THE DRUG AND COSMETIC ACT, 1940 AND RULES, 1945

By

Mr. Sohansinh Vaghela

Assistant Professor,

SIPS, Gandhinagar

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ACTS

Chapters of the act

Chapter I: Introduction & Definitions

Chapter II: DTAB, DCC, CDL

Chapter III: Import of drugs & Cosmetics

Chapter IV: Manufacture, Sale & distribution of drugs & cosmetics

Chapter IVA: Provisions relating to Ayurvedic, Siddha & Unani drugs.

Chapter V: Miscellaneous

LIST OF AMENDING ACTS

LIST OF AMENDING ACTS AND ADAPTATION ORDERS -------- (correct, improve)

1. The Drugs (Amendment) Act, 1955
2. The Drugs (Amendment) Act, 1960
3. The Drugs (Amendment) Act, 1962
4. The Drugs and Cosmetics (Amendment) Act, 1964
5. The Drugs and Cosmetics (Amendment) Act, 1972
6. The Drugs and Cosmetics (Amendment) Act, 1982
7. The Drugs and Cosmetics (Amendment) Act, 1995
8. The Drugs and cosmetics (Amendment) Act, 2008

OBJECTIVES

- To regulate the **import, manufacture, distribution and sale** of drugs & cosmetics through licensing.
- Manufacture, distribution and sale of drugs and cosmetics by **qualified persons only**.
- To prevent **substandard** in drugs.
- To regulate the manufacture and sale of **Ayurveda, Siddha and Unani drugs.**
- To establish **Drugs Technical Advisory Board(DTAB)** and **Drugs Consultative Committees(DCC)** for Allopathic and allied drugs and cosmetics.

DEFINITIONS

- Drug
- Cosmetics
- Misbranded Drug
- Adulterated Drug
- Spurious Drug
- Manufacture

DEFINITIONS

Drugs :

- All medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation (suppression) or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes.
- Such substance (other than food) intended to affect the structure or any other function of the human body or intended to be used for destruction of vermin or insects which cause disease in the human beings or animals.
- All the substances intended for use as components of drug including empty gelatin capsule and,
- Such devices intended for internal or external use in diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals.

DEFINITIONS

DEFINITIONS

Cosmetic:

Any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic.

DEFINITIONS

Ayurvedic, Siddha, or Unani drug:

- Includes all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, and manufactured exclusively in accordance with the formulae described in, the authoritative books of Ayurveda, Siddha and Unani systems of medicine, specified in the First Schedule.

DEFINITIONS

Misbranded drugs :

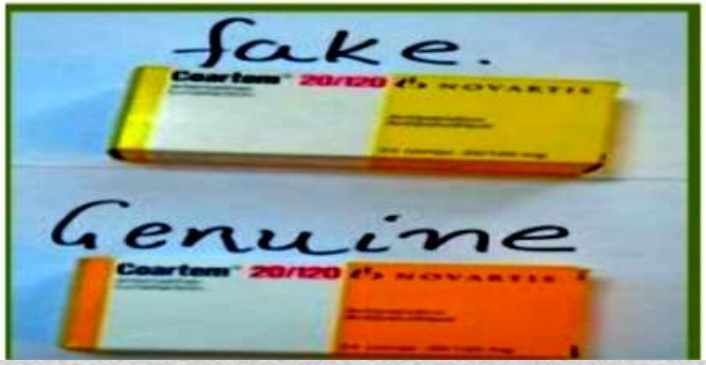
a) if it is so **coloured, coated, powdered or polished** that damage is concealed or if it is made to appear of **better or greater therapeutic** value than it really is; or

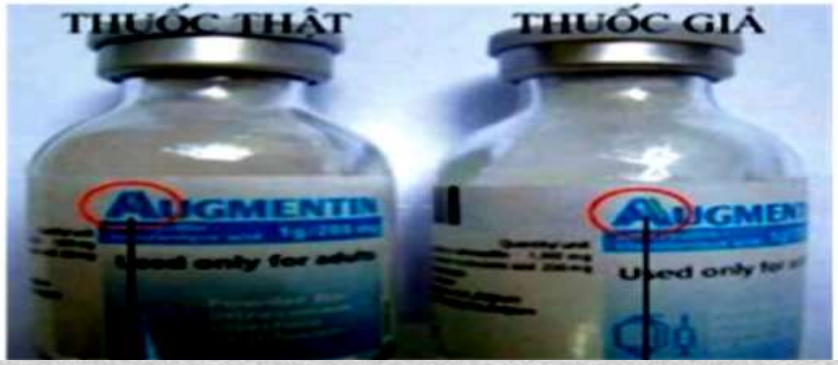
b) if it is **not labelled** in the prescribed manner.

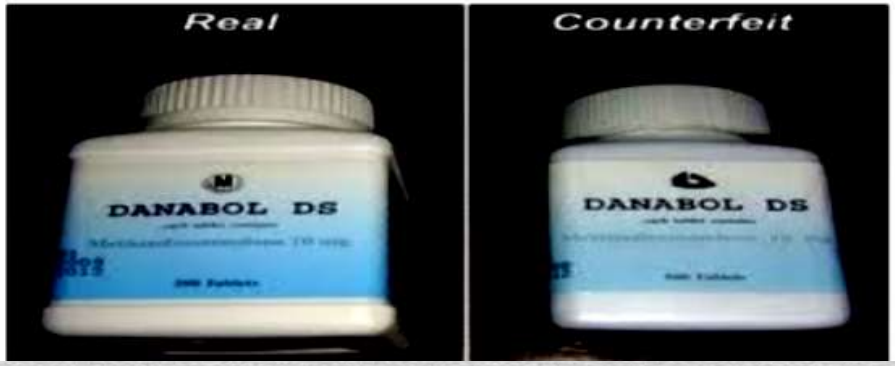
c) if its label or container or anything accompanying the drug bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular.

DEFINITIONS

Misbranded drugs :







DEFINITIONS

Adulterated drug :

a) if it consists, in whole or in part, of any **filthy, putrid (dirty)** or **decomposed** substance; or

b) if it has been prepared, packed or stored under **insanitary conditions** whereby it may have been contaminated with filth or whereby it may have been rendered **injurious to health**; or

c) if its container is composed in whole or in part, of any **poisonous or deleterious substance** which may render the contents injurious to health.

d) If it bears or contains, a colour other than prescribed which may be used for the purpose of colouring only or

e) If any substance mixed with it so as to reduce its quality or strength.

- E.g. supply of cheap cottonseed oil in stead of olive oil

DEFINITIONS

Spurious drugs : (fake)

a) If it is imported under a name which belongs to another drug; or
b) if it is an imitation of, or a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug
c) If the label or container of which bears the name of an individual or company purporting to be the manufacturing of drug, which individual or company is fictitious or does not exists.
d) If it has been substituted wholly or in part by another drug or substance;
e) If it purports to be the product of a mfg of whom it is not truly a product.

- e.g. when methamphetamine is sold as cocaine

DEFINITIONS

Manufacture :

In relation to any drug or cosmetic, it includes any process or part of a process for **making, altering, ornamenting, finishing, packing, labelling, breaking up or otherwise treating or adopting** any drug or cosmetic with a view to its sale or distribution but does not include the compounding or dispensing of any drug, or the packing of any drug or cosmetic, in the ordinary course of retail business.

DEFINITIONS

New Drug

a) A new substance of chemical, biological or biotechnological origin; in bulk or prepared dosage form; used for prevention, diagnosis, or treatment of disease in man or animal; which, except during local clinical trials, has not been used in the country to any significant extent; and which, except during local clinical trials, has not been recognized in the country as effective and safe for the proposed claims;

b) A drug already approved by the licensing authority mentioned in certain claims, which is now proposed to be marketed with modified or new claims, namely, indications, dosage forms (including sustained release dosage form) and route of administration;

DEFINITIONS

(c) A fixed dose combination of two or more drugs, individually approved earlier for certain claims, which are now proposed to be combined for the first time in a fixed ratio, or if the ratio of ingredients in an already marketed combination is proposed to be changed, with certain claims, viz. indications, dosage form (including sustained release dosage form) and route of administration

Administration of the Acts and Rules

For efficient administration of the acts and rules, the following agencies have been provided:

- **Advisory**
  - Drugs Technical Advisory Board (DTAB)
  - Drugs Consultative Committee
- **Analytical**
  - Central Drugs Laboratory
  - Drugs Control Laboratories in States
  - Government Analysis
- **Executive**
  - Licensing Authorities
  - Controlling Authorities
  - Drugs Inspectors
  - Customs Collectors

D-TAB

- Under the provision of the act the central Government appoints the drugs Technical Advisory Board to advice the central and state Government on technical matters arising out of the administration of this act, and to carry out the other function assigned to it by this act.
- Constituted by Central Government to advise the Central and State Governments on technical matters arising out of administrations of the Act
- It consists of 18 members of whom; 8 are ex-officio, 5 nominated and 5 elected members.

Constitution of D-TAB

Ex-officio members

1. Director General of Health Sciences (Chairman)
2. Drugs Controller of India
3. Director, Central Drugs Laboratory Calcutta
4. Director Central Research Institute, Kasauli
5. Director Indian Vetenary Research Institute, Izantnagar
6. President, Pharmacy Council of India
7. President, Medical Council of India
8. Director, Central Drug Research Institute, Lucknow.

Nominated Members

1. Two persons nominated by central Government from amongst persons who are in charge of drugs control in states.
2. One person from Pharma. Industry nominated by the Central Govt.
3. Two Government Analysts, nominated by Central Government.

Constitution of D-TAB

Elected Members

1. A teacher in pharmacy or pharma. chemistry or pharmacognosy on the staff of an Indian university or an affiliated college, elected by the Executive Committee of PCI.
2. A teacher in medicine or therapeutics on the staff of an Indian University or an affiliated College, elected by the Executive Committee of PCI
3. One Pharmacologist elected by the Governing body of ICMR
4. One person elected by council of Central Medical Education
5. One person elected by Council of IPA.

- The nominated and elected members hold the office for three years but are eligible for renomination and re-election.
- The Central Govt. appoints a Secretary, provides clerical & other staff to board.
- The board may appoint sub-committees and may appoint persons who are not board members either temporarily or for some period not exceeding 3 years.

Drugs Consultative Committee(DCC)

Drugs Consultative Committee(DCC):

- It is also an **advisory body** constituted by central government.
  - to advice the central and state governments and the Drug Technical Advisory Board on any matter to secure uniformity throughout India in the administration of this act.
- Constitution:
  1. Two representatives of the **Central Government nominated by central government**
  2. One representative of each **State Government nominated by concerned Government**
- There is separate ‘ The ayurvedic, siddha and unani drugs consultative committee constituted under the act.
- The Drugs Consultative Committee shall **meet when required**
- Has power to regulate its own procedure.

The Central Drugs Laboratory

- Provides for the establishment of a Central Drugs Laboratory under the control of a director appointed by Central Government.
- The Laboratory established in Calcutta has been entrusted with the following functions
  - To analyse or test samples of drugs or cosmetics sent to it by the cosmetics collectors or courts.
  - To carry out such other duties entrusted to it by the Central Govt. or with its permission, by State Govt., after consultation with DTAB.

The Central Drugs Laboratory (CDL)

Established in **Calcutta**, under the control of a director appointed by the Central Government.

Functions:

- **Analysis or test** of samples of drugs/cosmetics sent by the custom collectors or courts.
- Analytical **Q.C.** of the imported samples.
- Collection, storage and distribution of **internal standards.**
- Preparation of **reference standards** and their maintenance.
- Maintenance of **microbial cultures.**
- **Any other duties** entrusted by Central Government.
- Acting as an **appellate authority** in matter of disputes.

Product	Laboratory
Sera, serum proteins injection, Vaccines, Toxins, Antigens, Anti-toxins, Sterilized surgical ligature & suture, Bacteriophages	Central Research Institute, Kasauli,
vaccines, toxoids & diagnostic antigens,for Vetenary Use	Vetenary Research Institute, Izantnagar
oral poliomyelitis vaccines	Pasteur Institute of India., Coonoor.,
homeopathic medicines	Homeopathic Pharmacopoeial Lab. Ghaziabad.
Condoms	Central Pharmacopoeial Lab. Gaziabad.
Human blood and human blood products including components to test of HIV antibodies	(a)National Inst. of Communicable Disease, (b)Department of Microbiology, Delhi. (c)National Institute of Virology, Pune

The Central Drugs Laboratory (CDL)

Dispatch of samples for test or analysis.

1. Samples for test or analysis under subsection (4) of Section 25 of the Act shall be sent by registered post in a sealed packet, enclosed, together with a memorandum in Form 1, in an outer cover addressed to the Director.
2. The packet as well as the outer cover, shall be marked with a distinguishing number.
3. A copy of the memorandum in Form 1 and a specimen impression of the seal used to seal the packet shall be sent separately by registered post to the Director.

The Central Drugs Laboratory (CDL)

- Recording of condition of seals: On receipt of the packet, it shall be opened by an officer authorized in writing in that behalf by the Director who shall record the condition of the seal on the packet.
- Report of result of test or analysis: After test or analysis the result of the test or analysis, together with full protocols of the tests applied, shall be supplied forthwith to the sender in Form 2.
- Fees: The fees for test and analysis shall be specified in Schedule B.
- Signature of certificates: Certificates issued under these Rules by the Laboratory shall be signed by the Director or by an officer authorized by the Central Government by notification in the official Gazette to sign such certificates.

The Central Drugs Laboratory (CDL)

Drug control laboratories in state:

- In Gujarat three laboratories established which collect, analyzed and report the various sample of the drugs and food.

1. Baroda: Established in 1959.
2. Bhuj: Established in 1979.
3. Rajkot: Established in 1983

Function:

- Testing of drug sample
- Analysis of food sample
- Analysis of excise sample

- The laboratory has the following division:-

1. Pharmaceutical Chemistry Division
2. Immunology Division
3. Pharmacology Division
4. Pharmacognocy Division
5. Food Division
6. Ayurvedic Division

Government analyst

Qualification of government analysist

1. A graduate in medicine or science or pharmacy or pharm. chemistry of a recognized University, with at least 5 years of experience in the testing of drugs in a lab. under the control of (a) Govt. Analyst (b) Head of an institution or approved testing laboratory
2. A PG in medicine or science or pharmacy or pharm. chemistry of a recognized University, with at least 3 years of experience in the testing of drugs in a laboratory under the control of a) Govt. Analyst b) Head of an institution or approved testing laboratory
3. Associate ship diploma of the Institution of Chemist, India, with "Analysis of drugs & Pharmaceuticals" as one of the subject with not less than 3 years of experience, in the testing of drugs in a laboratory under the control of as mentioned in 1&2.

Government analyst

Government Analyst:

- Means An relation to Ayurvedic, Siddha or Unani drugs a person appointed by central or state govt. under section 33-F
- An relation to any other drugs or cosmetics a person appointed by central or state govt. under section 20

Duties of Government Analyst:

- Analyse or test samples of drugs/cosmetics sent to him by inspectors or other persons under the act and to furnish reports of the results of test or analysis.
- Forward to Government from time to time, reports giving the results of analysis works and research with a view to their publication at the discretion of Government.

Government analyst

Procedure

- On receipt of package of sample from an Inspector the Government Analyst should compare the seals on the package with the specimen seals and note its condition. On completion of test, reports in triplicate together with full protocols of the tests or analysis should be sent to the Investigator.
- Government Analyst has to submit a report in form 1 and unless full protocols are supplied, the report cannot be regarded as conclusive evidence.

Drug Inspector (DI)

Drug Inspector

- A person to be appointed as a Drug Inspector should have no financial interest in the import, manufacture or sale of the drug or cosmetics,
- Drug Inspector is a Public Servant under sec 21 of Indian panel code. analyst has to submit a report in form 1 and unless full protocols are supplied, the report cannot be regarded as conclusive evidence.

Drug Inspector (DI)

Qualifications for DI

- For appointment as DI, person must have a degree in Pharmacy/Pharmaceutical Chemistry/Medicine with specialization in Clinical Pharmacology/Microbiology from a recognized University;
- For inspection of manufacture of substances in Schedule c, the DI must have
- 1) at least 18 months experience in manufacture of at least one of the substance specified in schedule C
- 2) at least 18 month experience in testing one of the item in schedule C
- 3) gained experience of NLT 3 yrs. in inspection of firms manufacturing any of the substances of Schedule C during their tenure as services as DI

Drug Inspector (DI)

Power of DI:

A. Inspect:

- any premises where in any drug or cosmetic is being manufactured.
- any premises where in any drug or cosmetic is being sold, or stocked or exhibited or offered for sale, or distributed ;

B. Take samples of any drug or cosmetic:

- which is being manufactured or being sold or is stocked or exhibited or offered for sale, or is being distributed
- from any person who is in the course of conveying, delivering or preparing to deliver such drug or cosmetic to a purchaser or a consignee.

Drug Inspector (DI)

Power of DI:

At all reasonable times with necessary assistance

- search any person, in connection with an offence relating to manufacture sale or distribution has been, or is being, committed; or
- stop and search any vehicle, vessel, or other conveyance which, he has reason to believe, is being used for carrying any drug or cosmetic in respect of which an offence has been, or is being, committed,
- order in writing the person in possession of the drug or cosmetic not to dispose of any stock that of for a specified period not exceeding 20 days or, unless the alleged offence is such that the defect may be removed by the possessor of the drug or cosmetic, seize the stock of such drug or cosmetic and any substance or article by means of which the offence has been ,or is being, committed

Drug Inspector (DI)

Power of DI:

- examine any record, register, document or any other material object with any person or in any place mentioned above and seize the same if it is likely to furnish the evidence as an offence
- require any person to produce any record, register, or other document relating require any person to produce any record, register, or other document relating to the manufacture for sale or for distribution of any drug or cosmetic n respect to which an offence has been committed
- Exercise such other powers as may be necessary for carrying out the purposes of the Acts or Rules.

Duties of Drug Inspectors (DI)

In relation to sale of drugs and cosmetics:

1) To inspect at least once a year all establishments licensed for sale of drugs in the area assigned to him and to satisfy himself whether the conditions of the licenses are observed or not
2) If he thinks necessary to obtain and send samples of imported drugs and cosmetics for test or analysis, which are being sold or stocked in contravention of the provisions of this Act
3) To investigate any complaint made in writing to him
4) To institute prosecutions in case of the breach of the Act and Rules
5) To maintain the records relating to all inspections and actions taken by him and to submit copies of such records to the controlling authority
6) To make inquiries and inspections regarding the sale of drugs in contravention of the Act
7) To detain the imported packages, if he suspects to contain drugs the import of which is prohibited

Duties of Drug Inspectors (DI)

In relation to manufacture of drugs and cosmetics:

1) To inspect at least once a year all premises licensed for manufacture of drugs in the area assigned to him and to satisfy himself whether the conditions of the licenses and provisions of the Act and Rules are observed or not
2) To inspect premises licensed for mfg. of drugs specified in Schedule C and C(l) and to observe process of manufacture, means employed for standardization and testing of drugs, storage conditions, qualifications of technical staff employed and all other details of construction, location, administration of establishment etc. which are likely to affect potency or purity of product.
3) To send after each inspection, a detailed report of inspection to controlling authority with details of conditions of licence and provisions of the Act and Rules being observed and those not observed.
4) To take samples of drugs mfg. on premises and send them for test or analysis
5) To check all records and registers required to be maintained under rules.
6) To institute prosecutions for breaches of Act

Procedure of Inspectors

- An Inspector taking any samples must pay its fair price & may require written acknowledgement for the same. If price tendered is refused or when Inspector seizes any stock of any drug or cosmetic, he should issue the receipt for the same in prescribed form. (Form 16)
- He should inform the concerned person, the purpose of taking the sample in form 17 & divide the sample to four parts In his presence. Each portion is then sealed & suitably marked. The person from whom the sample is taken must also be allowed to add his mark of seal on the packet. If sample taken from a manufacturing premises, it should be divided to three portions only.
- If the sample if made into small volume is likely to deteriorate, Inspector can take three or more containers when necessary after suitably marking it.

Procedure of Inspectors

- One portion of sample is to be restored to the person, second part send to Government analyst and third one is preserved for production before the court, if required & fourth is sent to warrantor if any.
- Inspector should sent sample to Government Analyst by registered post or by hand in sealed packet enclosed together with memorandum in Form 18 in an outer cover addressed to Government analyst.
- If the confiscated drug is not of standard quality, it should be reported to court accordingly & court may order destruction of drug under the supervision of Inspector in presence of such authority that the court may prescribe.
- If confiscated drug is of standard quality, Inspector may report court accordingly and court may order sale of drugs by public auction to any party holding a requisite license.

Procedure of Inspectors

- Any record, register or any other document sized by the Inspector should be returned to the persons from whom they seized or who produce the same within period of 20 days of such seizure or produce.
- When an Inspector seizes any record, register or document, or any other material object, he should as soon as inform the same to the judicial magistrate & take his orders to the custody thereof.
- Every person for time being in charge of any premises where any drug or cosmetic is mfg. or is kept for sale or distribution, on being required by the Inspector is legally bound to disclose to the inspector the place where drug or cosmetic is being manufactured or kept.
- Wilfully obstructing the Inspector or refusing to provide any record or register is punishable with imprisonment up to three years, or with fine or both.

Controlling Authority

All inspectors at central and state level are under their control.

Qualifications:

- He is a graduate in Pharmacy/Pharmaceutical chemistry/Medicine with specialization in Clinical pharmacology or Microbiology from a University established in India
- He has experience in mfg or testing of drugs or enforcement of the provisions of the Act for a minimum period of 5 yrs. (The requirement of academic qualification is not applicable to inspectors and Government Analysts appointed before 12th Apr 1989.)

Licensing Authorities

- Any application for the grand or renewal of license for the import, manufacture, sale, distribution etc. of any drug or cosmetic is to be made to the LA. Drug Controller, India has been notified as Central License Approving authority.

Qualifications:

- He should be graduate in Pharmacy/Pharmaceutical Chemistry/ Medicine with specialization in Clinical Pharmacology/Microbiology from a recognized University; &
- He has experienced in manufacture or testing of drugs or enforcement of the provisions of act for a minimum period of 5 years.

Licensing Authorities

Licensing Authority

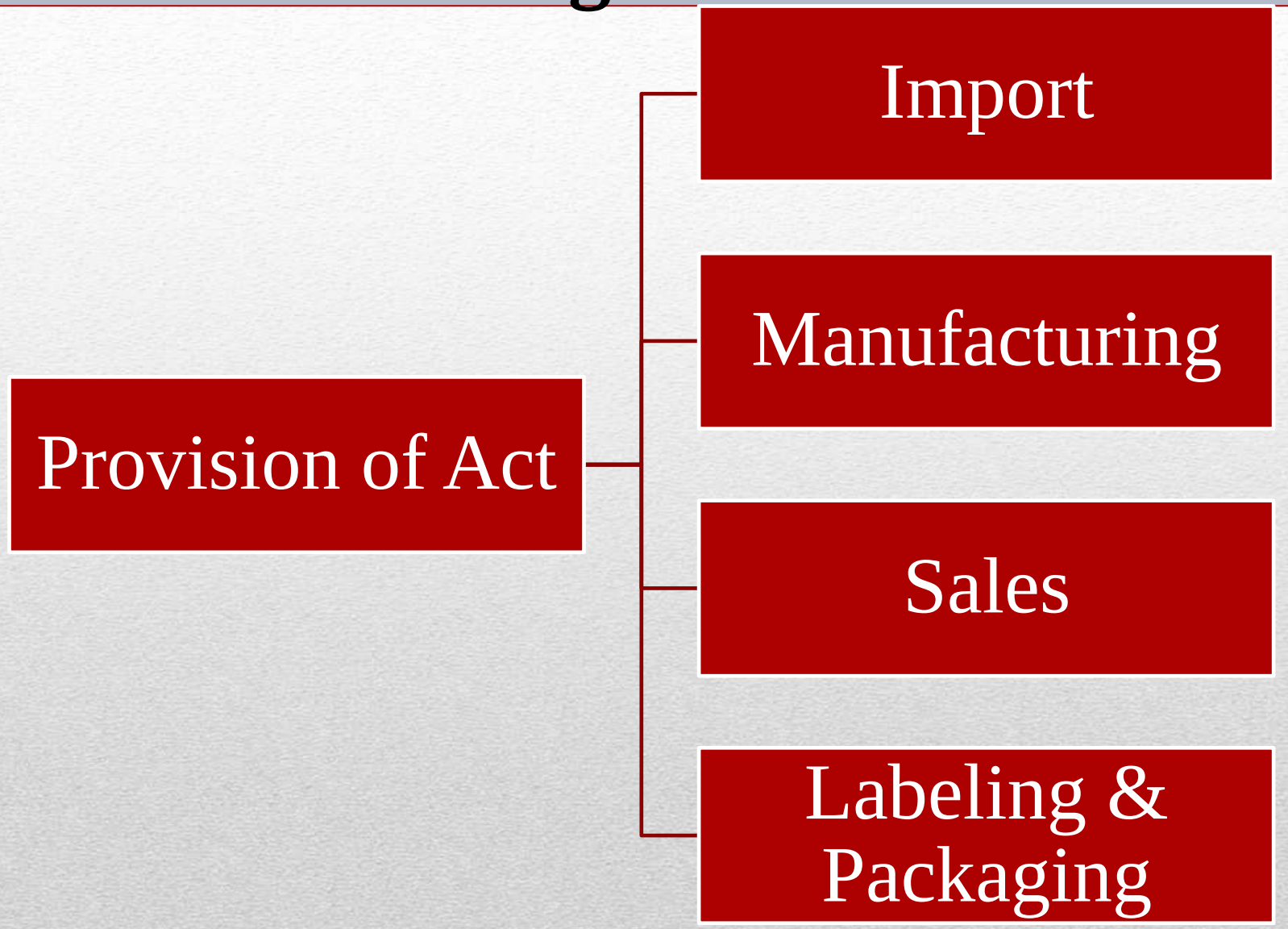
- **State Govt.:**
  - Each State Govt. employs Licensing Authority to issue license for manufacture, sale, distribution of drugs / cosmetics within the state. They can Issue / refuse license/Cancel or suspend license
  - Central Govt. appoints licensing authority to issue license for import of drugs
  - **Drugs controller of India is central license approving authority**

Licensing Authorities

Duties:

1. to inspect all establishments licensed for the sale of drugs within the area assigned to him;
2. to satisfy himself that the conditions of the licence are being observed;
3. to procure and send for test or analysis, if necessary, imported packages.
4. to investigate any complaint.
5. to maintain a record of all inspections made and action taken by him in the performance of his duties,
6. to make such enquiries and inspections as may be necessary to detect the sale of drugs in contravention to the Act;

Licensing Authorities



Drug Import

- For the purpose of import, which is deemed to be the process of a bringing a material from a place outside India to a place in India, a drug are classified below:

A) Drug whose import is prohibited

B) Drug which may be imported under license or permit

C) Drug which can be imported without license

Drug Import

Classes of drugs prohibited to import

- **Misbranded** drugs
- Drugs of **substandard quality**
- Drugs claiming to cure diseases specified in **Sch-J**
- **Adulterated** drugs
- **Spurious** drugs
- Drugs whose manufacture, sale/distribution are **prohibited in original country**, except for the purpose of test, examination and analysis.
- **Patent/Proprietary** medicines whose true formula is not disclosed.

Drug Import

Classes of drugs Import 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

Drug Import

Import of the biological drugs(C/C1)

Conditions to be fulfilled:

1. Licensee must have adequate **facility for the storage.**
2. Licensee must maintain a **record of the sale.**
3. Licensee must **allow an inspector to inspect** premises and to check the records.
4. Licensee must **furnish the sample** to the authority.
5. Licensee must not sell drugs from which sample is withdrawn and he is advised **not to sale, and recall the batch** from the market.

Drug Import

Import of the Schedule-X drugs (Narcotic & Psychotropic drugs):
Conditions to be fulfilled:

1. Licensee must have adequate **storage facility.**
2. Applicant must be **reputable** in the occupation, trade or business.
3. The license **granted even** before should **not be suspended or cancelled.**
4. The licensee has **not been convicted any offence** under the Drugs and Cosmetics Act or Narcotic and Psychotropic Substances Act.

Drug Import

Drugs Imported for examination, test or analysis

Conditions to be fulfilled:

1. License is necessary under form-11
2. Must use imported drugs **only for said purpose** and at the place specified in the license.
3. Must keep the **record** with respect to quantities, name of the manufacturer and date of import.
4. Must **allow an inspector** to inspect the premises and check the records.

Drug Import

Drugs imported for personal use

Conditions to be fulfilled:

- **Up to 100 average doses** may be imported **without any permit**, provided it is part of passenger's luggage.(articles)
- More than 100 doses imported with license.
  - Apply on form no.-12-A,12-B
- Drugs must be **bonafide personal use.**
- Drugs must be **declared** to the custom collectors if so directed.

Drug Import

Import of drugs without license

- Substances **not used for medicinal purpose**
- 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

Drug Import

Import of new drug

- No new drugs are allowed to imported without the sanction of the licensing authority.
- The importer of new drug when applying for permission, shall produce all documentary evidence & other evidences relating to its standards, standards of quality & purity, strength, and such other information including the clinical trials; to the licensing authority.

Drug Import

Import of new drug

- No new drugs are allowed to imported without the sanction of the licensing authority.
- The importer of new drug when applying for permission, shall produce all documentary evidence & other evidences relating to its standards, standards of quality & purity, strength, and such other information including the clinical trials; to the licensing authority.

Cosmetic Import

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

Drug Import

Places through which the drugs are imported

The import of drug in India is allowed only through following places.

By Sea: Mumbai, Chennai, Kolkata, Cochin Vishakhapattanam & Nhava sheva

By Air: Delhi, Mumbai, Chennai, Kolkatta, Ahmedabad & Hyderabad

By Rail:

- Ferozpure cantt & Amritsar RIY station (for drugs coming from pakistan)
- Ranaghat, Bongaon & Mahiassan (for drugs coming from Bangladesh)
- Raxaul (for drugs coming from Nepal)

Drug Import: Offences & Penalties

Offences	Penalties
Import of spurious OR adulterated drug OR drug which involves risk to human beings or animals OR drug not having therapeutic values	a) 3 years imprisonment and 5000 Rs. fine on first conviction b) 5 years imprisonment OR 10000 Rs. fine OR both for subsequent conviction
Contravention of the provision	a) 6 months imprisonment OR 500 Rs. fine OR both for first conviction b) 1 year imprisonment OR 1000 Rs. fine for subsequent offence

MANUFACTURE

Manufacture

- Manufacture of drug is a totally controlled process and drug can be manufactured and under license subject to following :

1. Infrastructure facilities
2. Technical Manpower
3. Analytical Laboratories
4. Records
5. Inspection and sampling of drug

Manufacture

Kind of manufacturing License:

For the manufacturing of drugs the following categories of licenses can be granted.

Manufacturing Licence for

1. Manufacture of Sch-C and C1 drug
2. Manufacture of Sch-X drugs
3. Manufacture of other than in Sch X and Sch-C/C1
4. Loan license
5. Drug meant for examination , test or analysis
6. Repackaging license

Manufacture

Prohibition of manufacture

1. Drug not of standard quality or **misbranded, adulterated or spurious.**
2. **Patent or Proprietary** medicine
3. Drugs in **Sch-J**
4. **Risky** to human beings or animals
5. Drugs **without therapeutic value**
6. Preparation containing **cyclamates**

Manufacture

Manuf. of drugs those in Schedule- C/C1(Biological)

Conditions:

- Drugs must be issued in previously **sterilized sealed glass** or suitable container
- Containers should comply with **Sch-F**
- Some classes tested for **aerobic & anaerobic microorganism**. eg. Sera ,Insulin, Pituitary hormones.
- Serum tested for **abnormal toxicity**
- Parenteral in doses of 10 ml or more should be tested for freedom from **Pyrogens**
- Separate lab. for **culture** & manipulation of **spore bearing Pathogens**
- **Test for sterility** should be carried out.

Manufacture

Manufacture of Sch-X drugs (Narcotic & Psychotropic drugs)

Conditions:

- **Accounts of all transactions** regarding manuf. Should be maintained in serially.(Preserved for 5 years)
- Have to sent **invoice of sale** to licensing authority every 3 months
- Store drugs in **direct custody of responsible person.**
- Preparation must be labeled with XRx
- Marketed in packings **not exceeding**
  - 100 unit dose –Tablets/Capsules
  - 300 ml- Oral liquid
  - 5 ml - Injection

Manufacture

Manuf. of drugs **other than** in Sch- C/C1 and X

Conditions:

- Premises should comply with **schedule 'M'**
- Adequate **facility for testing**, separate from manufacturing
- Adequate **storage facility**
- **Records** maintained for at least 2 years from date of Exp.
- Should provide **sample to authority**
- Furnish **data of stability**
- Maintain the **inspection book**
- Maintain **reference samples** from each batch

Manufacture

Loan License

Definition:

- A person (applicant) who does not have his own arrangements(factory) for manufacture but who wish to manufacturing facilities **owned by another licensee**. Such licenses are called Loan licenses.

Loan licenses are issued for:

1) Drugs other than specified in C/C1 & X.
2) Drugs specified in Schedule-C/C1

Manufacture

Loan License

Conditions:

1. Application must be supported by parent firm.
2. Drugs inspector inspect the premises of parent firm & assess the spare capacity.
3. Loan licensee is required to test each batch of raw material & finished products.
4. Record of testing should be maintained for 5 years, or 2 years in case of expiry dated drugs.
5. If the licence of the parent firm is cancelled/suspended the loan licensee will also be deemed to be suspended or cancelled.
6. Patent or proprietary medicines should contains the constituents in therapeutic/prophylactic quantities.
7. Patent medicines should be safe for use in the context of vehicles & additives.
8. The ingredients & their quantities must have therapeutic justification.
9. The production must be supervised by competent person of loan licence

Repackaging license

Definition:

- Process of **breaking up** any drug from a bulk container into small packages and labeling with a view to their sale and distribution.
- Repackaging of drugs is granted of drugs other than Schdule-C/C1 and X.

Repackaging license

Conditions:

1. Adequate space & equipments should be provided.
2. Repacking must be supervised by competent person.
3. Adequate arrangement for analysis of raw materials & repacked drug.
4. Maintain records of analysis for at least 3 years from date of manufacture, 3 months for expiry dated drugs.
5. Adequate space for storage of drugs.
6. Licensee should allow an inspector to inspect premises, records & take sample of drugs.
7. Licensee should be displayed on the premises.
8. Factory premises must comply with condition prescribed in Sch.-M
9. If any change in competent staff immediately informs to authority.

Penalties related to Manufacture

OFFENCES	PENALTIES
Manufacture of any spurious drugs OR adulterated drugs cause Death	imprisonment not less than 5 Year which may be extend to life imprisonment and not less than 10,OOORs. fine 2-6 years imprisonment & Rs.10000 fine on subsequent conviction
Manufacture of adulterated drugs- not cause death	1-3 years imprisonment and Rs.5000 fine 2-6 years imprisonment & Rs.10000 fine on subsequent conviction
Manuf. of contravention provisions	Imprisonment from 1-2 years with time

Penalties related to Manufacture

OFFENCES	PENALTIES
Person who do not keep record OR disclose information,	Imprisonment up to 1 year & Rs.1000 fine
Manufacturer who gives a false warranty, that drugs do not contravene any provision of the Act	Imprisonment up to 1 year & Rs.500 fine or both

Manufacture of cosmetics

- Prohibited for the following classes of drug:
  - Misbranded or spurious cosmetics and of substandard quality
  - Cosmetics containing hexachlorophene or mercury compounds
  - Cosmetics containing color which contain more than-
    - 2 ppm of arsenic, 20 ppm of lead, 100 ppm of heavy metals
- Eye preparations containing coal-tar color
- List of cosmetics
- Skin Powders, Skin Powder For Infants, Tooth Powder, Tooth Paste, Skin Creams, Hair Oils, Shampoo-soap-based, Shampoo-synthetic Detergent Based, Hair Cream

Penalties related to Cosmetic Manufacture

OFFENCES	PENALTIES
Manufacture of spurious cosmetics	3 years imprisonment & fine.
Contravention of the provision	1 year imprisonment & Rs. 2000 fine

Sale of Drugs

Sale of Drugs

1. Classes of drugs prohibited to be sold
2. Wholesale of biological (C/CI) drugs
3. Wholesale of other than those specified in C/CI and X
4. Wholesale of Sch-X drugs
5. Retail sale
   I. General licences
   II. Restricted licences
6. Offences & Penalties

Sale of Drugs

1. Classes of drugs prohibited to be sold

- Misbranded, spurious, adulterated and drugs not of standard quality Patent/Proprietary drugs with undisclosed formula
- Sch-J drugs
- Expired drugs.
- Drugs used for consumption by government schemes such as E.S.I.S., Armed force.
- Physician's samples
- Drugs Manufactured/Imported In Contravention of The Provisions of The Act.

Sale of Drugs

2. Wholesale of biological (C/CI)

Conditions:

1. Adequate premises, which should not be less than Equipped with the facilities for the proper storage of the drugs.
2. Licensee should take precautions while storage
3. The drug should be sold only to those persons who are licensed to retail them.
4. Premises should be in the charge of the competent person —who is register pharmacist OR who has passed the matriculation examination with four years experience in dealing with drug.
5. For any additional category to sell, licensee should obtain the permission.

Sale of Drugs

Exemption: It does not apply to the sale of drugs to-

- Hospital institute
- Medical institute
- Educational institute
- Research institute
- Government authorities

6. Record of the purchases and sales should be maintained under following headings:
   - Date of purchases and sales
   - Names/addresses of firms from whom purchased and persons to whom sold.
   - Names, quantities and batch no. of drugs
   - Names of the manufacturers.
   - Records should be preserved for 3 years from the date of sale.
7. Licence should be displayed on premises

Sale of Drugs

3. Wholesale of other than those specified in C/CI and X

Condition:

1. all the conditions (no.1-7) as discussed above in part(c).
2. The licensee should comply with the provision of the drugs and cosmetics act-1940 and rules there under.
3. The compounding is made by or under the direct and personal supervision of a qualified person.

Sale of Drugs

4. Wholesale of Sch.- X

Condition:

1. all the conditions (no.1-7) as discussed above in part(c) and 8-9 of part (d) are also applicable to sch-X
2. The licensee should forward to the licensing authority copies of the invoices of sale made to the retail dealers.

Sale of Drugs

5. Retail sale

- Two licences are issued
  1. General licences
  2. Restricted licences
- General licences are granted to persons who have premises for the business & who engaged the services of qualify persons to supervise the sale & do compounding & dispensing.
- Issue for following category:
  - Other than those specified in sch.-c/cl & x
  - For drugs specified in sch.-c/c1
  - For sch.-x drugs

Sale of Drugs

Conditions

1. The licensee must have adequate premises 10 M2 equipped with facility for storage.
2. Requirement prescribed to run pharmacy as per sch. N
3. All register & records should be prevented for 2 years.
4. Licensee must allow an inspector to inspect the premises register & records.
5. If any changes in qualified staff report to the licensing authority.
6. Precaution should be taken for the storage of sch. c/cl drug.
7. The licence should be displayed at prominent place.
8. Maintain the inspection book.

Sale of Drugs

Conditions

9. Drug should be sold only to license holder.
10. Drug should be purchased from license manufacturer.
11. Do not stock & sell expired dated drug.
12. No drug intended for physician sample central govt. health scheme.
13. Veterinary product stored separately & labeled with "NOT FOR HUMAN USE".
14. If drug dispensed after compounding it shall be recorded in prescription register.

Thank You