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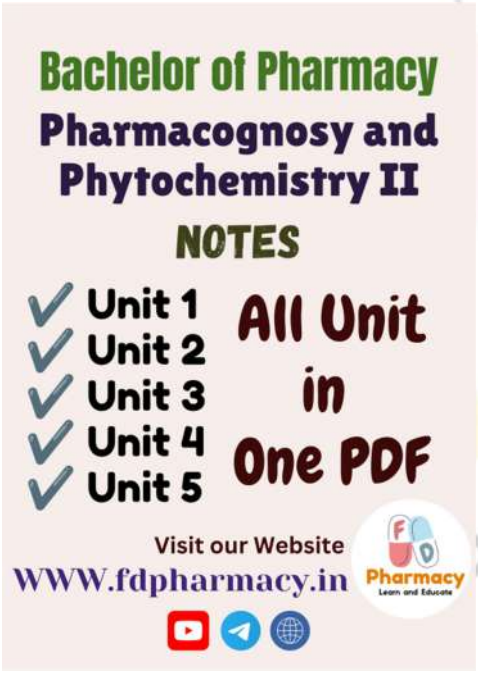
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PHARMACEUTICAL JURISPRUDENCE

UNIT 2

TOPIC :

- **Sale of Drugs –** Wholesale, Retail sale and Restricted license. Offences and penalties

SALE OF DRUGS

- The sale of drugs and cosmetics in India is governed by the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945.
- The aim is to regulate the sale, distribution, and storage of medicines to ensure that only qualified persons handle drugs and that patients receive safe and genuine medicines.
- Every person or firm engaged in drug sale must obtain a license from the State Drug Control Authority.

Types of drug sales

Drug sale is generally classified into:

1. Wholesale Sale
2. Retail Sale
3. Restricted License Sale

WHOLESALE SALE OF DRUGS

- The wholesale sale of drugs refers to the sale of medicines or pharmaceuticals to dealers, hospitals, dispensaries, or other license holders — not directly to the general public.
- It is regulated under the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945, mainly under Rule 64.
- The purpose of regulating wholesale sale is to ensure that only genuine, standard-quality medicines are supplied through qualified dealers.

Definition

Wholesale sale means selling drugs for the purpose of resale or distribution to another license holder, hospital, or institution, and not for direct consumption by patients.

Licensing Authority

- The State Drug Control Authority or Licensing Authority appointed under the Act grants the Wholesale License.
- The license is granted after inspection of premises and verification of qualifications.

Application for Wholesale License

Forms Used:

Purpose	Application Form	License Granted in
Sale of general drugs (non-biological, non-Schedule X)	Form 19	Form 20B
Sale of drugs specified in Schedule C & C(1)**	Form 19	Form 21B
Sale of Schedule X (narcotic/psychotropic) drugs	Form 19	Form 21G

Note: Schedule C & C(1)** includes biological and special products like vaccines, sera, insulin, etc.
Schedule X includes highly controlled substances like morphine, barbiturates, etc.

Premises Requirements

- The shop must have a separate area dedicated for drug storage and sale.
- It should have:
  - Minimum area: usually 10 m^2 (as per state rules).
  - Proper lighting and ventilation.
  - Storage facilities to maintain required temperature and humidity.
  - Refrigerator or cold storage for thermolabile drugs (e.g., vaccines, insulin).

Competent Person in Charge

- Wholesale sale must be conducted under the supervision of a competent person, who should be:
  1. A Registered Pharmacist, OR
  2. A person who has passed SSLC (10th standard) and has at least 4 years of experience in drug dealing, OR
  3. A person who has passed the Diploma in Pharmacy or Graduation in Science (with Chemistry or Biology) with 1 year of experience.

The name of the competent person must be mentioned in the license and displayed on the premises.

Conditions of Wholesale License (Rule 64)

The license holder must comply with the following important conditions:

1. Drugs to be sold only to authorized persons such as:
    - Other licensed wholesalers or retailers,
    - Hospitals, dispensaries, or registered medical practitioners.
2. Drugs must be purchased only from licensed manufacturers or dealers.
3. Drugs must be stored properly as per manufacturer's specifications.
4. No sale of expired, spurious, or misbranded drugs.
5. Records of purchase and sale must be maintained for all drugs, especially for Schedule H, H1, and X drugs.
6. License and certificates must be displayed prominently in the premises.
7. Drugs should be transported carefully to avoid contamination or deterioration.
8. Maintain invoices and bills with details like batch number, expiry date, and supplier name.

Record Maintenance

The wholesaler must maintain:

- Stock register showing quantity received and sold.
- Invoices/Bills containing:
    - Name and address of purchaser,
    - Name of the drug,
    - Batch number, manufacturer name,
    - Date of sale and expiry date.
- Schedule H and X drugs require prescription record books and sales registers for traceability.
- All records must be retained for at least 2 years from the date of sale.

Renewal and Validity of License

- The license is valid for 5 years from the date of issue.
- Application for renewal should be made before expiry (usually 3 months prior).
- Renewal may be refused if:
  - The licensee has violated rules,
  - Sold spurious or substandard drugs,
  - Failed to maintain proper records.

Inspection

- The Drug Inspector visits wholesale premises regularly to:
  - Verify the stock and records,
  - Check storage conditions,
  - Take samples for testing,
  - Ensure compliance with GMP and license conditions.

Suspension or Cancellation of License

The Licensing Authority may suspend or cancel a wholesale license if:

- The license holder violates any condition of license.
- Spurious, adulterated, or substandard drugs are found.
- Drugs are sold to unauthorized persons.
- The competent person is absent without replacement.

Before cancellation, the licensee is given a show-cause notice and an opportunity to be heard.

Offences and Penalties (for Wholesalers)

Offence	Relevant Section	Penalty
Selling drugs without valid license	Section 18(c)	Imprisonment up to 1 year or fine up to ₹10,000, or both
Selling substandard drugs	Section 27(d)	Imprisonment up to 2 years and fine up to ₹20,000
Selling spurious or adulterated drugs	Section 27(a)/(b)	Imprisonment 10 years to life + fine ₹10 lakh or 3× drug value
Failing to maintain records	Rule 65(5)(3)	Suspension or cancellation of license
Obstruction of Drug Inspector	Section 22(3)	Imprisonment up to 3 years or fine up to ₹5,000

RETAIL SALE OF DRUGS

- The retail sale of drugs means selling medicines directly to the public for personal or household use.
- It includes dispensing of medicines on prescription by a registered medical practitioner (RMP) and sale of over-the-counter (OTC) drugs.
- Retail sale is governed mainly by Rules 65 to 68 of the Drugs and Cosmetics Rules, 1945.
- The main aim is to ensure that only qualified pharmacists handle and dispense drugs to ensure patient safety and correct medication use.

Definition

Retail sale means the sale of any drug directly to the consumer (patient or public), usually through a chemist or pharmacy, for personal consumption and not for resale.

Licensing Authority

- The State Drug Control Department (Licensing Authority) issues Retail Drug Licenses after verifying:
  - The premises,
  - The qualifications of the pharmacist, and
  - The storage facilities.

Application for Retail License

Purpose	Application Form	License Form
For general allopathic drugs (non-biological)	Form 19	Form 20
For Schedule C & C(1) drugs (biologicals like vaccines, sera, etc.)	Form 19	Form 21
For Schedule X drugs (narcotic/psychotropic substances)	Form 19	Form 20F / 21F

A single license may be issued to cover more than one category of drugs if the conditions for each are satisfied.

Premises Requirements

- The pharmacy should have:
  - Minimum area: 10 m^2 (for retail alone)
  - 15 m^2 (if both retail and wholesale are conducted at the same premises).
  - Proper lighting and ventilation.
  - Refrigerator for thermolabile drugs (e.g., insulin, vaccines).
  - Clean storage area free from contamination, pests, and moisture.

Qualified Person (Registered Pharmacist)

- Retail sale must be conducted under the personal supervision of a Registered Pharmacist.
- The pharmacist must:
  - Hold a valid registration under the State Pharmacy Council.
  - Be present throughout the working hours.
  - Supervise dispensing, labeling, and storage.
  - Check the prescription for accuracy, dose, and drug interactions.
- If the pharmacist is absent, no sale of prescription drugs (Schedule H, H1, X) is allowed.

Conditions of Retail License (Rule 65)

The following are the major conditions attached to a retail sale license:

1. Drugs must be purchased only from licensed dealers or manufacturers.
2. Sale of prescription drugs (Schedule H, H1, and X) only on the written prescription of a registered medical practitioner.
3. No sale of expired or spurious drugs.
4. Maintain records of all purchases and sales, especially for Schedule H1 and X drugs.
5. Proper labeling and packing of dispensed drugs:
   - Label should include name of drug, patient, and prescribing doctor.

6. Display of License and Pharmacist's Certificate prominently in the premises.
7. Storage as per manufacturer's instructions (especially for temperature-sensitive products).
8. Maintain a prescription register and retain records for at least 2 years from the date of sale.
9. No advertisement or misleading claims for drugs.

Records to be Maintained

Type of Record	Details Maintained	Retention Period
Purchase Record	Name of supplier, invoice no., batch no., expiry date	2 years
Sales Record	Name of doctor/patient, prescription no., drug details	2 years
Schedule H1 Register	Serial no., name of prescriber, patient details, quantity supplied	3 years
Schedule X Register	Batch no., manufacturer, quantity in/out, balance stock	2 years

Records must be updated daily and available for inspection by the Drug Inspector.

Renewal and Validity

- Retail drug license is valid for 5 years.
- It should be renewed before expiry (preferably 3 months prior).
- Renewal may be refused if:
  - License conditions are violated,
  - Pharmacist not available,
  - Sale of substandard or spurious drugs is detected.

Sale of Different Categories of Drugs

Category	Schedule	Sale Condition
Non-prescription (OTC) drugs	Not listed in any Schedule	Can be sold without prescription
Prescription drugs	Schedule H, H1	Only on prescription by RMP
Biological & Special products	Schedule C & C(1)	On prescription; proper storage needed
Narcotic/Psychotropic drugs	Schedule X	Strict records and doctor's prescription required

Responsibilities of the Retail Pharmacist

Responsibility	Description
Prescription Checking	Verify dosage, interactions, and authenticity of prescription.
Counseling	Explain correct method of administration, side effects, and storage to patients.
Dispensing Accuracy	Ensure correct drug, strength, and quantity are dispensed.
Record Maintenance	Keep proper records for all transactions.
Storage Management	Maintain proper temperature and segregation of drugs.
Ethical Practice	Avoid substitution or sale of spurious drugs.

Inspection and Control

- Drug Inspector appointed under Section 21 of the Act can:
  - Inspect premises and verify records.
  - Take samples of drugs for testing.
  - Check expiry dates and storage conditions.
  - Recommend suspension or cancellation of license in case of violations.

Suspension or Cancellation of License

The Licensing Authority may suspend or cancel the license if:

- The license holder violates any conditions.
- A non-pharmacist sells prescription drugs.
- The premises are unhygienic or unsafe.
- Spurious or expired drugs are sold.

The licensee must be given a show-cause notice and an opportunity to be heard before cancellation.

Offences and Penalties (for Retail Sale)

Offence	Relevant Section	Penalty
Sale of drugs without a valid license	Section 18(c)	Imprisonment up to 1 year or fine up to ₹10,000, or both
Sale of misbranded drugs	Section 27(b)	Imprisonment up to 1 year or fine up to ₹20,000, or both
Sale of spurious or adulterated drugs	Section 27(a)/(b)	Imprisonment 10 years to life, fine ₹10 lakh or 3× drug value
Sale of substandard drugs	Section 27(d)	Imprisonment up to 2 years, fine up to ₹20,000
Sale without prescription (Schedule H/X)	Rule 65	License suspension or cancellation
False or misleading advertisement	Section 29	Fine up to ₹1,000 (first offence), ₹2,000 or imprisonment (subsequent)

RESTRICTED LICENSE SALE

- Restricted License Sale refers to the sale of certain classes of drugs by persons who are not qualified pharmacists, but are granted a restricted license by the Licensing Authority.
- Such a license permits the sale of specific non-prescription (OTC) drugs that are safe for use without medical supervision.
- It is meant for small shops or dealers in rural or semi-urban areas where full-fledged pharmacies or registered pharmacists are not available.

Definition

A Restricted License is a special permission granted under the Drugs and Cosmetics Rules, 1945, allowing a person (other than a qualified pharmacist) to sell certain categories of drugs, mainly non-prescription drugs, under specific conditions laid down by the Licensing Authority.

Purpose of Restricted License

The restricted license system was created to:

- Ensure availability of essential medicines in remote and rural areas.
- Allow sale of safe drugs that do not require prescription or pharmacist supervision.
- Prevent misuse of dangerous drugs by restricting high-risk categories (Schedule H, H1, X, etc.).
- Maintain control and traceability of drug distribution even in small-scale setups.

Authority and Legal Basis

- Governed by Rule 67A and Rule 68A of the Drugs and Cosmetics Rules, 1945.
- The State Licensing Authority (generally Drug Controller or Drug Inspector) issues the license.
- The licensee is known as a Restricted License Holder.

Forms Used

Type of License	Application Form	License Form
For sale of drugs (not including those specified in Schedule C, C(1), H, H1, or X)	Form 19A	Form 20A
For sale of drugs specified in Schedule C (excluding C(1), H, and X)**	Form 19A	Form 21A

Note: Schedule H, H1, and X drugs cannot be sold under a restricted license.

Drugs Allowed under Restricted License

Only non-prescription and non-biological drugs can be sold.
Examples include:

- Paracetamol tablets, Aspirin, Analgesic balms
- Antacids, Oral rehydration salts (ORS)
- Povidone-iodine, Antiseptic solutions
- Bandages, Cotton, Surgical spirit
- Vitamin and mineral supplements (non-prescription doses)
- Ointments, liniments, and mild cough syrups without codeine

Drugs NOT Allowed under Restricted License

- Prescription drugs (Schedule H, H1, X)
- Biological and special products (Schedule C & C(1)) like vaccines, sera, insulin, etc.
- Narcotic and psychotropic drugs
- Antibiotics (except those declared as OTC by the government)

Eligibility for Restricted License

To obtain a restricted license, the applicant must:

- Have a clean and hygienic shop or premises for drug storage.
- Ensure drugs are stored away from direct sunlight, moisture, and heat.
- Provide refrigeration facilities if necessary for permitted drugs.
- Maintain records of purchase and sale.
- Purchase drugs only from licensed dealers or manufacturers.
- Agree to inspection by Drug Inspectors at any time.

Application Procedure

1. Submit Form 19A to the Licensing Authority.
2. Attach:
    - Details of the premises and ownership.
    - List of drugs to be sold.
    - Proof of storage facility and hygienic conditions.
3. The Drug Inspector inspects the premises.
4. If conditions are satisfied, the license is issued in Form 20A or 21A.

Conditions of Restricted License (Rule 65 & 68A)

1. Drugs must be purchased only from licensed dealers or manufacturers.
2. Only permitted drugs (not in Schedule C, C(1), H, H1, X) can be sold.
3. The license must be displayed prominently in the premises.
4. Drugs should be stored properly as per manufacturer's instructions.
5. The licensee must maintain purchase records with supplier name, invoice number, batch number, and expiry date.
6. No prescription drugs shall be sold.
7. Drugs must not be advertised or misrepresented for false claims.
8. Licensee shall permit inspection by the Drug Inspector.
9. The license is valid for 5 years and must be renewed before expiry.

Records to be Maintained

Although simpler than a retail pharmacy, the restricted license holder must maintain:

Type of Record	Details
Purchase Register	Name of supplier, batch no., expiry date, quantity purchased
Sales Register	Date of sale, name of drug, batch number
Stock Register	Total quantity received and sold
Invoice/Receipt File	Original invoices from licensed wholesalers/manufacturers

All records must be kept for at least 2 years and produced for inspection when required.

Renewal and Validity

- Validity: 5 years from the date of issue.
- Renewal: Apply at least 3 months before expiry using the same Form 19A.
- Fee: As prescribed by the State Government.
- Renewal may be refused if:
  - Conditions of license are violated.
  - Sale of unauthorized or expired drugs.
  - Improper storage or unhygienic conditions.

Display Requirements

The licensee must display:

1. License in Form 20A / 21A prominently.
2. List of drugs permitted for sale.
3. "Restricted License—Drugs sold without prescription only" signboard.

Inspection and Enforcement

- Conducted by the Drug Inspector (under Section 22 of the Act).
- Inspector checks:
  - Validity of license.
  - Type of drugs sold.
  - Storage and labeling.
  - Source of purchase and record-keeping.
- If violation is found, inspector may seize drugs, suspend license, or prosecute under the Act.

Suspension or Cancellation

The Licensing Authority may suspend or cancel the restricted license if:

- Licensee violates any condition of the license.
- Sells drugs not permitted under the restricted license.
- Fails to maintain proper records.
- Stores or sells expired or spurious drugs.

Offences and Penalties

Offence	Relevant Section	Penalty
Sale without restricted license	Section 18(c)	Imprisonment up to 1 year or fine up to ₹10,000, or both
Sale of drugs beyond permitted list	Section 27(b)	Imprisonment up to 1 year or fine up to ₹20,000, or both
Sale of spurious/adulterated drugs	Section 27(a)/(b)	Imprisonment up to 10 years or life, fine ₹10 lakh or 3× drug value
Non-maintenance of records	Rule 68A	Suspension or cancellation of license
Misleading advertisement	Section 29	Fine up to ₹1,000 (first offence), ₹2,000 or imprisonment (subsequent)

Advantages of Restricted License

- Ensures availability of essential drugs in remote areas.
- Reduces dependence on pharmacists in villages.
- Provides legal control and supervision even for small drug sellers.
- Promotes safe and rational drug use among the public.