



SNS COLLEGE OF PHARMACY AND HEALTH SCIENCES

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THE PHARMACY ACT 1948

- The **Pharmacy Council of India (PCI)** is the statutory body of government of India also called as central council constituted under the Pharmacy Act, 1948.
- The Council was first constituted on 4 March 1948.
- The Pharmacy Council of India is constituted by central government every five years.
- They are based in New Delhi which is linked to the Ministry of Health Services and Family welfare.

OBJECTIVES OF PCI

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

FUNCTIONS OF PCI

- To prescribe minimum standard of education required for qualifying as a pharmacist.
- Framing of Education Regulations prescribing the conditions to be fulfilled by the institutions seeking approval of the PCI for imparting education in pharmacy.
- To ensure uniform implementation of the educational standards throughout the country.
- Inspection of Pharmacy Institutions seeking approval under the Pharmacy Act to verify availability of the prescribed norms.
- To approve the course of study and examination for pharmacists i.e. approval of the academic training institutions providing pharmacy courses.
- To withdraw approval, if the approved course of study or an approved examination does not continue to be in conformity with the educational standards prescribed by the PCI.

- To approve qualifications granted outside the territories to which the Pharmacy Act extends i.e. the approval of foreign qualification.
- To maintain Central Register of Pharmacists.

CONSTITUTION & COMPOSITION OF PCI

- (i) Six members, among whom at least one teacher of pharmaceutical chemistry, pharmacy. Pharmacology and pharmacology elected by the University Grants Commission.
- (ii) Six members, four of whom are persons possessing a degree or diploma in and practicing pharmacy or pharmaceutical chemistry, nominated by the Central Government.
- (iii) One member elected from amongst themselves by the members of the Medical Council of India.
- (iv) The Director General of Health Services or an authorized person by him.
- (v) The Drugs Controller of India or an authorized person by him
- (vi) The Director of Central Drugs Laboratory
- (vii) A representative of the University Grants Commission,
- (viii) A representative of the All India Council for Technical Education
- (ix) One member to represent each state elected from each state council and who is a registered pharmacist,
- (x) One member to represent each state nominated by the State Government who is a registered pharmacist.
- (xi) One member to represent each Union territory, nominated by the Union territory Council, being eligible for registration under section 31 of the Pharmacy Act.

PRESIDENT AND VICE-PRESIDENT OF PCI

- The President and Vice-President of the Central Council shall be elected by the members of the said Council from among themselves.
- The President or Vice-President shall hold office as such for a term not exceeding five years and not extending beyond the expiry of his term as member of the Central Council, but subject to his being a member of the Central Council, he shall be eligible for re-election.

THE EXECUTIVE COMMITTEE

- (1) The Central Council shall, as soon as may be, constitute an Executive Committee consisting of the President (who shall be Chairman of the

Executive Committee) and Vice-President, *ex officio*, and five other members elected by the Central Council from amongst its members.

(2) A member of the Executive Committee shall hold office as such until the expiry of his term of office as member of the Central Council, but, subject to his being a member of the Central Council, he shall be eligible for re-election.

EDUCATION REGULATIONS

(1) Subject to the provisions of this section, the Central Council may, subject to the approval of the Central Government, make regulations, to be called the Education Regulations, prescribing the minimum standard of education required for qualification as a pharmacist.

(2) In particular and without prejudice to the generality of the foregoing power, the Education Regulations may prescribe-

(a) the nature and period of study and of practical training to be undertaken before admission to an examination;

(b) the equipment and facilities to be provided for students undergoing approved courses of study;

(c) the subjects of examination and the standards therein to be attained;

(d) any other conditions of admission to examinations.

(3) Copies of the draft of the Education Regulations and of all subsequent amendments thereof shall be furnished by the Central Council to all State Governments, and the Central Council shall before submitting the Education Regulations or any amendment thereof, as the case may be, to the Central Government for approval take into consideration the comments of any State Government received within three months from the furnishing of the copies as aforesaid.

(4) The Education Regulations shall be published in the Official Gazette and in such other manner as the Central Council may direct.

(5) The Executive Committee shall from time to time report to the Central Council on the efficacy of the Education Regulations and may recommend to the Central Council such amendments thereof as it may think fit.

APPLICATION OF EDUCATION REGULATIONS TO STATES

At any time after the constitution of the State Council under after consultation with the State Council, the State Government may, by notification in the Official Gazette, declare that the Education Regulations shall take effect in the State.

APPROVED COURSES OF STUDY AND EXAMINATIONS

(1) Any authority in a State which conducts a course of study for pharmacists may apply to the Central Council for approval of the course, and the Central Council, if satisfied, after such enquiry as it thinks fit to make, that the said course of study is in conformity with the Education Regulations, shall declare the said course of study to be an approved course of study for the purpose of admission to an approved examination for pharmacists.

(2) Any authority in a State which holds an examination in pharmacy may apply to the Central Council for approval of the examination, and the Central Council, if satisfied, after such enquiry as it thinks fit to make, that the said examination is in conformity with the Education Regulations, shall declare the said examination to be an approved examination for the purpose of qualifying for registration as a pharmacist under this Act.

(3) Every authority in the State which conducts an approved course of study or holds an approved examination shall furnish such information as the Central Council may, from time to time, require as to the courses of study and training and examination to be undergone, as to the ages at which such courses of study and examination are required to be undergone and generally as to the requisites for such courses of study and examination.

Withdrawal of approval

(1) Where the Executive Committee reports to the Central Council that an approved course of study or an approved examination does not continue to be in conformity with the Education Regulations, the Central Council shall give notice to the authority concerned of its intention to take into consideration the question of withdrawing the declaration of approval accorded to the course of study or examination, as the case may be, and the said authority shall within three months from the receipt of such notice

forward to the Central Council through the State Government such representation in the matter as it may wish to make.

(2) After considering any representation which may be received from the authority concerned and any observations thereon which the State Government may think fit to make, the council may declare that the course of study or the examination shall be deemed to be approved only when completed or passed, as the case may be, before a specified date.

THE CENTRAL REGISTER

(1) The Central Council shall cause to be maintained in the prescribed manner a register of pharmacists to be known as the Central Register, which shall contain the names of all persons for the time being entered in the register for a State.

(2) Each State Council shall supply to the Central Council five copies of the register for the State as soon as may be after the first day of April of each year, and the Registrar, of each State Council, shall inform the Central Council, without delay, all additions to, and other amendments in, the Register for the State made from time to time.

(3) It shall be the duty of the Registrar of the Central Council to keep the Central Register in accordance with the orders made by the Central Council, and from time to time to revise the Central Register and publish it in the Gazette of India.

REGISTRATION IN THE CENTRAL REGISTER

The Registrar of the Central Council shall, on receipt of the report of registration of a person in the register for a State, enter his name in the Central Register.

INSPECTION

(1) The Executive Committee may appoint such number of Inspectors for the purpose of investigation.

(2) An Inspector may-

(a) inspect any institution which provides an approved course of study;

- (b) attend at any approved examination;
- (c) inspect any institution whose authorities have applied for the approval of its course of study or examination;

(3) The Inspector shall report to the Executive Committee after every inspection.

(4) The Executive Committee shall forward a copy of every such report to the authority or institution concerned, and shall also forward a copy together with any comments thereon which the said authority or institution may have made, to the Central Government and to the Government of the State in which the authority or institution is situated.

STATE PHARMACY COUNCIL

CONSTITUTION AND COMPOSITION OF STATE PHARMACY COUNCIL

The State Government shall constitute a State Pharmacy Council consisting of the following members, namely:-

- (a) Six members, elected from amongst themselves by registered pharmacists of the State;
- (b) Five members, of whom at least three shall be persons possessing a prescribed degree or diploma in pharmacy or pharmaceutical chemistry or registered pharmacists, nominated by the State Government;
- (c) One member elected from amongst themselves by the members of each Medical Council or the Council of Medical Registration of the State, as the case may be;
- (d) The chief administrative medical officer of the State *ex officio* or if he is unable to attend any meeting, a person authorized by him in writing to do so;
- (e) The officer-in-charge of drugs control organization of the State under the Drugs and Cosmetics Act, 1940 *ex officio* or if he is unable to attend any meeting, a person authorized by him in writing to do so;
- (f) The Government Analyst under the Drugs and Cosmetics Act, 1940 *ex officio*, or where there is more than one, such one as the State Government may appoint in this behalf;

INTER-STATE AGREEMENTS

For the constitution of a Joint State Pharmacy Council two or more State Government may enter into an agreement that the State Council of one State shall serve the needs of the other participating States.

COMPOSITION OF JOINT STATE PHARMACY COUNCILS

A Joint State Council shall consist of the following members, namely:-

- (a) such number of members, being not less than three and not more than five as the agreement shall provide elected from amongst themselves by the registered pharmacists of each of the participating States;
- (b) such number of members, being not less than two and not more than four as the agreement shall provide, nominated by each participating State Government;
- (c) one member elected from amongst themselves by the members of each Medical Council or the Council of Medical Registration of each participating State as the case may be;
- (d) the chief administrative medical officer of each participating State, *ex officio*, or if he is unable to attend any meeting, a person authorized by him in writing to do so;

The officer-in-charge of drugs control organization of each participating State under the Drugs and Cosmetics Act, 1940, *ex officio*, or if he is unable to attend any meeting, a person authorized by him in writing to do so;

- (e) the Government Analyst under the Drugs and Cosmetics Act, 1940 of each participating State, *ex officio*, or where there is more than one in any such State, such one as the State Government may appoint in this behalf.

President and Vice-President of State Council

- (1) The President and Vice-President of the State Council be elected by the members from amongst themselves.
- (2) The President or Vice-President shall hold office as such for a term not exceeding five years and not extending beyond the expiry of his term as a member of the State Council, but subject to his being a member of the State Council, he shall be eligible for re-election.

INSPECTION

(1) A State Council may, with the previous sanction of the State Government, appoint Inspectors having the prescribed qualifications.

(2) An Inspector may-

(a) inspect any premises where drugs are compounded or dispensed and submit a written report to the Registrar;

(b) enquire whether a person who is engaged in compounding or dispensing of drugs is a registered pharmacist;

(c) investigate any complaint made in writing in respect of any contravention of this Act and report to the Registrar;

(d) institute prosecution under the order of the Executive Committee of the State Council;

(3) Any person wilfully obstructing an Inspector in the exercise of the powers conferred on him by or under this Act or any rules made thereunder shall be punishable with imprisonment for a term which may extend to six months, or with fine not exceeding one thousand rupees, or with both.

THE EXECUTIVE COMMITTEE

(1) The State Council shall, as soon as may be, constitute an Executive Committee consisting of the President (who shall be Chairman of the Executive Committee) and Vice-President, *ex officio* and such number of other members elected by the State Council from amongst themselves as may be prescribed.

(2) A member of the Executive Committee shall hold office as such until the expiry of his term of office as member of the State Council, but, subject to his being a member of the State Council, he shall be eligible for re-election.

REGISTRATION OF PHARMACISTS

PREPARATION AND MAINTENANCE OF REGISTER

(1) The State Council shall as soon as possible after it is constituted assume the duty of maintaining the register in accordance with the provisions of this Act.

(2) The register shall include the following particulars, namely:-

- (a) The full name and residential address of the registered person;
- (b) The date of his first admission to the register;
- (c) His qualifications for registration;
- (d) His professional address, and if he is employed by any person, the name of such person;
- (e) such further particulars as may be prescribed.

PREPARATION OF FIRST REGISTER

(1) For the purpose of preparing the first register, the State Government shall by notification in the Official Gazette constitute a Registration Tribunal consisting of three persons, and shall also appoint a Registrar who shall act as Secretary of the Registration Tribunal.

(2) The State Government shall, by the same or a like notification, appoint a date on or before which applications for registration, which shall be accompanied by the prescribed fee, shall be made to the Registration Tribunal.

(3) The Registration Tribunal shall examine every application received on or before the appointed date, and if it is satisfied that the applicant is qualified for registration shall direct the entry of the name of the applicant on the register.

(4) The Registrar shall amend the register in accordance with the decisions of the authority appointed and shall thereupon issue to every person whose name is entered in the register a certificate of registration in the prescribed form.

QUALIFICATIONS FOR ENTRY ON FIRST REGISTER

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

- (a) holds a degree or diploma in pharmacy or pharmaceutical chemistry or a chemist and druggist diploma of an Indian University or a State

Government, as the case may be, or a prescribed qualification granted by an authority outside India,

or

(b) holds a degree of an Indian University other than a degree in pharmacy or pharmaceutical chemistry, and has been engaged in the compounding of drugs in a hospital or dispensary or other place in which drugs are regularly dispensed on prescriptions of medical practitioners for a total period of not less than three years,

or

(c) has passed an examination recognised as adequate by the State Government for compounders or dispensers, or

(d) has been engaged in the compounding of drugs in a hospital or dispensary or other place in which drugs are regularly dispensed on prescriptions of medical practitioners for a total period of not less than five years prior to the date notified.

QUALIFICATIONS FOR SUBSEQUENT REGISTRATION

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

(a) satisfies the conditions prescribed with the prior approval of the Central Council, or where no conditions have been prescribed, the conditions entitling a person to have his name entered on the first register as set out or

(b) is a registered pharmacist in another State, or

(c) possesses a qualification approved under section 14:

Provided that no person shall be entitled to have his name entered on the register unless he has passed a matriculation examination or an examination prescribed as being equivalent to a matriculation examination.

(2) After the Education Regulations have taken effect in the State, a person shall on payment of the prescribed fee be entitled to have his name entered on the register if he has attained the age of eighteen years, if he resides, or carries on the

business or profession of pharmacy, in the State and if he has passed an approved examination or possesses a qualification approved under section 14 or is a registered pharmacist in another State.

SCRUTINY OF APPLICATIONS FOR REGISTRATION

(1) After the date appointed, applications for registration shall be addressed to the Registrar of the State Council and shall be accompanied by the prescribed fee.

(2.) If upon such application the Registrar is of opinion that the applicant is entitled to have his name entered in the register under the provisions of this Act for the time being applicable , he shall enter the name of the applicant in the register:

Provided that no person whose name has under the provisions of this Act been removed from the register of any State shall be entitled to have his name entered in the register except with the approval of the State Council recorded at a meeting.

(3.) Any persons, whose application for registration is rejected by the Registrar, may within three months from the date of such rejection appeal to the State Council, and the decision of the State Council thereon shall be final.

(4.) Upon entry in the register of a name under section, the Registrar shall issue a certificate of registration in the prescribed form.

RENEWAL FEES

(1) The State Government may, by notification in the Official Gazette, direct that for the retention of a name on the register after the 31st day of December of the year following the year in which the name is first entered on the register , there shall be paid annually to the State Council such renewal fee as may be prescribed, and where such direction has been made, such renewal fee shall be due to be paid before the first day of April of the year to which it relates.

(2) Where a renewal fee is not paid by the due date, the Registrar shall remove the name of the defaulter from the register:

(3) On payment of the renewal fee, the Registrar shall issue a receipt therefor and such receipt shall be proof of renewal of registration.

ENTRY OF ADDITIONAL QUALIFICATIONS

A registered pharmacist shall on payment of the prescribed fee be entitled to have entered in the register any further degrees or diplomas in pharmacy or pharmaceutical chemistry which he may obtain.

REMOVAL FROM REGISTER

(1) Subject to the provisions of this section, the Executive Committee may order that the name of a registered pharmacist shall be removed from the register, where it is satisfied, after giving him a reasonable opportunity of being heard and after such further inquiry, if any, as it may think fit to make,-

(i) that his name has been entered into the register by error or on account of misrepresentation or suppression of a material fact, or

(ii) that he has been convicted of any offence or has been guilty of any infamous conduct in any professional respect which in the opinion of the Executive Committee, renders him unfit to be kept in the register, or

(iii) that a person employed by him for the purposes of his business of pharmacy or employed to work under him in connection with any business of pharmacy has been convicted of any such offence or has been guilty of any such infamous conduct as would, if such person were a registered pharmacist, render him liable to have his name removed from the register.

(2) An order may direct that the person whose name is ordered to be removed from the register shall be ineligible for registration in the State under this Act either permanently or for such period as may be specified.

(3) An order shall be subject to confirmation by the State Council and shall not take effect until the expiry of three months from the date of such confirmation.

(4) A person aggrieved by an order which has been confirmed by the State Council may, within thirty days from the communication to him of such confirmation, appeal to the State Government, and the order of the State Government upon such appeal shall be final.

(5) A person whose name has been removed from the register shall forthwith surrender his certificate or registration to the Registrar, and the name so removed shall be published in the Official Gazette.

RESTORATION TO REGISTER

The State Council may at any time for reasons appearing to it sufficient order that upon payment of the prescribed fee the name of a person removed from the register shall be restored thereto:

Provided that where an appeal against such removal has been rejected by the State Government, an order under this section shall not take effect until it has been confirmed by the State Government.

ISSUE OF DUPLICATE CERTIFICATE OF REGISTRATION

Where it is shown to the satisfaction of the Registrar that a certificate of registration has been lost or destroyed, the Registrar may, on payment of the prescribed fee, issue a duplicate certificate in the prescribed form.

MISCELLANEOUS

PENALTY FOR FALSELY CLAIMING TO BE REGISTERED

(1) If any person whose name is not for the time being entered into the register of the State falsely pretends that it is so entered or uses in connection with his name or title any words or letters reasonably calculated to suggest that his name is so entered, he shall be punishable on first conviction with fine which may extend to five hundred rupees and on any subsequent conviction with imprisonment extending to six months or with fine not exceeding one thousand rupees or with both:

(2) The use of the description "pharmacist", "chemist", "druggist", "pharmaceutist", "dispenser", "dispensing chemist", or any combination of such words or of any such word with any other word shall be deemed to be reasonably calculated to suggest that the person using such description is a person whose name is for the time being entered in the register of the State.

DISPENSING BY UNREGISTERED PERSONS

(1) On or after such date as the State Government may by notification in the Official Gazette appoint in this behalf, no person other than a registered pharmacist shall compound, prepare, mix, or dispense any medicine on the prescription of a medical practitioner ;

Provided that this sub-section shall not apply to dispensing by a medical practitioner of medicine for his own patients, or with the general or special sanction of the State Government, for the patients of another medical practitioner.

(2) Whoever contravenes the provisions of shall be punishable with imprisonment for a term which may extend to six months, or with fine not exceeding one thousand rupees or with both.

FAILURE TO SURRENDER CERTIFICATE OF REGISTRATION

If any person whose name has been removed from the register fails without sufficient cause forthwith to surrender his certificate of registration he shall be punishable with fine which may extend to fifty rupees.