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PHARMACEUTICAL JURISPRUDENCE

UNIT 3

TOPIC :

- **Pharmacy Act-1948** : Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils; constitution and functions, Registration of Pharmacists, Offences and Penalties



Pharmacy Act, 1948

The Pharmacy Act, 1948 was enacted by the Government of India to regulate the profession of pharmacy in India.

Before this Act, anyone could sell or dispense medicines, leading to unsafe and unethical practices.

Hence, this law was passed to ensure that only qualified and registered pharmacists handle medicines, ensuring public safety and professional standards in the field of pharmacy.

Objectives of the Pharmacy Act, 1948

1. To regulate the profession of pharmacy in India.
2. To establish Pharmacy Councils at the central and state levels to control and monitor pharmacy education and practice.
3. To prescribe minimum standards of education required for qualification as a pharmacist.
4. To maintain a register of pharmacists (list of qualified pharmacists in each state).
5. To prohibit unqualified persons from practicing as pharmacists.
6. To promote ethical and professional conduct among pharmacists.
7. To ensure safe dispensing and handling of medicines to protect public health.

Important Definitions

Term	Definition
Pharmacy	The art and science of preparing, compounding, dispensing, and proper utilization of drugs and medicines.
Pharmacist	A person whose name is entered in the register of pharmacists maintained under the Act.
Registered Pharmacist	A person who is duly qualified and registered under the Pharmacy Act to practice pharmacy.
Central Council	The Pharmacy Council of India (PCI) established under Section 3 of the Act.
State Council	The State Pharmacy Council constituted under Section 19 of the Act.
Register	The official record containing names of all registered pharmacists in

Pharmacy Council of India (PCI)

The Pharmacy Council of India (PCI) is the statutory body constituted by the Central Government under Section 3 of the Pharmacy Act, 1948. It is responsible for regulating the pharmacy education and profession in India.

The PCI ensures that the standards of education, training, and professional ethics in pharmacy are maintained uniformly across the country.

Objectives of PCI

1. To regulate the pharmacy profession in India.
2. To prescribe and maintain minimum educational standards for pharmacists.
3. To approve pharmacy institutions and courses for registration as pharmacists.
4. To maintain the Central Register of Pharmacists.
5. To promote professional ethics, competence, and standards among pharmacists.
6. To advise the Central and State Governments on matters relating to pharmacy education and practice.

Composition of PCI

The Pharmacy Council of India consists of three categories of members:

A. Elected Members:

1. Six members elected by the University Grants Commission (UGC) from among teachers of pharmacy in Indian universities or colleges granting pharmacy degrees or diplomas.
2. One member elected by the Medical Council of India (MCI) from among its members.
3. One member elected by each State Pharmacy Council from among its members.

B. Nominated Members:

1. Six members nominated by the Central Government from experts in pharmacy, chemistry, or medicine.

C. Ex-officio Members:

1. Director General of Health Services (DGHS)
2. Drugs Controller of India (DCGI)
3. Director of Central Drugs Laboratory (CDL), Kolkata
4. Director of Pharmacopoeia Laboratory (Indian Pharmacopoeia Commission)

Functions of the PCI

A. Educational Functions:

1. Prescribe minimum standards of education required for qualification as a pharmacist.
2. Frame Education Regulations (ERs) under Section 10 of the Act.
3. Approve courses of study and examinations in pharmacy.
4. Inspect pharmacy colleges and institutions for compliance with PCI norms.
5. Withdraw approval from institutions that fail to meet prescribed standards.

B. Professional Functions:

1. Maintain the Central Register of Pharmacists.
2. Regulate professional conduct and ethics of pharmacists.
3. Ensure uniform implementation of pharmacy laws across all states.
4. Promote continuing education and training programs for pharmacists.

C. Advisory Functions:

1. Advise the Central and State Governments on matters concerning pharmacy education and practice.
2. Provide expert opinions on policy formulation, recognition of qualifications, and pharmacy manpower planning.

Powers of the PCI

- Power to approve or disapprove pharmacy institutions.
- Power to inspect and monitor pharmacy colleges periodically.
- Power to prescribe the course content, examination pattern, and internship training.
- Power to recognize or withdraw recognition of qualifications.
- Power to frame regulations and enforce disciplinary measures against unethical practices.



Education Regulations (ERs)

- The Pharmacy Council of India is empowered to make Education Regulations that prescribe the minimum standard of education required for qualification as a pharmacist.

Main Provisions of ERs:

1. Minimum Qualification for Admission:
 - 10+2 with Physics, Chemistry, and Biology/Mathematics.
2. Minimum Course of Study:
 - Diploma in Pharmacy (D.Pharm) – 2 years + practical training of 500 hours.
 - Degree in Pharmacy (B.Pharm) – 4 years.
3. Curriculum Standards:
 - Subjects, syllabus, practical training, and examination pattern.
4. Approval of Institutions:
 - Institutions must fulfill all requirements such as staff, infrastructure, laboratories, and equipment as per PCI norms.
5. Inspection:
 - PCI periodically inspects colleges to ensure compliance with ERs.

State Pharmacy Council (SPC)

The State Pharmacy Council (SPC) is a statutory body constituted by the State Government under Section 19 of the Pharmacy Act, 1948.

It is responsible for the implementation of the Act at the state level, primarily dealing with the registration and regulation of pharmacists, and ensuring that pharmacy practice and education in the state meet the required professional standards.

Objectives of the State Pharmacy Council

- To register qualified pharmacists within the state.
- To maintain an up-to-date register of pharmacists.
- To enforce the provisions of the Pharmacy Act, 1948 at the state level.
- To regulate the profession and practice of pharmacy within the state.
- To ensure that only qualified and registered pharmacists are engaged in dispensing drugs.
- To cooperate with the Pharmacy Council of India (PCI) for uniform standards of pharmacy education and practice.

Constitution of the State Pharmacy Council

Each State Government constitutes the State Pharmacy Council as follows:

(a) Elected Members

- Six members elected from among the registered pharmacists of the state.

(b) Nominated Members

- Five members nominated by the State Government, out of which at least three must be registered pharmacists.

(c) Ex-Officio Members

- One representative of the Medical Council of the State.
- Chief Administrative Medical Officer (Director of Health Services) of the State.
- Government Analyst appointed under the Drugs and Cosmetics Act, 1940.

In case two or more states form a Joint State Pharmacy Council, the composition may differ slightly as per mutual agreement between the states (under Section 20 of the Act).

Functions of the State Pharmacy Council

1. Registration of Pharmacists:

- To prepare and maintain the Register of Pharmacists in the state.
- To verify qualifications before granting registration.

2. Renewal of Registration:

- To renew the registration of pharmacists periodically and ensure updated records.

3. Approval of Educational Institutions:

- To approve or inspect institutions imparting pharmacy education in the state (in collaboration with PCI).

4. Disciplinary Actions:

- To conduct inquiries against pharmacists for professional misconduct or malpractice.
- To suspend or remove names from the register if found guilty.

5. Inspection and Regulation:

- To ensure proper standards of pharmacy practice in hospitals, community pharmacies, and drug stores.

6. Communication with PCI:

- To send reports, recommendations, and statistics to the Pharmacy Council of India for coordination and national planning.

Register of Pharmacists

- The SPC maintains a Register of Pharmacists, which includes:
 - Full name and address.
 - Qualification and date of registration.
 - Employment details (if applicable).
- Only those whose names appear in the register can legally practice pharmacy or dispense medicines.

Joint State Pharmacy Council (JSPC)

The Joint State Pharmacy Council (JSPC) is a statutory body formed when two or more states agree to establish a single council to perform the functions of the State Pharmacy Council jointly.

It is constituted under Section 20 of the Pharmacy Act, 1948.

The JSPC ensures uniform implementation of pharmacy laws, registration of pharmacists, and regulation of pharmacy practice and education across multiple states.

Objective of the Joint State Pharmacy Council

- To regulate the profession and practice of pharmacy in all the participating states.
- To register and maintain records of qualified pharmacists from the member states.
- To enforce the provisions of the Pharmacy Act, 1948 uniformly across participating states.
- To coordinate with the Pharmacy Council of India (PCI) on educational and professional standards.
- To ensure effective administration and optimum use of resources among small or neighboring states.

Composition of the Joint State Pharmacy Council

The Joint State Pharmacy Council generally consists of the following members:

(a) Elected Members:

- Six members elected from among the registered pharmacists of each participating state.

(b) Nominated Members:

- Five members nominated by the Governments of the participating states, out of which at least three must be registered pharmacists.

(c) Ex-Officio Members:

- One representative of the Medical Council of each participating state.
- The Chief Administrative Medical Officer (Director of Health Services) of each state.
- The Government Analyst appointed under the Drugs and Cosmetics Act, 1940, from each participating state.

Note: The total number of members and the exact distribution may vary as per the agreement between the states and the approval of the Central Government.

Functions of the Joint State Pharmacy Council

The JSPC performs the same functions as a State Pharmacy Council but for multiple states:

1. Registration of Pharmacists:

- To prepare and maintain the Register of Pharmacists for all participating states.
- To grant or renew registration only to those who fulfill the educational qualifications prescribed under the Pharmacy Act.

2. Approval of Institutions:

- To inspect and approve pharmacy institutions in the member states (in cooperation with PCI).

3. Regulation of Pharmacy Practice:

- To ensure that only registered pharmacists dispense medicines and handle drugs.
- To enforce ethical standards in pharmacy practice.

4. Disciplinary Control:

- To conduct inquiries into professional misconduct of registered pharmacists.
- To suspend or remove names from the register if necessary.

5. Communication with PCI and State Governments:

- To provide reports, recommendations, and data regarding pharmacy education and practice.

6. Renewal and Restoration of Registration:

- To renew registration periodically and restore names removed for valid reasons.

Advantages of the Joint State Pharmacy Council

- Promotes uniform regulation and standardization across states.
- Reduces administrative costs by sharing resources.
- Enhances coordination between smaller or neighboring states.
- Strengthens communication with PCI and central authorities.
- Ensures efficient management of pharmacy registration and regulation.



Registration of Pharmacists

- Registration of Pharmacists is one of the most important provisions of the Pharmacy Act, 1948.
- It ensures that only qualified and competent persons are allowed to practice pharmacy or dispense drugs in India.
- The registration process helps in maintaining a professional register of pharmacists, thereby ensuring public safety, ethical practice, and standardization of pharmacy services.

Objective of Registration

The main objectives of pharmacist registration are:

- To ensure that only trained and qualified persons handle and dispense medicines.
- To regulate the profession and practice of pharmacy in India.
- To maintain a state-wise record (register) of all practicing pharmacists.
- To promote ethical standards and professionalism in pharmaceutical practice.
- To protect the public from unqualified practitioners in the field of drugs and medicines.

Register of Pharmacists

Every State Pharmacy Council must prepare and maintain a register of pharmacists in the prescribed form.

This register includes the following details for each pharmacist:

- Full name and residential address
- Date of birth
- Qualification and institution name
- Date of registration
- Employment details (if any)
- Registration number and renewal status

The register is a public document, and certified copies can be obtained on request.

Eligibility for Registration

A person is eligible for registration as a pharmacist if they fulfill the following conditions:

(a) Minimum Age:

- The applicant must be at least 18 years old.

(b) Qualification:

- Must hold a Diploma or Degree in Pharmacy or a qualification recognized under the Pharmacy Council of India (PCI).

(c) Citizenship:

- Must be an Indian citizen or a person approved by the Central Government (in case of foreign nationals).

(d) Good Character:

- Must be of good moral character.

Procedure for Registration

The registration process usually involves the following steps:

1. Application Submission:

The candidate applies to the Registrar of the State Pharmacy Council in the prescribed form along with required documents (educational certificates, age proof, etc.).

2. Verification:

The council verifies the applicant's qualifications and eligibility.

3. Entry in Register:

Upon approval, the applicant's name is entered in the Register of Pharmacists.

4. Issuance of Certificate:

The registered pharmacist receives a Certificate of Registration (Registration Number).

5. Publication:

The council publishes the list of registered pharmacists in the official gazette.

Renewal of Registration

- Registration is valid for a specific period (usually 5 years).
- Pharmacists must apply for renewal before the expiry date.
- Renewal ensures that the register remains current and accurate.
- If a pharmacist fails to renew registration in time, their name may be removed from the register but can be restored upon payment of the prescribed fee and late renewal charges.

Removal of Names from Register

A pharmacist's name can be removed from the register if:

- They are convicted of an offence under the Pharmacy or Drugs and Cosmetics Act.
- They are found guilty of professional misconduct or unethical practice.
- They fail to renew their registration.

However, the person can appeal to the State Government or Pharmacy Council of India (PCI) for reconsideration.

Restoration of Name

- A pharmacist whose name was removed can apply for restoration.
- The council may restore the name upon satisfactory explanation and payment of fees.

Offences and Penalties

Offence	Description	Penalty
Unregistered practice	Practicing as a pharmacist without registration	Imprisonment up to 6 months or fine up to ₹1000 or both
False representation	Falsely claiming to be a registered pharmacist	Imprisonment up to 6 months or fine up to ₹1000 or both
Failure to surrender certificate	Not returning registration certificate after removal from register	Fine up to ₹50 for each day of default
Violation of	Running a pharmacy	Institution's disapproval and

education standards	institution without PCI approval	legal action under Pharmacy Act & PCI Rules
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