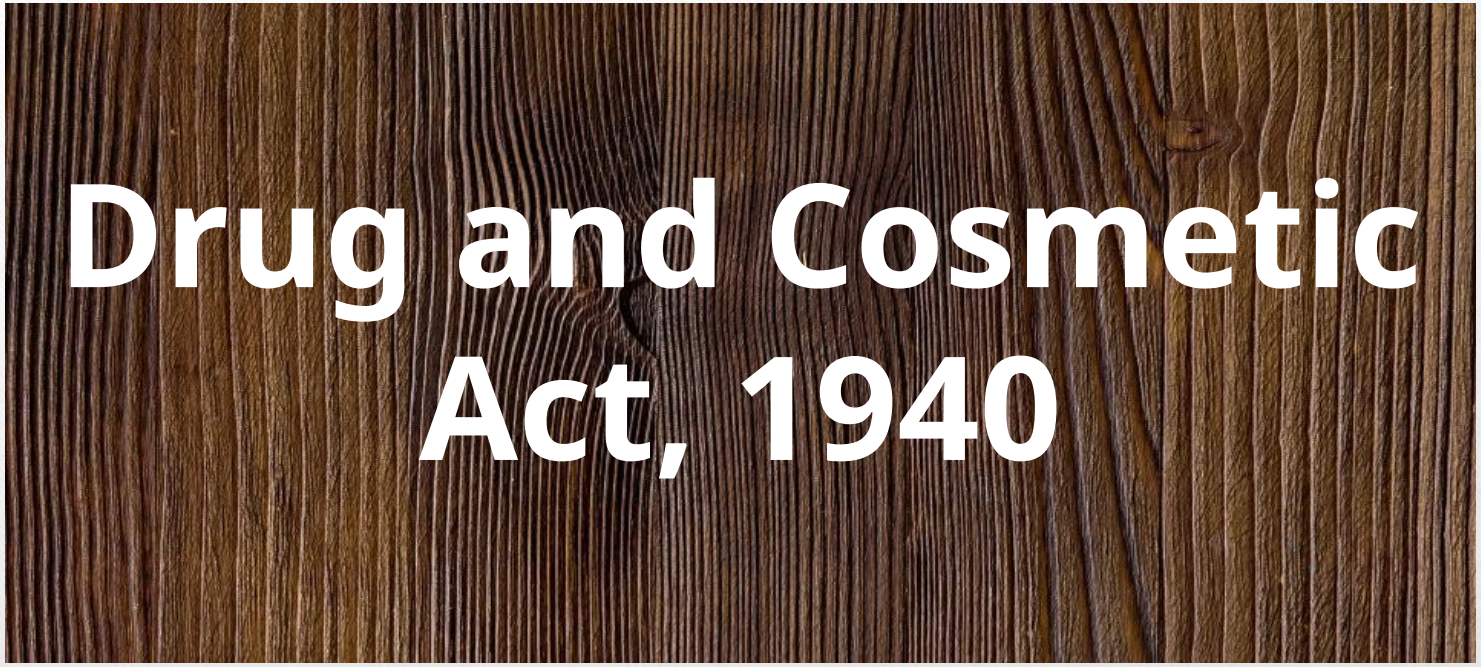
Drug and Cosmetic Act, 1940



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Contents

1.History
2.Objectives
3.Definitions
4.Administration of the Act and rule
5.Amendment and adaptations

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
- 1962-The scope of the Drugs Act was extended to Cosmatic 1962 and the title of the art was changed to Drugs & Cosmetic Act
- 1964 The drugs belonging to the systems of Ayurveda, Siddha and Unani (ASU) Systems were brought within the purview of the D&C

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.

LIST OF AMENDING ACTS AND ADAPTATION ORDER

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, 2016

5 Chapters

38 Sections

2 Schedules

Chapter 1
Introductory
[Section 1-5]

Chapter II
Technical advisory board
[Sections 5-7]

Chapter III
Import (Sections 8-15)

Chapter IV
MSD of D&C[16-33]
Chapter IVA-
ASU Drugs
[Sections 33B-330]

Chapter V
Miscellaneous
[Sections 33P 381]

CHAPTER I

INTRODUCTORY

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 3 [Ayurvedic, Siddha and Unani Tibb system of medicine]**

Cosmetics:- **as any product that is meant to be applied to the human body for the purpose of beautifying or cleansing. The definition however excludes soaps. In 1964, the act was amended to include Ayurveda and Unani drugs.**

Board:- **in relation to any other drug or cosmetic, the Drugs Technical Advisory Board constituted under section 5**

CHAPTER II

THE DRUGA TECHNICAL ADVISORY BOARD. THE CENTRAL DRUGS LABORATORY AND THE DRUGS CONSULTATIVE COMMITTEE

Constituted by the Central Government

- To advise on technical matters arising out of the administration of this Act
- To carry out other functions assigned to it by this Act.

FUNCTIONS:

- **To advice the central government and state governments on technical matters.**
- **Modifications and amendments in the D & C act with consultation of board.**

CHAPTER III

IMPORT OF DRUGS AND COSMETICS

- To IMPORT, with its grammatical variations and Cognate expressions means to bring into INDIA.

- **Standard Quality**:- In relation to a drug, that the drug complies with the standard Schedule

- **Misbranded drugs:-**Which is colored, coated, powdered or polished to conceal damage or to make it to appear of better or greater therapeutic value than really it is. Not labeled in prescribed manner.

- **Spurious drugs:-** If it is imported under a name which belongs to another drug If it is an imitation of or a substitute for another drug or resembles another drug in a manner likely to deceive

- **Adulterated drugs:-** Which contains any filthy, putrid or decomposed substance. Prepared or packed under insanitary conditions If it is composed of any poisonous or deleterious substance which may injure health

CHAPTER IV

MANUFACTURE, SALE AND DISTRIBUTION OF DRUGS AND COSMETICS

- ***manufacturer*** **should maintain proper records, registers, other documents regarding the manufacture or sale and should furnish all details when any inspection is done by the officials appointed by the Govt. for the same.**

- **Control Over Manufacture Of Ayurveda, Siddha And Unani Drugs**

- **Manufacture For Sale Of ASU Drugs**

- **Labeling and Packing of ASU Drugs**

CHAPTER V

Miscellaneous

Deals with :

- Rules to be laid before parliament
- Offences made by companies Penalties
- Offences made by Govt. department

Administration of the act & rules

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

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 Analysis

C) Executives:

1)Licensing authorities
2)Controlling authorities
3)Drug Inspectors
4) Customer collector

SCHEDULES

•**First schedule -** Names of books under Ayurvedic and Siddha systems

-Authoritative Books

-54 books of Ayurveda

-29 books of Siddha

books of Unani 12-

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


Thank You