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

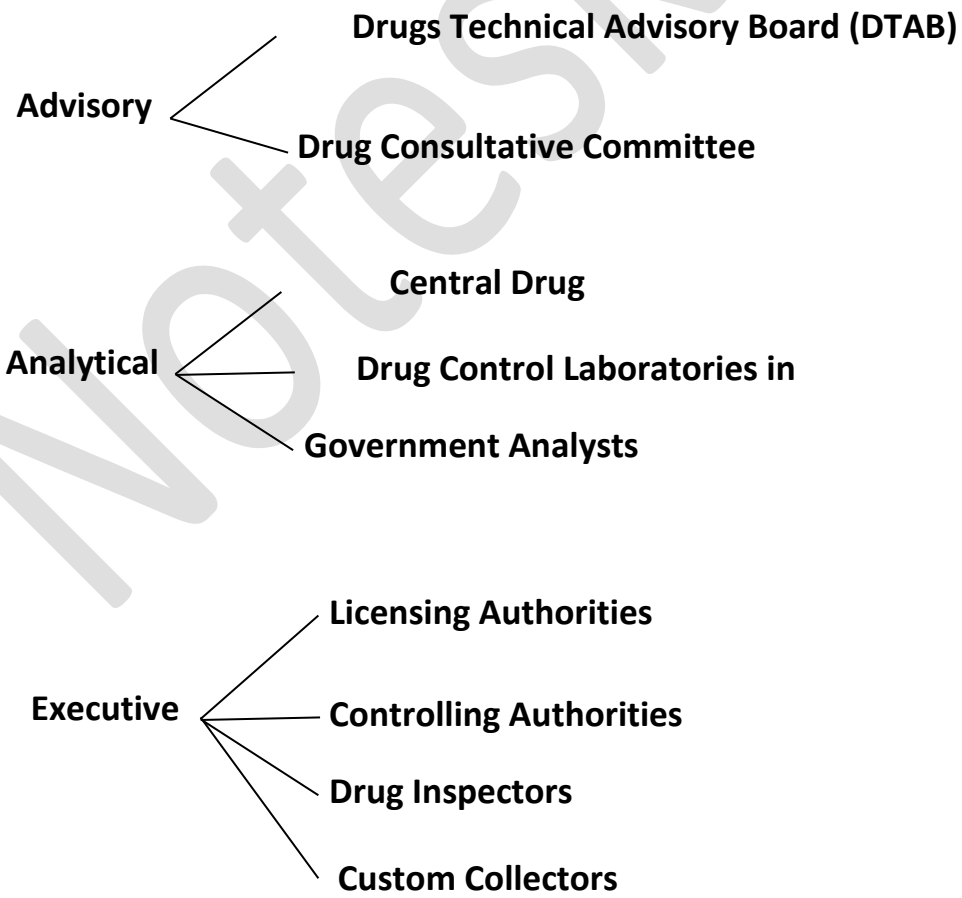
i. Imparted formulations in finished form
ii. Preparations for veterinary use
iii. Preparations for export.
iv. Vitamins / tonics | Cough preparations) antacids | laxatives in liquid oral forms / unit dose forms.
v. Physician's samples, pack sizes of dosage forms af for retail sale to hospitals.
vi.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