

Drugs and Cosmetics Act 1940 and Rules 1945

EBC's Bare Act

DRUGS AND COSMETICS ACT, 1940

along with

DRUGS AND COSMETICS RULES, 1945

together with

**State Amendments
Subject and Product Index**



Third Edition

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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

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, presumably for maintaining high standards of medical treatment.
- 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.

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

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; or
- 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.

Ex. Xental 400, Pentoxiphylline ,Targof Pure Drug Ltd.
Zental 400, Albendazole, Glaxo Smithkline

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;
or

(d) if it bears or contains, for purposes of colouring only, a **colour** other than one which is prescribed; or

(e) if it contains any **harmful or toxic substance** which may render it injurious to health; or

(f) if any substance has been **mixed** therewith so as to **reduce its quality or strength**.

e.g. supply of cheap cottonseed oil in place of olive oil.

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** unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or

(c) if the label or the container bears the name of an individual or company purporting to be the manufacturer of the drug, which **individual or company is fictitious or does not exist**; or

(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 manufacturer of whom it is not truly a product.

e.g., when methamphetamine is sold as cocaine

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.

References

- Available on www.cdsco.nic.in
- “Pharmaceutical Jurisprudence” by Dr.G.K.Jani; Atul prakashan; Fifth edition(2005-06); 28-133.
- Forensic Pharmacy by C.K. Kokate and S.B. Gokhle; Published by Pharma Book Syndicate; 152.

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