

# **DRUGS AND COSMETICS ACT**

# Contents of this chapter

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# Learning Objectives

- At the end of this lecture, student will be able to
  - Define the various definitions used in Drugs and Cosmetics Act
  - Enlist the Schedules to the act and rules

# History

British misrule-Providing poor healthcare system to Indian citizens

Observations made by-Drugs Enquiry Committee, Indian Medical Association

Reports in- Indian Medical Gazette during 1920-30

1940 – Drugs and Cosmetics Act

1945 – Rules under the Act

Extended to whole of India.....

# LIST OF AMENDING ACTS AND ADAPTATION ORDERS

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
9. The Drugs and cosmetics (Amendment) Act, 2013

# Objectives

- ❖ To regulate the **import, distribution and sale** of drugs & cosmetics through licensing in order to prevent substandard or harmful drugs and cosmetics.
- ❖ Excise control over the production of drugs and cosmetics in the country.
- ❖ To distribution and sale of drugs and cosmetics by **qualified persons only**.
- ❖ To prevent **substandard** in drugs.
- ❖ To regulate the manufacture and sale of **Ayurvedic, Siddha and Unani** drugs.
- ❖ To establish **Drugs Technical Advisory Board(DTAB)** and **Drugs Consultative Committees(DCC)** for Allopathic and allied drugs and cosmetics.

# 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 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.

## 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

## **Ayurveda Sidha and Unani Drugs:**

Include all medicines indented for internal or external use for or in diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals & manufactured exclusively in accordance with the formulae prescribed in authoritative books of Ayurvedic, siddha and Unani-Tibb systems of medicines.

## **Central License approving authority:**

Means Drug Controller of India appointed by the Central Government.

## **Drug: Includes**

- a) all medicines used for the internal or external use of human beings or animals and all substances indented to be used for or in diagnosis, treatment , mitigation or prevention of any disease or disorder in human beings or animals including preparation applied for repelling mosquitoes
- b) substances indented to affect the structure or any function of human body or indented to be used for the destruction of vermin or insects that cause disease in human beings or animals
- c) all substances indented for use as components of drug including empty gelatin capsules
- d) devices indented for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals.



## **Manufacture:**

Include any process or part of process for making, altering, ornamenting, finishing, packing, labeling, 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 drugs or packing of any cosmetics or drug in ordinary course of retail process.

## **Patent or Proprietary Medicine:**

In relation to Ayurveda, Sidha or Unani systems of medicine all formulations containing only such ingredients mentioned in the formulae described in authoritative books of Ayurveda, Sidha or Unani- Tibb systems of Medicine specified in the first schedule but does not include medicine which is administered by parenteral route also formulations included in authoritative books as mentioned in the first Schedule.

In relation to any other system of medicine, a drug which is a remedy or prescription presented in form ready for internal or external administration of human beings or animals and which is not included in edition of the Indian Pharmacopoeia for the time being or any Pharmacopoeia authorized in this behalf by the Central Government after constitution with the DTAB.

**Misbranded drugs:** A drug is deemed to be misbranded –

If it is so colored, coated, powdered or polished that damage is concealed or if it is made to appear of better or great therapeutic value than it really is.

If it is not labeled in prescribed manner; or

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

**Adulterated Drugs:** A drug is deemed to be adulterated –

If it consists in whole or in part, of any filthy, putrid or decomposed substance; or

If it has been prepared, packed or stored under insanitary conditions whereby it may have been rendered injurious to health; or

If its container is composed in whole or in part, of any poisonous or delirious substances which may render the contents injurious to health.

If it bears for purpose of coloring only a color other than one which is prescribed.

If it contains any harmful or toxic substance which may render it injurious to health; or

If any substance has been mixed there with so as to reduce its quality or strength.

**Spurious Drugs:** A drug is deemed to be spurious –

If it is imported or manufactured under a name which belongs to another drug.; or

If it is an imitation or is a substitute for, another drug or resembles another drug in a manner likely to deceive or unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drugs; or

If the label or container bears the name of an individual or company purporting to be the manufacture of the drug, which company or individual is fictitious or does not exist.

If it has been substituted wholly or in part by another drug or substance; or

If it purports to be the product of a manufacturer of whom it is not truly a product.

**Misbranded Cosmetics:** A cosmetic is deemed to be misbranded –

If it contains color which is not prescribe; or

If it is not labeled in prescribed manner; or

If the label or container of anything accompanying the cosmetic bears any statement which is false or misleading in particular.

**Spurious Cosmetics:** A cosmetic is deemed to be spurious –

If it is imported under a name which belongs to another cosmetic; or

If it is an imitation of, or a substitute for, or resembles another cosmetic in a manner likely to deceive or bears upon it or upon its label or container the name of another cosmetic, unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other cosmetic; or

If the label of the container bears the name of an individual or company purporting to be the manufacturer of the cosmetic, which individual or company is fictitious and does not exist; or

If it purports to be the product of a manufacturer of whom it is not truly a product.

# Schedules to the Act

**First schedule** – Names of **books** under **Ayurvedic** and **Siddha** systems

**Second schedule** – **Standard to be complied** with by imported drugs and by drugs manufactured for sale, sold, stocked or exhibited for sale or distribution

# Summary

## Drug:

Includes a) all medicines used for the internal or external use of human beings or animals and all substances intended to be used for or in diagnosis, treatment , mitigation or prevention of any disease or disorder in human beings or animals including preparation applied for repelling mosquitoes b) substances intended to affect the structure or any function of human body or intended to be used for the destruction of vermin or insects that cause disease in human beings or animals c) all substances intended for use as components of drug including empty gelatin capsules d) devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals.

❖ Definitions of cosmetics, spurious, adulterated drugs and cosmetics

# Thank You

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