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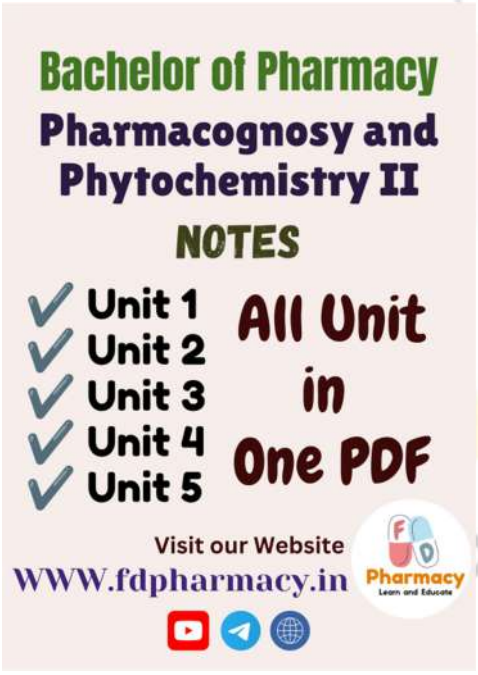
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PHARMACEUTICAL JURISPRUDENCE

UNIT 1

TOPIC :

- **Drugs and Cosmetics Act, 1940 and its rules 1945 :**
  Objectives, Definitions, Legal definitions of schedules to the Act and
  Rules
  Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties.

Drugs and Cosmetics Act, 1940 and Rules, 1945

- The Drugs and Cosmetics Act, 1940 is a central legislation enacted by the Government of India to regulate the import, manufacture, distribution, and sale of drugs and cosmetics in India.
- The Drugs and Cosmetics Rules, 1945 were framed under this Act to ensure proper implementation and to define the practical procedures for enforcement.
- This Act ensures that only safe, effective, and quality drugs and cosmetics are available to the public, and that their manufacture and sale are controlled under scientific and ethical standards.

Objectives of the Act

The main objectives of the Drugs and Cosmetics Act, 1940 are:

- To regulate the import, manufacture, distribution, and sale of drugs and cosmetics.
- To ensure that the drugs and cosmetics sold in India are safe, effective, and conform to prescribed quality standards.
- To prevent substandard, adulterated, misbranded, or spurious drugs and cosmetics from reaching the market.
- To provide proper control over the production and sale of biological and pharmaceutical products.
- To ensure uniform standards of drugs and cosmetics throughout the country.
- To protect the public from the health hazards of poor-quality drugs and cosmetics.
- To lay down the legal provisions regarding licensing, labeling, and packaging of drugs and cosmetics.

Important Definitions (Legal Definitions)

Term	Definition (as per the Act)
Drug	Includes all medicines for internal or external use of humans or animals and substances intended for diagnosis, treatment, mitigation, or prevention of disease. Also includes medical devices, disinfectants, and substances affecting body functions.
Cosmetic	Any article intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering appearance, including substances intended for use as ingredients of cosmetic products.
Ayurvedic, Siddha, or Unani Drug	All medicines intended for internal or external use for diagnosis, treatment, or prevention of diseases, prepared according to the formulae described in authoritative books of Ayurvedic, Siddha, or Unani Tibb systems.
Manufacture	All processes related to making, altering, ornamenting, finishing, packing, labeling, or otherwise producing any drug or cosmetic.
Misbranded Drug	A drug that is labeled falsely or misleadingly, or does not conform to the prescribed labeling or coloring standards.
Adulterated Drug	A drug that contains filthy, decomposed, or putrid substances, or is prepared, packed, or stored under insanitary conditions.
Spurious Drug	A drug that is an imitation or substitute of another drug, or falsely claims to be from a manufacturer of whom it is not truly from.
Patent or Proprietary Medicine	A drug that is not included in the official pharmacopoeia but is a ready-made formulation with a brand or trade name.
Pharmacopoeia	An official book containing a list of medicinal drugs with their formulas, descriptions, and standards.
Labeling	The process of affixing a printed or written label to the container of a drug or cosmetic giving required information.

Legal definitions of schedules to the Act and Rules

Schedule A – Forms and Applications

This Schedule legally prescribes forms and formats for various applications and licenses under the Act and Rules.

Example:
Application for a manufacturing license, renewal of a license, approval for testing laboratories, etc.

Legal Use:
Mandatory for all official communication and registration between applicant and drug authorities.

Schedule B – Fees for Tests and Analysis

Specifies the fees payable for testing and analysis of drugs and cosmetics by the Government Analyst or Central Drugs Laboratory.

Legal Use:
Prescribed fees must be paid before a sample is analyzed by a government laboratory.

Schedule C and C1 – Biological and Special Products

These Schedules define biological and special products (such as vaccines, sera, toxins, insulin, antibiotics, and vitamins) and lay down their standards, conditions of storage, and manufacture.

Legal Use:
Manufacturers must obtain special licenses and follow prescribed conditions under these Schedules.

Schedule D – Exemption from Certain Provisions for Import

Contains a list of drugs and classes of drugs that are exempted from specific provisions of import under Chapter III of the Act.

Legal Use:
Simplifies import procedures for certain categories (e.g., bulk drugs for reprocessing).

Schedule E1 – List of Poisonous Substances in ASU Drugs

Legally identifies poisonous substances used in Ayurvedic, Siddha, and Unani medicines that require special caution and labeling.

Legal Use:
Mandatory warning label: "Caution: To be taken under medical supervision."

Schedule F – Standards for Biological Products

Specifies the detailed legal standards for biological drugs such as bacterial vaccines, toxins, antitoxins, and sera.

Legal Use:
Manufacturers must comply with specified temperature, sterility, and quality control requirements.

Schedule F1 – Standards for Surgical Dressings

Defines legal standards for surgical dressings like bandages, gauze, and absorbent cotton wool.

Legal Use:
Mandatory compliance for manufacturers of sterile dressings.

Schedule FF – Standards for Ophthalmic Preparations

Specifies legal standards for ophthalmic (eye) preparations regarding sterility, purity, and packaging.

Legal Use:
Ensures patient safety in ocular medicines.

Schedule G – Prescription Drugs Requiring Medical Supervision

Lists drugs that must carry a cautionary label and can only be used under medical supervision.

Legal Labeling Requirement:
"Caution: It is dangerous to take this preparation except under medical supervision."

Schedule H – Prescription-Only Drugs

Lists drugs that can be sold only on the prescription of a registered medical practitioner.

Legal Labeling Requirement:
"Schedule H drug – Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only."

Schedule H1 – Critical Antibiotics and Anti-TB Drugs

Contains a list of antibiotics, anti-TB, and anti-microbial agents requiring strict sale record maintenance.

Legal Use:
Retailers must maintain a separate register of sale with patient, doctor, and drug details for 3 years.

Schedule J – Diseases for Which Drugs Cannot Claim to Cure

Lists diseases and conditions (e.g., cancer, diabetes, epilepsy) for which no drug can claim to prevent or cure under labeling or advertisement.

Legal Use:
Prevents false therapeutic claims in labeling or advertisements.

Schedule K – Exemptions from Licensing Requirements

Lists classes of drugs and conditions under which they are exempted from certain provisions of manufacture, sale, and distribution rules.

Legal Use:
Simplifies operations for hospitals, government institutions, and homeopathic medicines.

Schedule M – Good Manufacturing Practices (GMP)

Legally defines Good Manufacturing Practices and requirements of premises, plant, equipment, and personnel for pharmaceutical manufacturing.

Legal Use:
Mandatory for all manufacturing units; violation can lead to license suspension or cancellation.

Schedule M1 – GMP for Homeopathic Medicines

Specifies GMP standards for manufacture of homeopathic medicines.

Legal Use:
Ensures hygiene, quality, and safety in homeopathic manufacturing units.

Schedule M2 – GMP for Cosmetics

Provides Good Manufacturing Practices for cosmetic products.

Legal Use:
Ensures cosmetic products are safe, non-toxic, and produced under hygienic conditions.

Schedule N – Premises and Equipment Standards

Defines minimum requirements of area, furniture, storage, and facilities for retail and wholesale drug stores.

Legal Use:
Pharmacies must meet these standards to obtain or renew their licenses.

Schedule O – Standards for Disinfectants

Specifies composition and efficacy standards for disinfectants such as phenyl and bleaching powder.

Legal Use:
Ensures disinfectants meet minimum germicidal standards.

Schedule P – Life Period (Shelf Life) of Drugs

Specifies the legal shelf life and storage conditions for different drugs and formulations.

Legal Use:
Expiry date labeling must comply with Schedule P.

Schedule Q – Permitted Colors

Contains a list of permitted synthetic colors that can be used in drugs and cosmetics.

Legal Use:
Only colors approved under Schedule Q can be used to avoid toxicity.

Schedule R – Standards for Vaccines and Sera

Defines testing and quality standards for sera and vaccines.

Legal Use:
Ensures sterility and safety of immunological products.

Schedule S – Standards for Cosmetics

Specifies that cosmetics must conform to the standards laid down by the Bureau of Indian Standards (BIS).

Legal Use:
Ensures cosmetic products are non-toxic, safe, and standardized.

Schedule T – GMP for ASU Medicines

Specifies Good Manufacturing Practices for Ayurvedic, Siddha, and Unani (ASU) medicines.

Legal Use:
Ensures traditional drugs are produced hygienically and consistently.

Schedule U – Record-Keeping Requirements

Specifies the records and registers to be maintained by drug manufacturers and sellers (e.g., batch records, test results).

Legal Use:
Ensures traceability and accountability in manufacturing.

Schedule V – Standards for Patent or Proprietary Medicines

Specifies standards of strength, quality, and labeling for non-pharmacopoeial (patent or proprietary) medicines.

Legal Use:
Prevents misleading branding or non-standard formulations.

Schedule W – Generic Drugs

Lists drugs that must be sold or marketed under their generic names only

Legal Use:
Promotes affordability and rational prescribing.

Schedule X – Narcotic and Psychotropic Drugs

Lists habit-forming and psychotropic drugs (e.g., morphine, amphetamines, barbiturates).

Legal Use:
Strict control over manufacture, storage, and sale; requires special license and record maintenance.

Schedule Y – Clinical Trials and New Drugs

Provides legal requirements and ethical guidelines for conducting clinical trials, importing, and manufacturing new drugs.

Legal Use:
Protects subjects in clinical trials and ensures scientific validity.

Schedule Z – Pharmacovigilance (Proposed)

Draft Schedule defining standards for pharmacovigilance systems — monitoring adverse drug reactions (ADR) and post-marketing safety.

Legal Use:
Strengthens drug safety surveillance once officially adopted.

Import of Drugs

- The import of drugs and cosmetics into India is strictly regulated by the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945 to ensure that only safe, effective, and good-quality products enter the Indian market.
- The control of import is mainly governed by Chapter III (Sections 10 to 13) of the Act.
- The Central Government regulates import through the Central Drugs Standard Control Organization (CDSCO) under the supervision of the Drugs Controller General of India (DCGI).

Objectives of Import Control

- To prevent entry of substandard, adulterated, or spurious drugs into the country.
- To ensure that all imported drugs and cosmetics conform to prescribed Indian standards of quality, safety, and efficacy.
- To maintain uniform regulation of import, distribution, and sale.
- To protect public health by controlling harmful and unsafe substances.
- To ensure that clinical trial materials and new drugs are properly evaluated before being marketed.

Classes of Drugs and Cosmetics Prohibited from Import

- According to Section 10 of the Drugs and Cosmetics Act, 1940, the following classes of drugs and cosmetics cannot be imported into India:

Class	Reason for Prohibition
1. Misbranded Drugs	Drugs whose labeling or packaging is false, misleading, or does not provide true information.
2. Adulterated Drugs	Drugs contaminated with filth, decomposed substances, or prepared under unhygienic conditions.
3. Spurious Drugs	Drugs that are imitation or substitution of another drug, or falsely claim another manufacturer's name.
4. Drugs without proper labeling	Drugs that do not conform to labeling or packaging rules specified in the Act.
5. Drugs claiming to cure prohibited diseases	Drugs making false therapeutic claims (e.g., cancer, diabetes, epilepsy) listed in Schedule J.
6. Drugs not of standard quality	Drugs that do not meet the standards prescribed in the pharmacopoeia.
7. Cosmetics harmful or unsafe for use	Cosmetics containing toxic, injurious, or prohibited coloring or chemical agents.
8. Patent or Proprietary medicines with false claims	Drugs that misrepresent composition, use, or manufacturer.

Import Under License or Permit

All imports must be carried out under a valid license or permit issued by the Licensing Authority (generally the DCGI).
Different licenses are required depending on the purpose and type of drug.

A. Import License

Issued in Form 10 or Form 10-A under Rule 24.

Form No.	Purpose	Issued To
Form 10	License to import drugs other than Schedule X drugs.	Importers or pharmaceutical companies.
Form 10-A	License to import small quantities for examination, test, or analysis.	Research institutions, testing labs, etc.

B. Import Registration Certificate

Before obtaining a license, the foreign manufacturer must have a Registration Certificate in Form 41 under Rule 27A, which certifies:

- Name and address of the manufacturer.
- Manufacturing premises and the drugs allowed for export to India.

C. Import of Schedule X Drugs (Narcotic and Psychotropic Substances)

- Requires a special import license in Form 10, but with additional conditions under the Narcotic Drugs and Psychotropic Substances Act, 1985.
- Strict record maintenance and government permission are mandatory.

D. Import for Examination, Test, or Analysis

- License issued in Form 11.
- Such imported drugs must not be sold or used for therapeutic purposes.

E. Import of New Drugs

- Requires permission from the Licensing Authority (DCGI) as per Schedule Y.
- Importer must submit safety, efficacy, and stability data.

Import of Cosmetics

Cosmetics are also regulated under the same Act.

- No cosmetic that is unsafe, contains harmful ingredients, or violates labeling standards can be imported.
- A Registration Certificate in Form 43 is required before import.
- Standards for cosmetics are given under Schedule S and Q (permitted colors and ingredients).

Import Inspection and Control

- Drugs at the port of entry (sea or air) are examined by Port Officers/Inspectors appointed by the Central Government.
- If samples are suspected to be not of standard quality, they are sent to the Central Drugs Laboratory (CDL), Kolkata for testing.
- If found substandard, the consignment is detained or destroyed under Section 11.

Important Forms Used in Import

Form No.	Purpose
Form 8	Application for import license.
Form 9	Undertaking signed by manufacturer's authorized agent in India.
Form 10	Import license for drugs (excluding Schedule X).
Form 10-A	Import license for small quantities for test or analysis.
Form 11	License to import drugs for examination, test, or analysis.
Form 41	Registration certificate of manufacturer.
Form 43	Registration certificate for import of cosmetics.

Authorities Involved

- Central Drugs Standard Control Organization (CDSCO)
- Drugs Controller General of India (DCGI)
- Port Health Authority / Port Officers
- Central Drugs Laboratory (CDL), Kolkata
- Customs Department **(for clearance of consignments)**

Offences and Penalties

Offence	Penalty
Import of spurious or adulterated drugs likely to cause death or harm	Imprisonment up to 10 years and fine not less than ₹10 lakh or 3 times the value of the drugs, whichever is more.
Import of misbranded or substandard drugs	Imprisonment up to 3 years and/or fine up to ₹5,000.
Import of cosmetics containing harmful ingredients	Imprisonment up to 3 years and/or fine up to ₹5,000.
Obstruction of Inspector or providing false information	Imprisonment up to 3 years and/or fine up to ₹5,000.

In addition:

- The court may order confiscation or destruction of imported goods.
- The license may be suspended or cancelled.