D.PHARM • SECOND YEAR

Pharmacy Law & Ethics

CHAPTER 3

Drugs and Cosmetics Act 1940 and Rules 1945



ENGLISH CHAPTER NOTES

DIPLOMA IN PHARMACY

DRUGS AND COSMETICS ACT 1940 AND RULES 1945 AND NEW AMENDMENTS

HISTORICAL BACKGROUND

1930: Drugs Enquiry Committee, chaired by R. N. Chopra. → **1940**: Drugs Act enacted. → **1945**: Rules issued for detailed implementation.

OBJECTIVES

- Support access to safe and effective drugs.
- Regulate import, manufacture, distribution and sale.
- Set standards for quality and purity.
- Prevent substandard, adulterated and spurious products.
- Define duties of manufacturers, sellers and other stakeholders.
- Provide licensing, inspection, testing and enforcement authorities.

SCOPE

The Act extends throughout India. It covers drugs and cosmetics, with special provisions for Ayurvedic, Siddha and Unani drugs and notified medical devices.

CURRENT FRAMEWORK

Act: the main legal powers and duties.
Rules: detailed procedures, forms and conditions.
Medical Devices Rules, 2017: device-specific regulation.
New Drugs and Clinical Trials Rules, 2019: new drugs and clinical trials.
Cosmetics Rules, 2020: cosmetics regulation.

Amendments update the law. A draft Bill is a proposal, not an enacted replacement.

DEFINITIONS UNDER THE DRUGS AND COSMETICS ACT (SECTION 3)

DRUG — Section 3(b)

- All medicines for internal or external use in humans or animals.
- Substances used for diagnosis, treatment, mitigation or prevention of disease or disorder. This includes preparations applied to the human body to repel insects such as mosquitoes.
- Components of a drug, including empty gelatin capsules.

Examples: tablets, capsules, injections, vaccines and therapeutic antiseptics.

Notified substances and devices are also included, as explained next.

COSMETIC — Section 3(aaa)

An article applied to any part of the human body by rubbing, pouring, sprinkling, spraying, introducing or another method for:

- Cleansing
- Beautifying
- Promoting attractiveness
- Altering appearance

Components used in cosmetics are also included.

Examples: creams, perfumes, shampoos, lipsticks, powders and nail polishes.

Soap is not excluded from the Indian definition. Cleansing toilet soaps are cosmetics.

DEFINITIONS UNDER THE DRUGS AND COSMETICS ACT (SECTION 3)

MANUFACTURE – Section 3(f)

Any process or part of a process applied to a drug or cosmetic with a view to sale or distribution.

Making → Altering or finishing → Packing and labelling

It also includes ornamenting, breaking up, treating or adapting the product.

EXCLUDED

Compounding or dispensing a drug, or packing a drug or cosmetic, in the ordinary course of retail business.

Commercial repacking can be manufacture; ordinary retail packing is excluded.

IMPORT – Section 3(g)

"To import" means to bring into India.

Import controls are mainly in Chapter III and the applicable Rules.

From outside India → India

NOTIFIED CATEGORIES WITHIN "DRUG"

- **Section 3(b)(ii):** specified non-food substances affecting the structure or function of the human body, or destroying disease-causing vermin or insects in humans or animals.
- **Section 3(b)(iv):** specified devices used internally or externally for diagnosis, treatment, mitigation or prevention of disease or disorder in humans or animals.

These categories depend on Central Government Gazette notifications.

MISBRANDED, ADULTERATED, AND SPURIOUS DRUGS

MISBRANDED – Section 17

- Colouring, coating, powdering or polishing hides damage or makes the drug appear more therapeutically valuable.
- Labelling does not follow the prescribed manner.
- A label, container or accompanying material makes a false claim or is misleading.

ADULTERATED – Section 17A

- Contains filthy, putrid or decomposed matter.
- Made, packed or stored in insanitary conditions that may contaminate it or harm health.
- A poisonous container may make it harmful.
- Contains an unprescribed colour used only for colouring.
- Contains a harmful or toxic substance.
- Another substance is mixed in to reduce quality or strength.

SPURIOUS – Section 17B

- Made under another drug's name.
- Deceptively imitates or substitutes another drug without clearly revealing its true identity.
- Names a fictitious or non-existent manufacturer.
- Wholly or partly substituted by another drug or substance.
- Falsely claims to be a particular manufacturer's product.

Not of standard quality means failure to meet the prescribed standard; it is not automatically the same as every category above.

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