

Pharmacy act 1948 and rules -

Introduction

The pharmacy act 1948 was passed with broad objective of regulation practice of pharmacy in India. The act has been divided in to 5 chapters and 46 sections.

The primary obligation of pharmacy is to safe guard the public health by making available the right medicament. The act extend to the whole of India except the state Jammu & Kashmir.

It come into force on 4th March 1948

But the chapters relating to state pharmacy council registration of pharmacist and miscellaneous provision where state form such date as the state government might by notification in the official gazette.

Objective of pharmacy act 1948 -

- To regulate the pharmacy education in the country.
- To allow the registration as pharmacist under the pharmacy act.
- To regulate the profession and practice of pharmacy.

- Constitution of pharmacy council of India (PCI) responsible for evolving educational standards and regulation for the course in pharmacy.

* * * Definition * * *

Agreement — Agreement means an agreement entered in to under section 20. (inter state agreement regarding constitution of state councils).

Approval — Approval means approval by the state council under section 12. (courses of study and examination in pharmacy) or section 14 foreign qualification for the purpose of qualifying for registration under the act.

Central Council — Central Council means the pharmacy council of India constituted under section 3.

Central register — Central register means the register of pharmacist maintained by the central council under section 15A.

Register — Register means a register of pharmacist prepared and maintained under the act.

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

State Council - State Council means a State Council a pharmacy constituted under **Section - 19** and include a joint State Council of pharmacy in accordance with an agreement under **Section - 20** of the act.

Pharmacy Council of India

The central council (P.C.I) is constituted by the central government and the 1st central council was constituted in 1949.

It is reconstituted every 5 years and consist of following members —

① **Elected members** — 6-members including atleast one teachers each in pharmaceutical chemistry, pharmacology, pharmacognosy, or the teaching staff of an Indian university or an affiliated college granting a degree a D. Pharm. These members are elected by the university grants commission (U.G.C.)

One member elected by P.C.I from amongst its member (Medical Council of India).

One member who shall be considered pharmacist to represent each state elected by state council from amongst its members

② **Nominated members** — 6-members including atleast 4-person possessing degree of Diploma in pharmacy & engaged in the practice of pharmacy or pharmaceutical chemistry nominated by the central government.

A representative each of the university grant commission and all India Council for technical education.

One registered pharmacist to represent each state nominated by the state government / union territory administration.

③ Ex-officio members -

The director general of health services.

The director of central drug laboratory.

The drug controller in India.

Note - If the ex-officio members under C₁ and C₂ above are

unable to attend any meeting they can authorise a person each in writing to attend the meeting.

Imp

Education regulations - The P.C.I. also makes regulations called as education regulations with the approval of central government and prescribes the minimum qualification required for registration as a pharmacist.

The education regulations 1991 prescribes:

- The nature and period of study and of practical training (not less than 500 hours spread over a period of not less than 3 months provided that not less than 250 hours are devoted to actual dispensing of prescription in a recognised hospital / dispensary and pharmacy chemist / druggist or a licenced drug manufacturing unit.
- The equipment and facilities to be provided for students.
- Education regulations - 91 have replaced the education regulations - 81.
- The education regulations are approved by the central government.
- Education regulations and amendments there to are published in the official gazette. The executive committee of the central council is also required to report from time to time to the council on the efficacy of education regulations and recommend such amendments as it may think fit.

Application of Education regulation to State

Education regulations takes effect in a state from the date notified by the state government in the official gazette in consultation with the state council at any time after it is constituted. :-

It shall also maintain its account and other relevant records in the prescribed manners.

The accounts of the central council are audited and certified annually.

The central council also makes the regulation for —

- The management of its property.
- Manner of conducting election.
- Functions of the executive committee.
- The procedure for summoning and calling meetings, conduct of the business, the quorum.
- powers and duties of the president and vice president.
- Qualifications, terms of office and powers and duties of the registrar.

Approved courses of study and examinations

Any authority or institution in India conducting a course of study for pharmacist may apply to the central council for approval of courses and examinations.

The council then deputed its inspectors to visit the institution and ascertain whether the institution has the minimum facilities for running such a course or holding examinations in conformity with the education regulation.

The inspectors may also be required to attend any examination without interfering with its conduct to judge its standards.

With drawal of approval

Where the executive committee reports the central council that an approved course of study or an approved examination no longer continues to be in conformity with education regulations, the central council gives notice to the authority concerned of its intention to consider the withdrawal of approval.

Approval of Other qualification —

The central council may approved any qualification granted by an authority outside India to be an approved qualification —

For the purpose of qualifying for registration under this act if a sufficient guarantee of the requisite skills and knowledge is afforded

o **The central register of pharmacist** —

The council is required to maintain a register of pharmacist known as the central register; this register contains the names of all persons for the kind being entered in the registers of different States.

Elected members — 6 — registered pharmacist
 elected from amongst themselves & one member elected from the
 themselves by the members of M.C.T

Nominated members — 5 — members of whom
 at least one shall be possessing
 a degree or diploma in pharmacy or
 pharmaceutical chemistry or be registered
 pharmacist, nominated by the the
 State government.

Ex-officio members —

- chief administrative medical officer of the State.
- officer in charge of drug and cosmetic act 1940.
- Government analyst under the drug and cosmetic act as the State government may appoint in this behalf.

Joint State Council —

Elected members — 3 to 5 registered pharmacist
 elected from amongst themselves —
 however if agreed the no. of
 members elected by each of the
 participating State may varies but —

Shall be within 3 to 5 Only.

One member elected by the medical council of each state from amongst its members.

Nominated members - 2 to 4 members
nominated by each participating state of whom more than half shall be passing a degree or D. Pharm or Pharma clinic chemistry or be registered pharmacist.

Ex-officio members - chief administrative medical officer of each of the participating state.
officer in charge of the drug control organization of each participating state.
Government analyst of each participating state.

Inter State agreement -

Two or more state entering in to an agreement may agree for the constitution of a joint state council for all the participating state or that the state council of one state shall serve the needs of the other participating state. Such an agreement may also provide for:

◦ The apportionment of the expenditure b/w the participating State which of the participating State Government shall exercise the several functions of the State government under this act.

◦ Constitution b/w the participating State government either generally or with reference to particular matters arising under this act.

Registration of pharmacist

The pharmacy act provide for the registration of pharmacist to regulate the entry of persons in this profession. It ensures that only those persons having requisite qualification, training and experience relating to the compounding dispensing handling storage etc of the drug are allowed to enter the practice of pharmacy.

Name of the registered pharmacist are entered in the registers.

Maintained by the State councils and the central council.

The State gov: are responsible for the preparation of first registers in each State after the chapter relating to registration of pharmacist has taken effect in any.

State the register includes the following particulars—

The full name and residential address of the registered pharmacist.

The date of his first admission to the register.

His professional address and in case of employed persons the name of the employer and such other particulars as may be prescribed.

First Register

For the preparation of the first register the State Gov. constitutes a registration tribunal by notification in the official gazette.

The tribunal consists of three persons and a registrar is also appointed who acts as its secretary.

by the State Gov. and published. The first register is published by the State Gov. and person aggrieved by the decision of the tribunal may appeal within 60 days from the date of such publication to the authority appointed by the State Gov. in his behalf.

Qualifications for entry on Drugs Register -

A person who has attained the age of 10 years shall on payment of the prescribed fee be entitled to have his name entered in the Drugs Register if he resides or carries on the business or profession of pharmacy in the State and if he -

- Hold a degree or diploma in pharmacy or pharmaceutical chemistry or a chemist and druggist diploma or a state government. Hold a degree of a Indian University other than a degree or Indian diploma in pharmacy or pharmaceutical chemistry and been engaged in the compounding drug in hospital or dispensary.
- Has passed an examination recognised as adequate by the state government for compounder or dispenser.
- Has been engaged in the compounding of the drug hospital and dispensary in which other place in which drugs are regularly dispensed on prescriptions of medical practitioners.

Removal of names from Register. -

The executive committee of a state council may order that the name of a registered pharmacist shall be removed from the register if it is satisfied after giving him a reasonable opportunity heard and after necessary inquiry.

If his name has been entered in the register by error or on account of a misrepresentation or falsification of material fact.

If he has been convicted of any offence, or has been found guilty of any infamous conduct in any penal subject which in the opinion of the executive committee renders him unfit to be kept in the register.

If a person in his employment in connection with any business of pharmacy has been convicted of any such infamous conduct as would if such person himself were a registered pharmacist render him liable to have his name removed from a register.