Drugs and Cosmetics Act 1940 and Rules 1945 and New Amendments

Drugs And Cosmetics Act, 1940 & Rules, 1945

Introduction

- The **Drugs and Cosmetics Act, 1940** is a central legislation enacted by the Parliament of India to regulate the import, manufacture, distribution, and sale of drugs and cosmetics in India.
- It is supplemented by the **Drugs and Cosmetics Rules, 1945**, which provide detailed procedures and regulatory frameworks for enforcing the provisions of the Act.

Historical Background

- The Act was introduced following the death of 12 people in 1937 due to adulterated medicines in Bengal, highlighting the urgent need for regulatory intervention.
- To effectively implement the Act, the Drugs and Cosmetics Rules, 1945 were formulated.
- The law has undergone several amendments over time to address advancements in science, evolving regulatory needs, and public health concerns.

Objectives of the Drugs and Cosmetics Act, 1940

- The main objectives of the Act are:
    1. To ensure the availability of safe and effective drugs to the public.
    2. To regulate the import, manufacture, sale, and distribution of drugs and cosmetics.
    3. To ensure the quality, purity, and standard of drugs and cosmetics.
    4. To prevent the circulation of substandard, spurious, and adulterated drugs.
    5. To define the legal responsibilities of stakeholders such as manufacturers, wholesalers, retailers, and medical professionals.
    6. To establish administrative authorities including licensing authorities, inspectors, analysts, and Drug Control Officers.

Scope and Applicability

- The Act extends to the whole of India.
- It applies to:
    - **Allopathic drugs**
    - **Ayurvedic, Siddha, and Unani medicines (ASU)**
    - **Cosmetics**

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- **Medical devices** (added through later amendments

Structure of the Act

- The Drugs and Cosmetics Act, 1940, consists of:
  - **Chapters**: Divided into multiple chapters
  - **Sections**: 33 sections, each dealing with specific regulatory topics
  - **Schedules**: 25 schedules (labeled A to Y) define forms, fees, tests, classifications, and standards
  - The **Drugs and Cosmetics Rules, 1945**, lay down detailed rules and sub-rules for enforcement.

Definitions Under the Drugs and Cosmetics Act (Section 3)

1. Drug [Section 3(b)]

- Includes:
  - **All medicines** for internal or external use of human beings or animals.
  - Substances intended to be used for **diagnosis, treatment, mitigation, or prevention** of any disease.
  - **Substances (other than food)** intended to affect the structure or function of the body.
  - Components used in manufacture, testing, or evaluation.
- This definition includes:
  - Tablets, capsules, injections
  - Vaccines, diagnostic kits
  - Disinfectants and antiseptics (used on the body)

2. Cosmetic [Section 3(aaa)]

- Any article intended to be **rubbed, poured, sprinkled, or sprayed** on, introduced into, or otherwise applied to the human body for:
  - **Cleansing**
  - **Beautifying**
  - **Promoting attractiveness**
  - **Altering appearance**
- Does **not include soaps**.

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- Examples: Creams, perfumes, shampoos, lipsticks, powders, nail polishes.

3. Manufacture [Section 3(f)]

- Means the process of:
  - Making
  - Altering
  - Ornamenting
  - Finishing
  - Packing
  - Labeling
  - Breaking up or otherwise treating or adapting any drug or cosmetic.
- Includes **processing of drugs in any form** (even repackaging) for sale or distribution.

4. Import [Section 3(e)]

- Bringing drugs or cosmetics **into India from a foreign country** for the purpose of **use, distribution, or sale**.

5. Misbranded, Adulterated, and Spurious Drugs

- These terms are legally defined in Sections 17, 17A, and 17B respectively.

Misbranded Drugs:

- Drug is colored, coated, powdered, or polished in a misleading manner.
- Drug is not labeled in prescribed manner.
- Label bears false or misleading information.

Adulterated Drugs:

- Drug contains filthy, putrid, or decomposed substances.
- Drug has been prepared, packed, or stored under unsanitary conditions.
- Drug contains harmful or toxic substances.

Spurious Drugs:

- Drug is manufactured under a **false name**.
- Imitation of another brand or product.
- Label falsely claims it’s from another manufacturer.

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Legal Definition Of Schedules To The Act And Rules

- The Schedules under the Drugs and Cosmetics Rules provide detailed regulatory frameworks related to various categories of drugs and their management.

Each schedule has a specific legal significance:

Schedule	Purpose
Schedule A	Forms for licenses, applications, certificates, etc.
Schedule B	Fees for tests and analysis by government laboratories
Schedule C	Biological and special products (e.g., vaccines, insulin)
Schedule C(1)	Other special products (e.g., sterilized surgical dressings)
Schedule D	Exemptions for import under specific conditions
Schedule E1	List of poisonous substances
Schedule F	Standards for blood banks, vaccines
Schedule G	Drugs to be used under medical supervision
Schedule H	Prescription drugs (not to be sold without a doctor’s prescription)
Schedule H1	Antibiotics and habit-forming drugs; requires red label and record maintenance
Schedule X	Narcotics and psychotropic substances (highly regulated)
Schedule M	Good Manufacturing Practices (GMP) for drug manufacturing units
Schedule M-I	GMP for medical devices
Schedule P	Shelf life or expiry dates of drugs
Schedule R	Devices like condoms, surgical dressings, bandages
Schedule Y	Clinical trials and approval of new drugs

Each Schedule is legally binding and **non-compliance** can lead to cancellation of license and criminal prosecution.

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Import of drugs

Classes of Drugs and Cosmetics Prohibited from Import (Section 10)

- The following cannot be imported:
  - **Misbranded, adulterated, or spurious** drugs or cosmetics.
  - Drugs not of standard quality.
  - Drugs or cosmetics **prohibited for sale in the country of origin**.
  - Drugs or cosmetics **without a valid license** under the Rules.
  - Any product with **false or misleading labeling**.
  - Drugs whose shelf-life is expired or whose **safety is not established**.

Prohibited Imports also include:

- Narcotic drugs and psychotropic substances (except under special license).
- Substances prohibited under international treaties (e.g., UN conventions).

Note: The Central Government has the authority to **ban any drug** from being imported, if found harmful or lacking therapeutic value.

Import under License or Permit (Section 10A and Rules)

- Importation of drugs and cosmetics is allowed **only under a valid license** issued by the **Central Drugs Standard Control Organization (CDSCO)**.

Types Of Import Licenses:

1. **Form 10** – License to import drugs (excluding Schedule X drugs)
2. **Form 10A** – License to import drugs for personal use (non-commercial)
3. **Form 11** – License to import drugs for testing, analysis, or research
4. **Form 12** – Import license for Schedule X drugs
5. **Form 12A/B/C** – Permits for various special imports (for manufacture or testing)

Licensing Authority:

- **Drugs Controller General of India (DCGI)**, under CDSCO, is responsible for issuing import licenses.

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