

Chapter 2 Pharmacy Law & Ethics

Pharmacy Act 1948 & Rules

Introduction Pharmacy Act 1948:-

Before independence there were no regulations for the profession and practice of pharmacy. The drug enquiry committee recommended that the person practicing pharmacy that is the person responsible for compounding and dispensing of medicines should have a proper education background.

Health survey and development committee also made a similar type of recommendation consequently the Pharmacy Act come into force in March 1948.

Objectives of Pharmacy Act, 1948

The pharmacy act 1948 is passed with the main objects to regulate the profession and practice of pharmacy are as follows-

- To make better provisions for regulating profession and practicing of pharmacy.
- To rise the status of "Profession of Pharmacy" in India.
- To constitute "Pharmacy Council of India" For setting new standards in pharmacy education.
- To regulate pharmacy institution specially "Diploma in Pharmacy" through education regulations with registration of pharmacist.

Definitions:-

The pharmacy act was passed in March 1948 there were following components to followed by pharmacy act.

1. Registered Pharmacist :- Registered pharmacist means a person whose name is for the time being entered in the register of state in which he is for a time being residing or carrying on his profession or business of pharmacy.

2. Central council :- Central council means ""PCI constituted under section-3 of pharmacy Act 1948.

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3. Executive committee: - Executive committee means executive committee of control council or state council as the context may require.

4. State council: - State council means a "State Council of Pharmacy" constituted under section-19 and includes "Joint state council of Pharmacy" constituted in accordance with an agreement under section-20 of Pharmacy Act 1948.

5. Displaced person: - Any person who has left or has been displaced from place of his residence in Pakistan on or after 1 March 1947 on account of setting up of dominions of India and Pakistan or on account of civil disturbance or fear thereof and since then residing in India.

6. Central Register: - Central Register means the register of pharmacists maintained by the pharmacy council of India under section-15A.

7. Repatriates :- Repatriates means any person of Indian origin who has left or has been displaced from place of his residence in Burma, Sri Lanka, Uganda or any other countries, after 14th April 1947 on account of civil disturbance or fear thereof and since then residing in India.

8. Medicinal practitioner: - A person registered for medicinal practitioner of state who is declared by the state government of India.

A person registered or eligible for registration in the Register of dentists for a state under the dentist act 1948.

Pharmacy Council of India :-

The first pharmacy council was constituted in 1949. It is reconstructed every five years. The pharmacy council of India is constituted under section-3 of pharmacy Act 1948 and consists of following members.

- A. Elected members
- B. Nominated Members
- C. Ex-official members

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A. Elected members :-

- Six member elected by "**University Grand Comdition**" from among teachers working in Indian University or college affiliated to Indian University which grants degree or diploma in Pharmacy. Among these only one teacher of each the subject pharmaceutical chemistry, pharmacology, Pharmacognosy.
- One members elected from themselves by member of "**Medical council of India**"
- One registered Pharmacist to represent each state, selected from themselves by member of eachstate council.

B. Nominated Members:-

- Six members are nominated by the central government of whom at least four shall be processingdegree or D.Pharma and are in practice of pharmacy or pharmaceutical chemistry.
- A representative of University Grand Comdition.
- A representative of "**All India council for technical education**" (A.I.C.T.E.)

C. Ex-officio members:-

- The director general, health service, ex-officio.
- The drug controller of India.
- The director of central drug laboratory.

Function of PCI:-

1. To regulate pharmacy institution specially Diploma in Pharmacy through education regulation.
2. To frame periodically "Education Regulation" with approval of central government for setting new standard for pharmacy education.
3. To approve or disapprove course of study and examination in pharmacy.
4. To recognise foreign qualification in pharmacy for purpose of registration.
5. To maintain central register of pharmacist.

Power of PCI to regulation.

- Under section-10 of pharmacy Act, The pci is empowered to frame education regulations after approval of central government.
- Under section-18 a pharmacy act with approval of central government PCI is empowered to make regulations for the following purpose.
- Management of property of central council

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- Manner of conducting elections.
- Holding meetings to fix time, place, and conduct, of business in such meeting.
- Function of executive committee, holding meetings to fix time and place.
- Power and duties of president and vice president.
- Qualifications, terms, power and degree of registered, inspectors and other officers.

Education and Regulations:-

Under section-10 of pharmacy Act 1948 the PCI is empowered to frame education regulation after approval of central government. The education regulations prescribed minimum standards of educations for Pharmacists which includes-

1. Qualification of Pharmacist
2. Minimum qualification for admission to 1st year D.pharma.
3. Approval of institute conduction course of study.
4. Approval of examination
5. Eligible for appearing in examination at d.pharma part 1st and part 2nd.
6. Periods and other conditions of practical training.
7. Equipment and facilities to be provided by institutions.
8. Condition to fulfill by the examination authority.

Procedure of framing

Education regulation (ER) and Amendments.

- Under section-10 of pharmacy Act 1948 there is provision for framing education regulations for regulations and control of pharmacy institution. The central with approval of central govt. Make regulations called education regulations.
- Education regulation prescribe minimum standards of educations required for qualification as Pharmacists.
- Befor submitting the education regulations for approval of central forward copies of draft of education regulation to all state government.
- The state government of required to send comment to copy to draft.
- After considering the comments on the draft education regulation, The central council shall be submit the draft of education regulation to the central government for eight approval.
- After approval of central government education regulations are published in the official gazettes.

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The efficacy of education regulation shall be reported to central council by the executive council and may propose amendments. Some procedure also forward for efficiently amendments of state council.

- Application of education regulation to the state.
- Any time after constitution of state council with due consultation of state council state government may apply education regulation to the state by notification in the official gazettes.

State Pharmacy Council.

Section-19 of pharmacy Act 1948 provides for constitution and composition of state council. Every state government has to constitute state council accordingly which consists of following members.

1. Elected members
2. Nominated Members
3. Ex-officio members

1. Elected members: - Six members elected from among themselves by registered Pharmacist of state.

One member elected by the state Medical council from amongst its member.

2. Nominated Members: - Five members are nominated by the state government of whom atleast three should be degree are D.Pharm or pharmaceutical chemistry or should be registered Pharmacist.

3. Ex-officio members: - The chief administrative medical officer of the state ex-officio.

- The officer incharge of drug controller department of State.
- The government analyst deputed by the state government.
- President and Vice President of shall be elected by the members from amongst themselves.
- Subject to membership they hold office for the five years and are also eligible for re-election.

Elected and nominated Members hold office for five years however they may in written resign at any time. If any nominated or elected member remain absent without sufficient reason for three constitutive meetings. He is deemed to have vacated his seat casual vacancies filled only for the reminder term by fresh nomination or elections as the case may be.

Registration of pharmacist:-

The pharmacy act provides for registration of the pharmacist to regulate the entry of person in "Pharmacy professions" only person having requisite, qualifications, training, and experience are allowed to enter the professions. Name of registered Pharmacist are entered in the Register maintain by state council and central council.

The register include particulars:-

- Full name and residential address of registered Pharmacist.
- Date of first admission to register.
- Qualification for registration
- Professional address, Name of employer if employed.
- Such other particulars are may be prescribed.

First register:-

- For preparation of 1st register the state government constitutes a "Registration Tribunal" by notification in the official gazette.
- The tribunal consists of three person and a register. The registered act as secretary of tribunal.
- The state government by notification specify the date for submission of applications for registration. The applications for registration along with prescribed fee should be made on or before this date registration tribunal.
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Qualification for entry on 1st register:-

- A person above 18 years of age who resides or carries business or professions of pharmacy in the state on patient of prescribe fee is entitled for entry of the name in the 1st Register.
- Hold degree or diploma in Pharmacy of pharmaceutical chemistry or a "chemist" and "druggist" "Diploma of Indian University or state government". A qualification granted outside of India approved under section-14.
- Hold degree of and Indian University other than degree in pharmacy or pharmaceutical chemistry and has been engaged for a total period of time is more than than 3 years in compounding of drug in hospital or dispensary in other place.
- Passed an examination recognised as adequate by the state government for compounding or dispensing.

Procedure for Registration of Pharmacist:-

- Under provisions for section-33 of act state pharmacy council register name, Address, and, Qualifications of the Pharmacist in the state register an application in prescribed pro-forma is to be submitted to the register of respective State pharmacy council.
- The application should be accomplished by the prescribed fee and following document.

Document required for Registration of Pharmacist (P.C.I. Registration):-

1. 5 recent passport size photo
2. ID proof
3. Address proof
4. Hospital training certificate
5. Mark sheet of 1st year and 2nd year D.Pharma, If you want to get the registration of B.Pharma then its complete mark sheet all year.
6. Provision certificate
7. 10+2 marksheet

Renewal of Registration:-

- First registration continued till 31 December of year following the year in which it is granted there after registered Pharmacist should annually renew registration by the due date to retain his name on register of pharmacist.
- On failure to remit renewal fee before due date 1 April of subsequent year.
- The name defalter pharmacist is remove from the registered on payment of renewal fee the register issues receipt therefore.
- This stand as a proof of renewal of Registration in order to avoid such situation, pharmacist may voluntarily remit advance renewal fee in Lump Sum (ARFL).

Offences and Penalties:-

- Falsely claiming to be a registered Pharmacist.
- Dispensing by unregistered person.
- Will full obstruction to an inspector
- Failure to surrender certificate of registration.