DRUGS AND COSMETICS ACT 1940
AND RULES 1945

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 **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.

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.

Adulterated drug :

(a) if it consists, in whole or in part, of any **filthy, putrid** 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.

Spurious drugs :

(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**

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.

Patent or Proprietary medicine :

A drug which is a remedy or prescription presented in a form ready for internal or external administration of human beings or animals and which is **not included in the edition of**

the Indian Pharmacopoeia for the time being or any other Pharmacopoeia authorized in this behalf by the Central Government.

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

Drugs Technical Advisory Board(DTAB)

Ex-Officio:

(i) Director General of Health Services (Chairman)

(ii) Drugs Controller, India

(iii)Director of the Central Drugs Laboratory, Calcutta

(iv) Director of the Central Research Institute, Kasauli

(v)Director of Indian Veterinary Research Institute, Izatnagar

(vi) President of Medical Council of India

(vii) President of the Pharmacy Council of India

(viii)Director of Central Drug Research Institute, Lucknow

Nominated:

1) **Two** persons by the **Central Government.**
2) **One** person by the **Central Government** from the **pharmaceutical industry**
3) **Two** persons holding the appointment of **Government Analyst** under this Act,

Elected:

1)one person, to be elected by the Executive Committee of the **Pharmacy Council of India**,

2)one person, to be elected by the Executive Committee of the **Medical Council of India**,

3)one **pharmacologist** to be elected by the Governing Body of the Indian Council of Medical Research;

4)one person to be elected by the Central Council of the **Indian Medical Association**;

5)one person to be elected by the Council of the **Indian Pharmaceutical Association**;

Functions:

To **advise** the Central Government and the State Governments on technical matters.

To carry out the other functions assigned to it by this Act.

Drugs Consultative Committee(DCC)

It 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 required**
- Has power to regulate its own procedure.

Central Drug 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.