All About Drug and Cosmetics Act, 1940

By Nisha Singla

The Drug and Cosmetics Act, 1940 was enacted by the Department of Health under the Ministry of Health and Family Welfare after receiving the assent of the Governor General on April 10, 1940 and came into force on April 1, 1947.

Q1: What are the objectives of Drug and Cosmetic Act, 1940?

Ans. Objectives:

1. To regulate the import, manufacture, distribution and sale of drugs & cosmetics through licensing.
2. Manufacture, distribution and sale of drugs and cosmetics by qualified persons only.
3. To prevent substandard in drugs, presumably for maintaining high standards of medical treatment.
4. To regulate the manufacture and sale of Ayurvedic, Siddha and Unani drugs.
5. To establish Drugs Technical Advisory Board (DTAB) and Drugs Consultative Committees (DCC) for Allopathic and allied drugs and cosmetics.

Q2: What are the salient features of the Drug and Prohibition Act, 1940?

Ans. The salient features of the Drugs & Cosmetics Act, 1940 are as follows:

1. Maximum penalty life imprisonment and fine of Rs. 10 lakhs or 3 times the value of the confiscated goods, whichever is more.
2. Besides officers from the Drug Controller's Office, other gazette officers also authorized to launch prosecution under the Act;
3. Some of the offences cognizable and non-bailable;
4. Specially designated courts for trial of offences covered under the Act;
5. Provision for compounding of minor offences.

Q3: What do you understand by the term 'Drug'?

Ans. Definition of Drug is provided in the Act under interpretation clause as:

1. 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 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.
2. 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.
3. All the substances intended for use as components of drug including empty gelatin capsule and,
4. Such devices intended for internal or external use in diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals.

Q4: What do you understand by the term 'Cosmetic'?

Ans. As defined in the Act Cosmetic includes 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.

Q5: Is there any administrative structure provided by the Act to ensure its proper implementation?

Ans. Yes, there is a well organized administrative structure to ensure the smoothe functioning of the Act. Administration of the act and rules

A) Advisory :

1)Drugs Technical Advisory Board-DTAB

2)Drugs Consultative Committee-D.C.C.

B) Analytical :

1)Central Drugs Laboratory - CDL

2)Drug Control Laboratory in states

3)Government Analysts

C) Executives :

1)Licensing authorities

2)Controlling authorities

3)Drug Inspectors

Q6: What do you understand by CDL under Drug and Cosmetic Act?

Ans. CDL stands for Central Drug Laboratory 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.

Q7: What do you understand by Loan License?

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

Procedure:

Licence is obtained from licensing authority on application in prescribed forms (24-A , 27-A) with prescribed fees (Rs. 6000, 1500).

Loan licenses are issued for:

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

2) Drugs specified in Schedule-C/C1

Q8: What do you understand by Repackaging License?

Ans. 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 Schedule-C/C1 and X.

Procedure:

Licence is obtained from licensing authority (FDA) on application in prescribed

forms (24-B) with prescribed fees (Rs. 500, 200).

Q9: What are the classes of drugs prohibited from being sold?

Ans. Classes of drugs prohibited to be sold are:

- Misbranded, spurious, adulterated and drugs not of standard quality
- Patent/Proprietary drugs with undisclosed formula
- Sch-J drugs
- Expired drugs.

Q10: Write a note on Drugs Consultative Committee (DCC)?

Ans. t is also an advisory body constituted by central government.

Constitution:

- Two representatives of the Central Government
- One representative of each State Government

Functions:

- To advise the Central Government, the State Governments and the Drugs Technical Advisory Board on any other matter tending to secure uniformity throughout India in the administration of this Act.
- The Drugs Consultative Committee shall meet when require.
- Has power to regulate its own procedure.

Q11: What are the qualifications required to be a Government Analyst?

1. These officers are appointed by the Central or State Government and perform the duties.
2. Persons having Qualification for appointments as government as governmental analysis for drugs;
3. Must have a degree in Medicine/Ayurveda/Sidha/Unani system and not less than 3 year post-graduate experience in the analysis of drug.

Q12: What are the duties of a Government Analyst?

Ans. **Duties are as follows:**

1) The Government Analyst shall cause to be analysed or tested such samples or drugs and cosmetics as may be sent to him by Inspectors.
2) A Government Analyst shall from time to time forward reports to the Government giving the result of analytical work and research with a view to their publication.

Q13: Write a note on Licensing Authority?

Ans. Qualification:

1) All member should be Graduate in Pharmacy on Pharmaceutical Chemistry or in Medicine with Specialization in Clinical pharmacology or microbiology.
2) 5 year Experience in manufacture or testing of drugs.

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 licences 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;

Q14: What are the conditions for importing drugs for personal use?

Ans. Conditions to be fulfilled are:

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

Q15: What are the conditions to be fulfilled for importing Drugs for examination, test or analysis?

Ans. Conditions to be fulfilled are:

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.

Q16: Are there any drugs which can be imported without license?

Ans. Import of drugs without license is possible for the following:

- 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
- Pre-digested foods
- Ginger, Pepper, Cumin, Cinnamon

Q17: Is there any circumstance when the manufacture of cosmetics is prohibited?

Ans. **Manufacture of cosmetics prohibited for the following classes of drug:**

1. Misbranded or spurious cosmetics and of substandard quality
2. Cosmetics containing hexachlorophene or mercury compounds
3. Cosmetics containing color which contain more than-
   - 2 ppm of arsenic
   - 20 ppm of lead
   - 100 ppm of heavy metals
4. Eye preparations containing coal-tarcolor

Q18: Which Classes of drugs are prohibited from being 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, Armed force.
- Physician's samples

Q19: What were the important features of Drugs and Cosmetics (Amendment) Act, 2008?

Ans. Salient features of the Act, 2008 are:-

- Substantial enhancement in punishment
- Life imprisonment for offenders involved in manufacture, sale and distribution of spurious and adulterated drug likely to cause grievous hurt
- Minimum punishment of seven years which may extend to life imprisonment
- Provision for compensation to affected person

Q20: Which kind cosmetics import is prohibited?

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

Q21: The third schedule deals with?

Ans. It deals with the categories of drugs for which the central licensing authority is empowered to issue licence and permission.

Q22: Which Amendment of the Act led to the constitution of Medical Devices Technical Advisory Board?

Ans. Drug and Cosmetic (Amendment) Act, 2015 is to be credited for this.

Q23: Who is the Controlling authority under the Act?

Ans. (1) All Inspectors appointed by the Central Government shall be under the control of an officer

appointed in this behalf by the Central government and State Government

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

Q24: When the manufacture of a drug is prohibited under the Act?

Ans. **Under the following circumstance:**

1. Drug not of standard quality or misbranded, adulterated or spurious.
2. Patent medicine.
3. Drugs in Sch-J
4. Risky to animal/human.
    - Sch-X drugs(condition)
    - Store drugs in direct under of responsible person.
    - Invoice of sale must sent to licensing authority every 3 months.
5. Preparation must be labelled with XRx.
6. Marketed in packing not exceeding:

    100 unit dose

    300ml of oral liquid

    5ml- injection

7. Manufacture of drugs other than in Sch-C/C1
8. Adequate facility for testing, separating from manufacturing

    Premises should comply with schedule ‘M’.

    Adequate storage facility.

    Furnish data of stability.

    Maintain the inspection book.

    Maintain reference samples from each batch.

Q25: Whether there is any drug whose import is prohibited?

Ans. Yes, there are some drugs mentioned in the Act which are:

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

Q26: What is the penalty for obstructing Inspector?

Ans. If any person wilfully obstruct an Inspector in the exercise of the powers conformed upon him or refuse to produce any record, register or any other document when required or any document when required, he shall be punishable with imprisonment (jail) up to 3 year or with fine or with both.

Q27: What are the kinds of Licenses for the manufacturing of drugs?

Ans. The following categories of licenses can be granted. 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

Q28: Discuss the application of law relating to sea and customs?

Ans. The Customs Collector and other officers authorized in this behalf by the Central Government may detain any imported packages which he suspects to contain any drug or cosmetic the import of which is prohibited by this Act and report such detention to the Drugs Controller, India and if found necessary can forward any package or sample to CDL for analysis.

Q29: What do you understand by Registration Certificate?

Ans. It means a certificate issued by the License Authority for the registration of premises and drugs manufactured by the manufacturer meant for import into and use in India.

An application for the issue of a registration certificate should be made to License Authority along with the information and undertaking specified in schedule DI and DII. This certificate is valid for a period of 3 years.