmetics Act and Ruler in force.
- Any change in the qualified staff in charge should be steparted by licensee to licensing authority with in 1 month
- Any change in Constitution of licensed firm should be informed to licensing authority with in 3 months and in the meantime fresh Licenses should be obtained in the home of the firm with changed Constitution.

**Restricted licenses**

- Licenses for restricted sale of drugs other than those specified in Schedule C, $C_1$ and X and those specified in Schedule C, and C1 but not in Schedule X are issued in the form 20A and 21A Respectively.

**Condition for Best Restricted Licenses: -**

- Licensee must have adequate premises equipped with facilities for proper storage of drugs to which Licenses applies provided that this condition does not apply to vendors.
- Licensee should comply with provisions of Drugs and Cosmetics Act and rules in force.
- Drugs should be purchased only from a duly licensed dealer or manufacturer.
- If licensee is a vendor having no fined place of business, he should buy drugs from dealers specified in his Licenses.

**Drugs should be sold in their original containers.**

- Labeling and Packing of Drugs
- The Containers of all the drugs including patent or proprietary medicine are to be labelled in accordance with the Drugs and Cosmetics Rules 1945.

**Following particulars should be either printed on written in indelible ink and should appear in a conspicuous manner on label of the inner most container of any drug and every other Covering in which the Container is packed: -**

- Proper name of the drug should be printed in a more conspicuous manner than the trade name, if any.
- A Correct statement of the net contents in term of weight, measure, volume, number of units of activity as the Case of units of may be are expressed in motrin system.
- The name and address of manufactured. In case of the drug contained in an example or a similar small container it is enough if only the name of the manufacturer and his principal place of business is shown.
- Manufacturing Licenses Number, or mfg. Lic. No, or M. L.
- A distinctive batch number, the figuere reperesenting the batch number being preceded by the words 'Batch No, or B. No, or Lot No, or Lot.

## Expiry particulars.

- Precautionary information related to care in handling, use, distribution etc.
- Information suclated to storage all manner af use.
- General information such as 'physician's sample, not for sale etc.

## Packing of Drugs

The pack size of drugs meant for retail sale shall be as prescribed schedule P1 to the rules and for in Other drugs given bellow.

**1. less than 10 Tablets/ Capsules: Packing by integral number**

- More than 10 Tablets / Capsules: Multiples of 5

**2) Liquid oral pereparation: - 30ml (paediatric only) 60ml /100ml/200ml/450ml**

**3) Paediatric oral drops: 5ml/10ml/15ml**

**4) Eye / Ear / nasal drops: 3ml | 5ml | 10ml**

**5) Eye ointment: 3 gm / 5gml / 10gm.**

**However these provisions shall not apply to**

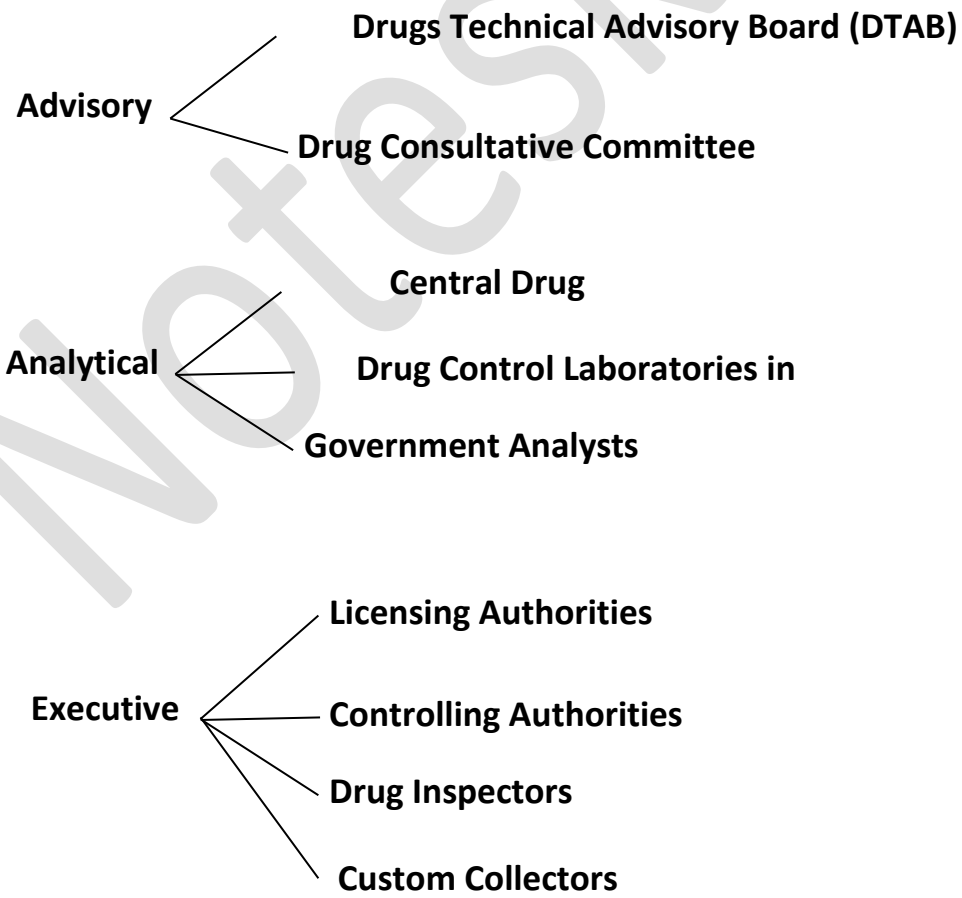
i. Imparted formulations in finished form
ii. Preparations for veterinary use
iii. Preparations for export.
iv. Vitamins / tonics | Cough preparations) antacids | laxatives in liquid oral forms / unit dose forms.
v. Physician's samples, pack sizes of dosage forms af for retail sale to hospitals.
vi. Pack sizes of large valume IV fluids.

**The Schedule X drugs shall be marketed in packing not exceeding: -**

i. 100 unit doses in the case of tablets / Capsules.
ii. 300ml in the case of aral liquid preparations.
iii. 5ml in case of injections.

## Administration of the Act and Rules

For the efficient administration of the Act and the Rules, the Following agencies have been



## Drug Technical Advisory Board (DTAB)

DTAB is constituted the Central Government to advise the Central and State Governments on technical matters arising out of the administration of this Act.

It consists of 18 members, of whom are ex-officio, 5 nominated and 5 elected members, as follows:

I. **Ex- officio members:**

a. Director General of Health Services (chairman)
b. Drug Controller of India.
c. Director, Central Drug laboratory, Kolkata
d. Director, Central Research Institute, Kasauli
e. Director, Indian Veterinary Research Institute, Izatnagar
f. President, Pharmacy Council of India
g. President, medical Council of India
h. Director, Central Drug Research Institute, Lucknow

II. **Nominated members.—**

- Two Persons nominated by the Central Government from amongst persons who are incharge of drugs Control in states.
- One person from the Pharmaceutical industry, nominated by the Central Government
- Two Government analyst, nominated by the Central Government.

III. **Elected members**

- A teacher in Pharmacy or Pharmaceutical Chemistry or Pharmacognosy on the staff of an Indian University or an affiliated - College, elected by the Executive Committee of the Pharmacy Council of India.
- A teacher in medicine or therapeutic on the staff of an Indian University or an affiliated college, elected by the Executive Committee of the medical Council of India.
- One Pharmacologist elected by the Governing body of the Indian Council of medical Research.
- One Person elected by the Council of the central medical Association.
- One Person to be elected the Council of the Indian Pharmaceutical Association.

## Drug Consultative Committee (DCC)

- The drugs Consultative Committee is constituted by the Central Government. It is an advisory committee for the Central and State governments and the DTAB.

- It Consists of two representatives nominated by the central Government and one nominee of each of state Governments.
- The Committee meets when required by Central Government to do so and is empowered to regulate its own procedure.

### Central Drug Laboratory

The Act provides for the establishment of a Central Drug Laboratory under the Control of a director appointed by Central Government. This laboratory established in Kolkata has been entrusted with the following functions.

To analyse or test samples of drugs or Cosmetics send to it by the Customs Collectors or Courts.

To carry out such other duties as entrusted to it by the Central Government or with its permission by the State Government after Consultation with the DTAB.

The functions of the laboratory in respect of sera, Solutions of serum proteins for injection, vaccines, toxins antigens, antitoxins, sterilised surgical ligature and sutures and bacteriophages are carried out at the Central Research Institute Kasauli.

## Government Analysts:

Government Analysts are appointed by the Central **Government** or a State **Government** V/S 33-F in relation to Ayurvedic, Siddha or Unani drugs and UV 20 in relation to any other drug or Cosmetic.

The Central Government may also similarly appoint Government Analysts, in respect of such drugs, classes of drugs, Cosmetic, classes of Cosmetics, as specified.

**Qualification of Government Analysts**

A graduate in medicine/ science / Pharmacy / Pharmaceutical Chemistry of a recognized university and have five years past graduate experience in the testing of drugs in a laboratory under the Control of

a) A Government Analyst:
b) Head of an approved institution or testing laboratory or has completed two years training testing of drugs, including items stated in Schedule C in Central Drugs Laboratory.
c) A post graduate in medicine | science / Pharmacy / Pharmaceutical Chemistry of a recognised University or Associate ship Diploma of the Institution of Chemists (India) obtained by Passing the said examination with Analysis of Drugs and Pharmaceuticals as one of the subjects with at least three years' experience in the testing of drugs in a laboratory under the Control.

Duties of Government Analysts:

To cause to be analysed or tested sample of drugs or cosmetics sent to under the act and to furnish reports of the results of test or analysis.

Forward to the Government from time to time, reports giving the results of analysis work and research with a view to their publication at the discretion of Government.

## Licensing Authorities

- Any Application for the grant or renewal of a licence for the import, manufacture, sale, distribution etc. Drug or of any Cosmetic is to be made to LA.
- The Qualification of a licensing authority has been prescribe under “Rule 49A” by the Drugs and Cosmetics Rules 1989.

### Qualification: -

No person shall be qualified to be a licensing authority under the Act unless-

1) He is graduate in Pharmacy /pharmaceutical chemistry, medicine with specialization in Clinical Pharmacology/ microbiology, from a recognised university.
2) 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.

## Controlling Authorities

- Drug Inspectors appointed under the Act are under the control of a Controlling authority.
- The qualification of a controlling authority has been Prescribed Under "Rule 50 A" by the Drugs and Cosmetics Rules, 1989.

### Qualification:

No Person shall be qualified to be a Controlling authority under the Act unless.

He is a graduate in Pharmacy / Pharmaceutical Chemistry/ medicine with specialization in Clinical Pharmacology/ microbiology, from a recognised university.

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.

## Drug Inspectors

- In relation to Ayurvedic, Siddha or Unani drug an Inspector appointed by the Central Government or a state Government V/S 33-G.
- In relation to any other drug or Cosmetic an Inspector appointed by the Central Government or a State Government v/s 21.
- The Central & State Governments are empowered to appoint Drug Inspectors and to assign them definite areas. Any person having financial interest in the import, manufacture or sale of the drugs or Cosmetics not be appointed as drugs Inspector.
- Drug Inspectors are deemed to be public servants and are officially subordinate to the controlling Authority.

### Qualification of Drug Inspectors: -

For appointment as Drug Inspectors a person must have a degree in Pharmacy as pharmaceutical Science or medicine with specialization in clinical Pharmacology or microbiology from an Indian University.

For Inspection of the manufacture of substances in Schedule C the persons appointed as Drug Inspectors must have-

- At least 18 month experience in the manufacture of at least one of the substances specified in schedule C.
- At least 18 month experience in the testing of at least one of the substances in schedule C in an Approved testing laboratory.
- Gained experience of not less than three years in the inspection of firms manufacturing any of the substances in Schedule C during the tenure of their service as Drug Inspectors.

### Powers of Inspectors:

Inspection of premises where any drug or Cosmetic is being manufactured and the means employed for standardising and testing the drug or Cosmetic.

Inspection of premises where any drug is being sold, or Stocked on exhibited or afforded for sale or distributed.

Taking samples of any drug or cosmetic which is being manufacture or being sold/Stocked/exhibited/affered for sale being distributed.

Taking samples of drug or Cosmetic from any person Conveying delivering or preparing to deliver such Drug or Cosmetic to a purchaser as a consignee.

Examine any record, register, document or any other material object with any person or in any place mentioned above and size the same if it is likely to furnish the evidence of an offence.

Require any person to produce any record, register or other document relating to manufacture, sale or distribution of any drug or cosmetic in respect of which on offence has been or is being committed.

## Duties of Drug Inspectors:

**A. Inspection of Premises licensed for sale:**

- Inspect not less than once a year all establishments licenced for the sale of drugs with in the area assigned to him and to satisfy himself that the conditions of the license are being observed.
- Procure and send for test or analysis if necessary imparted packages which he has reason to suspect contain drugs being sold in contravention of the provisions of the Act or the rules there under.
- Investigate any complaint made to him in writing and to institute prosecutions in respect of preaches of the "Act or Rules there under.
- Maintain a record of all inspections made and action taken by him in the performance of his duties, including the taking of sample and the seizure of stocks and to submit copies of such records to the controlling authority.
- Make such enquiries and inspections as may be necessary to detect the sale of drugs in contravention of the Act.
- When so authorised by the State Government to detain imported packages which he has reason to suspect contain drugs the import of which is prohibited.

**B. Inspection of manufacture of drugs or cosmetics.**

- To inspect not less than once a year all premises licensed for the manufacture of drugs with in the area allotted to him and to satisfy himself that the conditions of the license and the provisions of the Act and Rules there under are being observed.
- In the case of establishments licensed to manufacture products specified in Schedule C and C1 to inspect the plant and the process of manufacture the means employed for standardizing and testing the drug, 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 effect the pokncy or purity of the product.
- To send to the controlling Authority after each inspection a detailed report indicating the condition of the license and provisions of the Act and rules.
- To take the samples of the drugs manufactured on the premises and send them for test or analysis.
- To institute prosecution in respect of breaches of the Act and Rules.

# Chapter-4 | Pharmacy Law & Ethics

## Medicinal and Toilet Preparations Act 1955

- This Act was passed in 1955 in regard to collection of tax and excise duties on Medicinal and Toilet Preparations having alcohol, Narcotic drugs or Narcotics and the corresponding rules to the act where passed in 1956.

**Definition:** The definition and important terms of the Medicinal and Toilet Preparations Act 1955 are as follows-

1. **Alcohol:-** Alcohol is ethyl alcohol of any concentration and purity having the chemical composition C2H5OH.
2. **Excise officer:-** It is an officer of the excise department of any state and includes any person impowered by the collecting government to excercise of or any of the powers of an excise officers under this act.
3. **Medicinal prepration:-** Including all drugs which are prescription prepared for external and internal use of human beings or animals in treatment reduction and prevention of disease in human beings or any ones.
4. **Narcotic drugs:-** Those substance which is coca derivative or opium or Indian hemp and shall include any other substance which produced in human beings dependence tolerance and withdrawal of syndrome.
5. **Toilet prepration:-** This act was passed to collect tax and duties of excise imposed on medicinal and Toilet Preparations made up of alcohol and other narcotics drugs.

- **There are two modes of manufacture of medicinal and Toilet Preparations containing alcohol are as follows-**

## 1. Manufacture In-bond

## 2. Manufacture outside bond

- In the first case alcohol on which duity has not been paid shall be used under the excise supervision and in the case of manufacture outside bond only the alcohol on which duties has already be paid shall be used.

## 1. Manufacture In-bond (Bonded Laboratory) :

- Only one entrance and do to every compartment should be provided in the bonded factory.
- If the manufacturing is not suitable in situated near the distillery of spirit warehouse one plain spirit store should be arranged.
- A large room should be present to manufacture medicinal prepration and separated arrangement should be therefore manufacturing toilet prepration.
- In the bonded premises a room with basic furniture should be present to efficers incharge.
- Each window should be fitted with flexible iron rod placed four inches apart depth of 2inches in brick internally covered with strong wire netting or mesh diameter one inches.
- In the manufacturing outside each rooms abroad carrying with specific name and a serial number.
- Each pipe comming from the sink or wash basins in the manufacturing area should be attached to a common drainage system to dispose of the all the waste.

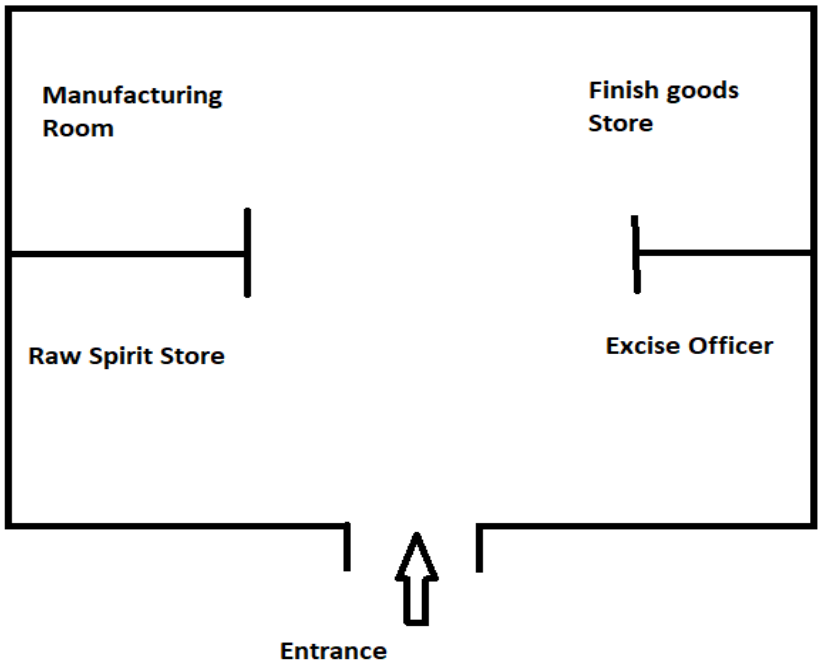



**Fig: Bonded Laboratory Design**

## License for bonded laboratory:

To manufacture alcholic prepration and narcotics and authorised license is need which is issued only if the individual already has the license to manufactures drugs as per drug and cosmetic act and rules. To obtained the license or in order to renew it and application is forwarded to the license authority who may be -

1. The excise commissioner when the license has to be obtained for a bonded manufacturing.
2. An officer oppointed by the state government when the license has to be obtained for non-bonded manufacturing.

## 2. Manufacture outside bond (Non-bonded laboratory)

- The production of the Medicinal and Toilet Preparations can be carried out without bond by the manufacturer after availability the respective license. An application for the license in the prescribed form is send to the officers appointed by the state government for this purpose. The license specification are same for the manufacturing of medicinal preparation outside bond and inside bond.
- Non-bonded manufacturing requires separate premises where only Medicinal and Toilet Preparations will be manufactured.

## License:

- The license required for manufacturing Medicinal and Toilet Preparations without bond can be obtained by giving an application to officers appointed by the state government.
- The application form and other condition of the license for manufacturing Medicinal Preparation outside bond (Non bond) are the same as those for manufacturing under bond.

**The following fee structure should be followed for obtaining a license for non-bonded manufacturing —**

- ✓ Consumption of alcohol is 125 L.P litres O less per annum Rs-10
- ✓ Consumptions of Alcohol per annum is more than 125 but less than 500 L.P litres – Rs - 25.
- ✓ For manufacturing ayurvedic unani prepration containg either self generated Alcohol or distilled Alcohol Rs-25.

## Offence and Penalties:

- ✓ The offence and related penalties to the medicinal and Toilet Preparations Act are in listed are as follows –

| Sr. | Offences | Penalties |
|---|---|---|
| 1. | Non-compliance with condition of license and failure to pay duty. | Imprisonment for up to 6 months or fine up to 200 or both. |
| 2. | Failure of excise officer on duty. | Imprisonment for up to 3 months fine up to 2000 or both. |
| 3. | Improper keeping of stocks or accounts | Fine up to 100 |
| 4. | Making fake entries are tearing pages from stock books | Fine up to 100 |
| 5. | Failure to furnish proof of export within specify period | Fine up to 2000. |

# Chapter-5 | Pharmacy Law & Ethics (Pharmaceutical Jurisprudence)

# Narcotic Drugs and Psychotropic Substances Act 1985 and Rules

- **Narcotic Drugs and psychotropic substances Act 1985 and Rules Objectives, Definitions, Authorities and Officers, Prohibition, Control and Regulation, Offences and Penalties.**

## Introduction:

- The central acts like Opium Act 1857, the opium Act, 1878 & the Dangerous Drugs Act, 1930 were erected a long time age.
- With the changing circumstances and the developments in the field illicit drugs traffic and drugs abuse at national and International level many drawbacks have come to notice in the said Acts.
- The government of India has repealed these old Acts passed the:
- These Acts established in 14 November 1985.
- It also provides the licensing system for both central & state government.

## Objectives:

- The main objective of this Act is to consolidate & Amend the low relating to Narcotic Drugs.
- To make stringent provision for control & Regulate the operation relating to Narcotic Drugs & Psychotropic substance and matters concerned there with it.

# Definitions:

**Addict:**

- A Person habitual to regular use of any Narcotic drugs or Psychotropic substances.

**Cannabis:**

1. **Charas:** Separated resin in crude or purified form obtained from the cannabis plant and raisin called ***"Hashish oil".***
2. **Ganja:** The flowering or fruiting tops of the cannabis plants.
3. **Caca Derivative:** Includes crude cocaine which is a methyl ester of benzoyl-ecogonine and its salts.
4. **Opium:** Means the coagulated juice of the opium poppy and its mixture with or without neutral material.

# Narcotics Control Bureau (NCB)

- NCB was established on 17th march 1986 to enable the full implementation of the NDPs Act 1985.

**Headquarter: Delhi**

- NCPs are the chief law enforcement and Intelligence agency of India.

# Authorities and Officers:

I. Central government to take measures for preventing and combating abuse of Narcotic drugs and illicit traffic therein.

II. Officers Of Central Government

- They appoint Narcotic commissioner and other officers. The functions are:
    1. The supervision of cultivation of opium poppy
    2. Production of Opium.

III. NDPS Consultative committee.
The committee shall advice the central government on the matters relating to the administration of the Act.

# Prohibition, Control and Regulation:

No person with the permission of the central government shall-

a) Cultivate coca plant or gather any portion of it.
b) Cultivate opium poppy or cannabis.
c) Produce, manufacture, sell, purchase, transport, warehouse, use, import, and export and NDPs except for medicinal and scientific purpose with government Approval.

### Psychotropic substances:

Any natural or synthetic drug that affects emotional state includes:

a) Antidepressants
b) Sedatives
c) Stimulants
d) Tranquillizers

# Offences:

- Contravention of provisions in respect of poppy plant opium and coco plant prepared opium, manufactured drugs and narcotics.
- Illegal import or export or external dealings in NDPs.
- Allowing use of premises and vehicles for commission of an offence under the Act.
- Embezzelment of opium by licensed cultivators.
- Contravention in respect of cannabis plant other than GANJA.

# Penalties:

- Rigorous imprisonment for 10-20 years also a Fine between ₹ 1 to 2 lakhs or more.
- Rigorous imprisonment up to 5 years and fine up to 5 years and fine up to ₹ 50000.

# Chapter - 6

# Drugs and Magic remedies (Objectionable Advertisements) Act 1954.

**Introduction:** It is seen in India that some person are selling magic remedies such as Kavach as mantras, talisman etc and claiming them as unive of treatment for any disease etc. Likewise advertisement in magjine new paper and premises of same doctors, Hakim or vaidhs or also found claiming to cure disease not cured by any other drugs or treatment.

The drugs and Magic remedies act 1954 is passed for regulating the advertisement of same drugs and the advertisement of remedies having qualities of magic.

## Definition:

The definition and important terms of the Drug And Magic Remedies Act 1954 are as follows.

1. Advertisements
2. Drugs
3. Magic Remedies

**1. Advertisements:** These are all notice, circular, label, wrapper or other documents and all announcement made orally or by means of producing or transmitting light sounds or smoke.

**2. Drugs :** drugs are substance use for the diagnosis, cure, mitigation, prevention or treatment of disease in human beings or animals for the alternation of any function of the body of human beings.

**3. Magic Remedies:** These are talismans, mantras, kavachas and other similar substance processing miraculous power and prevent or cure disease of the human being or animals.

## Prohibited of certain advertisements:

Following are the classes of advertisement prohibited under this act –

1. Advertisement of drugs:

- Miscarriage or for preventing conceptions in women.
- Removing manstrual disorder in women.
- Diagnosis, preventing or curing Appendicitis, arteriosclerosis, blindness, uterus disorders, Nervous system disorders and epilepsy, dropsy, female disorder etc.

## Offences and Penalties:

- If a person break the provision Act and rules by involving in the advertisement of prohibited drugs he will be punished with in prisonment for 6 month or fine or both.
- First conviction and imprisonment for one year or fine.
- If a company break the provision of the act every single person who was incharge of the company when the offence was committed or held responsible.

# Chapter-7

## Prevention of cruelty to Animals Act-1960:

**Objectives, Definitions, CPCSEA - brief overview, Institutional Animal Ethics Committee, Breeding and Stocking of Animals, Performance of Experiments, Transfer and Acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties.**

### Introduction:

The prevention of cruelty to animal Act 1960 which repeats the Act of 1890 has been eracted to prevent the infliction of unnecessary pain or suffering on animals As recognition of the general awareness about animal welfare the breeding of and experiment on animals (Control and Supervision) rules 1998 have been recently incorporated.

### In this Act, unless the context otherwise requires,--

- "Animal" means any living creature other than a human being;
- 
- "Board" means the board established under section 4, and as reconstituted from time to time under section 5a
- "captive animal" means any animal (not being a domestic animal) which is in captivity or confinement, whether permanent or temporary, or which is subjected to any appliance or contrivance for the purpose of hindering or preventing its escape from captivity or confinement or which is pinioned or which is or appears to be maimed;
- 
- "Domestic animal" means any animal which is tamed or which has been or is being sufficiently tamed to serve some purpose for the use of man or which, although it neither has been nor is being nor is intended to be so tamed, is or has become in fact wholly or partly tamed;
- "Local authority" means a municipal committee, district board or other authority for the time being invested by law with the control and administration of any matters within a specified local area;
- "Owner", used with reference to an animal, includes not only the owner but also any other person for the time being in possession or custody of the animal, whether with or without the consent of the owner;

## Objectives:

- To promote animal welfare generally
- To prevent the infliction of unnecessary pain or suffering on animals as well to prevent cruelty to animals.
- To provide guideline for housing, care breeding and maintenance source of experimental animals and acceptable experimental procedures for anaesthesia and euthanasia.
- The goal of these guidelines is to promate the human care of animals use in biomedical and behavioral research and testing.

## Definitions:

**Experiment:**

- Experiment means any project involving use of an animals for the acquisition of knowledge of a biological, psychological, ethalogical, physical or chemical nature and includes the uses of animal in the production of reagents and products such as antigens and antibodies, routine diagnostics, testing activity and establishment of transgenic stocks, for the purpose of saving or prolonging life or all eviating suffering or for campating any disease whether on human beings or animals.

## Institutional Animals Ethics Committee:

- Institutional Animals ethics committee means a body comprising of a group of person recognized and registered by the committee for the purpose of control and supervision on animals performed in an establishment which is constituted and operated in accordance with procedures specified for the purpose by the committee.

## Institutional Animals Ethics (IAE) committee

**Objective:**

- To Contribute to effective functioning of institutional Animal Ethics Committee (IAEC)
- Experiment should performed with due care and humanity.
- Experiment shall be performed in every case by or under the supervision of a person duly qualified.
- Committee was prescribed by the CPCSEA under PCA Act 1960 and Breeding and Experimentation rules 1998.

**Every institutional Animals ethics Committee shall include**

- A biological scientist
- Two scientist from different biological disciplines

- A veterinarian invited in the case of Animals
- The Scientist in charge of animals facility of the establishment concerned.
- A scientist from outside the institution.
- A non-scientific socially aware member
- A representative or nominee of the committee.
- A specialist may be co-opted while reviewing special progect using hazardous agents such as radioactive substances and deadly micro-organisms.

## Breeding and Stocking of Animals:

- Animal breeding is a branch of animal science that addresses the evaluation of the genetic value of livestock.
- Selecting for breeding animals with superior EBV in growth rate, egg, meat, milk or wool production, or with other desirable traits has revolutionized livestock production throughout the entire world.
- The scientific theory of animals breeding incorporates population genetics, quantitative genetics, statistics and recently molecular genetics, Animal breeding.
- Is the process of selective mating of animals with desirable genetic traits to maintain or enhance these traits in future generation.
- Only registered establishment carry on the business of breeding of animals or trade of animals for the purpose of experiment, every breeder establishment carrying on the business of breeding animals or trade of animals for the purpose of experiments shall apply for registrations with in experiments shall apply for registration within sixty days from the date of commencement of the breeding of and experiment on animals.

## Performance of experiments:

- Performing experiments on animals for the purpose of advancement by new discovery of knowledge which will be useful for saving any disease in human beings, animals or plants is lawful.
- The experiment shall neither be performed for the purpose of attaining or retaining manual skill except in schools, colleges and recognized training institutions, nor by way of or illustration or as a public demonstration.

## Transfer and acquisition of Animals for Experiment:

- Transfer of any animals by way of sale or otherwise by a breeder to any animals by way of sale or otherwise by a breeder to on unregistered establishment is not sale or otherwise except form a register breeder.
- Potential venders should be evaluated for the quality of animals to be supplied by them. A registered veterinarian should properly evaluate animals to be used in research.

- All animals must be acquired lawfully and the receiving institution should make reasonable attempts to ensure the all transactions involving animals procurement are conducted in a lawful manner.
- Animals not bred in a research facility are to be acquired lawfully as per the prevailing laws a health certificate should be obtained from a registered veterinarian.
- Researchers should make every effort to ensure that those responsible for transporting the animals to the facility provide adequate food, water, ventilation, space and impasse no unnecessary stress on the animals.

## Records:

- Every establishment institutional animals ethics committee shall maintain a record of the animals under its control and custody and furnish such information as the committee may from time to time required in the specific format all laboratories shall inform the exact number/species of animals regard by the committee as per the specific format.

## Power to suspend or revoke registration:

- If the committee is satisfied that the rules made by it are not being followed by any establishment breeder/ Institutional animals ethics committee, the committee may after giving reasonable opportunity of being heard in the matter, revoke the same either for a specified period or indefinitely or may allow the institutional animals ethics committee to carry on subject to such special condition as the committee may impose.

## Offences:

a) Not being registered under this Chapter, exhibits or trains any performing animal; or
b) Being registered under this Act, exhibits or trains any performing animal with respect to which, or in a manner with respect to which, he is not registered; or
c) Exhibits or trains as a performing animal, any animal which is not to be used for the purpose by reason of a notification issued under clause (ii) of section 22; or
d) Obstructs or wilfully delays any person or police officer referred to in section 25 in the exercise of powers under this Act as to entry and inspection; or
e) Conceals any animal with a view to avoiding such inspection; or
f) Being a person registered under this Act, on being duly required in pursuance of this Act to produce his certificate under this Act, fails without reasonable excuse so to do; or
g) Applies to be registered under this Act when not entitled to be so registered; he shall be punishable on conviction with fine which may extend to five hundred rupees, or with imprisonment which may extend to three months, or with both.

## Penalties:

Contravention of any order made by or committing of any condition imposed by the committee is punishable with fine extending to 200rs when the contravention or breach of condition takes place in any institution the person in charge of the institution shall be quality of offence and shall be punishable accordingly.

# Chapter-8
# The Poisons Act-1919

**Poisons Act-1919: Introduction, objective, definition, possession, possession for sales and sale of any poison, import of poisons**

## Introduction of Poisons Act-1919:

The Poison Act was first passed in 1904. But, the rules under it were not sufficient to control the trafficking of Poisons.

- The United Provinces (now Uttar Pradesh) government in 1910 as well as 1914 proposed some radical amendments to make it more effective.
- This view was supported by many local governments.
- Thus, Poisons Act of 1904 was replaced by Poisons Act, 1919.
- It is implemented in whole of India except Jammu & Kashmir.
- The act required that certain poisons be labeled and sold only by licensed dealers, and established penalties for the illegal sale or possession of poisons.
- The Poisons Act, 1919 was passed with a view to control the Import, Possession & Sale of poisons.

According to this act, Central govt is authorized to regulate import of poisons and State govt. is authorized to regulate, possession, possession for sale and sale of poisons within their respective areas.

The act is administered by the Central Drugs Standard Control Organization (CDSCO) under the Ministry of Health and Family Welfare, Government of India. The act is enforced by the State Drugs Control Departments.

## Objective of Poisons Act-1919:

The Poisons Act 1919 in India had the following objectives:

- To regulate the sale and possession of poisons in the country and to prevent the illegal use of these substances.
- To ensure that certain poisons are labeled and sold only by licensed dealers, in order to protect the public from the dangerous effects of toxic substances.
- To establish penalties for the illegal sale or possession of poisons, as a deterrent against such activities.
- To require that a register be kept of all poisons sold, including the name and address of the purchaser, in order to track the sale and use of these substances.
- To protect the public from the dangerous effects of toxic substances and to prevent the misuse of poisons.
- To provide for the regulation of the manufacture, stock, sale, and use of certain drugs and cosmetics.

- To provide penalties for contraventions of its provisions and to ensure compliance with the act.
- To ensure that the act is enforced by the State Drugs Control Departments and is administered by the Central Drugs Standard Control Organization (CDSCO) under the Ministry of Health and Family Welfare, Government of India.

## Definition of Poisons Act-1919:

- Poison" - The act defined a poison as any substance which, if used or applied in a certain way, would be likely to cause death, injury or damage to health.
- The act refers to the Pharmacy and Poisons Act 1933, and the Poisons List. Non-medical poisons are divided into two separate lists. List one substances may only be sold by a registered Pharmacist, and list two substances may be sold by a registered pharmacist or a licensed retailer.

## Possession for sale:

- Possession refers to the act of having control over or owning something. In legal terms, possession can refer to physical possession of an object, such as a piece of property or a weapon, or to constructive possession, which means that an individual has control or authority over something, even if they do not physically have it in their possession.
- In the context of the Poisons Act 1919 in India, possession would refer to an individual or organization having physical or constructive control over a poison, regardless of whether they own it or not.

**Power of the State Government to regulate possession for sale and sale of any poison**

- The State Government may by rule regulate within the whole or any part of the territories under its administration the possession for sale and the sale, whether wholesale or retail, of any specified poison.

a) The grant of licences to possess any specified poison for sale, wholesale or retail, and fixing of the fee (if any) to be charged for such licences
b) The classes of persons to whom alone such licences may be granted
c) The classes of persons to whom alone any such poison may be sold
d) The maximum quantity of any such poison which may be sold to any one person
e) The maintenance by vendors of any such poison of registers of sales, the particulars to be entered in such registers, and the inspection of the same
f) The safe custody of such poisons and the labelling of the vessels, packages or coverings in which any such poison is sold or possessed for sale
g) The inspection and examination of any such poison when possessed for sale by any such vendor.

## Possession of any poison:

- The State Govt. has the power to make rules regarding the possession of any specified poison in the local area where such poison can be used for murders or for Poisoning cattle and in the local area where such occurrences are very frequent.
- Any break of this is punishable with imprisonment up to 1 yr, or with a fine up to Rs. 1000/- or with both, together with confiscation of the poison in respect of which the breach has been committed.

## Import of Poisons

- Import of specified poison is allowed only under and in accordance with the conditions of a license, the central government may regulate the grant of such licenses.

## Offences & Penalties in the Poison Act 1919

- Unlawful possession for sale and sale of poison.
- Importation without a license of any poison the importation of which is for the time being restricted by central govt.
- Breach of any condition of a license for the importation of any poison granted to him are punishable.
- With the imprisonment up to 3 months or with a fine up to Rs. 500/- or with both, on a first conviction, and
- With imprisonment up to 6 months or with a fine up to Rs. 1000/- or with both, on a second or subsequent conviction.

# Chapter-9 | FSSAI | Pharmacy Law & Ethics

**FSSAI (Food Safety and Standards Authority of India) Act and Rules: brief overview and aspects related to manufacture, storage, sale and labelling of Food Supplements**

## FSSAI (Food Safety and Standards Authority of India) Act and Rules:

- The Food Safety and Standards Authority of India (FSSAI) Act, 2006 and its rules and regulations are the legal framework for food safety and standards in India.
- The Act establishes the FSSAI as the central regulatory authority responsible for laying down science-based standards for articles of food and regulating their manufacture, storage, distribution, sale, and import to ensure that they are safe and fit for human consumption.
- Under the FSSAI Act, all food business operators (FBOs) must be registered or licensed with the FSSAI and comply with the food safety and standards lay down by the Authority.
- The Act also provides for the appointment of food safety officers and enforcement of penalties for non-compliance.
- The FSSAI has framed regulations on various aspects of food safety and standards, including standards for food products, labeling and packaging requirements, hygiene and sanitation requirements for food businesses, and rules for food imports and exports.
- Some of the major regulations framed by the FSSAI include the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011, the Food Safety and Standards (Packaging and Labeling) Regulations, 2011, and the Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011.
- The FSSAI Act and its rules and regulations provide a comprehensive legal framework for food safety and standards in India and are aimed at protecting the health and well-being of the country's citizens.

## Food supplements:

- Food supplements are defined as concentrated sources of nutrients or other substances with a nutritional or physiological effect, intended to supplement the normal diet.
- They are typically marketed in the form of capsules, tablets, powders, soft gels, gels, drops, liquids, or bars and are taken by mouth as a supplement to the normal diet.
- Food supplements are commonly used to address deficiencies in the diet, improve overall health and well-being, or meet specific health needs such as for weight management, sports nutrition, or heart health. Some examples of common food supplements include vitamins, minerals, amino acids, herbal products, and probiotics.

## Manufacture of Food Supplements:

The manufacture of food supplements is a regulated industry, with strict standards in place to ensure the safety and quality of these products for human consumption. The regulations vary from country to country, but in general, the following are some of the key aspects of food supplement manufacturing:

1. Good Manufacturing Practices (GMP): Food supplement manufacturers must comply with Good Manufacturing Practices (GMP) standards, which lay down guidelines for the production, control, and storage of food supplements to ensure their safety and quality.

2. Raw Material Sourcing: Food supplement manufacturers must source high-quality raw materials from reputable suppliers and ensure that the materials meet the required standards for purity, potency, and quality.

3. Production Processes: Food supplement manufacturers must follow strict production processes to ensure that the supplements are made in a clean and hygienic environment and are free from contamination and deterioration.

4. Testing and Quality Control: The manufacture of food supplements must be accompanied by regular testing and quality control measures to ensure that the finished product meets the required standards for safety and quality.

5. Packaging and Labeling: The packaging and labeling of food supplements must comply with the regulations set by the relevant authorities, including the use of appropriate warning and caution statements, if necessary.

The manufacture of food supplements is a highly regulated industry, with strict standards in place to ensure their safety and quality for human consumption. Food supplement manufacturers must comply with these standards to protect the health and well-being of consumers.

## Storage, Sale and Labelling Of Food Supplements:

In India, the storage, sale, and labeling of food supplements are regulated by the Food Safety and Standards Authority of India (FSSAI) under the Food Safety and Standards Act, 2006 and its associated regulations. The following are some of the key aspects of the regulation of food supplements in India:

1. Storage: Food supplements must be stored in a clean and hygienic environment and must be protected from contamination and deterioration. Proper storage conditions, such as temperature and humidity controls, must be maintained to ensure the safety and quality of the food supplements.

2. Sale: Food supplements must be sold only by registered food business operators (FBOs) and must comply with the labeling and packaging requirements laid down by FSSAI.

3. Labeling: Food supplements must be labeled with all relevant information, including the name and address of the manufacturer, the name of the food supplement, the list of ingredients, and the recommended daily dose. The label must also carry appropriate warning and caution statements, if necessary, and must comply with the Food Safety and Standards (Labelling and Display) Regulations, 2011.

# Chapter-10

# National Pharmaceutical Pricing Authority:

**Drugs Price Control Order (DPCO) - 2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, pharmaceutical policy 2002, National List of Essential Medicines (NLEM)**

## National Pharmaceutical Pricing Authority:

The National Pharmaceutical Pricing Authority (NPPA) is an autonomous organization under the Ministry of Chemicals and Fertilizers in India. It was established in 1997 with the aim of fixing and revising the prices of controlled bulk drugs and formulations, and ensuring the availability and accessibility of medicines to the general public at affordable prices.

**The NPPA performs several functions, including:**

1. Fixing the prices of essential and life-saving drugs.
2. Monitoring the prices of decontrolled drugs to ensure that they do not exceed the ceiling price fixed by the government.
3. Imposing penalties and fines on companies found guilty of overcharging customers.
4. Monitoring the availability of essential drugs.
5. Ensuring the transparency of the pharmaceutical pricing mechanism in the country.

The NPPA plays a crucial role in ensuring the affordability and accessibility of medicines to all citizens in India, and helps in reducing the burden of out-of-pocket expenditure on healthcare for the general public.

## Drugs Price Control Order (DPCO) - 2013.

- The Drugs Price Control Order (DPCO) 2013 is an order issued by the Government of India under the Essential Commodities Act, 1955, which regulates the prices of essential and life-saving drugs in the country.
- Under the DPCO 2013, the National Pharmaceutical Pricing Authority (NPPA) is responsible for fixing and revising the prices of drugs under price control and monitoring the prices of decontrolled drugs.

- The order covers all formulations that are specified in the National List of Essential Medicines (NLEM), and the prices are revised periodically based on changes in the wholesale price index.
- The DPCO 2013 has helped in ensuring the availability and accessibility of essential medicines at affordable prices for the general public and reducing the burden of out-of-pocket expenditure on healthcare.
- It also promotes the growth of the domestic pharmaceutical industry by creating a fair and competitive market for bulk drugs and formulations.

## Objective:

The main objective of the Drugs Price Control Order (DPCO) 2013 is to regulate the prices of essential and life-saving medicines in India, with the aim of making them more affordable and accessible to the general public. The DPCO 2013 was implemented to control the rapidly rising cost of healthcare, which was putting a significant burden on the pockets of citizens.

The key objectives of the DPCO 2013 include:

1. Fixing the maximum prices of essential and life-saving drugs and formulations to ensure affordability for the general public.
2. Regulating the prices of bulk drugs and formulations that are specified in the National List of Essential Medicines (NLEM).
3. Monitoring the prices of decontrolled drugs to prevent them from becoming too expensive.
4. Encouraging the domestic pharmaceutical industry to promote growth and innovation while ensuring a fair and competitive market.
5. Reducing the burden of out-of-pocket expenditure on healthcare for the general public.

## Sale prices of bulk drugs:

- The sale price of bulk drugs is an important aspect of the pharmaceutical industry, as it determines the cost of raw materials used in the manufacture of formulations. The sale price of bulk drugs can be influenced by several factors, including supply and demand, production costs, government regulations, and market competition.
- In India, the sale price of bulk drugs is regulated by the Drugs Price Control Order (DPCO) 2013, which is an order issued by the Government of India under the Essential Commodities Act, 1955. Under the DPCO 2013, the National Pharmaceutical Pricing Authority (NPPA) is responsible for fixing and revising the prices of essential and life-saving drugs in the country.
- The sale price of bulk drugs under price control is determined by the NPPA based on various factors, including the manufacturing cost, market price trends, and wholesale price index. The NPPA takes into account the cost of raw materials, labor, and other production costs, as well as the prevailing market conditions, to determine the maximum sale price of

a bulk drug.

- In addition to price control, the NPPA also monitors the prices of decontrolled drugs to ensure that they do not exceed the ceiling price fixed by the government. If a company is found guilty of overcharging customers for decontrolled drugs, it may face penalties and fines imposed by the NPPA.
- The regulation of the sale price of bulk drugs helps in ensuring the affordability and accessibility of essential medicines, and reducing the burden of out-of-pocket expenditure on healthcare for the general public. It also promotes the growth of the domestic pharmaceutical industry by creating a fair and competitive market for bulk drugs and formulations.

## Retail price of formulations:

- The retail price of formulations is the price that a consumer pays for a finished dosage form of a drug, such as a tablet, capsule, syrup, etc.
- The retail price of formulations is influenced by various factors, including the cost of raw materials, production costs, marketing and distribution expenses, and government regulations.
- In India, the retail price of formulations is regulated by the Drugs Price Control Order (DPCO) 2013, which is an order issued by the Government of India under the Essential Commodities Act, 1955. Under the DPCO 2013, the National Pharmaceutical Pricing Authority (NPPA) is responsible for fixing and revising the maximum prices of essential and life-saving drugs in the country.
- The NPPA determines the ceiling price for essential and life-saving formulations based on the manufacturing cost, market price trends, and wholesale price index. The ceiling price is the maximum price that can be charged by manufacturers and suppliers for a particular formulation.
- In addition to price control, the NPPA also monitors the prices of decontrolled drugs to ensure that they do not become too expensive.
- The regulation of retail prices of formulations helps in ensuring the affordability and accessibility of essential medicines, and reduces the financial burden on patients and their families.

## Retail price and ceiling price of scheduled formulations:

- The retail price and ceiling price of scheduled formulations are related concepts in the regulation of drug prices in India. Scheduled formulations are those that are included in the National List of Essential Medicines (NLEM) and are considered essential for meeting the health needs of the population.
- The ceiling price of scheduled formulations is the maximum price that can be charged by

manufacturers and suppliers for a particular drug. The National Pharmaceutical Pricing Authority (NPPA) is responsible for fixing and revising the ceiling prices of scheduled formulations in India, based on various factors, such as the manufacturing cost, market price trends, and wholesale price index.

- The retail price of scheduled formulations is the price that a consumer pays for a finished dosage form of a drug. The retail price is determined by various factors, such as production costs, marketing and distribution expenses, and the bargaining power of the consumer. The NPPA regulates the retail price of scheduled formulations by setting a ceiling price, which is the maximum price that can be charged.

- It is important to note that while the NPPA regulates the retail price of scheduled formulations, the actual price paid by consumers may be lower or higher than the ceiling price, depending on various factors, such as discounts, offers, and the bargaining power of the consumer. The regulation of retail prices helps in promoting transparency in the pharmaceutical industry and creating a fair and competitive market for essential medicines.

## Pharmaceutical policy 2002:

The Pharmaceutical Policy 2002 is a policy document issued by the Government of India, which outlines the government's approach towards the pharmaceutical sector in India. The policy was released in 2002 and provides guidelines for the development and regulation of the pharmaceutical sector in India.

The main objectives of the Pharmaceutical Policy 2002 are to:

1. Promote the growth and development of the pharmaceutical industry in India and make it globally competitive.
2. Ensure the availability of quality, affordable and essential drugs to the public.
3. Encourage the production of bulk drugs and formulations within the country to reduce dependence on imports.
4. Promote exports of pharmaceutical products and increase the share of India's pharmaceutical exports in the world market.
5. Promote and encourage the use of generic drugs and make them more accessible to the public.
6. Foster innovation and research in the pharmaceutical sector and encourage the development of new drugs and technologies.
7. Encourage the use of modern technologies and methods for drug manufacturing and ensure compliance with international quality standards.
8. Regulate the pricing of drugs and ensure that they are affordable to the public.

The Pharmaceutical Policy 2002 has been instrumental in shaping the pharmaceutical sector in India and has helped in the growth and development of the domestic pharmaceutical industry. It has

also helped in promoting access to essential medicines and reducing the financial burden on patients and their families. The policy has been revised and updated over the years to keep pace with the changing needs of the pharmaceutical sector and the changing healthcare landscape in India.

## National List of Essential Medicines (NLEM):

- The National List of Essential Medicines (NLEM) is a list of essential medicines that are considered necessary for meeting the basic health needs of the population. It is a comprehensive list of drugs and medicines that are considered essential for public health, and is updated periodically to reflect the changing needs of the population.
- The NLEM is prepared and maintained by the Ministry of Health and Family Welfare, Government of India, and is based on the World Health Organization's (WHO) Model List of Essential Medicines. The list is reviewed and updated every two years to keep pace with the changing needs of the population and the advances in medical science.
- The NLEM includes a wide range of essential medicines, including those used for the treatment of common illnesses, life-threatening conditions, and chronic diseases. The list includes both generic and branded drugs and covers a wide range of therapeutic categories, such as anti-infective agents, cardiovascular drugs, and anti-cancer drugs, among others.
- The NLEM plays an important role in the regulation of drug prices in India and is used as a reference for fixing the maximum retail price of essential and life-saving medicines. The National Pharmaceutical Pricing Authority (NPPA) is responsible for fixing and revising the maximum prices of drugs included in the NLEM, based on the manufacturing cost, market price trends, and wholesale price index.
- The NLEM is an important tool for ensuring the availability of essential medicines to the public, and helps in promoting access to quality healthcare and reducing the financial burden on patients and their families. The list helps in promoting rational use of medicines and ensures that the most essential and life-saving drugs are available and accessible to the public.

# National List of Essential Medicines 2022

# Table of Contents

## Sections of Drug Classes

## Section 1
## Medicines used in Anaesthesia

### 1.1- General Anaesthetics and Oxygen

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 1.1.1 | Halothane | S,T | Liquid for inhalation |
| 1.1.2 | Isoflurane | S,T | Liquid for inhalation |
| 1.1.3 | Ketamine | P,S,T | Injection 10 mg/mL<br>Injection 50 mg/mL |
| 1.1.4 | Nitrous oxide | P,S,T | As licensed for medical purpose |
| 1.1.5 | Oxygen* | P,S,T | As licensed for medical purpose |
| 1.1.6 | Propofol | P,S,T | Injection 10 mg/mL |
| 1.1.7 | Sevoflurane | S,T | Liquid for inhalation |
| 1.1.8 | Thiopentone | P,S,T | Powder for injection 0.5 g<br>Powder for injection 1 g |

**Oxygen is also listed in **Section 27.5** - Medicines for COVID 19 management*

| **1.2-Local Anaesthetics** | | | |
|---|---|---|---|
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 1.2.1 | Bupivacaine | S,T | Injection 0.25 %<br>Injection 0.5 %<br>Injection 0.5 % with 7.5 % glucose |
| 1.2.2 | Lignocaine* | P,S,T | Topical forms 2-5 %<br>Injection 1 %<br>Injection 2 %<br>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)<br>Injection 2% (A) + 1:200000 (5 mcg/mL) (B) |
| **1.3- Preoperative Medication and Sedation for Short Term Procedures** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 1.3.1 | Atropine** | P,S,T | Injection 0.6 mg/mL |

**Lignocaine formulations are also listed in **Section 10.2.5** cardiovascular medicines- Antiarrhythmic medicines*

***Atropine formulations are also listed in -*

***A. Section 4.2.1** - Antidotes and Other Substances used in Management of Poisonings/Envenomation - Specific*
***B. Section 21.5.1** - Ophthalmological Medicines- Mydriatics*

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 1.3.2 | Glycopyrrolate | S,T | Injection 0.2 mg/mL |
| 1.3.3 | Midazolam* | P,S,T | Tablet 7.5 mg<br>Nasal Spray 0.5mg<br>Nasal Spray 1.25 mg<br>Injection 1 mg/mL<br>Injection 5 mg/mL |
| 1.3.4 | Morphine** | P,S,T | Injection 10 mg/mL<br>Injection 15 mg/mL |
| **Section 1.4 -Muscle Relaxants and Cholinesterase Inhibitors** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 1.4.1 | Atracurium | S,T | Injection 10 mg/mL |
| 1.4.2 | Baclofen | S,T | Tablet 5 mg<br>Tablet 10 mg<br>Tablet 20 mg |

**Midazolam formulations are also listed in -*

***A. Section 5.1.7-*** *Medicines used in Neurological Disorders Anticonvulsants/ Antiepileptics*
***B. Section 7.4.12-*** *Anti-cancer agents including Immunosuppressives, and Medicines used in Palliative Care*

***Morphine formulations are also listed in -*

***A. Section 2.2.2-*** *Analgesics, Antipyretics, Non-steroidal Anti-inflammatory Drugs (NSAIDs), Medicines used to treat Gout and Disease Modifying Agents used in Rheumatoid Disorders - Opioid Analgesics*
***B. Section 7.4.13 -*** *Anti-cancer agents including immunosuppressives, and medicines used in Palliative Care*

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 1.4.3 | Neostigmine* | S,T | Tablet 15 mg<br>Injection 0.5 mg/mL |
| 1.4.4 | Succinylcholine | S,T | Injection 50 mg/mL |
| 1.4.5 | Vecuronium | S,T | Powder for injection 4 mg<br>Powder for injection 10 mg |

## Section 2
## Analgesics, Antipyretics, Non-steroidal Anti-inflammatory Drugs (NSAIDs), Medicines used to treat Gout and Disease Modifying Agents used in Rheumatoid Disorders

### 2.1 - Non-opioid Analgesics, Antipyretics and Non-steroidal Anti-inflammatory Drugs

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 2.1.1 | Acetylsalicylic acid** | P,S,T | Tablet 300 mg to 500 mg<br>Effervescent/ Dispersible/ Enteric coated Tablet 300 mg to 500 mg |

**Neostigmine formulations are also listed in **Section 4.2.8** - Antidotes and Other substances used in Management of poisoning/Envenomation - Specific*

***Acetylsalicylic acid formulations are also listed in -*
***A. Section 5.2.1** - Medicines used in Neurological Disorders Antimigraine medicines*
***B. Section 10.5.1** - Cardiovascular medicines -Antithrombotic Medicines (Cardiovascular/ Cerebrovascular) - Antiplatelet and Antithrombotic Medicines*

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 2.1.2 | Diclofenac | P,S,T | Tablet 50 mg<br>Injection 25 mg/mL |
| 2.1.3 | Ibuprofen* | P,S,T | Tablet 200 mg<br>Tablet 400 mg<br>Oral liquid 100 mg/5 mL (p) |
| 2.1.4 | Mefenamic acid | P,S,T | Tablet 250 mg<br>Oral liquid 100 mg/5 mL (p) |
| 2.1.5 | Paracetamol** | P,S,T | Tablet 500 mg<br>Tablet 650 mg<br>Oral liquid 120 mg/5 mL (p)<br>Oral Liquid 125 mg/5 mL (p)<br>Oral Liquid 250 mg/5 mL (p)<br>Injection 150 mg/ mL<br>Suppository 80 mg<br>Suppository 170 mg |
| **2.2-Opioid Analgesics** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 2.2.1 | Fentanyl | S,T | Injection 50 mcg/mL |

**Ibuprofen formulations are also listed in **Section 5.2.2** - Medicines used in Neurological Disorders-Antimigraine Medicines*

*** Paracetamol formulations are also listed in -_*
***A. Section 5.2.3** - Medicines used in Neurological Disorders-Antimigraine Medicines*
***B. Section 27.4** - Medicines for COVID 19 Management*

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 2.2.2 | Morphine* | P,S,T | Tablet 10 mg<br>Injection 10 mg/mL<br>Injection 15 mg/mL |
| 2.2.3 | Tramadol** | S,T | Capsule 50 mg<br>Capsule 100 mg<br>Injection 50 mg/mL |
| **2.3-Medicines used to treat Gout** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 2.3.1 | Allopurinol*** | P,S,T | Tablet 100 mg<br>Tablet 300 mg |
| 2.3.2 | Colchicine | P,S,T | Tablet 0.5 mg |

**Morphine formulations are also listed in -*
***A. Section 1.3.4 -*** *Medicines used in Anaesthesia - Preoperative medication and sedation for short term procedures*
***B. Section 7.4.13 -*** *Anti-cancer agents including Immunosuppressives, and Medicines used in Palliative Care*

*** Tramadol formulations are also listed in*
***Section 7.4.15 -*** *Tramadol formulations are also listed in Anti-cancer agents including Immunosuppressives, and Medicines used in Palliative Care*

**** Allopurinol formulations are also listed in*
***Section 7.4.1 -*** *Allopurinol formulations are also listed in Anti-cancer agents including Immunosuppressives, and Medicines used in Palliative Care*

| 2.4-Disease Modifying Agents used in Rheumatoid Disorders | | | |
|---|---|---|---|
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 2.4.1 | Azathioprine* | S,T | Tablet 25 mg (p)<br>Tablet 50 mg |
| 2.4.2 | Hydroxychloroquine | P,S,T | Tablet 200 mg<br>Tablet 400 mg |
| 2.4.3 | Methotrexate** | P,S,T | Tablet 2.5 mg<br>Tablet 5 mg<br>Tablet 10 mg |
| 2.4.4 | Sulfasalazine | S,T | Tablet 500 mg |
| **Section 3<br>Antiallergics and Medicines used in Anaphylaxis** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 3.1 | Adrenaline | P,S,T | Injection 1 mg/mL |
| 3.2 | Cetirizine | P,S,T | Tablet 10 mg<br>Oral liquid 5 mg/5 mL (p) |

** Azathioprine formulations are also listed in **Section 7.3.1** - Anti-cancer agents including Immunosuppressives, and Medicines used in Palliative Care*

******* *Methotrexate formulations are also listed in **Section 7.1.30** - Anti-cancer agents including Immunosuppressives, and Medicines used in Palliative Care*

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 3.3 | Dexamethasone* | P,S,T | Tablet 0.5 mg<br>Tablet 2 mg<br>Tablet 4 mg<br>Oral liquid 0.5 mg/5 mL (p)<br>Injection 4 mg/mL |
| 3.4 | Hydrocortisone** | P,S,T | Tablet 5 mg<br>Tablet 10 mg<br>Powder for Injection 100 mg<br>Powder for Injection 200 mg |
| 3.5 | Pheniramine | P,S,T | Injection 22.75 mg/mL |
| 3.6 | Prednisolone*** | P,S,T | Tablet 5 mg<br>Tablet 10 mg<br>Tablet 20 mg<br>Oral liquid 5 mg/5 mL (p)<br>Oral liquid 15 mg/5 mL (p) |

***Dexamethasone formulations are also listed in -***
***A. Section 7.4.3 -*** *Anti-cancer agents including Immunosuppressives, and Medicines used in Palliative Care*

***B. Section 18.1.1 -*** *Hormones, other Endocrine Medicines and Contraceptives - Adrenal Hormones and Synthetic Substitutes*
***C. Section 27.1 -*** *Medicines for COVID 19 Management*

***** Hydrocortisone formulations are also listed in **Section 18.1.3 -** Hormones, other Endocrine Medicines and Contraceptives- Adrenal Hormones and Synthetic Substitutes*

****Prednisolone formulations are also listed in -***
***A. Section 7.2.4 -*** *Anti-cancer agents including Immunosuppressives, and Medicines used in Palliative Care - Hormones and Anti-Hormones used in cancer therapy*
***B. Section 18.1.5 -*** *Hormones, other Endocrine Medicines and Contraceptives -Adrenal Hormones and Synthetic Substitutes*
***C. Section 21.2.1 -*** *Ophthalmological Medicines- Anti-inflammatory Medicine*

| Section 4<br>Antidotes and Other Substances used in Management of Poisonings/Envenomation | | | |
|---|---|---|---|
| **4.1-Nonspecific** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 4.1.1 | Activated Charcoal | P,S,T | Powder (as licensed) |
| **4.2 Specific** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 4.2.1 | Atropine* | P,S,T | Injection 0.6 mg/mL |
| 4.2.2 | Calcium gluconate** | P,S,T | Injection 100 mg/mL |
| 4.2.3 | D- Penicillamine | P,S,T | Capsule 150 mg (p)<br>Capsule 250 mg |
| 4.2.4 | Desferrioxamine | S,T | Powder for injection 500 mg |
| 4.2.5 | Methylthioninium chloride (Methylene blue) | S,T | Injection 10 mg/mL |

***Atropine formulations are also listed in -*
***A. Section 1.3.1 -** Medicines used in Anaesthesia -Preoperative Medication and Sedation for short term procedures*
***B. Section 21.5.1 -** Ophthalmological Medicines- Mydriatics*

*** Calcium gluconate formulations are also listed in **Section 26.3 -** Vitamins and minerals*

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 4.2.6 | N-acetylcysteine | P,S,T | Sachet 200 mg<br>Injection 200 mg/mL |
| 4.2.7 | Naloxone | P,S,T | Injection 0.4 mg/mL |
| 4.2.8 | Neostigmine* | P,S,T | Injection 0.5 mg/mL |
| 4.2.9 | Pralidoxime chloride (2-PAM) | P,S,T | Injection 25 mg/mL |
| 4.2.10 | Snake venom antiserum** | P,S,T | Soluble/ liquid polyvalent - As licensed<br>Lyophilized polyvalent - As licensed |
| 4.2.11 | Sodium nitrite | S,T | Injection 30 mg/mL |
| 4.2.12 | Sodium thiosulphate | S,T | Injection 250 mg/mL |

***** *Neostigmine formulations are also listed in* ***Section 1.4.3*** *- Medicines used in Anaesthesia - Muscle relaxants and cholinesterase inhibitors*

****** *Snake Venom antiserum is also listed in* ***Section 19.2.7.*** *- Immunologicals - Sera and immunoglobulins (Liquid/ Lyophilized)*

| Section 5<br>Medicines used in Neurological Disorders | | | |
|---|---|---|---|
| **Section 5.1-Anticonvulsants/ Antiepileptics** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 5.1.1 | Carbamazepine* | P,S,T | Tablet 100 mg<br>Tablet 200 mg<br>Tablet 400 mg<br>Modified Release -<br>Tablet 200 mg<br>Tablet 400 mg<br>Oral liquid 100 mg/5 mL (p) |
| 5.1.2 | Clobazam | S,T | Tablet 5 mg<br>Tablet 10 mg |
| 5.1.3 | Diazepam** | P,S,T | Oral liquid 2 mg/5 mL (p)<br>Injection 5 mg/mL<br>Suppository 5 mg |
| 5.1.4 | Levetiracetam | S,T | Tablet 250 mg<br>Tablet 500 mg<br>Tablet 750 mg<br>Modified Release Tablet 750 mg<br>Oral liquid 100 mg/mL (p)<br>Injection 100 mg/mL |
| 5.1.5 | Lorazepam | P,S,T | Tablet 1 mg<br>Tablet 2 mg<br>Injection 2 mg/mL<br>Injection 4 mg/mL |

***Carbamazepine formulations are also listed in **Section 23.2.2.3** Medicines used in treatment of Psychiatric disorder - Medicines used in Bipolar disorders*
*** Diazepam formulations are also listed in **Section 7.4.4** - Anti-cancer agents including Immunosuppressives, and Medicines used in Palliative Care - Medicines used in Palliative Care*

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 5.1.6 | Magnesium sulphate | S,T | Injection 500 mg/mL |
| 5.1.7 | Midazolam* | P,S,T | Tablet 7.5 mg<br>Tablet 15 mg<br>Nasal Spray 0.5 mg/actuation<br>Nasal Spray 1.25 mg/actuation<br>Injection 1 mg/mL<br>Injection 5 mg/mL |
| 5.1.8 | Phenobarbitone | P,S,T | Tablet 30 mg<br>Tablet 60 mg<br>Oral liquid 20 mg/5 mL (p) |
| | | S,T | Injection 200 mg/mL |
| 5.1.9 | Phenytoin | P,S,T | Tablet 50 mg<br>Tablet 100 mg<br>Tablet 300 mg<br>Modified Release Tablet 300 mg<br>Oral liquid 30 mg/5 mL (p)<br>Oral liquid 125 mg/5 mL (p)<br>Injection 25 mg/mL<br>Injection 50 mg/mL |

***Midazolam formulations are also listed in -***
***A. Section 1.3.3 -*** *Medicines used in Anaesthesia - Preoperative Medication and Sedation for short term procedures*
***B. Section 7.4.12 -*** *Anti-cancer agents including Immunosuppressives, and Medicines used in Palliative Care - Medicines used in Palliative Care*

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 5.1.10 | Sodium Valproate* | P,S,T | Tablet 200 mg<br>Tablet 300 mg<br>Tablet 500 mg<br><br>Modified Release -<br>Tablet 300 mg<br>Tablet 500 mg<br><br>Oral liquid 200 mg/5 mL (p) |
| | | S,T | Injection 100 mg/mL |
| **Section 5.2- Antimigraine Medicines** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 5.2.1 | Acetylsalicylic acid** | P,S,T | Tablet 300 mg to 500 mg<br>Effervescent/ Dispersible/ Enteric coated Tablet 300 mg to 500 mg |

***Sodium Valproate formulations are also listed in-*
***Section 23.2.2.2** - Medicines used in treatment of Psychiatric Disorders -Medicines used in Bipolar disorders- Medicines used in mood disorders*

****Acetylsalicyclic acid formulations are also listed in -*
***A. Section 2.1.1** - Analgesics, Antipyretics, Non-steroidal Anti-inflammatory Drugs (NSAIDs), Medicines used to treat Gout and Disease Modifying Agents used in Rheumatoid Disorders - Non-opioid Analgesics, Antipyretics and Non-steroidal Anti-inflammatory Drugs*
***B. Section 10.5.1** - Cardiovascular medicines- Antiplatelet and Antithrombotic Medicines*

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 5.2.2 | Ibuprofen* | P,S,T | Tablet 200 mg<br>Tablet 400 mg<br>Oral liquid 100 mg/5 mL (p) |
| 5.2.3 | Paracetamol** | P,S,T | Tablet 500 mg<br>Tablet 650 mg<br>Oral liquid 120 mg/5mL (p)<br>Oral Liquid 125 mg/5mL (p)<br>Oral Liquid 250 mg/5mL (p) |
| 5.2.4 | Sumatriptan | P,S,T | Tablet 25 mg<br>Tablet 50 mg |
| **Section 5.2.1 - For Prophylaxis** | | | |
| 5.2.1.1 | Amitriptyline*** | P,S,T | Tablet 10 mg<br>Tablet 25 mg<br>Tablet 75 mg |

***Ibuprofen formulations are also listed in **Section 2.1.3** - Analgesics, Antipyretics, Non-steroidal Anti-inflammatory Drugs (NSAIDs), Medicines used to treat Gout and Disease Modifying Agents used in Rheumatoid Disorders Non-opioid Analgesics, Antipyretics and Non-steroidal Anti- inflammatory Drugs*

***Paracetamol formulations are also listed in -*
***A. Section 2.1.5** - Analgesics, Antipyretics, Non-steroidal Anti-inflammatory Drugs (NSAIDs), Medicines used to treat Gout and Disease Modifying Agents used in Rheumatoid Disorders - Non-opioid analgesics, antipyretics and nonsteroidal anti-inflammatory medicines*
***B. Section 27.4** - Medicines for COVID 19 management*

****** Amitriptyline formulations are also listed in -*
***A. Section 7.4.2** - Anti-cancer agents including Immunosuppressives, and Medicines used in Palliative Care - Medicines used in Palliative Care-*
***B. Section 23.2.1.1** - Medicines used in treatment of Psychiatric Disorders -Medicines used in mood disorders- Medicines used in depressive disorders*

| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
|---|---|---|---|
| 5.2.1.2 | Flunarizine | P,S,T | Tablet 5 mg<br>Tablet 10 mg |
| 5.2.1.3 | Propranolol | P,S,T | Tablet 10 mg<br>Tablet 20 mg<br>Tablet 40 mg |
| **Section 5.3- Antiparkinsonism Medicines** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 5.3.1 | Levodopa (A) + Carbidopa (B) | P,S,T | Tablet 100 mg (A) + 10 mg (B)<br>Tablet 100 mg (A) + 25 mg (B)<br>Tablet 250 mg (A) + 25 mg (B)<br><br>Modified Release -<br>Tablet 100 mg (A) + 25 mg (B)<br>Tablet 200 mg (A) + 50 mg (B) |
| 5.3.2 | Trihexyphenidyl | P,S,T | Tablet 2 mg |
| **Section 5.4-Medicines used in Dementia** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 5.4.1 | Donepezil | S,T | Tablet 5 mg<br>Tablet 10 mg |

## Section 6
## Anti-infective Medicines

### 6.1-Anthelminthics

### 6.1.1- Intestinal Anthelminthics

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 6.1.1.1 | Albendazole* | P,S,T | Tablet 400 mg<br>Chewable Tablet 400 mg<br>Oral liquid 200 mg/5 mL (p) |
| 6.1.1.2 | Mebendazole | P,S,T | Tablet 100 mg<br>Oral liquid 100 mg/5 mL (p) |

### 6.1.2 Antifilarial

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 6.1.2.1 | Albendazole* | P,S,T | Tablet 400 mg<br>Chewable Tablet 400 mg<br>Oral liquid 200 mg/5 mL (p) |
| 6.1.2.2 | Diethylcarbamazine (DEC) | P,S,T | Tablet 50 mg<br>Tablet 100 mg<br>Oral liquid 120 mg/5 mL (p) |

** Albendazole formulations are also listed **Section 6.1.1.1** - in Anti-infective Medicines-Antifilarial*

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 6.1.2.3 | Ivermectin | P,S,T | Tablet 6 mg<br>Tablet 12 mg |
| **6.1.3 - Anti-schistosomal and Anti-trematodal Medicine** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 6.1.3.1 | Praziquantel | S,T | Tablet 600 mg |
| **6.2-Antibacterials** | | | |
| **6.2.1 Beta-lactam Medicines** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 6.2.1.1 | Amoxicillin | P,S,T | Capsule 250 mg<br>Capsule 500 mg<br>Oral liquid 125 mg/5 mL (p)<br>Oral liquid 250 mg/5 mL (p)<br>Powder for Injection 250 mg<br>Powder for Injection 500 mg<br>Powder for injection 1000 mg |
| 6.2.1.2 | Amoxicillin (A) + Clavulanic acid (B) | P,S,T | Tablet 500 mg (A) + 125 mg (B)<br>Oral liquid 200 mg (A) + 28.5 mg (B)/5 mL (p)<br>Dry Syrup 125 mg (A) + 31.25 (B)/ 5 mL (p) |
| | | S,T | Powder for Injection 500 mg (A) + 100 mg (B)<br>Powder for Injection 1 g (A) + 200 mg (B) |

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 6.2.1.3 | Ampicillin | P,S,T | Powder for Injection 500 mg<br>Powder for Injection 1000 mg |
| 6.2.1.4 | Benzathine benzylpenicillin | P,S,T | Powder for Injection 6 lac units<br>Powder for Injection 12 lac units<br>Powder for injection 24 lac units |
| 6.2.1.5 | Benzylpenicillin | P,S,T | Powder for injection 5 lac units<br>Powder for injection 10 lac units |
| 6.2.1.6 | Cefadroxil | P,S,T | Tablet 500 mg<br>Tablet 100 mg<br>Oral liquid 125 mg/5 mL (p) |
| 6.2.1.7 | Cefazolin | P,S,T | Powder for Injection 500 mg<br>Powder for Injection 1000 mg |
| 6.2.1.8 | Cefixime | S,T | Tablet 200 mg<br>Tablet 400 mg<br>Oral liquid 50 mg/5 mL (p)<br>Oral liquid 100 mg/5 mL (p) |
| 6.2.1.9 | Cefotaxime* | S,T | Powder for Injection 250 mg<br>Powder for Injection 500 mg<br>Powder for Injection 1000 mg |
| **Cefotaxime formulations are also listed in **Section 6.7.5.2** - Anti-infective Medicines- Antiviral Medicines- Medicines for treating Opportunistic Infections in People living with HIV* | | | |

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 6.2.1.10 | Ceftazidime | S,T | Powder for Injection 250 mg<br>Powder for Injection 1000 mg |
| 6.2.1.11 | Ceftriaxone | S,T | Powder for Injection 250 mg<br>Powder for Injection 500 mg<br>Powder for Injection 1000 mg<br>Powder for Injection 2000 mg |
| 6.2.1.12 | Cloxacillin | P,S,T | Capsule 250 mg<br>Capsule 500 mg<br>Oral Liquid 125 mg/5 mL (p)<br>Powder for Injection 250 mg |
| 6.2.1.13 | Piperacillin (A) + Tazobactam (B) | T | Powder for Injection 1000 mg (A) + 125 mg (B)<br>Powder for Injection 2000 mg (A) + 250 mg (B)<br>Powder for Injection 4000 mg (A) + 500 mg (B) |
| 6.2.1.14 | Meropenem | T | Powder for Injection 500 mg (as trihydrate)<br>Powder for Injection 1000 mg (as trihydrate) |
| **6.2.2 - Other Antibacterials** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 6.2.2.1 | Azithromycin* | P,S,T | Tablet 250 mg<br>Tablet 500 mg<br>Oral liquid 200 mg/5 mL (p)<br>Powder for Injection 500 mg |
| 6.2.2.2 | Cefuroxime | P,S,T | Tablet 500 mg<br>Oral liquid 125 mg/ 5 mL (p)<br>Injection 1500 mg |
| **Azithromycin formulations are also listed in **Section 6.7.6.1** Anti-infective Medicines - Medicines used in the management of HIV- Additional Medicines for Syndromic Management of Sexually Transmitted Infections* | | | |

*a infection*

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 6.2.2.3 | Ciprofloxacin* | P,S,T | Tablet 250 mg<br>Tablet 500 mg<br>Oral liquid 250 mg/ 5 mL (p)<br>Injection 200 mg/ 100 mL |
| 6.2.2.4 | Clarithromycin** | S,T | Tablet 250 mg<br>Tablet 500 mg<br>Oral liquid 125 mg/5 mL (p) |
| 6.2.2.5 | Clindamycin*** | P,S,T | Capsule 150 mg<br>Capsule 300 mg<br>Injection 150 mg /mL |
| 6.2.2.6 | Co-trimoxazole [Sulphamethoxazole (A) + Trimethoprim (B)]**** | P,S,T | Tablet 400 mg (A) + 80 mg (B)<br>Tablet 800 mg (A) + 160 mg (B)<br>Oral liquid 200 mg (A) + 40 mg (B)/5 mL (p) |

***** Ciprofloxacin formulations are also listed in -***
***A. Section 16.2** - Ear, Nose and ThroatMedicines,*
***B. Section 21.1.2** - Ophthalmological Medicines- Anti-infective Medicines,*

*** Clarithromycin formulations are also listed in **Section 6.4.3** - Anti-infective medicines- Anti-tuberculosis Medicines*

*****Clindamycin formulations are also listed in -***
***A. Section 6.7.5.3** - Anti-infective Medicines- Antiviral Medicines- Medicines for treating Opportunistic Infections in People living with HIV*
***B. Section 6.9.3.1** - Anti-infective Medicines- Drugs for amoebiasis and other parasitic infections -Antipneumocystosis and antitoxoplasmosis medicines*
***C. Section 6.10.1.5** - Anti-infective Medicines- Antimalarial medicines- For curative treatment*

**** Co-trimoxazole formulations are also listed in **Section 6.9.3.2** - Anti-infective Medicines- Medicines for amoebiasis and other parasitic infections -Antipneumocystosis and antitoxoplasmosis medicines*

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 6.2.2.7 | Doxycycline* | P,S,T | Capsule 100 mg<br>Dry Syrup 50 mg/5 mL (p)<br>Power for Injection 100 mg |
| 6.2.2.8 | Gentamicin | P,S,T | Injection 10 mg/mL<br>Injection 40 mg/mL |
| 6.2.2.9 | Metronidazole** | P,S,T | Tablet 200 mg<br>Tablet 400 mg<br>Oral liquid 200 mg/5 mL (p)<br>Injection 500 mg/100 mL |
| 6.2.2.10 | Nitrofurantoin | P,S,T | Tablet 100 mg<br>Oral liquid 25 mg/5 mL (p) |
| 6.2.2.11 | Phenoxymethyl penicillin | P,S,T | Tablet 250 mg |
| 6.2.2.12 | Procaine Benzylpenicillin | P,S,T | Powder for injection<br>1000 mg (=1 million IU) |
| 6.2.2.13 | Vancomycin | S,T | Capsule 125 mg<br>Capsule 250 mg<br>Powder for Injection 250 mg<br>Powder for Injection 500 mg<br>Powder for Injection 1000 mg |

**Doxycycline formulations are also listed in **Section 6.10.2.1** - Anti-infective Medicines- Antimalarial medicines- For prophylaxis*
***Metronidazole formulations are also listed in **Section 6.9.1.1** - Anti-infective Medicines - Antiprotozoal Medicines - Medicines for amoebiasis and other parasitic infections*

| **6.3 - Antileprosy Medicines** | | | |
|---|---|---|---|
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 6.3.1 | Clofazimine* | P,S,T | Capsule 50 mg<br>Capsule 100 mg |
| 6.3.2 | Dapsone | P,S,T | Tablet 50 mg<br>Tablet 100 mg |
| 6.3.3 | Rifampicin** | P,S,T | Capsule 150 mg<br>Capsule 300 mg |
| **6.4-Antituberculosis Medicines** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 6.4.1 | Amikacin | S,T | Injection 100 mg/mL<br>Injection 250 mg/mL<br>Injection 500 mg/mL |
| 6.4.2 | Bedaquiline | T | Tablet 100 mg |
| 6.4.3 | Clarithromycin*** | S,T | Tablet 250 mg<br>Tablet 500 mg<br>Tablet 750 mg |

***Clofazimine formulations are also listed **Section 6.4.5** - Anti-infective Medicines - Anti-tuberculosis medicines*

****Rifampicin formulations are also listed in **Section 6.4.15** - Anti-infective Medicines - Anti-tubercular medicine*

*****Clarithromycin formulations are also listed in **Section 6.2.2.4** - Anti-infective Medicines- Antibacterials -Other Antibacterials*

| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
|---|---|---|---|
| 6.4.4 | Clofazimine* | S,T | Capsule 50 mg<br>Capsule 100 mg |
| 6.4.5 | Cycloserine | S,T | Capsule 125 mg<br>Capsule 250 mg |
| 6.4.6 | Delamanid | T | Tablet 50 mg |
| 6.4.7 | Ethambutol | P,S,T | Tablet 200 mg<br>Tablet 400 mg<br>Tablet 600 mg<br>Tablet 800 mg |
| 6.4.8 | Ethionamide | S,T | Tablet 125 mg<br>Tablet 250 mg |
| 6.4.9 | Isoniazid | P,S,T | Tablet 100 mg<br>Tablet 300 mg<br>Oral Liquid 50 mg/5 mL (p) |
| 6.4.10 | Levofloxacin | P,S,T | Tablet 250 mg<br>Tablet 500 mg<br>Tablet 750 mg |
| 6.4.11 | Linezolid | P,S,T | Tablet 300 mg<br>Tablet 600 mg |
| 6.4.12 | Moxifloxacin | P,S,T | Tablet 400 mg |
| ***Clofazimine formulations are also listed in **Section 6.3.1** - Anti-infective Medicines - Antileprosy medicines* | | | |

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 6.4.13 | Para-aminosalicylic acid | S,T | Granules (As licensed) |
| 6.4.14 | Pyrazinamide | P,S,T | Tablet 500 mg<br>Tablet 750 mg<br>Tablet 1000 mg<br>Tablet 1500 mg<br>Oral liquid 250 mg/5 mL (p) |
| 6.4.15 | Rifampicin* | P,S,T | Capsule 150 mg<br>Capsule 300 mg<br>Capsule 450 mg<br>Capsule 600 mg<br>Oral liquid 100 mg/ 5 mL (p) |
| 6.4.16 | Streptomycin | P,S,T | Powder for Injection 750 mg<br>Powder for Injection 1000 mg |
| **6.5 - Antifungal Medicines** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 6.5.1 | Amphotericin B** | S,T | a) Amphotericin B (conventional) - Injection 50 mg/vial<br>b) Lipid Amphotericin B - Injection 50 mg/vial<br>c) Liposomal Amphotericin B - Injection 50 mg/vial |

**Rifampicin formulations are also listed in **Section 6.3.3** - Anti-infective Medicines- Antileprosy medicines*
***Amphotericin B formulations are also listed **Section 6.9.2.1** - Anti-infective Medicines Antileishmaniasis medicines*

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 6.5.2 | Clotrimazole* | P,S,T | Pessary 100 mg |
| 6.5.3 | Fluconazole | P,S,T | Tablet 50 mg<br>Tablet 100 mg<br>Tablet 150 mg<br>Tablet 200 mg<br>Tablet 400 mg<br>Oral liquid 50 mg/ 5 mL (p) |
| | | S,T | Injection 200 mg / 100 mL |
| 6.5.4 | Griseofulvin | P,S,T | Tablet 125 mg<br>Tablet 250 mg<br>Tablet 375 mg |
| 6.5.5 | Itraconazole | S,T | Capsule 100 mg<br>Capsule 200 mg<br>Oral liquid 10 mg/mL |
| 6.5.6 | Mupirocin | P,S,T | Ointment 2% |
| 6.5.7 | Nystatin | S,T | Pessary 1 Lac IU<br>Oral Liquid 1 Lac IU/mL (p) |
| 6.5.8 | Terbinafine | P,S,T | Cream 1% |

***Clotrimazole formulations are also listed in -*
***A. Section 6.7.5.4** - Anti-infective Medicines Antiviral medicines- Medicines for treating Opportunistic Infections in People living with HIV*
***B. Section 11.1.1** - Dermatological Medicines (Topical)- Antifungal medicines*
***C. Section 16.3** - Ear, Nose and Throat Medicines*

| | | | |
|---|---|---|---|
| **6.6 - Antiviral Medicines** | | | |
| **6.6.1 - Antiherpes Medicines** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 6.6.1.1 | Acyclovir* | P,S,T | Tablet 200 mg<br>Tablet 400 mg<br>Tablet 800 mg<br>Powder for Injection 250 mg<br>Powder for Injection 500 mg<br>Oral liquid 400 mg/5 mL (p) |
| **6.6.2 - Anti-cytomegalovirus (CMV) medicines** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 6.6.2.1 | Valganciclovir** | S, T | Tablet 450 mg<br>Powder for oral solution 50 mg/mL |
| **6.7- Medicines used in the Management of HIV** | | | |
| **6.7.1 Nucleoside Reverse Transcriptase Inhibitors** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 6.7.1.1 | Abacavir | S,T | Tablet 60 mg (p)<br>Tablet 300 mg |

**Acyclovir formulations are also listed in -*
***A. Section 6.7.5.1** - Anti-infective Medicines -Medicines used in the management of HIV - Medicines for treating Opportunistic Infections in People living with HIV*
***B. Section 21.1.1** - Ophthalmological Medicines- Anti-infective medicine*

***Valganciclovir formulations are also listed in **Section 6.7.5.5** - Anti-infective Medicines- Antiviral medicines -Medicines for treating Opportunistic Infections in People living with HIV*

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 6.7.1.2 | Abacavir (A) + Lamivudine (B) | S,T | Tablet 60 mg (A) + 30 mg (B) (p)<br>Tablet 600 mg (A) + 300 mg (B) |
| 6.7.1.3 | Lamivudine | S,T | Tablet 100 mg<br>Tablet 150 mg |
| 6.7.1.4 | Tenofovir Disproxil Fumarate (TDF)* | S,T | Tablet 300 mg |
| 6.7.1.5 | Tenofovir Disproxil Fumarate (A) + Lamivudine (B) | S,T | Tablet 300 mg (A) + 300 mg (B) |
| 6.7.1.6 | Tenofovir Disproxil Fumarate (A) + Lamivudine (B) + Dolutegravir (C) | P,S,T | Tablet 300 mg (A) + 300 mg (B) + 50 mg (C) |
| 6.7.1.7 | Tenofovir Disproxil Fumarate (A) + Lamivudine (B) + Efavirenz (C) | S,T | Tablet 300 mg (A) + 300 mg (B) + 600 mg (C) |
| 6.7.1.8 | Zidovudine | S,T | Tablet 300 mg<br>Oral liquid 50 mg/5 mL (p) |
| 6.7.1.9 | Zidovudine (A) + Lamivudine (B) | S,T | Tablet 60 mg (A) + 30 mg (B) (p)<br>Tablet 300 mg (A) + 150 mg (B) |

** Tenofovir Disproxil Fumarate formulations are also listed in **Section 6.8.6 - Anti-infective Medicines  Medicines used in Hepatitis B and Hepatitis C***

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 6.7.1.10 | Zidovudine (A) + Lamivudine (B) + Nevirapine (C) | S,T | Tablet 60 mg (A) + 30 mg (B) + 50 mg (C) (p)<br>Tablet 300 mg (A) + 150 mg (B) + 200 mg (C) |
| **6.7.2 Non-nucleoside Reverse Transcriptase Inhibitors** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 6.7.2.1 | Efavirenz | S,T | Tablet 200 mg (p)<br>Tablet 600 mg |
| 6.7.2.2 | Nevirapine | P,S,T | Tablet 200 mg<br>Dispersible Tablet 50 mg (p)<br>Oral liquid 50 mg/ 5 mL (p) |
| **6.7.3 Integrase Inhibitors** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 6.7.3.1 | Dolutegravir | S,T | Tablet 50 mg |
| 6.7.3.2 | Raltegravir | S,T | Tablet 400 mg |
| **6.7.4 Protease Inhibitors** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 6.7.4.1 | Atazanavir (A) + Ritonavir (B) | S,T | Tablet 300 mg (A) +<br>Tablet 100 mg (B) |

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 6.7.4.2 | Darunavir | S,T | Tablet 600 mg |
| 6.7.4.3 | Darunavir (A) + Ritonavir (B) | S,T | Tablet 600 mg (A) + Tablet 100 mg (B) |
| 6.7.4.4 | Lopinavir (A) + Ritonavir (B) | S,T | Tablet 100 mg (A) + 25 mg (B)<br>Tablet 200 mg (A) + 50 mg (B)<br>Oral Liquid 80 mg (A) + 20 mg (B) /mL (p)<br>Capsule/ Sachet (containing pellets/granules) 40 mg (A) + 10 mg (B) (p) |
| 6.7.4.5 | Ritonavir | S,T | Tablet 100 mg |

**6.7.5 Medicines for treating Opportunistic Infections in People living with HIV**

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 6.7.5.1 | Acyclovir* | P,S,T | Injection 250 mg |
| 6.7.5.2 | Cefotaxime** | P,S,T | Injection 1000 mg |
| 6.7.5.3 | Clindamycin*** | P,S,T | Tablet 300 mg |

***Acyclovir formulations are also listed in -*
***A. Section 6.6.1.1** - Anti-infective Medicines -Antiviral medicines -Anti-herpes medicines*
***B. Section 21.1.1** - Ophthalmological Medicines- Anti-infective Medicine*

*** Cefotaxime formulations are also listed in **Section 6.2.1.9** - Anti-infective Medicines - Antibacterials- Beta-Lactam medicines*

****Clindamycin formulations are also listed in -**A. Section 6.2.2.5** - Anti-infective Medicines - Antibacterials -Other antibacterials*
***B. Section 6.9.3.1** - Anti-infective Medicines - Medicines for amoebiasis and other parasitic infections - Antipneumocystosis and antitoxoplasmosis medicines*
***C. Section 6.10.1.5** - Anti-infective Medicines - Antimalarial medicines- For curative treatment*

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 6.7.5.4 | Clotrimazole* | P,S,T | Ointment 1 % |
| 6.7.5.5 | Valganciclovir** | S,T | Tablet/Capsule 450 mg |
| **6.7.6 Additional Medicines for Syndromic Management of Sexually Transmitted Infections** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 6.7.6.1 | Azithromycin*** | P,S,T | Tablet 1000 mg |
| **Section 6.8 -Medicines used in Hepatitis B and Hepatitis C** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 6.8.1 | Daclatasvir | S,T | Tablet 30 mg<br>Tablet 60 mg |
| 6.8.2 | Entecavir | S,T | Tablet 0.5 mg<br>Tablet 1 mg<br>Oral liquid 0.05 mg/mL (p) |

***Clotrimazole formulations are also listed in -*
***A. Section 6.5.2** - Anti-infective Medicines -Antifungal medicines*
***B. Section 11.1.1** - Dermatological Medicines (Topical)- Antifungal medicines*
***C. Section 16.3** - Ear, Nose and Throat Medicines*

****Valganciclovir formulations are also listed in **Section 6.6.2.1** - Anti-infective Medicines - Antiviral medicines -Anti Cytomegalovirus (CMV) medicines*

*****Azithromycin formulations are also listed in **Section 6.2.2.1** - Anti-infective Medicines - Other antibacterials*

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 6.8.3 | Ribavirin | S,T | Capsule 200 mg |
| 6.8.4 | Sofosbuvir | S,T | Tablet 400 mg |
| 6.8.5 | Tenofovir Alafenamide Fumarate (TAF) | S,T | Tablet 25 mg |
| 6.8.6 | Tenofovir Disproxil Fumarate (TDF)* | S,T | Tablet 300 mg |
| **Section 6.9 -Antiprotozoal Medicines** | | | |
| **6.9.1 - Medicines for Amoebiasis and other Parasitic Infections** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 6.9.1.1 | Metronidazole** | P,S,T | Tablet 200 mg<br>Tablet 400 mg<br>Injection 500 mg/100 mL<br>Oral liquid 200 mg/5 mL (p) |

***** *Tenofovir Disproxil Fumarate formulations are also listed in* ***Section 6.7.1.4*** *- Anti-infective Medicines Medicines used in the management of HIV- Nucleoside reverse transcriptase inhibitors*

****** *Metronidazole formulations are also listed in* ***Section 6.2.2.9*** *- Anti-infective Medicines - Antibacterials Beta-lactam medicines - Other antibacterials*

| **6.9.2 - Antileishmaniasis Medicines** | | | |
|---|---|---|---|
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 6.9.2.1 | Amphotericin B* | S,T | a) Amphotericin B (conventional)- Injection 50 mg<br>b) Lipid Amphotericin B- Injection 50 mg<br>c) Liposomal Amphotericin B- Injection 50 mg |
| 6.9.2.2 | Miltefosine | P,S,T | Capsule 50 mg |
| 6.9.2.3 | Paromomycin | P,S,T | Injection 375 mg/mL |
| **6.9.3 - Antipneumocystosis and Antitoxoplasmosis Medicines** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 6.9.3.1 | Clindamycin** | P,S,T | Capsule 150 mg<br>Capsule 300 mg |

***Amphotericin B formulations are also listed in **Section 6.5.1** - Anti-infective Medicines- Antifungal medicines*

****Clindamycin formulations are also listed in -*
***A. Section 6.2.2.5** - Anti-infective Medicines - Antibacterials -Other antibacterials*
***B. Section 6.7.5.3** - Anti-infective Medicines - Antiviral medicines- Medicines for treating Opportunistic Infections in People living with HIV*
***C. Section 6.10.1.5** - Anti-infective Medicines- Antimalarial Medicines - For curative treatment*

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 6.9.3.2 | Co-trimoxazole* [Sulphamethoxazole (A) + Trimethoprim (B)] | P,S,T | Tablet 400 mg (A) + 80 mg (B)<br>Tablet 800 mg (A) + 160 mg (B)<br>Oral liquid 200 mg (A) + 40 mg (B)/5 mL (p) |
| **6.10-Antimalarial Medicines** | | | |
| **6.10.1 - For curative treatment** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 6.10.1.1 | Artemether (A) + Lumefantrine (B) | P,S,T | Tablet 20 mg (A) + 120 mg (B)<br>Tablet 40 mg (A) + 240 mg (B)<br>Tablet 80 mg (A) + 480 mg (B) |
| 6.10.1.2 | Artesunate | P,S,T | Powder for Injection 60 mg<br>Powder for Injection 120 mg |
| 6.10.1.3 | Artesunate (A) + Sulphadoxine - Pyrimethamine (B) | P,S,T | Combi pack (A+B)<br>1 Tablet 25 mg (A) + 1 Tablet (250 mg + 12.5 mg) (B)<br>1 Tablet 50 mg (A) + 1 Tablet (500 mg + 25 mg) (B)<br>1 Tablet 100 mg (A) + 1 Tablet (750 mg + 37.5 mg) (B)<br>1 Tablet 150 mg (A) + 2 Tablet (500 mg + 25 mg) (B)<br>1 Tablet 200 mg (A) + 2 Tablet (750 mg + 37.5 mg) (B) |
| ***Co-trimoxazole formulations are also listed in **Section 6.2.2.6** - Anti-infective Medicines- Antibacterials - Other antibacterials* | | | |

| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
|---|---|---|---|
| 6.10.1.4 | Chloroquine | P,S,T | Tablet 150 mg<br>Oral liquid 50 mg/5 mL |
| 6.10.1.5 | Clindamycin* | P,S,T | Capsule 150 mg<br>Capsule 300 mg |
| 6.10.1.6 | Primaquine | P,S,T | Tablet 2.5 mg<br>Tablet 7.5 mg<br>Tablet 15 mg |
| 6.10.1.7 | Quinine | P,S,T | Tablet 300 mg<br>Injection 300 mg/mL |
| **6.10.2 - For prophylaxis** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 6.10.2.1 | Doxycycline**[#] | P,S,T | Capsule 100 mg<br>Oral liquid 50 mg/ 5mL<br>[#]for prophylaxis of *P. vivax* |
| 6.10.2.2 | Mefloquine[#] | T | Tablet 250 mg<br>[#]Only for use as chemoprophylaxis for long term travellers like military and travel troops, travelling from low endemic to high endemic area. |

** Clindamycin formulations are also listed in -*
***A. Section 6.2.2.5 -*** *Anti-infective Medicines - Antibacterials -Other antibacterials*
***B. Section 6.7.5.3 -*** *Anti-infective Medicines - Antiviral medicines- Medicines for treating Opportunistic Infections in People living with HIV*
***C. Section 6.9.3.1 -*** *Anti-infective Medicines - Antipneumocystosis and antitoxoplasmosis medicines*

******** *Doxycycline formulations are also listed in* ***Section 6.2.2.7*** *- Anti-infective Medicines- Antibacterials - Other antibacterials*

| Section 7<br>Anti-cancer agents including Immunosuppressives and Medicines used in Palliative Care | | | |
|---|---|---|---|
| **7.1 - Antineoplastic medicines** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 7.1.1 | 5-Fluorouracil | T | Injection 250 mg/ 5 mL |
| 7.1.2 | 6-Mercaptopurine | T | Tablet 50 mg |
| 7.1.3 | Actinomycin D | T | Powder for Injection 0.5 mg |
| 7.1.4 | All-trans retinoic acid | T | Capsule 10 mg |
| 7.1.5 | Arsenic trioxide | T | Injection 1mg/ mL |
| 7.1.6 | Bendamustine hydrochloride | T | Injection 25 mg/ vial<br>Injection 100 mg/vial |
| 7.1.7 | Bleomycin | T | Powder for Injection 15 units |
| 7.1.8 | Bortezomib | T | Powder for Injection 2 mg |
| 7.1.9 | Calcium folinate | T | Tablet 15 mg<br>Injection 3 mg/mL |
| 7.1.10 | Capecitabine | T | Tablet 500 mg |

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 7.1.11 | Carboplatin | T | Injection 10 mg/mL |
| 7.1.12 | Chlorambucil | T | Tablet 2 mg<br>Tablet 5 mg |
| 7.1.13 | Cisplatin | T | Injection 1mg/mL |
| 7.1.14 | Cyclophosphamide | T | Tablet 50 mg<br>Powder for Injection 500 mg |
| 7.1.15 | Cytosine arabinoside | T | Injection 100 mg/vial<br>Injection 500 mg/vial<br>Injection 1000 mg/vial |
| 7.1.16 | Dacarbazine | T | Powder for Injection 200 mg<br>Powder for Injection 500 mg |
| 7.1.17 | Daunorubicin | T | Injection 5 mg/mL |
| 7.1.18 | Docetaxel | T | Powder for Injection 20 mg<br>Powder for Injection 80 mg |
| 7.1.19 | Doxorubicin | T | Injection 2 mg/mL |
| 7.1.20 | Etoposide | T | Capsule 50 mg<br>Injection 20 mg/mL |
| 7.1.21 | Gefitinib | T | Tablet 250 mg |

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 7.1.22 | Gemcitabine | T | Powder for Injection 200 mg<br>Powder for Injection 1000 mg |
| 7.1.23 | Hydroxyurea* | T | Capsule 500 mg |
| 7.1.24 | Ifosfamide | T | Powder for Injection 1000 mg<br>Powder for Injection 2000 mg |
| 7.1.25 | Imatinib | T | Tablet 100 mg<br>Tablet 400 mg |
| 7.1.26 | Irinotecan HCl trihydrate | T | Solution for injection 20 mg/ mL |
| 7.1.27 | L-Asparaginase | T | Powder for Injection 5000 KU<br>Powder for Injection 10000 KU |
| 7.1.28 | Lenalidomide | T | Capsule 5 mg<br>Capsule 25 mg |
| 7.1.29 | Melphalan | T | Tablet 2 mg<br>Tablet 5 mg |
| 7.1.30 | Methotrexate** | S,T | Tablet 2.5 mg<br>Tablet 5 mg<br>Tablet 10 mg<br>Injection 50 mg/mL |

***Hydroxyurea formulations are also listed in **Section 8.1.6** - Medicines affecting Blood Antianaemia Medicines*

***Methotrexate formulations are also listed in **Section 2.4.3** - Analgesics, Antipyretics, Non-steroidal Anti-inflammatory Drugs (NSAIDs), Medicines used to treat Gout and Disease Modifying Agents used in Rheumatoid Disorders - Disease Modifying Agents used in Rheumatoid Disorders*

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 7.1.31 | Oxaliplatin | T | Injection 5 mg/mL in 10 mL vial<br>Injection 5 mg/mL in 20 mL vial |
| 7.1.32 | Paclitaxel | T | Injection 30 mg/5 mL<br>Injection 100 mg/16.7 mL |
| 7.1.33 | Rituximab | T | Injection 10 mg/mL |
| 7.1.34 | Temozolomide | T | Capsule 20 mg<br>Capsule 100 mg<br>Capsule 250 mg |
| 7.1.35 | Thalidomide | T | Capsule 50 mg<br>Capsule 100 mg |
| 7.1.36 | Trastuzumab | T | Injection 440 mg/50 mL |
| 7.1.37 | Vinblastine | T | Injection 1 mg/mL |
| 7.1.38 | Vincristine | T | Injection 1 mg/mL |
| **7.2-Hormones and Anti-hormones used in Cancer Therapy** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 7.2.1 | Bicalutamide | T | Tablet 50 mg |
| 7.2.2 | Letrozole | T | Tablet 2.5 mg |

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 7.2.3 | Leuprolide acetate | T | Powder for injection 3.75 mg<br>Powder for injection 11.25 mg<br>Powder for injection 22.5 mg |
| 7.2.4 | Prednisolone* | S,T | Tablet 10 mg<br>Tablet 20 mg<br>Tablet 40 mg<br>Oral liquid 5 mg/5 mL (p)<br>Oral liquid 15 mg/5 mL (p)<br>Injection 20 mg/2 mL |
| 7.2.5 | Tamoxifen | T | Tablet 10 mg<br>Tablet 20 mg |
| **7.3 - Immunosuppressive Medicines** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 7.3.1 | Azathioprine** | T | Tablet 50 mg |
| 7.3.2 | Cyclosporine | T | Capsule 25 mg<br>Capsule 50 mg<br>Capsule 100 mg<br>Oral liquid 100 mg/mL (p)<br>Injection 50 mg/mL |

***Prednisolone formulations are also listed in -*

***A. Section 3.6** - Antiallergics and Medicines used in Anaphylaxis*

***B. Section 18.1.5** - Hormones, other Endocrine Medicines and Contraceptives -Adrenal Hormones and synthetic substitutes*

***C. Section 21.2.1** - Ophthalmological Medicines - Antiinflammatory Medicine*

***Azathioprine formulations are also listed in **Section 2.4.1** - Analgesics, Antipyretics, Non-steroidal Anti-inflammatory Drugs (NSAIDs), Medicines used to treat Gout and Disease Modifying Agents used in Rheumatoid Disorders - Disease Modifying Agents used in Rheumatoid Disorders*

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 7.3.3 | Mycophenolate mofetil | T | Tablet 250 mg<br>Tablet 500 mg |
| 7.3.4 | Tacrolimus | T | Capsule 0.5 mg<br>Capsule 1 mg<br>Capsule 2 mg |
| **7.4-Medicines used in Palliative Care** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 7.4.1 | Allopurinol* | S,T | Tablet 100 mg |
| 7.4.2 | Amitriptyline** | S,T | Tablet 10 mg<br>Tablet 25 mg |
| 7.4.3 | Dexamethasone*** | S,T | Tablet 0.5 mg<br>Tablet 4 mg<br>Injection 4 mg/mL |

**Allopurinol formulations are also listed in **Section 2.3.1** - Analgesics, Antipyretics, Non-steroidal Anti-inflammatory Drugs (NSAIDs),Medicines used to treat Gout and Disease Modifying Agents used in Rheumatoid Disorders - Medicines used to treat Gout*

***Amitriptyline formulations are also listed in **A. Section 5.2.5** - Medicines used in Neurological Disorders - Anti-migraine medicines -*
*For prophylaxis*
***B. Section 23.2.1.1** - Medicines in treatment of Psychiatric Disorders -Medicines used in mood disorders- Medicines used in depressive disorders*

****Dexamethasone formulations are also listed in*
***A. Section 3.4** - Antiallergics and medicines used in anaphylaxis*
***B. Section 18.1.1** - Hormones, other Endocrine Medicines and Contraceptives - Adrenal hormones and synthetic substitutes*
***C. Section 27.1** - Medicines for COVID-19 management*

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 7.4.4 | Diazepam* | S,T | Tablet 2 mg<br>Tablet 5 mg<br>Injection 5 mg/mL |
| 7.4.5 | Filgrastim | T | Injection 300 mcg |
| 7.4.6 | Fluoxetine** | S,T | Capsule 20 mg |
| 7.4.7 | Haloperidol*** | S,T | Tablet 1.5 mg<br>Tablet 5 mg<br>Injection 5 mg/mL |
| 7.4.8 | Lactulose**** | S,T | Oral liquid 10 g/15 mL |
| 7.4.9 | Loperamide | S,T | Tablet 2 mg |

***Diazepam formulations are also listed **Section 5.1.3** - Medicines used in Neurological Disorders - Anticonvulsants/Antiepileptics*

****Fluoxetine formulations are also listed in***
***A. Section 23.2.1.3** - Medicines in used in treatment of Psychiatric Disorders - Medicines used in mood disorders - Medicines used in depressive disorders*
***B. Section 23.4.2** - Medicines used in treatment of Psychiatric Disorders - Medicines used in obsessive compulsive disorders and panic attacks*

*****Haloperidol formulations are also listed in **Section 23.1.3** -*
*Medicines used in treatment of psychiatric Disorders - Medicines used in psychotic disorders*

******Lactulose formulations are also listed in **Section 17.5.3** -*
*Gastrointestinal Medicines - Laxatives*

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 7.4.10 | Metoclopramide* | S,T | Tablet 10 mg<br>Oral liquid 5 mg/5 mL (p)<br>Injection 5 mg/mL |
| 7.4.11 | Mesna | T | Injection 100 mg/mL |
| 7.4.12 | Midazolam** | S,T | Injection 1 mg/mL |
| 7.4.13 | Morphine*** | S,T | Tablet 10 mg<br>Modified Release Tablet 30 mg |
| 7.4.14 | Ondansetron**** | S,T | Tablet 4 mg<br>Tablet 8 mg<br>Oral liquid 2 mg/5 mL (p)<br>Injection 2 mg/mL |

**Metoclopramide formulations are also listed in* ***Section 17.2.2*** *-*
*Gastrointestinal Medicines Antiemetics*

********Midazolam formulations are also listed in -*
***A. Section 1.3.3*** *- Medicines used in Anaesthesia - Preoperative medication and sedation for short term procedures*
***B. Section 5.1.7*** *- Medicines used in Neurological Disorders -Anticonvulsants/Antiepileptics*

*********Morphine formulations are also listed in -*
***A. Section 1.3.4*** *- Medicines used in Anaesthesia - Preoperative medication and sedation for short term procedures*
***B. Section 2.2.2*** *- Analgesics, Antipyretics, Non-steroidal Anti-inflammatory Drugs (NSAIDs), Medicines used to treat Gout and Disease Modifying Agents used in Rheumatoid Disorders - Opioid Analgesics*

**********Ondansetron formulations are also listed* ***Section 17.2.3*** *- Gastrointestinal Medicines anti-ulcer medicines*

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 7.4.15 | Tramadol* | S,T | Capsule 50 mg<br>Capsule 100 mg<br>Injection 50 mg/mL |
| 7.4.16 | Zoledronic acid | T | Powder for Injection 4 mg |

## Section 8
## Medicines affecting Blood

### 8.1- Antianaemia Medicines

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 8.1.1 | Erythropoietin | S,T | Injection 2000 IU/mL<br>Injection 10000 IU/mL |
| 8.1.2 | Ferrous salts<br>(a) Iron Dextran<br>(b) Iron sorbitol citrate complex | P,S,T | Tablet equivalent to 60 mg of elemental iron<br>Injection 50 mg/mL<br>Injection 50 mg/mL |
| 8.1.3 | Ferrous Salt (A)+ Folic acid (B) | P,S,T | Tablet 45 mg elemental iron (A) + 400 mcg (B)<br>Tablet 100 mg elemental iron (A) + 500 mcg (B)<br>Oral liquid 20 mg elemental iron (A) + 100 mcg/mL (B) (p) |

**Tramadol formulations are also listed in **Section 2.2.3** - Analgesics, Antipyretics, Non-steroidal Anti-inflammatory Drugs (NSAIDs), Medicines used to treat Gout and disease Modifying agents used in Rheumatoid Disorders- Opioid Analgesics*

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 8.1.4 | Folic Acid | P,S,T | Tablet 1 mg<br>Tablet 5 mg |
| 8.1.5 | Hydroxocobalamin | P,S,T | Injection 1 mg/mL |
| 8.1.6 | Hydroxyurea* | S,T | Capsule 500 mg |
| 8.1.7 | Iron sucrose | S,T | Injection 20 mg/mL |
| **8.2 - Medicines affecting Coagulation** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 8.2.1 | Enoxaparin** | S,T | Injection 40 mg/ 0.4 mL<br>Injection 60 mg/ 0.6 mL |
| 8.2.2 | Heparin*** | S,T | Injection 1000 IU/mL<br>Injection 5000 IU/mL |
| 8.2.3 | Phytomenadione (Vitamin $K_1$) | P,S,T | Tablet 10 mg<br>Injection 10 mg/mL |
| 8.2.4 | Protamine Sulphate | S,T | Injection 10 mg/mL |
| 8.2.5 | Tranexamic acid | P,S,T | Tablet 500 mg<br>Injection 100 mg/mL |

** Hydroxyurea formulations are also listed in **Section 7.1.26 -** Anti-cancer agents including Immunosuppressives, and Medicines used in Palliative Care Antineoplastic medicines*

*** Enoxaparin formulations are also listed in*
***A. Section 10.5.4 -** Cardiovascular Medicines - Antiplatelet and Antithrombotic Medicines*
***B. Section 27.2 -** Medicines for COVID 19 management*

**** Heparin formulations are also listed in **Section 10.5.5 -** Cardiovascular Medicines - Antiplatelet and Antithrombotic Medicines*

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 8.2.6 | Warfarin | S,T | Tablet 1 mg<br>Tablet 2 mg<br>Tablet 3 mg<br>Tablet 5 mg |

## Section 9
## Blood products and Plasma substitutes

**9.1 - Blood and Blood components**

All forms of the following as approved by licensing authority are considered as included in NLEM. However, considering the process, technology and other relevant aspects, they should be considered differently for purposes such as procurement policy, pricing etc.

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 9.1.1 | Fresh frozen plasma | S,T | As licensed |
| 9.1.2 | Platelet rich plasma/ Platelet concentrates | S,T | As licensed |
| 9.1.3 | Red blood cells/ Packed RBCs | S,T | As licensed |
| 9.1.4 | Whole blood | S,T | As licensed |

| | | | |
|---|---|---|---|
| **9.2 - Plasma substitutes** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 9.2.1 | Dextran-40 | S,T | Injection 10 % |
| **9.3 - Plasma fractions for specific use** | | | |
| In case of coagulation factors and other blood products, irrespective of variation in source, all forms of these products as approved by licensing authority are considered as included in NLEM. However, considering the source, process, technology and other relevant aspects, they should be considered differently for purposes such as procurement policy, pricing etc. | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 9.3.1 | Coagulation factor IX | S,T | Powder for Injection 600 IU |
| 9.3.2 | Coagulation factor VIII | S,T | Powder for Injection 250 IU<br>Powder for Injection 500 IU |
| 9.3.3 | Cryoprecipitate | S,T | As licensed |

## Section 10
## Cardiovascular Medicines

### 10.1-Medicines used in Angina

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 10.1.1 | Diltiazem | P,S,T | Tablet 30 mg<br>Tablet 60 mg<br>Modified Release Tablet 180 mg |
| | | S, T | Injection 5 mg/mL |
| 10.1.2 | Glyceryl trinitrate | P,S,T | Sublingual Tablet 0.5 mg |
| | | S,T | Injection 5 mg/mL |
| 10.1.3 | Isosorbide dinitrate | P,S,T | Tablet 5 mg<br>Tablet 10 mg |
| 10.1.4 | Metoprolol | P,S,T | Tablet 25 mg<br>Tablet 50 mg<br>Tablet 100 mg<br>Modified Release Tablet 100 mg |
| | | S,T | Injection 1 mg/mL |

| **10.2 - Antiarrhythmic medicines** | | | |
|---|---|---|---|
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 10.2.1 | Adenosine | S,T | Injection 3 mg/mL |
| 10.2.2 | Amiodarone | S,T | Tablet 100 mg<br>Tablet 200 mg<br>Injection 50 mg/mL |
| 10.2.3 | Digoxin* | S,T | Tablet 0.25 mg<br>Oral liquid 0.05 mg/mL<br>Injection 0.25 mg/mL |
| 10.2.4 | Esmolol | S,T | Injection 10 mg/mL |
| 10.2.5 | Lignocaine** | S,T | Injection 2% |
| 10.2.6 | Verapamil | S,T | Tablet 40 mg<br>Tablet 80 mg<br>Injection 2.5 mg/ mL |
| **10.3 - Antihypertensive Medicines** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 10.3.1 | Amlodipine | P,S,T | Tablet 2.5 mg<br>Tablet 5 mg<br>Tablet 10 mg |

**Digoxin formulations are also listed in **Section 10.4.1** - Cardiovascular Medicines - Medicines used in Shock and Heart Failure*

***Lignocaine formulations are also listed in **Section 1.2.2** - Medicines used in Anaesthesia - Local Anaesthetics*

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 10.3.2 | Enalapril | P,S,T | Tablet 2.5 mg<br>Tablet 5 mg |
| 10.3.3 | Hydrochlorothiazide * | P,S,T | Tablet 12.5 mg<br>Tablet 25 mg |
| 10.3.4 | Labetalol | P,S,T | Tablet 50 mg<br>Tablet 100 mg |
| | | P,S,T | Injection 5 mg/mL |
| 10.3.5 | Ramipril | P,S,T | Tablet 2.5 mg<br>Tablet 5 mg |
| 10.3.6 | Sodium nitroprusside | S, T | Injection 10 mg/mL |
| 10.3.7 | Telmisartan | P,S,T | Tablet 20 mg<br>Tablet 40 mg<br>Tablet 80 mg |
| **10.4 - Medicines used in Shock and Heart failure** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 10.4.1 | Digoxin** | S,T | Tablet 0.25 mg<br>Oral liquid 0.05 mg/mL<br>Injection 0.25 mg/mL |

**Hydrochlorothiazide formulations are also listed in **Section 15.2** - Diuretics*

***Digoxin formulations are also listed in **Section 10.2.3** - Cardiovascular Medicines - Antiarrhythmic medicines*

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 10.4.2 | Dobutamine | S,T | Injection 50 mg/mL |
| 10.4.3 | Dopamine | S,T | Injection 40 mg/mL |
| 10.4.4 | Noradrenaline | S,T | Injection 2 mg/mL |
| 10.4.5 | Spironolactone* | P,S,T | Tablet 25 mg<br>Tablet 50 mg |
| **10.5- Antiplatelet and Antithrombotic Medicines** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 10.5.1 | Acetylsalicylic acid** | P,S,T | Conventional/Effervescent/ Dispersible/ Enteric coated Tablets 150 mg<br>Conventional/Effervescent/ Dispersible/ Enteric coated Tablets 325 mg<br>Enteric coated Tablet 75 mg<br>Enteric coated Tablet 100 mg |

**Spironolactone formulations are also listed in **Section 15.4** - Diuretics*

***Acetylsalicyclic acid formulations are also listed in -*
***A. Section 2.1.1** - Analgesics, Antipyretics, Non-steroidal Anti-inflammatory Drugs (NSAIDs), Medicines used to treat Gout and Disease Modifying Agents used in Rheumatoid Disorders - Non-opioid Analgesics, Antipyretics and Non-steroidal Anti-inflammatory Drugs*
***B. Section 5.2.1** - Medicines used in Neurological Disorders- Antimigraine medicines*

| | | | |
|---|---|---|---|
| 10.5.2 | Clopidogrel | P,S,T | Tablet 75 mg<br>Tablet 150 mg |
| 10.5.3 | Dabigatran | S, T | Tablet 110 mg<br>Tablet 150 mg |
| 10.5.4 | Enoxaparin* | S,T | Injection 40 mg/ 0.4 mL<br>Injection 60 mg/ 0.6 mL |
| 10.5.5 | Heparin** | S,T | Injection 1000 IU/mL<br>Injection 5000 IU/mL |
| 10.5.6 | Streptokinase | S,T | Injection 750,000 IU<br>Injection 15,00,000 IU |
| 10.5.7 | Tenecteplase | S,T | Injection 30 mg/vial<br>Injection 40 mg/vial |
| **10.6 - Hypolipidemic Medicines** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 10.6.1 | Atorvastatin | P,S,T | Tablet 10 mg<br>Tablet 20 mg<br>Tablet 40 mg<br>Tablet 80 mg |

****Enoxaparin formulations are also listed in -*
***A. Section 8.2.1** - Medicines affecting Blood - Medicines affecting coagulation*
***B. Section 27.2** - Medicines for COVID 19 management*

***Heparin formulations are also listed in **Section 8.2.2** - Medicines affecting Blood - Medicines affecting coagulation*

## Section 11
## Dermatological Medicines (Topical)

### 11.1 - Antifungal Medicines

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 11.1.1 | Clotrimazole* | P,S,T | Cream 1 %<br>Lotion 1 % |

### 11.2 - Antibacterial Medicines

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 11.2.1 | Framycetin | P,S,T | Cream 1 % |
| 11.2.2 | Fusidic acid | P,S,T | Cream 2 % |
| 11.2.3 | Silver sulphadiazine | P,S,T | Cream 1 % |

### 11.3-Antiinflammatory and Antipruritic Medicines

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 11.3.1 | Betamethasone valerate | P,S,T | Cream 0.05 %<br>Cream 0.1 % |

*****Clotrimazole formulations are also listed in -*

***A. Section 6.5.2 -*** *Anti-infective Medicines -Antifungal medicines*

***B. Section 6.7.5.4 -*** *Anti-infective Medicines Antiviral medicines- Medicines used in the management of HIV*

***C. Section 16.3 -*** *Ear, Nose and ThroatMedicines*

| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
|---|---|---|---|
| 11.3.2 | Calamine | P,S,T | Lotion (As per IP) |
| **11.4 - Keratolytic agents** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 11.4.1 | Benzoyl peroxide | P,S,T | Gel 2.5 % - 5 % |
| 11.4.2 | Coal tar (A) + Salicylic Acid (B) | P,S,T | Solution 1 % (A) + 3 % (B) |
| 11.4.3 | Podophyllin resin | S,T | Solution 20 % |
| 11.4.4 | Salicylic acid | P,S,T | Ointment 3-6 % |
| **11.5 - Scabicides and Pediculicides** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 11.5.1 | Permethrin | P,S,T | Lotion 1 %<br>Cream 5 % |
| **11.6 Miscellaneous** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 11.6.1 | Glycerin/glycerol (as mentioned in IP) | P,S,T | Topical |

| Section 12<br>Diagnostic agents | | | |
|---|---|---|---|
| **12.1 - Ophthalmic Medicines** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 12.1.1 | Fluorescein | S,T | Ophthalmic Strips |
| 12.1.2 | Proparacaine* | S,T | Eye Drops 0.5% |
| 12.1.3 | Tropicamide** | S,T | Eye drop 1 % |
| **12.2 - Radiocontrast Media** | | | |
| 12.2.1 | Barium sulphate | S,T | Oral Liquid 95% w/v |
| 12.2.2 | Gadobenate dimeglumine | T | Injection 529 mg/mL |
| 12.2.3 | Iohexol | S,T | Injection 140 to 350 mg iodine/mL |
| 12.2.4 | Meglumine diatrizoate | S,T | Injection 60 % w/v<br>Injection 76 % w/v |

***** *Proparacaine formulations are also listed in* ***Section 21.3.1*** *- Ophthalmological Medicines- Local Anaesthetics*

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****** *Tropicamide formulations are also listed in* ***Section 21.5.4*** *- Ophthalmological Medicines Mydriatics*

| Section 13<br>Dialysis components (Haemodialysis and Peritoneal Dialysis) | | | |
|---|---|---|---|
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 13.1 | Haemodialysis fluid | S,T | As licensed |
| 13.2 | Peritoneal dialysis solution | S,T | As licensed |
| **Section 14**<br>**– Antiseptics and Disinfectants** | | | |
| **14.1 Antiseptics** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 14.1.1 | Chlorhexidine | P,S,T | Solution 5% (Concentrate) |
| 14.1.2 | Ethyl alcohol (Denatured) | P,S,T | Solution 70% |
| 14.1.3 | Hydrogen peroxide | P,S,T | Solution 6 % |
| 14.1.4 | Methylrosanilinium chloride (Gentian Violet) | P,S,T | Topical preparation 0.25% to 2% |
| 14.1.5 | Povidone iodine* | P,S,T | Solution 4 % to 10 % |
| **Povidone Iodine formulations are also listed in **Section 21.1.5** - Ophthalmological Medicines - Anti-infective medicine* | | | |

| **14.2 Disinfectants** | | | |
|---|---|---|---|
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 14.2.1 | Glutaraldehyde | S,T | As Licensed |
| 14.2.2 | Potassium permanganate | P,S,T | Crystals for topical solution |
| **Section 15 Diuretics** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 15.1 | Furosemide | P,S,T | Tablet 40 mg<br>Oral liquid 10 mg/mL<br>Injection 10 mg/ mL |
| 15.2 | Hydrochlorothiazide * | P,S,T | Tablet 25 mg<br>Tablet 50 mg |
| 15.3 | Mannitol | P,S,T | Injection 10 %<br>Injection 20 % |
| 15.4 | Spironolactone** | P,S,T | Tablet 25 mg<br>Tablet 50 mg |
| ** Hydrochlorothiazide formulations are also listed in **Section 10.3.3** - Antihypertensive Medicines*<br>***Spironolactone formulations are also listed in **Section 10.4.5** - Cardiovascular Medicines - Medicines used in shock and heart failure* | | | |

| Section 16<br>Ear, Nose and Throat Medicines | | | |
|---|---|---|---|
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 16.1 | Budesonide* | P,S,T | Nasal Spray 50 mcg/dose<br>Nasal Spray 100 mcg/dose |
| 16.2 | Ciprofloxacin** | P,S,T | Drops 0.3 % |
| 16.3 | Clotrimazole*** | P,S,T | Drops 1 % |
| 16.4 | Xylometazoline | P,S,T | Nasal drops 0.05 %<br>Nasal drops 0.1 % |

***Budesonide formulations are also listed in **Section 24.1** - Medicines acting on the respiratory tract - Antiasthmatic Medicines*

****Ciprofloxacin formulations are also listed in*
***A. Section 6.2.2.3** - Anti-infective Medicines- Antibacterials -Other Antibacterials*
***B. Section 21.1.2** - Ophthalmological Medicines- Anti-infective Medicines*

*****Clotrimazole formulations are also listed in -*
***A. Section 6.5.2** - Anti-infective Medicines -Antifungal medicines*
***B. Section 6.7.5.4** - Anti-infective Medicines Antiviral medicines- Medicines used in the management of HIV*
***C. Section 11.1.1** - Dermatological Medicines (Topical) -Antifungal medicines*

## Section 17
## Gastrointestinal Medicines

### 17.1 - Antiulcer Medicines

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 17.1.1 | Omeprazole | P,S,T | Capsule 10 mg<br>Capsule 20 mg<br>Capsule 40 mg<br>Powder for oral liquid 20 mg |
| 17.1.2 | Pantoprazole | S,T | Injection 40 mg |

### 17.2 Antiemetics

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 17.2.1 | Domperidone | P,S,T | Tablet 10 mg<br>Oral Liquid 1 mg/mL |
| 17.2.2 | Metoclopramide* | P,S,T | Tablet 10 mg<br>Injection 5 mg/mL |
| 17.2.3 | Ondansetron* | S,T | Tablet 4 mg<br>Oral Liquid 2 mg/5 mL (p)<br>Injection 2 mg/ mL |

**Metoclopramide formulations are also listed in **Section 7.4.10** - Anti-cancer agents including Immunosuppressives, and Medicines used in Palliative Care Medicines used in Palliative Care*

***Ondansetron formulations are also listed in **Section 7.4.14** - Anti-cancer agents including Immunosuppressives, and Medicines used in Palliative Care Medicines used in Palliative Care*

| | | | |
|---|---|---|---|
| **17.3 – Anti-inflammatory medicines** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 17.3.1 | 5-aminosalicylic acid (Mesalazine/ Mesalaine) | S, T | Tablet 400 mg<br>Suppository 500 mg<br>Retention Enema |
| **17.4–Antispasmodic medicines** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 17.4.1 | Dicyclomine | P,S,T | Tablet 10 mg<br>Oral Solution 10 mg/5mL<br>Injection 10 mg/ mL |
| 17.4.2 | Hyoscine butyl bromide | P,S,T | Tablet 100 mg<br>Injection 20 mg/ mL |
| **17.5– Laxatives** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 17.5.1 | Bisacodyl | P,S,T | Tablet 5 mg<br>Suppository 5 mg |
| 17.5.2 | Ispaghula | P,S,T | Granules/ Husk/ Powder |

| – | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 17.5.3 | Lactulose* | S,T | Oral Liquid 10 g/15 mL |
| **17.6 Medicines used in diarrhea** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 17.6.1 | Oral rehydration salts** | P,S,T | As licensed |
| 17.6.2 | Zinc Sulphate | P,S,T | Dispersible Tablet 20 mg |
| **17.7– Other medicines** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 17.7.1 | Somatostatin | T | Powder for Injection 3 mg |

***Lactulose formulations are also listed in **Section 7.4.8 -** Anti-cancer agents including Immunosuppressives, and Medicines used in Palliative Care - Medicines used in Palliative Care*

****Oral rehydration salts formulations are also listed in **Section 25.3 -** Solutions correcting water, electrolyte disturbances and acid-base disturbances*

## Section 18
## Hormones, other Endocrine Medicines and Contraceptives

### 18.1-Adrenal Hormones and Synthetic substitutes

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 18.1.1 | Dexamethasone* | S,T | Tablet 0.5 mg<br>Injection 4 mg/mL |
| 18.1.2 | Fludrocortisone | S,T | Tablet 0.1 mg |
| 18.1.3 | Hydrocortisone** | P,S,T | Tablet 5 mg<br>Tablet 10 mg<br>Tablet 20 mg<br>Powder for Injection 100 mg |
| 18.1.4 | Methylprednisolone *** | S,T | Injection 40mg/mL |

**Dexamethasone formulations are also listed in -*
***A. Section 3.4 -*** *Antiallergics and Medicines used in Anaphylaxis*
***B. Section 7.4.3 -*** *Anti-cancer agents including Immunosuppressives, and Medicines used in Palliative Care - Medicines used in Palliative Care*

***C. Section 27.1 -*** *Medicines for COVID–19 Management*

******** *Hydrocortisone formulations are also listed in* ***Section 3.5 -*** *Antiallergics and Medicines used in Anaphylaxis*

********* *Methylprednisolone formulations are also listed in* ***section 27.3-*** *Medicines for COVID - 19 management*

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 18.1.5 | Prednisolone* | P,S,T | Tablet 5 mg<br>Tablet 10 mg<br>Tablet 20 mg<br>Oral liquid 5 mg/5 mL (p)<br>Oral liquid 15 mg/5 mL (p) |
| **18.2 – Contraceptives** | | | |
| **18.2.1 - Hormonal Contraceptives** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 18.2.1.1 | Ethinylestradiol (A)+ Levonorgestrel (B) | P,S,T | Tablet 0.03 mg (A) +<br>Tablet 0.15 mg (B) |
| 18.2.1.2 | Levonorgestrel | P,S,T | Tablet 0.75 mg<br>Tablet 1.5 mg |
| 18.2.1.3 | Ormeloxifene (Centchroman) | P,S,T | Tablet 30 mg |

**Prednisolone formulations are also listed in -*
***A. Section 3.7 -*** *Antiallergics and Medicines used in Anaphylaxis*
***B. Section 7.2.4 -*** *Anti-cancer agents including Immunosuppressives, and Medicines used in Palliative Care–Hormones and anti- hormones used in cancer therapy*
***C. Section 21.2.1 -*** *Ophthalmological Medicines - Antiinflammatory medicine*

| | | | |
|---|---|---|---|
| **18.2.2 - Intrauterine Devices** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 18.2.2.1 | Hormone releasing IUD | T | Contains 52 mg of Levonorgestrel |
| 18.2.2.2 | IUD containing Copper | P,S,T | As licensed |
| **18.2.3 - Barrier methods** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 18.2.3.1 | Condom | P,S,T | As Licensed as per the standards of Drugs Rules, 1945 |
| **18.3 - Medicines used in Diabetes Mellitus** | | | |
| **18.3.1 - Insulins and other Antidiabetic agents** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 18.3.1.1 | Glimepiride | P,S,T | Tablet 1 mg<br>Tablet 2 mg |
| 18.3.1.2 | Insulin (Soluble) | P,S,T | Injection 40 IU/mL |
| 18.3.1.3 | Insulin Intermediate Acting (NPH) | P,S,T | Injection 40 IU/mL |

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 18.3.1.4 | Insulin Glargine | P,S,T | Injection 100 IU/mL |
| 18.3.1.5 | Insulin Premix Injection 30:70 (Regular : NPH) | P,S,T | Injection 40 IU/mL |
| 18.3.1.6 | Metformin | P,S,T | Tablet 500 mg<br>Tablet 1000 mg<br>Modified release Tablet 1000 mg |
| 18.3.1.7 | Teneligliptin | P,S,T | Tablet 20 mg |
| **18.3.2 - Medicines used to treat Hypoglycemia** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 18.3.2.1 | Glucose* | P,S,T | Injection 25 % |
| **18.4-Ovulation Inducers** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 18.4.1 | Clomiphene citrate | T | Tablet 50 mg<br>Tablet 100 mg |
| 18.4.2 | Human chorionic gonadotropin | S,T | Injection 2000 IU<br>Injection 5000 IU<br>Injection 10000 IU |
| **Glucose formulations are also listed in **Section 25.1** - Solutions correcting water, electrolyte disturbances and acid-base disturbances* | | | |

| | | | |
|---|---|---|---|
| **18.5-Progestogens** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 18.5.1 | Medroxyprogesterone acetate | P,S,T | Tablet 5 mg<br>Tablet 10 mg<br>Injection 150 mg/ mL |
| 18.5.2 | Norethisterone | P,S,T | Tablet 5 mg |
| **18.6-Thyroid and Antithyroid Medicines** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 18.6.1 | Carbimazole | P,S,T | Tablet 5 mg<br>Tablet 10 mg<br>Tablet 20 mg |
| 18.6.2 | Levothyroxine | P,S,T | Tablet 12.5 mcg to 150 mcg*<br>(*Several strengths are available in market such as 12.5,25,50,62.5, 75, 88,100, 112mcg. Therefore, it was considered to give a range of available strengths) |

## Section 19
## Immunologicals

In case of these biologicals, irrespective of variation in source, composition and strengths, all the products of the same vaccine/ sera/ immunoglobulin, as approved by licensing authority are considered as included in NLEM. However, considering the source, process, technology and other relevant aspects, different products of the same biological should be considered differently for purposes such as procurement policy, pricing etc.

**19.1-Diagnostic agents**

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 19.1.1 | Tuberculin, Purified Protein derivative | P,S,T | As Licensed |

**19.2-Sera and Immunoglobulins (Liquid/ Lyophilized)**

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 19.2.1 | Anti-rabies immunoglobulin | P,S,T | As Licensed |
| 19.2.2 | Anti-tetanus immunoglobulin | P,S,T | As Licensed |
| 19.2.3 | Anti-D immunoglobulin | S,T | As Licensed |
| 19.2.4 | Diphtheria antitoxin | P,S,T | As Licensed |
| 19.2.5 | Hepatitis B immunoglobulin | S,T | As Licensed |
| 19.2.6 | Human normal immunoglobulin | T | As Licensed |
| 19.2.7 | Snake Venom Antiserum* | P,S,T | a) Soluble/ liquid polyvalent - As Licensed<br>b) Lyophilized polyvalent - As Licensed |

**Snake Venom antiserum also listed in **Section 4.2.12** - Antidotes and Other Substances used in Management of Poisonings/Envenomation – Specific*

**19.3-Vaccines**

a) All the vaccines which are under Universal Immunization Program of India (UIP) will be deemed included in NLEM. Presently, the UIP has BCG, DPT, OPV, measles, Hepatitis B, Japanese encephalitis, Pentavalent Vaccines and Rota virus vaccine.

b) The vaccines, which have been approved by National Technical Advisory Group on Immunization (NTAGI) and planned to be given under UIP, will be deemed to be included as and when listed in UIP. These vaccines are inactivated polio vaccine (IPV) and Measles Rubella (MR).

c) In future, the vaccines which are under consideration, if and when included in UIP, will also be deemed included from the date of inclusion in UIP. These are pneumococcal and HPV vaccines.

**For Universal Immunization**

| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
|---|---|---|---|
| 19.3.1 | BCG vaccine | P,S,T | As licensed |
| 19.3.2 | DPT+ Hib+ Hep B vaccine | P,S,T | As licensed |
| 19.3.3 | DPT vaccine | P,S,T | As licensed |
| 19.3.4 | Hepatitis B vaccine | P,S,T | As licensed |
| 19.3.5 | Japanese encephalitis vaccine | P,S,T | As licensed |

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 19.3.6 | Measles vaccine | P,S,T | As licensed |
| 19.3.7 | Oral poliomyelitis vaccine | P,S,T | As licensed |
| 19.3.8 | Rotavirus vaccine | P,S,T | As licensed |
| 19.3.9 | Tetanus toxoid | P,S,T | As licensed |
| **19.4 - For Specific Group of Individuals** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 19.4.1 | Rabies vaccine | P,S,T | As licensed |
| **Section 20<br>Medicines for Neonatal Care** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 20.1 | Alprostadil | S,T | Injection 0.5 mg/mL |
| 20.2 | Caffeine | S,T | Oral liquid 20 mg/mL<br>Injection 20 mg/mL |
| 20.3 | Surfactant | S,T | Suspension for intratracheal instillation (As licensed) |

# Section 21
# Ophthalmological Medicines

## 21.1-Anti-infective Medicines

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 21.1.1 | Acyclovir* | P,S,T | Ointment 3% |
| 21.1.2 | Ciprofloxacin** | P,S,T | Drops 0.3%<br>Ointment 0.3% |
| 21.1.3 | Natamycin | P,S,T | Drops 5 % |
| 21.1.4 | Povidone iodine*** | P,S,T | Drops 5 % |

## 21.2-Antiinflammatory Medicine

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 21.2.1 | Prednisolone**** | P,S,T | Drops 1 % |

**Acyclovir formulations are also listed in -*
***A.*** *Anti-infective Medicines -Antiviral medicines -Anti-herpes medicines* ***Section 6.6.1.1***
***B.*** *Anti-infective Medicines -Medicines used in the management of HIV -Medicines for treating Opportunistic Infections in People living with HIV* ***Section 6.7.5.1***

********Ciprofloxacin formulations are also listed in -*
***A. Section 6.2.2.3 -*** *Anti-infective Medicines- Antibacterials - Other Antibacterials*
***B. Section 16.2 –*** *Ear, Nose and Throat Medicines*

*********Povidone Iodine Also listed in* ***Section 14.1.5 -*** *Antiseptics and Disinfectants- Antiseptics*

**********Prednisolone formulations are also listed in -*
***A. Section 3.7 -*** *Antiallergics and Medicines used in Anaphylaxis*
***B. Section 7.2.4 -*** *Anti-cancer agents including Immunosuppressives, and Medicines used in Palliative Care – Hormones and anti-hormones used in cancer therapy*
***C. Section 18.1.5 -*** *Hormones, other Endocrine Medicines and Contraceptives- Adrenal Hormones and synthetic substitutes*

| | | | |
|---|---|---|---|
| **21.3- Local Anaesthetic** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 21.3.1 | Proparacaine* | P,S,T | Drops 0.5 % |
| **21.4-Miotics and Antiglaucoma Medicines** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 21.4.1 | Acetazolamide | P,S,T | Tablet 250 mg |
| 21.4.2 | Latanoprost | P,S,T | Drops 0.005 % |
| 21.4.3 | Pilocarpine | P,S,T | Drops 2 %<br>Drops 4 % |
| 21.4.4 | Timolol | P,S,T | Drops 0.25 %<br>Drops 0.5 % |
| **21.5-Mydriatics** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 21.5.1 | Atropine** | P,S,T | Drops 1%<br>Ointment 1% |

***Proparacaine formulations are also listed in listed in **Section 12.1.2** - Diagnostic agents- Ophthalmic Medicines*

****Atropine formulations are also listed in -*
***A. Section 1.3.1** - Medicines used in Anaesthesia -Preoperative medication and sedation for short term procedures*
***B. Section 4.2.1** - Antidotes and Other substances used in Management of poisoning/Envenomation - specific*

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 21.5.2 | Homatropine | P,S,T | Drops 2% |
| 21.5.3 | Phenylephrine | P,S,T | Drops 5 %<br>Drops 10 % |
| 21.5.4 | Tropicamide* | P,S,T | Drops 1 % |
| **21.6-Miscellaneous** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 21.6.1 | Carboxymethyl cellulose | P,S,T | Drops 0.5%<br>Drops 1% |
| 21.6.2 | Hydroxypropyl methylcellulose | T | Injection 2% |
| **Section 22<br>Oxytocics and Antioxytocics** | | | |
| **22.1 - Oxytocics and Abortifacient** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 22.1.1 | Dinoprostone | S,T | Tablet 0.5 mg<br>Gel 0.5 mg |
| 22.1.2 | Methylergometrine | P,S,T | Tablet 0.125 mg<br>Injection 0.2 mg/mL |
| ***Tropicamide formulations are also listed in **Section 12.1.3 -** Diagnostic agents - Ophthalmic Medicines* | | | |

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 22.1.3 | Mifepristone | P,S,T | Tablet 200 mg |
| 22.1.4 | Misoprostol | P,S,T | Tablet 100 mcg<br>Tablet 200 mcg |
| 22.1.5 | Oxytocin | P,S,T | Injection 5 IU/mL<br>Injection 10 IU/mL |
| **22.2 - Medicines used in Preterm Labour** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 22.2.1 | Betamethasone | P,S,T | Injection 4 mg/mL |
| 22.2.2 | Nifedipine | S,T | Tablet 10 mg |
| **Section 23<br>Medicines used in treatment of Psychiatric Disorders** | | | |
| **23.1 - Medicines used in Psychotic Disorders** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 23.1.1 | Clozapine | T | Tablet 25 mg<br>Tablet 50 mg<br>Tablet 100 mg |
| 23.1.2 | Fluphenazine | P,S,T | Injection 25 mg/mL |

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 23.1.3 | Haloperidol* | S,T | Tablet 2 mg<br>Tablet 5 mg<br>Tablet 10 mg<br>Tablet 20 mg<br>Oral liquid 2 mg/5 mL<br>Injection 5 mg/mL |
| 23.1.4 | Risperidone | P,S,T | Tablet 1 mg<br>Tablet 2 mg<br>Tablet 4 mg<br>Oral liquid 1 mg/mL<br>Injection (Long acting) 25 mg<br>Injection (Long acting) 37.5 mg |
| **23.2 - Medicines used in Mood Disorders** | | | |
| **23.2.1 - Medicines used in Depressive Disorders** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 23.2.1.1 | Amitriptyline** | P,S,T | Tablet 10 mg<br>Tablet 25 mg<br>Tablet 50 mg<br>Tablet 75 mg |

***Haloperidol formulations are also listed in **Section 7.4.7 -** Anti-cancer agents including Immunosuppressives, and Medicines used in Palliative are- Medicines used in Palliative Care*

****Amitriptyline formulations are also listed in -*
***A. Section 5.2.5 -** Medicines used in Neurological Disorders - Anti-migraine medicines- For prophylaxis*
***B. Section 7.4.2 -** Anti-cancer agents including Immunosuppressives, and Medicines used in Palliative are- Medicines used in Palliative Care*

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 23.2.1.2 | Escitalopram | P,S,T | Tablet 5 mg<br>Tablet 10 mg<br>Tablet 20 mg |
| 23.2.1.3 | Fluoxetine* | P,S,T | Capsule 10 mg<br>Capsule 20 mg<br>Capsule 40 mg<br>Capsule 60 mg |
| **23.2.2 - Medicines used in Bipolar Disorders** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 23.2.2.1 | Lithium | S,T | Tablet 300 mg |
| 23.2.2.2 | Sodium valproate** | P,S,T | Tablet 200 mg<br>Tablet 300 mg<br>Tablet 500 mg<br>Modified Release -<br>Tablet 300 mg<br>Tablet 500 mg |
| 23.2.2.3 | Carbamazepine*** | P,S,T | Tablet 100 mg<br>Tablet 200 mg<br>Tablet 400 mg<br>Modified Release -<br>Tablet 200 mg<br>Tablet 400 mg<br>Oral liquid 100 mg/5 mL (p) |
| ***Fluoxetine formulations are also listed in -***<br>***A. Section 7.4.6 -*** *Anti-cancer agents including Immunosuppressives, and Medicines used in Palliative are- Medicines used in Palliative Care*<br>***B. Section 7.4.6 -*** *Medicines used in treatment of psychiatric Disorders - Medicines used in obsessive compulsive disorders and panic attacks*<br>******** *Sodium Valproate formulations are also listed in* ***Section 5.1.10 -*** *Medicines used in Neurological Disorders -Anticonvulsants /antiepileptics*<br>*********Carbamazepine formulations are also listed in* ***Section 5.1.1 -*** *Medicines used in Neurological Disorders- Anticonvulsants/antiepileptics* | | | |

| 23.3 - Medicines used in Generalized Anxiety and Sleep Disorders | | | |
|---|---|---|---|
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 23.3.1 | Clonazepam | P,S,T | Tablet 0.25 mg<br>Tablet 0.5 mg<br>Tablet 1 mg |
| 23.3.2 | Zolpidem | P,S,T | Tablet 5 mg<br>Tablet 10 mg |
| **23.4 - Medicines used in Obsessive Compulsive Disorders and Panic attacks** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 23.4.1 | Clomipramine | P,S,T | Capsule 10 mg<br>Capsule 25 mg<br>Capsule 75 mg |
| 23.4.2 | Fluoxetine* | S,T | Capsule 10 mg<br>Capsule 20 mg<br>Capsule 40 mg<br>Capsule 60 mg |

**Fluoxetine formulations are also listed in -*
***A. Section 7.4.6 -*** *Anti-cancer agents including Immunosuppressives, and Medicines used in Palliative are- Medicines used in Palliative Care*
***B. Section 23.2.1.3 –*** *Medicines used in treatment of Psychiatric Disorders - Medicines used in mood disorders - Medicines used in depressive disorders*

| 23.5 – Medicines used in Disorders due to Psychoactive substance abuse | | | |
|---|---|---|---|
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 23.5.1 | Buprenorphine | P,S,T | Tablet (Sub-lingual) 0.4 mg |
| 23.5.2 | Buprenorphine (A) + Naloxone (B) | P,S,T | Tablet (Sub-lingual) 0.4 mg (A) + 0.1 mg (B)<br>Tablet (Sub-lingual) 2 mg (A) + 0.5 mg (B) |
| 23.5.3 | Nicotine (for nicotine replacement therapy) | P,S,T | Oral Dosage forms 2 mg<br>Oral Dosage forms 4 mg |
| **Section 24**<br>**Medicines acting on the Respiratory tract** | | | |
| **24.1 - Antiasthmatic Medicines** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 24.1.1 | Budesonide* | P,S,T | Inhalation (MDI/DPI) 100 mcg/dose<br>Inhalation (MDI/DPI) 200 mcg/dose<br>Respirator solution for use in nebulizer 0.5 mg/mL<br>Respirator solution for use in nebulizer 1 mg/mL |
| ***Budesonide formulations are also listed in **Section 16.1** - Ear, Nose and Throat Medicines* | | | |

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 24.1.2 | Budesonide (A) + Formoterol (B) | P,S,T | Inhalation (MDI/DPI) 100 mcg (A)<br>+ 6 mcg (B)<br>Inhalation (MDI/DPI) 200 mcg (A)<br>+ 6 mcg (B)<br>Inhalation (MDI/DPI) 400 mcg (A)<br>+ 6 mcg (B) |
| 24.1.3 | Hydrocortisone* | P,S,T | Powder for Injection 100 mg<br>Powder for Injection 200 mg |
| 24.1.4 | Ipratropium | P,S,T | Inhalation (MDI/DPI) 20 mcg/dose<br>Respirator solution for use in nebulizer 250 mcg/mL |
| 24.1.5 | Montelukast | S,T | Tablet 4 mg<br>Tablet 5 mg<br>(including chewable tablets)<br>Tablet 10 mg |
| 24.1.6 | Salbutamol | P,S,T | Tablet 2 mg<br>Tablet 4 mg<br>Oral liquid 2 mg/5 mL<br>Inhalation (MDI/DPI*) 100 mcg/dose<br>Respirator Solution (Solution for Nebulizer 5 mg/mL) |

***Hydrocortisone formulations are also listed in -***
***A. Section 3.5 -*** *Antiallergics and Medicines used in Anaphylaxis*
***B. Section 18.1.3 -*** *Hormones, other Endocrine Medicines and Contraceptives- Adrenal hormones and synthetic substitutes*

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 24.1.7 | Tiotropium | P,S,T | Inhalation (MDI) 9 mcg/dose<br>Inhalation (DPI) 18 mcg/dose |
| MDI- Metered Dose Inhaler<br>DPI- Dry Powder Inhaler | | | |
| **Section 25<br>Solutions correcting Water, Electrolyte disturbances and Acid-base disturbances** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 25.1.1 | Glucose* | P,S,T | Injection 5 %<br>Injection 10 %<br>Injection 25 %<br>Injection 50 % |
| 25.1.2 | Glucose(A) + Sodium chloride (B) | P,S,T | Injection 5% (A) + 0.9 % (B) |
| 25.1.3 | Oral rehydration salts** | P,S,T | As licensed |
| 25.1.4 | Potassium chloride | P,S,T | Oral liquid 500 mg/5 mL |
| | | S,T | Injection 150 mg/mL |
| **Glucose formulations are also listed in **Section 18.4.2.1** - Hormones, other Endocrine Medicines and Contraceptives - Medicines used in diabetes mellitus - Medicines used to treat hypoglycemia*<br><br>***Oral rehydration salts are also listed in **Section 17.6.1** - Gastrointestinal Medicines - Medicines used in diarrhea* | | | |

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 25.1.5 | Ringer lactate | P,S,T | Injection (as per IP) |
| 25.1.6 | Sodium bicarbonate | P,S,T | Injection (as per IP) |
| 25.1.7 | Sodium chloride | P,S,T | Injection 0.9% |
| | | S,T | Injection 3% |
| **25.2-Miscellaneous** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 25.2.1 | Water for Injection | P,S,T | Injection |
| **Section 26<br>Vitamins and Minerals** | | | |
| | **Medicine** | **Level of Healthcare** | **Dosage form(s) and strength(s)** |
| 26.1 | Ascorbic acid (Vitamin C) | P,S,T | Tablet 100 mg<br>Tablet 500 mg |
| 26.2 | Calcium carbonate | P,S,T | Tablet 625 mg (equivalent to elemental calcium 250 mg)<br>Tablet 1250 mg (equivalent to elemental calcium 500 mg) |
| 26.3 | Calcium gluconate* | P,S,T | Injection 100 mg/mL |
| 26.4 | Cholecalciferol | P,S,T | Solid oral dosage form 1000 IU<br>Solid oral dosage form 60000 IU<br>Oral liquid 400 IU/mL |
| ***Calcium Gluconate formulations are also listed in **Section 4.2.2** - Antidotes and Other substances used in poisoning/Envenomation – Specific* | | | |

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 26.5 | Pyridoxine | P,S,T | Tablet 10 mg<br>Tablet 50 mg<br>Tablet 100 mg |
| 26.6 | Riboflavin | P,S,T | Tablet 10 mg |
| 26.7 | Thiamine | P,S,T | Tablet 100 mg<br>Injection 100 mg/mL |
| 26.8 | Vitamin A | P,S,T | Capsule/Tablet 50000 IU (including Chewable Tablet)<br>Oral liquid 100000 IU/mL<br>Injection 50000 IU/mL |
| **Section 27<br>Medicines for COVID 19 management** | | | |
| 27.1 | Dexamethasone* | P,S,T | Tablet 0.5 mg<br>Tablet 2 mg<br>Tablet 4 mg<br>Oral liquid 0.5 mg/5 mL (p)<br>Injection 4 mg/mL |
| 27.2 | Enoxaparin** | S,T | Injection 40 mg/ 0.4 mL<br>Injection 60 mg/ 0.6 mL |

***Dexamethasone is also listed in -***
***A. Section 3.4 -** Antiallergics and Medicines used in Anaphylaxis*
***B. Section 7.4.3 -** Anti-cancer agents including Immunosuppressives, and Medicines used in Palliative are- Medicines used in Palliative Care*
***C. Section 18.1.1 -** Hormones, other Endocrine Medicines and Contraceptives - Adrenal hormones and synthetic substitutes*

***Enoxaparin is also listed in -***
***A. Section 8.2.1 -** Medicines affecting Blood - Medicines affecting coagulation*
***B. Section 10.5.4 -** Cardiovascular medicines - Antiplatelet and Antithrombotic Medicines*

| | Medicine | Level of Healthcare | Dosage form(s) and strength(s) |
|---|---|---|---|
| 27.3 | Methylprednisolone * | S,T | Injection 40 mg/mL |
| 27.4 | Paracetamol** | P,S,T | Tablet 500 mg<br>Tablet 650 mg<br>Oral liquid 120 mg/5 mL (p)<br>Oral Liquid 125 mg/5 mL (p)<br>Oral Liquid 250 mg/5 mL (p) |
| 27.5 | Oxygen*** | P,S,T | As licensed for medical purpose |

***Methylprednisolone** *is also listed in* ***Section 18.1.4*** *- Hormones, other Endocrine medicines and Contraceptives- Adrenal Hormones and synthetic substitutes*

****Paracetamol** *is also listed in*
***A. Section 2.1.5*** *- Analgesics, antipyretics, non steroidal anti-inflammatory medicines, medicines used to treat Gout and disease Modifying agents used in Rheumatoid Disorders- Non-opioid analgesics, antipyretics and nonsteroidal anti-inflammatory medicines*
***B. Section 5.2.3*** *- Medicines used in Neurological Disorders-Antimigraine medicines*

***** *Oxygen is also listed in Medicines used in* ***Section 1.1.5*** *- Anaesthesia- General Anaesthetics and Oxygen*

All modified release formulations of same strength such as sustained release, controlled release, extended release, prolonged release etc. are included.

# Chapter-11

# Code of Pharmaceutical Ethics

**Code of Pharmaceutical Ethics: Definition, ethical principles, ethical problem solving, registration, code of ethics for Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath.**

## Definition of Code of Pharmaceutical Ethics:

- The Code of Pharmaceutical Ethics refers to a set of guidelines and principles that govern the behavior of pharmaceutical professionals in their interactions with patients, healthcare providers, and other stakeholders.
- It outlines the standards of conduct and professional practice expected of pharmacists, pharmacy technicians, and other pharmaceutical professionals, and helps to ensure that they act with integrity, competence, and responsibility.

**Ethical problem solving:**

Ethical problem-solving in pharmacy involves a systematic approach to identifying and resolving ethical dilemmas that arise in the course of providing pharmaceutical care. The process typically involves the following steps:

1. Identify the ethical issue: The first step in ethical problem-solving is to identify the ethical issue or dilemma at hand. This may involve analyzing a particular situation, reviewing relevant policies and guidelines, and consulting with colleagues or other experts as needed.

2. Gather information: Once the ethical issue has been identified, the pharmacist should gather all relevant information and data to help understand the problem and evaluate possible solutions.

3. Analyze the ethical issue: The pharmacist should then analyze the ethical issue, taking into account all relevant factors, including patient rights, professional obligations, legal requirements, and any other relevant considerations.

4. Consider possible solutions: Based on the analysis of the ethical issue, the pharmacist should consider possible solutions to the problem. This may involve brainstorming with colleagues, reviewing relevant guidelines and policies, or seeking advice from experts in the field.

5. Evaluate the solutions: The pharmacist should evaluate the potential benefits and risks of each proposed solution, taking into account the interests of all stakeholders, including the patient, other healthcare providers, and the public.

6. Choose and implement the solution: After evaluating the possible solutions, the pharmacist should choose the most appropriate solution and implement it in a timely and effective manner.

7. Monitor and review: Finally, the pharmacist should monitor the situation and review the results of the chosen solution, making any necessary adjustments or modifications as needed.

By following these steps, pharmacists can effectively identify and resolve ethical dilemmas in pharmacy, while ensuring that they provide the highest quality of care to their patients and maintain the highest standards of professional conduct.

## Code of ethics for Pharmacist in relation to his job:

**1) Pharmaceutical services**

- Pharmacy premises (medicine shops) should be registered.
- Emergency medicines and common medicines should be supplied to the patient without any delay

**2) Conduct of pharmacy**

- Error of accidental contamination in the preparation, dispensing and supply of medicines should be checked in a pharmacy.

**3) Handling of prescription**

- A pharmacist should receive a prescription without any comment on it that may cause anxiety to the patient
- No part of the prescription should be changed without the consent of the prescriber. In case of changing the prescription should be referred back to the prescriber.

**4) Handling of drugs**

- A Prescription should always be dispensed correctly and carefully with standard quality drug or excipients. Drugs that have abusive potential should not be supplied to any one.

**5) Apprentice pharmacist**

- Experienced pharmacist should provide all the facilities for practical training of the apprentice pharmacists.
- Until and unless the apprentice proves himself or herself certificate should not be granted to him/her.

## Pharmacists in Relation to his trade:

**1. Price Structure:**

- Prices charged from customers should be fair and in keeping with the quality and quantity of commodity supplied and the labor 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.

**2. Fair Trade Practices:**

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

**3. Purchase of Drugs:**

- Drugs should always be purchased from genuine and reputable sources and a pharmacist should always be on his guard not to aid or abet, directly or indirectly the manufacture, possession, distribution and sale of spurious or sub- standard drugs.

**4. Hawking of Drugs:**

- Hawking of drugs and medicinal should not be encouraged nor should any attempt be made to solicit orders for such substances from door to door.
- `Self-service` method of operating pharmacies and drug - stores should not be used as this practice may lead to the distribution of therapeutic substances without an expert supervision and thus would encourage self- medication, which is highly undesirable.

**5. 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 offer about refund of money.
    b. Misleading, or exaggerated statements or claims.
    c. The word "Cure" in reference to an ailment or symptoms of ill-health.
    d. A guarantee of therapeutic efficacy.
    e. An appeal to fear

## Pharmacists in Relation to his profession:

1. Extend help to fellow pharmacist in emergency need.
2. Should Maintain Standard of the profession.
3. Should try to weed out corruption in profession and society
4. He should not be afraid of bringing or causing a miscreant to be brought to book, may be a member of his own profession.
5. Should have up to date Knowledge of Professional matters 6. Should have fair knowledge of laws related to his profession

## Pharmacists in Relation to his medical profession:

1. **Limitation of Professional Activities:** Pharmacist under no circumstances, take to medical practice i.e. diagnosing drug and prescribing medicines. In emergency he can give first aid to the person. Should not recommend a medical practitioner,
2. **Clandestine Arrangement:** No pharmacist should enter into the secret arrangement and contract with the physician to offer him any commission or any other advantage.
3. **Liaison with Public:** Being a liaison between medical profession and people, a pharmacist will always keep himself updated with the modern development of pharmacy by regular reading of books, magazines etc.

## Pharmacist's Oath:

- At this time, I vow to devote my professional life to the service of all humankind through the profession of pharmacy.
- I will consider the welfare of humanity and relief of human suffering my primary concerns.
- I will apply my knowledge, experience, and skills to the best of my ability to assure optimal drug therapy outcomes for the patients I serve.
- I will keep abreast of developments and maintain professional competency in my profession of pharmacy.
- I will maintain the highest principles of moral, ethical, and legal conduct.
- I will embrace and advocate change in the profession of pharmacy that improves patient care.
- I take these vows voluntarily with the full realization of the responsibility with which I am entrusted by the public.

# Chapter-12

# Medical Termination of Pregnancy Act and Rules

**Medical Termination of Pregnancy Act and Rules – basic understanding/salient features**

## Introduction:

- The medical termination of pregnancy act (MTP Act) is linked with abortion practices. It has been recently amended in the year 2020 and has been in effect since 1971. According to the amendment, the period within which abortion can be done has been increased.
- The abortion can now be done within the period of 20 to 24 weeks. As per the rules under the act of "medical termination of pregnancy" the consent of the women which is considered to be of utmost priority.
- However, in case the pregnancy happens to a girl who is below 18 years of age, in that case the guardians hold the right to decide about aborting the child.
- This law has the objective of protecting the interest of girl children within the society and also giving priority to the opinion of a would-be mother.

## Medical Termination of Pregnancy Act and Rules – basic understanding:

- The Medical Termination of Pregnancy Act (MTP Act) is a legislation enacted by the Indian Parliament in 1971, which allows women to terminate a pregnancy under certain conditions.
- The act permits the termination of pregnancy up to 20 weeks of gestation, but beyond that, it requires the approval of a medical board.

The MTP Act also lays down certain conditions that need to be fulfilled for the termination of pregnancy. These include:

1. **Consent:** The woman's consent is mandatory for the termination of pregnancy.

2. **Reason:** The termination of pregnancy must be carried out for reasons such as the woman's health, her life, contraceptive failure, or rape.
3. **Medical Practitioner:** The termination must be performed by a registered medical practitioner.
4. **Place:** The termination must be carried out in a registered medical facility.
5. **Time:** The termination can only be performed within the first 20 weeks of pregnancy, beyond that, it requires the approval of a medical board.

The MTP Act also lays down guidelines for the establishment of medical facilities for the termination of pregnancy, training and qualification of medical practitioners, and the procedure for the approval of medical boards.

## Salient features of Medical Termination of Pregnancy Act and Rules:

The Medical Termination of Pregnancy Act, 1971 is an Indian law that regulates the conditions under which a pregnancy can be terminated. Here are some of the salient features of the MTP Act, 1971:

1. Legalization of Abortion: The MTP Act legalized abortion in India, subject to certain conditions.
2. Conditions for Abortion: The MTP Act allows for abortion if the pregnancy poses a risk to the physical or mental health of the mother, if there is a risk of the child being born with physical or mental abnormalities, or if the pregnancy is a result of rape or failure of contraception.
3. Time Limit for Abortion: The Act permits abortion up to 20 weeks of pregnancy. However, in certain cases, such as when the woman's life is in danger or in case of fetal abnormalities, abortion can be carried out beyond the 20-week limit.
4. Who can Perform Abortions: The Act permits only registered medical practitioners to perform abortions. In addition, the Act requires that certain qualifications and experience be met by the medical practitioner performing the abortion.
5. Consent: The Act requires that the woman seeking an abortion must give her informed consent, and the consent of the spouse, if married, is also required in certain cases.
6. Confidentiality: The Act ensures confidentiality for women seeking an abortion, and prohibits disclosure of the identity of the woman seeking an abortion, except in certain circumstances.
7. Establishment of Committees: The Act mandates the establishment of committees to oversee the implementation of the law and to ensure that the procedure is being carried out safely and legally.
8. Penalties: The Act provides for penalties for non-compliance with the provisions of the law, including imprisonment and fines.

# Chapter-13

# Role of all the government pharma regulator bodies

**Role of all the government pharma regulator bodies – Central Drugs Standards Control Organization (CDSCO), Indian Pharmacopoeia Commission (IPC)**

## Role of all the government pharma regulator bodies:

- Regulatory authorities act as a guardian that ensures the safety, efficacy and quality of drugs available to the public, to identify the strengths and weaknesses of drug regulation and to propose strategies to improve drug regulation.
- They also play a vital role to ensure and increase regulatory implementation in non-regulated parts of the world for safety of people residing there.

### Major Regulatory Agencies World Wide

Every country has its own regulatory authority, which is responsible to enforce the rules and regulations and issue guidelines for drug development, licensing, registration, manufacturing, marketing and labeling of pharmaceutical products.

| Country | Name of Regulatory Authority |
|---|---|
| USA | Food and Drug Administration (FDA) |
| UK | Medicines and Healthcare Products Regulatory Agency (MHRA) |
| Australia | Therapeutic Goods Administration (TGA) |
| India | Central Drug Standard Control Organization (CDSCO) |

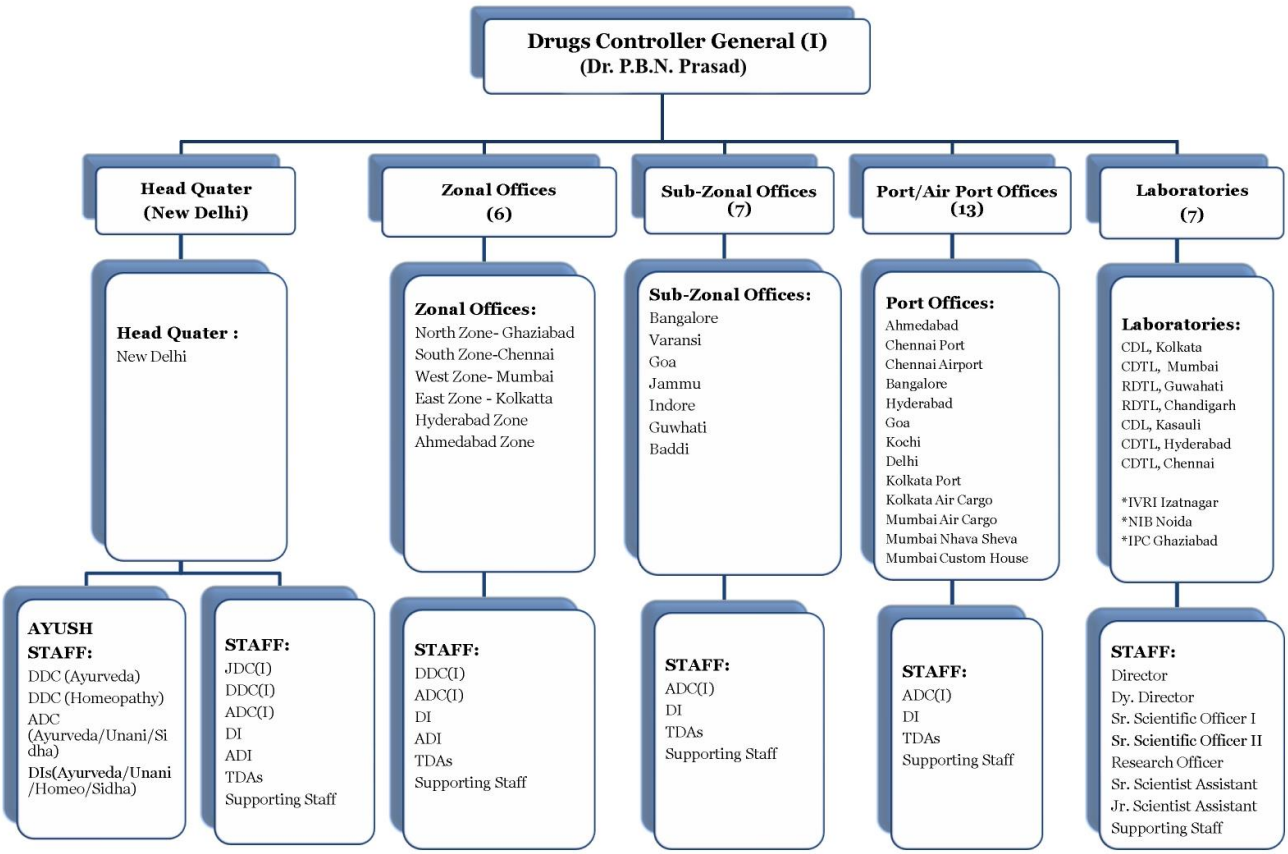
# Central Drugs Standards Control Organization (CDSCO):

- The Central Drugs Standard Control Organization (CDSCO) under Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India is the National Regulatory Authority (NRA) of India. Its headquarter is located at FDA Bhawan, Kotla Road, New Delhi 110002 and also has six zonal offices, four sub zonal offices, thirteen Port offices and seven laboratories spread across the country.
- The Drugs & Cosmetics Act, 1940 and rules 1945 have entrusted various responsibilities to central & state regulators for regulation of drugs & cosmetics.
- It envisages uniform implementation of the provisions of the Act & Rules made there under for ensuring the safety, rights and wellbeing of the patients by regulating the drugs and cosmetics. CDSCO is constantly thriving upon to bring out transparency, accountability and uniformity in its services in order to ensure safety, efficacy and quality of the medical product manufactured, imported and distributed in the country.
- Under the Drugs and Cosmetics Act, CDSCO is responsible for approval of Drugs, Conduct of Clinical Trials, laying down the standards for Drugs, control over the quality of imported Drugs in the country and coordination of the activities of State Drug Control Organizations by providing expert advice with a view of bring about the uniformity in the enforcement of the Drugs and Cosmetics Act.
- Further CDSCO along with state regulators, is jointly responsible for grant of licenses of certain specialized categories of critical Drugs such as blood and blood products, I. V. Fluids, Vaccine and Sera.

**Major functions of CDSCO:**

Regulatory control over the import of drugs, approval of new drugs and clinical trials, meetings of Drugs Consultative Committee (DCC) and Drugs Technical Advisory Board (DTAB), approval of certain licenses as Central License Approving Authority is exercised by the CDSCO headquarters.

# The organization chart:




# Indian Pharmacopoeia Commission (IPC)

### Introduction:

- Indian Pharmacopoeia Commission (IPC) is an autonomous institution of the Ministry of Health and Family Welfare which sets standards for all drugs that are manufactured, sold and consumed in India.
- The set of standards are published under the title Indian Pharmacopoeia (IP) which has been modelled on and historically follows from the British Pharmacopoeia.
- The standards that are in effect since 1 December 2010, are the Indian Pharmacopoeia 2010 (IP 2010).
- The Pharmacopoeia 2014 was released by Health Minister Ghulam Nabi Azad on 4 November 2013.

- The Pharmacopoeia 2018 was released by Secretary, Ministry of Health & Family Welfare, and Government of India.

**Mission**

- To promote public and animal health in India by bringing out authoritative and officially accepted standards for quality of drugs including active pharmaceutical ingredients, excipients and dosage forms, used by health professionals, patients and consumers.

**Vision**

- To promote the highest standards of drugs for use in human and animals within practical limits of the technologies available for manufacture and analysis.

**Objectives**

- To develop comprehensive monographs for drugs to be included in the Indian Pharmacopoeia, including active pharmaceutical ingredients, pharmaceutical aids and dosage forms as well as medical devices and to keep them updated by revision on a regular basis.
- To develop monographs for herbal drugs, both raw drugs and extracts/formulations therefrom.
- To accord priority to monographs of drugs included in the National Essential Medicines List and their dosage forms.
- To take note of the different levels of sophistication in analytical testing/ instrumentation available while framing the monographs.
- To accelerate the process of preparation, certification and distribution of IP Reference Substances, including the related substances, impurities and degradation products.
- To collaborate with pharmacopoeias like the Ph Eur, BP, USP, JP, ChP and International Pharmacopoeia with a view to harmonizing with global standards.
- To review existing monographs periodically with a view to deleting obsolete ones and amending those requiring upgrading /revision.
- To organize educational programs and research activities for spreading and establishing awareness on the need and scope of quality standards for drugs and related articles /materials.
- To publish the National Formulary of India for updating medical practitioners and other healthcare professionals.
- To act as a National Coordination Centre for Pharma-covigilance Programme of India.

# Pharmacopoeia –

### Introduction of Pharmacopoeia:

- Pharmacopoeia has been the authoritative organization working to ensure the consistency and quality of medicines.
  Pharmacopoeia is the formulation of drugs. It is the standard book for preparation of drugs.
  The book is published in a country under the authority of its own government.
  Pharmacopoeia is derived from Greek word

**Pharmakon – Drugs**
**Copoeia – Means to make**

### Type of Pharmacopoeia / List of Pharmacopeia

- We cannot call it a specific type because every country has a own Pharmacopoeia.
- First of all, let's know about our Indian Pharmacopoeia. When did this book become public, Which edition of it is running now?
  - ✓ Indian Pharmacopoeia
  - ✓ British Pharmacopoeia
  - ✓ United States Pharmacopoeia

### Indian Pharmacopoeia:

- The Indian Pharmacopoeia is published by the Indian Pharmacopoeia commission (IPC) on behalf of the ministry of health and family welfare Government of India.
- Bengal Pharmacopoeia 1844 – But this book was not made public, just this name was kept.
  Legal and official book published by IPC-1945.
- Indian Pharmacopoeia Headquarter – Ghaziabad (Uttar Pradesh)
  Indian Pharmacopoeia commission (IPC) regulated by Ministry Of Health And Family Welfare.
- Indian Pharmacopoeia is written in English and official title of monographs given in Latin.
- The Indian Pharmacopoeia is being processed to fulfill the requirement in the Drug And Cosmetics Act 1940 and rules 1945.
  In 1946 the government of India published the Indian Pharmacopoeia list which served as the suppliment to British Pharmacopoeia.
  After publication of list the government of India constituted a parmanent Indian Pharmacopoeia committee in 1948.

The following table describes the publication history of the Indian Pharmacopoeia.

| Edition | Year | Volumes | Addendum/Supplement |
|---|---|---|---|
| 1st Edition | **1955** | – | Supplement 1960 |
| 2nd Edition | **1966** | – | Supplement 1975 |
| 3rd Edition | **1985** | 2 | Addendum 1989 |
| | | | Addendum 1991 |
| 4th Edition | **1996** | 2 | Addendum 2000 |
| | | | Vet Supplement 2000 |
| | | | Addendum 2002 |
| | | | Addendum 2005 |
| 5th Edition | **2007** | 3 | Addendum 2008 |
| 6th Edition | **2010** | 3 | Addendum 2012 |
| 7th Edition | **2014** | 4 | Addendum 2015 |
| | | | Addendum 2016 |
| 8th Edition | **2018** | 4 | Addendum 2019 |
| | | | Addendum 2021 |

9th edition 2022

**Scan To learn about Indian Pharmacopoeia**

# Chapter-14
# Good Regulatory practices

**Good Regulatory practices (documentation, licenses, renewals, e-governance) in Community Pharmacy, Hospital pharmacy, Pharma Manufacturing, Wholesale business, inspections, import, export of drugs and medical devices**

## Good Regulatory practices:

**Introduction:**

- Good Regulatory Practices (GRP) is processes, systems, tools, and methods for improving the quality of regulations that are internationally recognised.
- Before government initiatives are implemented, GRP systematically implements public consultation and stakeholder involvement, as well as impact analysis of government proposals to ensure they are fit for purpose and will achieve the goals set out.

**Objectives:**

- GRP provide a means of establishing sound and effective oversight of medical products as an important part of health system performance and sustainability.
- If consistently and effectively implemented, they can lead to higher quality regulation, improved regulatory decision-making and compliance, increased efficiency of regulatory systems, and better public health outcomes.
- They help to ensure that regulatory systems remain current as technologies and the systems in which they are used continue to evolve.

## Community Pharmacy:

- In community pharmacy, GRP involves ensuring that all licenses and permits are up to date, and that all documentation related to drug dispensing, labeling, and storage is in compliance with local regulations.
- E-governance is used for managing drug dispensing records and renewals of prescriptions. Inspections are conducted regularly to ensure that the pharmacy is in compliance with regulatory standards.

**Documentation for Hospital pharmacy License:**

The documents essential for obtaining a sale license are:

- Constitution of the entity, Memorandum of Association (MOA), Articles of Association (AOA) for a company, partnership deed, LLP agreement in case of partnership and LLP.

- ID proof of partner/director/proprietor.
- Documents related to premises – Copy of ownership documents of property or rental agreement and NOC (No Objection Certificate) from the owner of the rented premises as the case may be.
- Site plan and key plan of the premises.
- Copy of Board resolution permitting obtaining of a license.
- Proof of availability of storage space as cold storage, refrigerator, etc.
- Copy of challan as proof of depositing fee.
- Affidavit regarding non-conviction of proprietor/partner/director and the firm.
- The affidavit from the registered pharmacist/competent person.
- Cover letter with name and designation of the applicant
- Declaration form in a prescribed format
- Applicant's qualification certificate

**For a pharmacist at a retail sale:**

- Proof of qualification
- Registration of local pharmacy council
- Appointment letter

**For a pharmacist at a wholesale sale:**

- Proof of qualification
- Experience certificate
- Appointment letter

**Prerequisites for Obtaining a License**

- **Pharmacist/ Competent Individual:** The pharmacist must be qualified in the case of a retail business. In the case of a wholesale business, the individual must be a graduate with 1-year experience or an undergraduate with 4 years of experience.
- **Space Requirement:** The other important requirement is space, that is the area of the pharmacy/unit. For both wholesale and retail licenses the area of the pharmacy/unit should be

15 square meters. In the case of a retail and medical shop, it should be 10 square meters. The clear height of the sales premises shall be as per the guidelines laid down under the National Building Code of India, 2005.

- **Storage Facility:** The other important requirement is storage facility since some drugs require to be stored in low temperatures, refrigerators and air conditioners are a must.
- **Technical Staff:** The retail pharmacy staff must be experienced with in-depth knowledge. The staff of the wholesale pharmacy must be a graduate with a minimum of 1-year experience or an undergraduate having four years of experience.

**Types of Drug License**

Looking at the definition of "drug", the pharmaceutical business in India requires the following types of licenses:

- **Manufacturing License**– License issued to a business that manufactures drugs inclusive of allopathic/homoeopathy medicines.
- **Sale License** – License issued for the sale of drugs. It has the following bifurcations: – Wholesale Drug License – Retail Drug License
    - **Wholesale License** – A drug wholesaler must obtain a wholesale licence. Wholesale means the sale of the drug to a person/retailer to further sell it.
    - **Retail License** – A retail license is required for the retail sale of drugs. A retail sale means the sale of drugs or cosmetics for the consumption of the end consumer. Retailers can sell it to a dispensary, hospital, educational, medical, or research institute. Retailers engaged in pharmaceuticals, cosmetics, stand-alone pharmacists, ayurvedic shops, etc need this license.
- **Loan License** – License issued to a business that does not own the manufacturing unit but uses the manufacturing facilities of another licensee.
- **Import License** – License is issued to any dealer importing the products for the manufacturing of drugs or is engaged in the business of importing drugs in India.
- **Multi-Drug License** – License issued to businesses that own pharmacies in multiple states with the same name.

**Renewal of license**

- Renewal of Sale license should be made on the application form same as the form submitted during the grant of the new license along with the necessary fee.

- The Fee for the renewal of the license is same as the grant of license. The late fee for the renewal of the license is as follows that is applicable up to six months.

**Late fee for Renewal (Per month)**

- Rs. 500+500 Rs. 1000.00 Rs. 500+500 Rs. 1000.00
- Rs. 250+250 Rs 500..00
- Rs. 250.00
- Rs. 250.00

**Documents Required for Renewal**

a) Copy of last renewal
b) Affidavit of Pharmacist and current rent agreement
c) Address proof of the authorised proprietor/applicant
d) Affidavit of the liable person for day-to-day working and for any violation of drug laws

**Import and Export of Drugs and Medical Devices:**

- GRP in import and export involves compliance with regulatory requirements for the import and export of drugs and medical devices.
- Licenses and permits must be obtained before importing or exporting, and documentation related to import/export procedures, customs clearance, and transportation must be maintained.

**E-Governance of license:**

- E-governance of license refers to the use of electronic systems and technologies to manage the process of issuing, renewing, and revoking licenses by government authorities. This approach replaces traditional paper-based systems with digital platforms that allow for more efficient, transparent, and secure processing of licenses.
- E-governance of license can benefit both the government and the public by reducing administrative costs, improving accuracy and consistency of license data, and increasing access to services. It also allows for greater automation and integration with other government systems, which can improve data sharing and decision-making.
- The process of e-governance of license typically involves the use of online portals, mobile apps, and other digital platforms to allow citizens and businesses to apply for and manage licenses. These platforms may incorporate features such as online payment, document uploading, and real-time status updates.
- Overall, e-governance of license is an important aspect of digital transformation in government, which aims to improve service delivery and make government operations more efficient and transparent.

# Chapter-16

**Blood bank – basic requirements and functions**

## Blood bank:

- A blood bank is a facility that collects, stores, and provides blood for transfusions.
- Blood banks play a crucial role in modern medicine, as they provide a vital resource for patients who require blood transfusions due to medical conditions, surgeries, and accidents.
- Blood banks collect blood donations from volunteer donors, which are then screened, processed, and stored for future use.
- The blood is typically separated into various components, including red blood cells, plasma, and platelets, which can be used to treat different medical conditions.
- Blood banks also maintain a database of blood types and the antibodies present in the donated blood, which helps match blood products with patients in need.
- This helps ensure that patients receive safe and compatible blood transfusions.
- Blood banks may also conduct research into new blood products and transfusion techniques, as well as provide education and training to healthcare professionals and the public on the importance of blood donation and transfusion safety.

## Requirement:

(i) **Space:** The area required for setting up the facility is only 10 square metres, well lighted, clean and preferably air-conditioned.

(ii) **Manpower:** In the present phase no additional staff is required. One of the existing doctors and technicians should be designated for this purpose. They should be trained in the operation of blood storage centres and other basic procedures like storage, grouping, cross- matching and release of blood. The medical officer designated for this purpose will be responsible for overall working of the storage centre.

(iii) **Electricity:** Regular 24 hours supply is essential. Provision of backup Generator is required.

(iv) **Equipment:** Each FRU should have the following.

## Function:

The primary function of a blood bank is to collect, process, test, and store blood and blood products for use in transfusion therapy. Here are some of the specific functions of a blood bank:

1. **Blood collection:** The blood bank collects blood from voluntary blood donors through blood drives or at the blood bank itself. The blood is collected using sterile techniques and appropriate collection equipment.
2. **Blood processing:** Once the blood is collected, it undergoes processing to separate the various components of blood such as red blood cells, white blood cells, platelets, and plasma.
3. **Blood testing:** All donated blood must be tested for various infectious diseases such as HIV, Hepatitis B and C, and syphilis to ensure that the blood is safe for transfusion.
4. **Blood storage:** The blood bank stores the various blood components at appropriate temperatures to maintain their viability and potency.
5. **Blood transfusion:** The blood bank provides blood and blood products to hospitals and medical facilities for transfusion to patients who require them due to various medical conditions such as surgery, trauma, and cancer treatments.
6. **Blood inventory management:** The blood bank maintains an inventory of blood and blood products and ensures that an adequate supply is available to meet the demands of the community.
7. **Donor recruitment and retention:** The blood bank actively promotes blood donation and encourages donors to donate regularly.
8. **Research and development:** The blood bank may conduct research to improve transfusion therapy and develop new blood products to meet the evolving needs of the medical community.

# Chapter-15

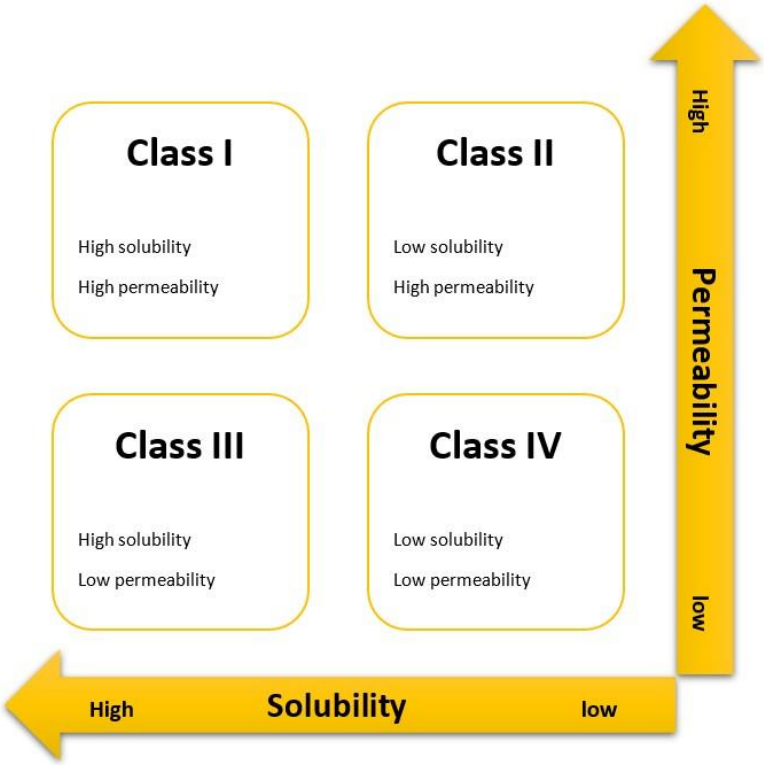
**Introduction to BCS system of classification, Basic concepts of Clinical Trials, ANDA, NDA, New Drug development, Schedule Y. Brand v/s Generic, Trade name concept, Introduction to Patent Law and Intellectual Property Rights, Emergency Use Authorization.**

## Introduction to BCS system of classification:

The Bio pharmaceutics Classification System (BCS) is a scientific framework developed to predict the behavior of a drug product in the human body based on its physicochemical properties.

**The BCS classifies drugs into four categories (BCS Class I to IV) based on their solubility and permeability.**

- BCS Class I drugs are highly soluble and highly permeable, meaning they dissolve readily in the gastrointestinal tract and are easily absorbed into the bloodstream.
  **Examples of BCS Class I drugs include caffeine and ibuprofen.**
- BCS Class II drugs are poorly soluble but highly permeable.
- These drugs may have difficulty dissolving in the gastrointestinal tract, but once absorbed, they can pass through cell membranes easily.
  **Examples of BCS Class II drugs include ketoconazole and danazol.**
- BCS Class III drugs are highly soluble but poorly permeable, meaning they dissolve easily in the gastrointestinal tract but may have difficulty passing through cell membranes.
  **Examples of BCS Class III drugs include atenolol and cimetidine.**
- BCS Class IV drugs are poorly soluble and poorly permeable, meaning they have difficulty dissolving in the gastrointestinal tract and passing through cell membranes.
  **Examples of BCS Class IV drugs include griseofulvin and diazepam.**




## Basic concepts of Clinical Trials:

- Clinical trials are research studies that test how well new medical treatments, devices, or procedures work in humans.
- They are research studies in which people volunteer to help find answers to specific health questions.
- When carefully conducted, they are the safest and fastest way to find new treatments and ways to improve health.

## Basic concepts of clinical trials:

1. Study design: A clinical trial is designed to answer a specific research question or hypothesis. The design of the study determines how the intervention will be tested and how the data will be collected and analyzed.

2. Randomization: Participants in clinical trials are randomly assigned to different groups, such as the treatment group and the control group. Randomization helps to ensure that the groups are similar in terms of important characteristics, such as age, gender, and disease severity, and that any observed differences between the groups are due to the intervention being tested.

3. Blinding: Blinding refers to whether the participants, researchers, and/or data analysts are aware of which group a participant has been assigned to. Blinding helps to prevent bias in the study results.

4. Informed consent: Before participating in a clinical trial, participants must provide informed consent. Informed consent involves providing detailed information about the study, including its risks and benefits, and obtaining the participant's voluntary agreement to participate.

5. Endpoint: An endpoint is a measurable outcome that is used to evaluate the effectiveness of the intervention being tested. Endpoints can be clinical (such as disease progression or death) or surrogate (such as blood pressure or cholesterol levels).

6. Phase: Clinical trials are often conducted in phases.

    - Phase I trials test the safety and tolerability of a new intervention in a small group of healthy volunteers.
    - Phase II trials test the effectiveness and safety of the intervention in a larger group of patients.
    - Phase III trials test the effectiveness and safety of the intervention in an even larger group of patients, and compare the intervention to standard treatment or placebo.
    - Phase IV trials are conducted after the intervention has been approved for use, and evaluate its long-term safety and effectiveness.

## Abbreviated New Drug Application (ANDA):

- An Abbreviated New Drug Application (ANDA) is a type of application that a generic drug manufacturer must submit to the U.S. Food and Drug Administration (FDA) when seeking approval to market and sell a generic version of an existing, FDA-approved brand-name drug.
- A generic drug product is one that is comparable to an innovator drug product in dosage form, strength, route of administration, quality, performance characteristics, and intended use.

## New Drug Application (NDA):

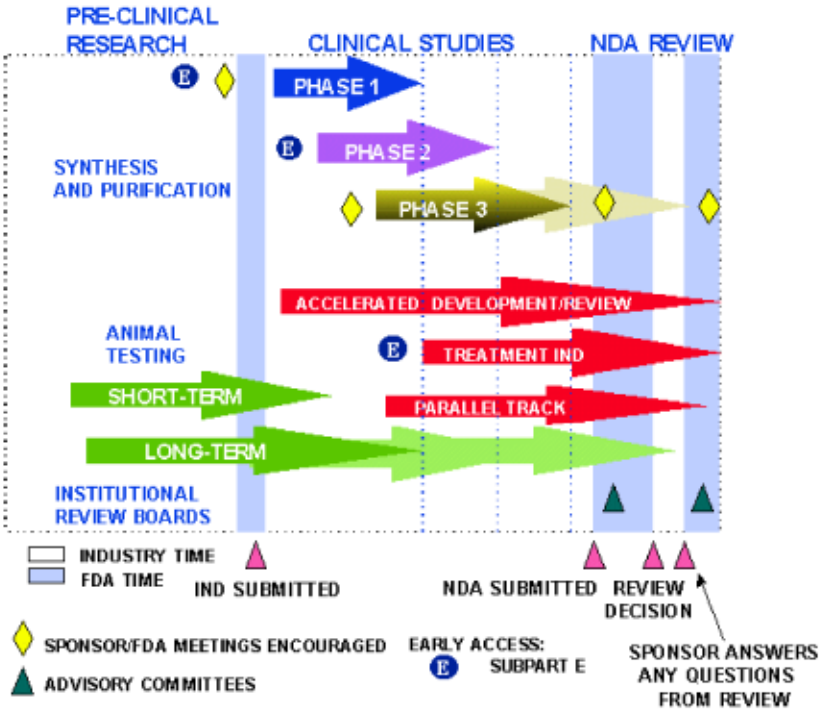
- A New Drug Application (NDA) is a regulatory submission that a pharmaceutical company files with the US Food and Drug Administration (FDA) to seek approval to market a new drug for human use.
- The NDA contains all the data and information about the drug that has been collected during the drug development process, including data from preclinical studies, clinical trials, manufacturing and quality control, and labeling information.
- The NDA serves as a comprehensive document that provides the FDA with all the necessary information to make a decision on whether to approve the drug for marketing.
- The FDA reviews the NDA to determine if the drug is safe and effective for its intended use and if the benefits of the drug outweigh the risks.

**The goals of the NDA are to provide enough information to permit FDA reviewer to reach the following key decisions:**

- Whether the drug is safe and effective in its proposed use(s), and whether the benefits of the drug outweigh the risks.
- Whether the drug's proposed labeling (package insert) is appropriate, and what it should contain.
- Whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity.

## New Drug development:

- New drug development is the process of discovering, designing, and testing new medications for treating specific diseases or health conditions.
- It involves a long and complex process of research and development, which begins with identifying potential drug targets and compounds that can modify those targets.
- The process includes various stages, such as pre-clinical testing, clinical trials, regulatory approval, and post-marketing surveillance.




- New drug development is a complex and time-consuming process, often taking several years or even decades to bring a new drug to market.
- However, it is a critical component of modern medicine, as it allows researchers to identify new treatments for previously untreatable diseases, and improve existing treatments to better meet the needs of patients.

## Schedule Y:

- Schedule Y is a part of the Drugs and Cosmetics Act, 1940 in India. It lays out the guidelines for clinical trials of drugs and medical devices that are conducted in India.
- The purpose of Schedule Y is to ensure that clinical trials are conducted in an ethical and safe manner, while also maintaining the quality of the data obtained from these trials.
- The guidelines laid out in Schedule Y are mandatory for all clinical trials conducted in India, and failure to follow these guidelines can result in legal action.

**The key components of Schedule Y include:**

1. Clinical trial approval process: All clinical trials in India must be approved by the Drug Controller General of India (DCGI) before they can begin. The application for approval must include detailed information about the drug or device being tested, the study design, and the qualifications of the investigators conducting the trial.

2. Informed consent: Before participating in a clinical trial, all participants must provide informed consent. This means that they must be fully informed about the purpose of the trial, the potential risks and benefits, and any other relevant information that may impact their decision to participate.

3. Ethics committee: Each clinical trial must have an independent ethics committee that is responsible for reviewing and approving the study design, ensuring that the trial is conducted in an ethical manner, and protecting the rights and welfare of the participants.

4. Monitoring and reporting: Clinical trials must be monitored throughout the study to ensure that they are being conducted in accordance with the approved study design and ethical guidelines. Any adverse events or other issues must be reported to the DCGI and the ethics committee in a timely manner.

## Brand v/s Generic:

(Credit: Pharmaeducation)

| Features | Generic Drugs | Brand Name Drugs |
|---|---|---|
| **Definition** | A generic drug is an off-patent pharmaceutical product that is manufactured by a pharmaceutical company in the same strength, dosage form, route of administration, safety, quality, performance characteristics, and intended use after expiring the patent of the relevant brand name drug (Innovator drug). | A Brand name drug is a pharmaceutical product that is developed and marketed under a patent or registered trademark by a pharmaceutical company. But it is approved after establishing the drug's safety and effectiveness through animal and clinical (human) studies. Also, brand name drugs known as innovator drugs. |
| **Patents** | Off patent. | Patent protected. |
| **Trade Name** | Marketed under the Generic name of the drug. | Marketed under a unique proprietary name given by the company. |
| **Application** | ANDA required for USFDA approval. | NDA required for USFDA approval. |
| **Manufactured by** | Manufactured by several pharmaceutical companies after patents expiration of the relevant brand name drug. | Developed and manufactured by an innovator company. |
| **Animal & Clinical study** | Not required to perform. | Essential to perform. |
| **Price** | Cheaper. | Costly than generic drugs. |
| **Appearance (Color, Shape, Size)** | Look different from relevant brand name drug. | Unique look as design during product development. |
| **Name variation** | Same Generic drug name in any country. | Same or different brand names in different countries. |
| **Excipients** | May contain the same or altered but acceptable excipients from relevant brand name drug. | Uses acceptable excipients by the innovator company during development. |
| **Availability** | After expiration of patents and exclusivities | From product launch after proving the safety and effectiveness. |
| **Examples** | Paracetamol tablet | Tylenol, Para, NAPA, Mapap, Nortemp, Ofirmev, Acamol. Acetalgin, Calpol, Febridol, Hedanol, Daleron, Depo. |

## Trade name concept:

- A trade name is a term used to refer to a company or business entity's name, often used to identify and distinguish it from other similar entities in the market. It is also sometimes referred to as a "business name" or "doing business as" (DBA) name.
- Trade names can be registered with the government to protect the name from being used by other businesses in the same industry, but this is not always necessary.
- A trade name is a name used by a business or company to identify itself and distinguish it from others in the market. It can be registered or unregistered, and is often used interchangeably with the terms "company name" or "business name".
- Trademark, which is a legal protection for a specific symbol, word, or phrase used to identify a particular brand, a trade name is simply the name that a company uses to conduct business.

## Introduction to Patent Law:

A patent is an exclusive right granted for an invention, which is a product or a process that provides, in general, a new way of doing something, or offers a new technical solution to a problem.

To get a patent, technical information about the invention must be disclosed to the public in a patent application.

- The history of Patent law in India starts from 1911 when the Indian Patents and Designs Act, 1911 was enacted.
- The Patents Act, 1970 is the legislation that till date governs patents in India. It first came into force in 1972.
- The Office of the Controller General of Patents, Designs and Trade Marks or CGPDTM is the body responsible for the Indian Patent Act.
- The Patent Office has its headquarters in Calcutta and has branches in New Delhi, Chennai and Mumbai. The office of the CGPDTM is based in Mumbai. Nagpur hosts the office of the Patent Information System and also the National Institute for Intellectual Property Management.
- The Controller General supervises the Act's administration and also offers advice to the government on related matters.
- The Patents Act has been repeatedly amended in 1999, 2002, 2005, 2006 respectively. These amendments were required to make the Patents Act TRIPS compliant. TRIPS stands for Trade-Related Aspects of Intellectual Property Rights.
- The major amendment in the Patent Act was in 2005, when product patents were extended to all fields of technology like food, drugs, chemicals and microorganisms. The Rules under Patent Act were also amended in 2012, 2013, 2014.

**Salient features of the Patents (Amendment) Act 2005 related to product patents:**

1. Extension of product patent protection to products in sectors of drugs, foods and chemical.
2. Term for protection of product patent shall be for 20 years.
3. Introduction of a provision for enabling grant of compulsory license for export of medicines to countries which have insufficient or no manufacturing capacity; provided such importing country has either granted a compulsory license for import or by notification or otherwise allowed importation of the patented pharmaceutical products from India (in accordance with the Doha Declaration on TRIPS and Public Health)
4. Section 3 (d) regarding patentability.

## Intellectual Property rights:

- Intellectual Property rights mean providing property rights through patents, copyrights and trademarks. Holders of intellectual property rights have a monopoly on the usage of property or items for a specified time period.
- The term intellectual property began to be used in the 19th Century. Only in the 20th century did it become part of the world's legal systems.

**Type of Intellectual Property rights:**

The 4 main types of intellectual property are listed below.

- **Patents** – It is used for protecting new inventions, ideas, or processes. Patent holders need to pay periodic government renewal fees. An approved patent is for a limited time period. Know more about Patents Act in India.
- **Copyrights** – It protects the ideas, examples would be written works, music, art, etc.
- **Trademarks** – It is something that protects the symbols, colors, phrases, sounds, design etc.
- **Trade Secrets** – It may be strategies, systems, formulas, or other confidential information of an organization that provides them a competitive advantage in the market.

## Emergency Use Authorization:

- The Emergency Use Authorization (EUA) authority allows FDA to help strengthen the nation's public health protections against chemical, biological, radiological, and nuclear (CBRN) threats including infectious diseases, by facilitating the availability and use of medical countermeasures (MCMs) needed during public health emergencies.
- EUA allows the FDA to authorize the use of an unapproved medical product, or the use of an approved medical product for an unapproved purpose, during an emergency. This authorization is granted when the FDA determines that the benefits of the product outweigh its known and potential risks, and that there are no adequate, approved, and available alternatives to the product for the intended use.
- EUA can be granted for a variety of medical products, including drugs, vaccines, and diagnostic tests, among others. During the COVID-19 pandemic, EUA has been used extensively to accelerate the development and distribution of COVID-19 vaccines, treatments, and diagnostic tests.

# Chapter-17

# Clinical Establishment Act and Rules – Aspects related to Pharmacy

**Clinical Establishment Act and Rules – Aspects related to Pharmacy**

## Introduction:

- The Clinical Establishments (Registration and Regulation) Act, 2010 has been enacted by the Central Government to provide for registration and regulation of all clinical establishments in the country with a view to prescribe the minimum standards of facilities and services provided by them.
- The Act has taken effect in the four States namely; Arunachal Pradesh, Himachal Pradesh, Mizoram, Sikkim, and all Union Territories except the NCT of Delhi since 1st March, 2012 vide Gazette notification dated 28th February, 2012.
- The States of Uttar Pradesh, Uttarakhand, Rajasthan, Bihar, Jharkhand, Assam and Haryana have adopted the Act under clause (1) of article 252 of the Constitution.
- The Clinical Establishment Rules are a set of guidelines and regulations issued by the government of India to regulate the functioning of clinical establishments across the country.

**Here are some lists of Clinical Establishment Rules:**

1. **The Clinical Establishments (Registration and Regulation) Act, 2010:** This is the primary legislation governing clinical establishments in India. It provides for the registration and regulation of all clinical establishments, including hospitals, clinics, and diagnostic centers.

2. **Minimum Standards of Medical Education and Training Regulations, 2020:** These regulations prescribe the minimum standards for medical education and training in India. They also specify the criteria for the recognition of medical colleges and institutions.

3. **National Accreditation Board for Hospitals & Healthcare Providers (NABH) Standards:** These standards were developed by the Quality Council of India in consultation with various stakeholders, including healthcare providers, experts, and patient groups. They provide a framework for assessing the quality and safety of healthcare services in India.

4. **Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002:** These regulations set out the code of conduct and ethics for medical practitioners in India. They provide guidelines for professional behavior, patient care, and confidentiality.

5. **Consumer Protection Act, 2019:** This is a comprehensive law that protects the rights of consumers in India. It provides for the establishment of consumer courts and the redressal of consumer grievances, including those related to healthcare services.

6. **Drugs and Cosmetics Act, 1940:** This act regulates the import, manufacture, and sale of drugs and cosmetics in India. It sets out the standards for the quality, safety, and efficacy of these products.

7. **Indian Nursing Council Act, 1947:** This act governs the nursing profession in India. It provides for the establishment of the Indian Nursing Council and the regulation of nursing education and practice.

The Clinical Establishment Act, pharmacies are classified as clinical establishments and are required to be registered with the relevant authorities.

The Act lays down certain rules and regulations that pharmacies need to follow to ensure the safety and well-being of their patients. Some of the key aspects related to pharmacy under the Clinical Establishment Act are:

1. **Registration:** The Act mandates that all clinical establishments, including pharmacies, must be registered with the appropriate regulatory authority. The registration process includes providing information on the ownership, location, infrastructure, and services offered by the pharmacy.

2. **Qualifications and Training:** The Act specifies that the pharmacists working in a pharmacy must possess the necessary qualifications and training as per the Pharmacy Council of India guidelines. The pharmacists are also required to renew their registration every five years and undergo regular training to stay updated with the latest developments in the field of pharmacy.

3. **Quality of Drugs and Services:** The Act mandates that pharmacies must ensure the quality of drugs and services offered to patients. This includes proper storage of medicines, maintaining proper records of medicines dispensed, and ensuring that the medicines are not expired or substandard.

4. **Patient Safety:** The Act lays down guidelines for patient safety in pharmacies. This includes ensuring that the prescriptions are legible and accurate, maintaining patient confidentiality, and providing adequate information on the use of medicines to patients.

5. **Grievance Redressal:** The Act provides for a mechanism to address grievances of patients and their relatives. The pharmacy is required to have a complaint redressal mechanism in place, and patients can approach the relevant authorities in case of any complaints.

# Chapter-18

## Biomedical Waste Management Rules 2016

**Biomedical Waste Management Rules 2016 – Basic aspects, and aspects related to pharma manufacture to disposal of pharma / medical waste at homes, pharmacies, and hospitals**

### Biomedical Waste Management Rules 2016:

- Biomedical waste refers to any waste generated during the diagnosis, treatment, or immunization of humans or animals or research activities pertaining thereto or in the production or testing of biological products. Proper management of biomedical waste is crucial to protect the environment and prevent the spread of infections.
- The Biomedical Waste Management Rules 2016 are a set of regulations that provide guidance on the safe handling, segregation, transportation, and disposal of biomedical waste. These rules are applicable to all persons who generate, collect, store, transport, treat, dispose of or handle biomedical waste in any form.

**Basic Aspects of Biomedical Waste Management Rules 2016:**

1. Segregation: Biomedical waste should be segregated at the point of generation into different color-coded containers as per the type of waste. For example, yellow for anatomical waste, red for infectious waste, blue for glassware, and white for waste sharps.

2. Storage: Biomedical waste should be stored in leak-proof and puncture-resistant containers that are properly labeled and securely fastened. The containers should be kept in a separate area designated for biomedical waste storage.

3. Transportation: Biomedical waste should be transported in closed vehicles with appropriate markings indicating the type of waste being transported.

4. Treatment and Disposal: Biomedical waste should be treated and disposed of in an environmentally sound manner as per the guidelines provided in the rules. The treatment and disposal methods may include autoclaving, incineration, microwave treatment, chemical disinfection, or any other method approved by the regulatory authority.

**Aspects Related to Pharma Manufacture to Disposal of Pharma / Medical Waste:**

Pharmaceutical manufacturing facilities generate a significant amount of biomedical waste. The waste generated may include expired or unused drugs, contaminated packaging, and production-related waste.

1. Segregation: Pharmaceutical waste should be segregated from other types of biomedical waste and stored separately in dedicated containers.
2. Disposal: Pharmaceutical waste should be disposed of by incineration or through authorized recyclers or collectors. The waste should not be disposed of in open landfills or dumped in water bodies.
3. Reverse Logistics: The pharmaceutical industry must establish a system for the collection and disposal of unused and expired medicines. The system must ensure the safe and secure transport of the waste to the designated disposal facility.

**Pharmacies:**

Pharmacies generate a significant amount of pharmaceutical waste in the form of expired or unused medicines, packaging material, and syringes.

1. Segregation: Pharmaceutical waste should be segregated from other types of waste and stored separately in designated containers.
2. Disposal: Pharmaceutical waste should be disposed of by incineration or through authorized recyclers or collectors. The waste should not be disposed of in open landfills or dumped in water bodies.

**Hospitals:**

Hospitals generate a large volume of biomedical waste in the form of sharps, infectious waste, and anatomical waste.

1. **Segregation:** Biomedical waste should be segregated at the point of generation into different color-coded containers as per the type of waste.
2. **Storage:** Biomedical waste should be stored in designated areas that are secure, inaccessible to unauthorized persons, and equipped with appropriate safety measures.
3. **Transportation:** Biomedical waste should be transported in closed vehicles with appropriate markings indicating the type of waste being transported.
4. **Treatment and Disposal:** Biomedical waste should be treated and disposed of in an environmentally sound manner as per the guidelines provided in the rules.
5. **Home Care:** Patients who generate biomedical waste at home, such as used syringes or bandages, should be provided with clear instructions on how to store and dispose of the waste. The waste should be stored in puncture-resistant containers and disposed of through authorized collectors or recyclers.

# Chapter-19

**Bioethics - Basic concepts, history and principles. Brief overview of ICMR's National Ethical Guidelines for Biomedical and Health Research involving human participants**

## Introduction

Bioethics is an interdisciplinary field of study that examines the ethical, social, and legal implications of biomedical research, healthcare delivery, and healthcare policy.

Bioethics is concerned with questions of right and wrong in healthcare, and it seeks to provide ethical guidance to healthcare professionals, researchers, and policymakers.

### Basic Concepts of Bioethics

- Bioethics is concerned with the ethical dilemmas that arise in the practice of medicine and biomedical research.
- These dilemmas may involve questions of patient autonomy, beneficence, non-maleficence, justice, and the sanctity of life. Patient autonomy refers to the right of patients to make decisions about their own healthcare, based on their own values and preferences.
- Beneficence refers to the duty of healthcare professionals to promote the well-being of their patients. Non-maleficence refers to the duty of healthcare professionals to avoid harming their patients. Justice refers to the fair distribution of healthcare resources, while the sanctity of life refers to the value that is placed on human life.

### History of Bioethics

- Bioethics emerged as a distinct field of study in the late 1960s and early 1970s, as a response to a series of high-profile ethical controversies in the fields of medicine and biomedical research.
- One of the most well-known of these controversies was the Tuskegee syphilis study, in which African American men with syphilis were left untreated so that researchers could study the natural progression of the disease.
- This study was widely criticized for its unethical treatment of vulnerable populations and led to the development of the Belmont Report, which established the ethical principles of respect for persons, beneficence, and justice.

### Principles of Bioethics

The principles of bioethics are based on the ethical considerations that arise in the practice of medicine and biomedical research. These principles include:

1. Respect for Persons: This principle requires that individuals be treated with dignity and respect, and that their autonomy and freedom of choice be respected.
2. Beneficence: This principle requires that healthcare professionals act in the best interests of their patients and that they seek to promote the well-being of their patients.
3. Non-Maleficence: This principle requires that healthcare professionals avoid causing harm to their patients and that they take steps to prevent harm.
4. Justice: This principle requires that healthcare resources be distributed fairly and that all individuals have access to the healthcare they need.

## Indian Council of Medical Research (ICMR):

- The Indian Council of Medical Research (ICMR) is the premier medical research organization in India, and it has developed the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants.
- These guidelines provide guidance to researchers, ethics committees, and other stakeholders on the ethical conduct of biomedical and health research involving human participants.
- The guidelines are based on the principles of respect for persons, beneficence, non-maleficence, and justice, and they provide guidance on a wide range of issues, including informed consent, confidentiality, risk assessment, and the use of vulnerable populations in research.

### Informed Consent

- One of the most important principles in biomedical and health research involving human participants is informed consent.
- Informed consent is a process by which participants are provided with information about the research, including its purpose, methods, risks, and benefits, and are given the opportunity to ask questions and make an informed decision about whether or not to participate.
- The ICMR guidelines emphasize the importance of obtaining informed consent from participants in biomedical and health research.
- They require that the consent process be conducted in a language that the participant understands, and that the information be provided in a way that is easy to understand.

### Confidentiality and Privacy

- Another important principle in biomedical and health research involving human participants is confidentiality and privacy.
- The ICMR guidelines require that participants' confidentiality and privacy be protected throughout the research process.
- Researchers must take steps to ensure that participants' personal information is kept confidential and that their privacy is respected.

- They must also obtain participants' permission before using their personal information for any other purpose.

**Risk Assessment**

- Risk assessment is an important component of biomedical and health research involving human participants.
- The ICMR guidelines require that researchers conduct a risk assessment before initiating any research involving human participants.
- The risk assessment should consider the potential risks and benefits of the research, as well as the vulnerability of the participants.
- Researchers must take steps to minimize the risks to participants and ensure that the potential benefits of the research outweigh the potential risks.

**Use of Vulnerable Populations**

- The ICMR guidelines recognize that certain populations are vulnerable and may require special protections in biomedical and health research.
- These vulnerable populations include children, pregnant women, mentally ill individuals, and individuals with disabilities.
- The guidelines require that researchers take extra care when conducting research with these populations and that they obtain informed consent from the participants and their guardians, if applicable.

**Ethics Committee Review**

- The ICMR guidelines require that all research involving human participants be reviewed and approved by an ethics committee.
- The ethics committee is responsible for ensuring that the research is conducted in an ethical and responsible manner and that the rights and welfare of the participants are protected.
- The committee must include members from diverse backgrounds, including medical professionals, social scientists, legal experts, and community representatives.

# Chapter-20

## Introduction to the Consumer Protection Act

### Consumer Protection Act

- The Consumer Protection Act, implemented in 1986, gives easy and fast compensation to consumer grievances. It safeguards and encourages consumers to speak against insufficiency and flaws in goods and services.
- If traders and manufacturers practice any illegal trade, this act protects their rights as a consumer. The primary motivation of this forum is to bestow aid to both the parties and eliminate lengthy lawsuits.
- This Protection Act covers all goods and services of all public, private, or cooperative sectors, except those exempted by the central government.
- The act provides a platform for a consumer where they can file their complaint, and the forum takes action against the concerned supplier and compensation is granted to the consumer for the hassle he/she has encountered.

### Consumer Rights and Responsibilities:

**The Rights of the Consumer**

- **Right to Safety-** Before buying, a consumer can insist on the quality and guarantee of the goods. They should ideally purchase a certified product like ISI or AGMARK.
- **Right to Choose-** Consumer should have the right to choose from a variety of goods and in a competitive price.
- **Right to be informed-** The buyers should be informed with all the necessary details of the product, make her/him act wise, and change the buying decision.
- **Right to Consumer Education-** Consumer should be aware of his/her rights and avoid exploitation. Ignorance can cost them more.
- **Right to be heard-** This means the consumer will get due attention to express their grievances at a suitable forum.
- **Right to seek compensation-** The defines that the consumer has the right to seek redress against unfair and inhumane practices or exploitation of the consumer.

**The Responsibilities of the Consumer**

- **Responsibility to be aware –** A consumer has to be mindful of the safety and quality of products and services before purchasing.
- **Responsibility to think independently**– Consumer should be well concerned about what they want and need and therefore make independent choices.
- **Responsibility to speak out-** Buyer should be fearless to speak out their grievances and tell traders what they exactly want
- **Responsibility to complain-** It is the consumer's responsibility to express and file a complaint about their dissatisfaction with goods or services in a sincere and fair manner.
- **Responsibility to be an Ethical Consumer-** They should be fair and not engage themselves with any deceptive practice.

## How to File a Complaint?

- Within two years of purchasing the product or services, the complaint should be filled.
- In the complaint, the consumer should mention the details of the problem. This can be an exchange or replacement of the product, compensation for mental or physical torture. However, the declaration needs to be reasonable.
- All the relevant receipts, bills should be kept and attached to the complaint letter.
- A written complaint should be then sent to the consumer forum via email, registered post, fax or hand-delivered. Acknowledgement is important and should not be forgotten to receive.
- The complaint can be in any preferred language.
- The hiring of a lawyer not required.
- All the documents sent and received should be kept.

# Chapter-21

## Introduction to the Consumer Protection Act

- Medical devices are defined by the World Health Organization (WHO) as any instrument, apparatus, machine, software, implant, reagent, material or other similar or related article intended for use in the diagnosis, treatment, or prevention of disease or other medical conditions.
- Medical devices can vary in complexity and function, from simple tools like thermometers to complex machinery like MRI machines.

Medical devices are typically categorized into four classes, based on their level of risk to patients and users:

1. Class I: Low-risk devices, such as elastic bandages, surgical instruments, and examination gloves.
2. Class II: Moderate-risk devices, such as X-ray machines, infusion pumps, and surgical drapes.
3. Class III: High-risk devices, such as heart valves, implantable pacemakers, and breast implants.
4. Class IV: Very high-risk devices, such as deep brain stimulators and artificial pancreas systems.

**Basic Aspects Related to Manufacture and Sale of Medical Devices**

- **Regulatory Compliance -** Medical devices are regulated by various government agencies such as the US Food and Drug Administration (FDA), the European Medicines Agency (EMA), and the Japanese Pharmaceuticals and Medical Devices Agency (PMDA). Manufacturers of medical devices must comply with the regulations set forth by these agencies to ensure the safety and efficacy of their products.
- **Design and Development -** Medical devices must be designed and developed in a way that ensures their safety and effectiveness. This includes conducting clinical trials, performing risk assessments, and adhering to quality control standards.
- **Manufacturing -** Medical devices must be manufactured in a controlled environment that meets Good Manufacturing Practices (GMP) to ensure their quality and safety. The manufacturing process should be documented and validated to ensure consistency and reliability of the final product.
- **Labeling and Instructions for Use -** Medical devices must be labeled with clear instructions for use and warnings about potential risks. The labeling should include the name and address of the manufacturer, the intended use of the device, and any necessary precautions or warnings.

- **Post-Market Surveillance -** Manufacturers of medical devices must monitor their products' performance after they have been sold to the market. This includes monitoring adverse events and taking appropriate action to address any safety concerns that arise.
- **Marketing and Sales -** Medical devices must be marketed and sold in a way that is consistent with their intended use and in compliance with regulatory requirements. Manufacturers must ensure that their marketing materials are truthful and not misleading and that their sales representatives are properly trained and educated about the products they are selling.