PHARM.D • YEAR 3

Pharmaceutical Jurisprudence

CHAPTER 1

Pharmaceutical Legislations: A Brief Review

PPT CHAPTER COVER



DOCTOR OF PHARMACY

Why pharmaceutical legislation matters

Pharmaceutical legislation is the legal framework governing medicines and pharmacy-related activities.

QUALITY

Prevent adulterated, spurious and substandard products from reaching patients.

ACCOUNTABILITY

Control manufacture, import, distribution and sale through defined duties and oversight.



PROFESSIONAL PRACTICE

Require appropriate education, registration and ethical conduct.

ACCESS

Support medicine availability and fair pricing through the relevant legal mechanisms.

Public protection depends on effective standards, competent personnel and enforcement — not merely on having an Act.

From a public problem to a legal response

THE PROBLEM



Unreliable medicine quality, weak testing systems and unevenly, trained personnel created avoidable health risks.

THE ENQUIRY



Expert committees examined drug supply, healthcare services and the pharmaceutical industry, then recommended reforms.

THE RESPONSE



Legislation, rules, laboratories, licensing and professional councils developed over time.

An expert committee recommends policy. → Parliament enacts an Act. → Rules provide operational detail under legai thority.

Do not confuse a recommendation, a draft proposal and an enforceable legal requirement.

Key laws: products and the profession

1940

DRUGS AND COSMETICS ACT

Regulates the import, manufacture, distribution and sale of drugs and cosmetics.



1945

DRUGS RULES

Provide detailed requirements such as licences, standards, labels and schedules.



1948

PHARMACY ACT

Regulates pharmacy education and pharmacist registration.



Remember the distinction:

product regulation is not the same as professional registration.

The Pharmacy Act is from 1948, not 1954. Read each Act together with its applicable rules and later amendments.

Key laws: later developments



1970 – PATENTS ACT

Protects qualifying inventions. Pharmaceutical product patents became available after the 2005 amendment.



1985 – NDPS ACT

Controls narcotic drugs and psychotropic substances while allowing authorised medical and scientific use.



2010 – CLINICAL ESTABLISHMENTS ACT

Provides registration and minimum-standard requirements where applicable.



2013 – DPCO

The current base price-control Order, read with amendments and notifications.

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