D.PHARM • SECOND YEAR

Pharmacy Law & Ethics

CHAPTER 1

General Principles of Law and Acts Related to Drugs & Pharmacy Profession



ENGLISH CHAPTER NOTES

DIPLOMA IN PHARMACY

GENERAL PRINCIPLES OF LAW (IN PHARMACY)

LAW: A system of rules recognized and enforced by the State to regulate behaviour.
In pharmacy, law controls medicines and professional practice to protect public health.

Criminal Law

Deals with offences against the State.
Examples: spurious drugs and unlawful drug supply.

Civil Law

Deals with disputes between people or organizations.
Negligent dispensing may lead to a compensation claim.

Administrative Law

Governs regulatory powers and decisions.
Examples: licensing, inspections and action by drug authorities or Pharmacy Councils.

Constitutional Law

Provides the basic legal framework, rights and distribution of government powers.

PURPOSES IN PHARMACY

- Regulate the profession.
- Ensure medicine safety, efficacy and quality.
- Protect people from harmful or substandard drugs.
- Maintain professional standards and ethical conduct.

HISTORY OF PHARMACY LEGISLATION IN INDIA

WHY DID LEGISLATION DEVELOP?

Uneven standards, unqualified dispensing and poor-quality medicines created a need for stronger controls.

1940 — Drugs and Cosmetics Act

A legal framework for controlling drug import, manufacture, distribution and sale.

1945 — Drugs Rules

Detailed requirements for putting the Act into practice.

1946 — Bhore Committee Report

An important health-service reform report, published before Independence.

1947 — Independence

Professional regulation continued to develop in independent India.

1948 — Pharmacy Act

Created Pharmacy Councils and a framework for pharmacist education and registration.



REMEMBER

- Drug legislation existed before Independence. The statement "there was no formal drug regulation before **1947**" is incorrect.
- The Bhore Report of **1946** is not a post-Independence event.

IMPORTANT ACTS RELATED TO DRUGS AND PHARMACY PROFESSION IN INDIA

Drugs and Cosmetics Act, 1940

MAIN FOCUS: Drugs and cosmetics.

- Regulates import, manufacture, distribution and sale.
- Provides for licences, quality standards and testing.
- Helps prevent the supply of unsafe, substandard and spurious products.
- The legal framework also includes provisions for Ayurvedic, Siddha and Unani drugs.

Pharmacy Act, 1948

MAIN FOCUS: The pharmacy profession.

- Establishes the Pharmacy Council of India (PCI) and State Pharmacy Councils.
- PCI sets minimum educational standards and approves courses and examinations.
- State Pharmacy Councils register pharmacists and maintain State registers.
- Supports qualified, accountable pharmacy practice.

KEY DIFFERENCE

Drug regulation and pharmacist registration are different requirements. A drug-sale licence is not a pharmacist registration certificate.

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