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PHARMACEUTICAL JURISPRUDENCE

UNIT 3

TOPIC :

- **Medicinal and Toilet Preparation Act-1955 :** Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations. Offences and Penalties.

Medicinal and Toilet Preparations (Excise Duties) Act, 1955

The Medicinal and Toilet Preparations (Excise Duties) Act, 1955 is an important law enacted by the Government of India to regulate and control the manufacture, distribution, and taxation of alcohol-containing preparations used for medicinal and toilet purposes.

This Act ensures that alcohol and narcotic substances used in medicinal and cosmetic products are properly controlled to prevent their misuse while enabling their lawful use in pharmaceuticals.

Objectives of the Act

The main objectives of the Medicinal and Toilet Preparations (Excise Duties) Act, 1955 are:

1. To levy and collect excise duty on all medicinal and toilet preparations containing alcohol, opium, or other narcotic substances.
2. To regulate manufacture and storage of such preparations in order to prevent misuse.
3. To ensure that alcohol used for medicinal or cosmetic purposes is used lawfully and not diverted for drinking.
4. To maintain uniform taxation and control across all states of India.
5. To ensure public health and safety by monitoring narcotic and intoxicating ingredients in formulations.
6. To control exports and imports of such preparations containing alcohol or narcotics.

Definitions (as per the Act)

Term	Definition
Alcohol	Includes ethyl alcohol of any strength and purity, including denatured spirit, rectified spirit, and absolute alcohol.
Medicinal Preparation	Any drug or formulation containing alcohol, opium, Indian hemp, or other narcotic substances used internally or externally for prevention, cure, or treatment of diseases.
Toilet Preparation	Any cosmetic or toilet article containing alcohol or other narcotic substances, used for cleansing, beautifying, or grooming (e.g., perfumes, aftershaves, lotions).
Bonded Manufactory	A licensed premises where alcoholic medicinal or toilet preparations are manufactured without immediate payment of excise duty.
Non-bonded (Outside Bond) Manufactory	A licensed premises where such preparations are manufactured after paying excise duty on alcohol in advance.
Excise Duty	A tax levied on the manufacture of goods within the country.

Licensing

Every manufacturer of medicinal or toilet preparations containing alcohol or narcotics must obtain a license before starting production.

Types of Licenses:

1. Bonded License: For manufacturing in a bonded (duty unpaid) area under government supervision.
2. Non-Bonded License: For manufacturing in non-bonded premises where alcohol duty is paid before use.

Conditions for Licensing:

- Application to the State Excise Commissioner with complete details of the premises and manufacturing process.
- The premises must be secure, ventilated, and approved by the authorities.
- The licensee must maintain proper accounts and records of alcohol receipt, use, and product output.
- The license can be revoked or suspended for violations.

Manufacture in Bond (Bonded Manufactory)

Manufacturing of alcoholic medicinal or toilet preparations without immediate payment of excise duty is called In-Bond Manufacture.

Key Features:

- Takes place in a bonded warehouse under direct supervision of an Excise Officer.
- Alcohol used in manufacturing is received free of duty.
- Excise duty is charged only on the final product when it leaves the bonded premises.
- Strict record-keeping and government supervision are mandatory.

Advantages:

- Duty is payable only on the finished product.
- Reduces the burden of paying duty on raw alcohol before use.
- Better control over misuse of alcohol.

Examples:

Manufacture of cough syrups, tinctures, and alcoholic elixirs in large pharmaceutical industries.

Manufacture Outside Bond (Non-Bonded Manufactory)

When alcohol used for manufacturing medicinal or toilet preparations is purchased after paying excise duty, the manufacturing unit is called non-bonded or outside bond manufactory.

Key Features:

- Alcohol used is duty-paid before use.
- The manufacturing process is not under continuous government supervision.
- Records must still be maintained and inspected periodically.
- Commonly used by small-scale manufacturers.

Disadvantages:

- Duty is paid on alcohol in advance, even before production.
- No refund is given for losses during manufacturing.

Export of Alcoholic Preparations

- "Export of alcoholic preparations" refers to the sending or transporting of medicinal or toilet preparations containing alcohol, opium, or narcotic drugs to countries outside India.
- These products are manufactured either in bond or outside bond, and the export must comply with the Excise Rules and Customs Regulations of India.
- The export process is closely monitored to ensure that no diversion of alcohol occurs for unlawful purposes.

Objective

- To promote international trade in Indian pharmaceutical and cosmetic products.
- To regulate export of preparations containing alcohol, narcotics, or psychotropic substances under strict excise control.
- To prevent illegal diversion of alcohol-containing preparations into the domestic market.

Licensing Requirements

1. The manufacturer or exporter must possess a valid manufacturing license under the Medicinal and Toilet Preparations (Excise Duties) Act, 1955.
2. A special export permit or license is required from the State Excise Commissioner or Central Excise Authority.
3. Customs clearance is mandatory before export.
4. In certain cases, a No Objection Certificate (NOC) may be needed from the Drugs Controller General of India (DCGI) or Narcotics Commissioner, depending on the composition of the product.

Conditions for Export

1. **Application for Export:**
   - The exporter must submit an application specifying the quantity, composition, destination country, and purpose of export.
2. **Approval by Excise Authorities:**
   - The Excise Officer verifies the stock and ensures that all duties are paid or exempted as per export provisions.
3. **Packaging and Sealing:**
   - The alcoholic preparation must be packed, sealed, and labeled as per excise and customs regulations.
   - Labels should clearly state "For Export Only".
4. **Documentation:**
   - Exporters must maintain detailed records including export license, invoices, shipping bills, and excise clearance certificates.
5. **Transport and Supervision:**
   - Goods are transported under bonded conditions or excise supervision until they are cleared by customs.
6. **Duty Exemption or Refund:**
   - Exported products are exempted from excise duty, or the exporter may claim a refund (rebate) of the duty already paid on alcohol used in the product.
   - This is to avoid double taxation, since the product will not be sold in India.

Types of Export

1. **Direct Export:**
   - The manufacturer exports the finished product directly to a foreign country.
2. **Indirect Export:**
   - The product is sold to an Indian export agent or company that exports it further.
3. **Export Under Bond:**

- The product is exported without payment of excise duty, subject to the condition that proof of export is furnished to the Excise Officer

Control and Supervision

- The Excise Officer or Customs Officer ensures that the goods meant for export are not diverted to the domestic market.
- Detailed inspection and verification of containers, seals, and documents are done before clearance.
- Any discrepancy or illegal diversion is treated as a serious offence under the Act.

Manufacture of Ayurvedic Preparations

- Ayurvedic preparations are formulations prepared as per the principles of Ayurveda, using herbal, mineral, or animal origin ingredients.
- Examples: *Asava, Arishta, Bhasma, Churna, Taila, Avaleha*, etc.
- Some Ayurvedic formulations (like *Asava* and *Arishta*) contain alcohol naturally produced by fermentation of herbal ingredients.

Key Points

- The alcohol used in Ayurvedic preparations is self-generated (not added externally) during fermentation.
- Therefore, no excise duty is levied on the alcohol that is naturally produced.
- However, if rectified spirit or any external alcohol is added during manufacture, the product becomes subject to excise duty.
- Manufacturers must hold a valid license under this Act, specifying the types of Ayurvedic preparations to be made.
- Manufacturing premises must be inspected and approved by the Excise Officer.

Manufacture of Homeopathic Preparations

- Homeopathic preparations are made according to the principles of Homeopathy, where drugs are diluted successively with alcohol or water to prepare tinctures and potencies.
- Alcohol (ethyl alcohol) is the most common solvent used for dilution and preservation.

Key Points

- Since alcohol is an essential ingredient, excise duty applies to homeopathic preparations containing alcohol.
- The manufacturer must obtain a license from the Excise Department and maintain a bonded laboratory or warehouse if using duty-free spirit.
- Homeopathic tinctures and potencies must be manufactured under excise supervision.
- Manufacturers are required to keep accurate accounts of spirit received, used, and balance remaining.

Examples

- *Mother tinctures*, *dilutions*, *external applications* (liniments, lotions).

Manufacture of Patent & Proprietary Preparations

- "Patent or Proprietary preparations" means formulations not included in any recognized pharmacopoeia (like IP, BP, or USP), but are manufactured and marketed under a brand name or trade name.
- These may be allopathic, Ayurvedic, or Unani in nature.
- Examples: *Cough syrups, tonics, liniments, elixirs, and pain balms*.

Key Rules

- If these preparations contain alcohol, opium, or narcotic drugs, they are liable to excise duty under this Act.
- A manufacturing license must be obtained, specifying the formula, process, and alcohol content of each product.
- The duty is charged based on the percentage of alcohol and the volume manufactured.
- Manufacturers must maintain daily production registers and submit monthly returns to the excise authority.

Offences and Penalties

Offence	Penalty
Manufacture or sale without license	Imprisonment up to 6 months or fine up to ₹2,000, or both
Unlawful possession or misuse of alcohol	Imprisonment up to 1 year or fine up to ₹2,000, or both
Non-maintenance or falsification of records	Imprisonment up to 1 year or fine up to ₹2,000, or both
Obstruction of excise officer	Imprisonment up to 6 months or fine
Tampering with duty-paid goods	Confiscation of goods and cancellation of license