



# भारतीय भेषजी परिषद्

( भेषजी अधिनियम, 1948 के अंतर्गत स्थापित )

## PHARMACY COUNCIL OF INDIA

( CONSTITUTED UNDER THE PHARMACY ACT, 1948 )

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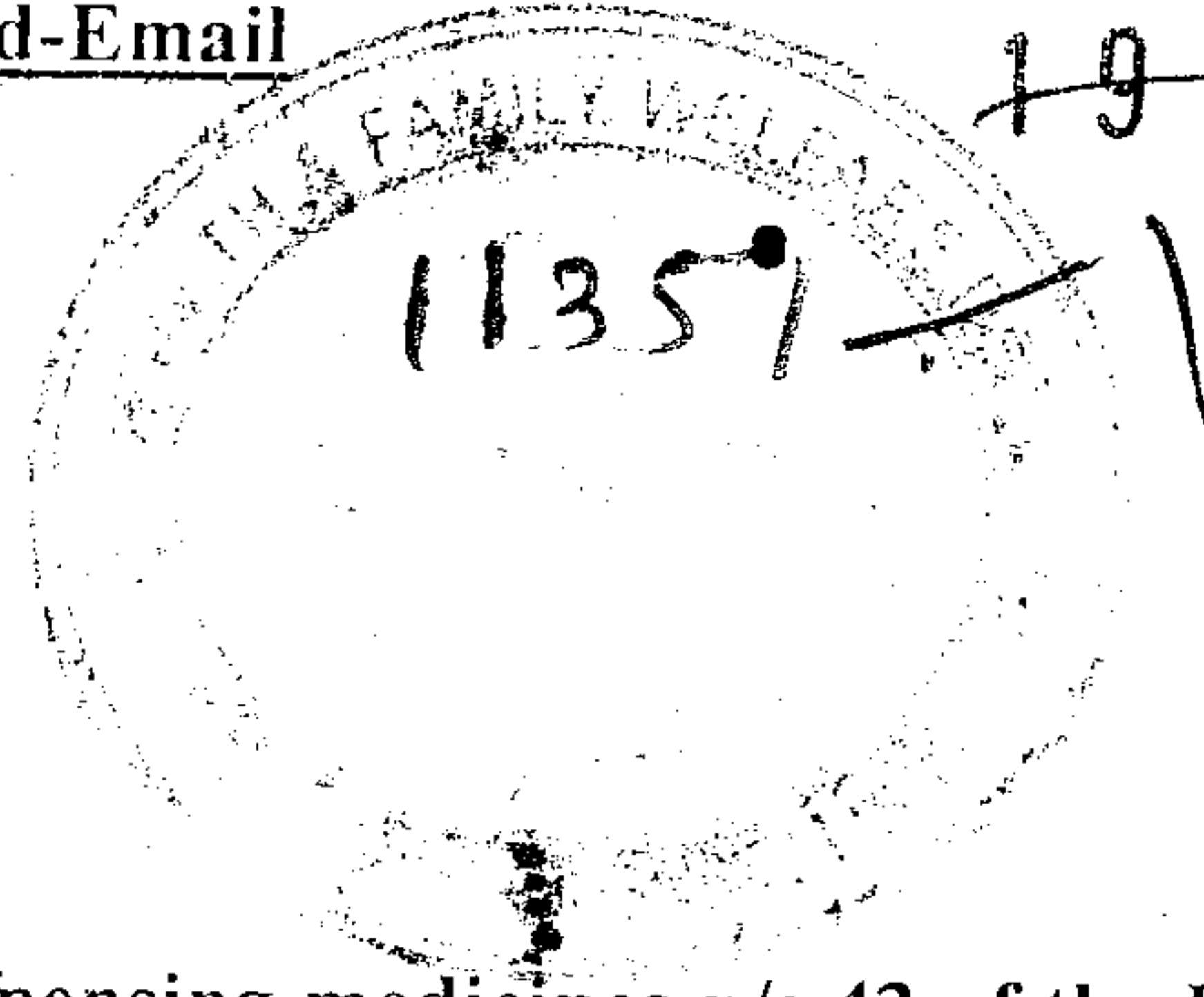
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By Hand-Email

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The Secretary  
Govt. of India  
Ministry of Health & F.W.  
Deptt. of Health (PMS Section)  
Nirman Bhawan  
NEW DELHI - 110 011.



**Sub: Presence of pharmacist essential for dispensing medicines u/s 42 of the Pharmacy Act, 1948.**

Sir/Madam

With reference to the subject cited above, it is informed that -

- 65<sup>th</sup> Indian Pharmaceutical Congress was held on 20-22 December, 2013 at Delhi NCR where pharmacists from various facets of pharmaceutical profession like industry, regulatory, teaching, community pharmacy, hospital pharmacy etc. gathered on a common platform for various collaborative professional activities.
- During the said conference, a Resolution was passed to take up the matter with the Health Ministry to ensure that medicines are always dispensed only by or under the supervision of a registered pharmacist in the best interest of the public health. A copy of the said Resolution as received from IPA, Community Pharmacy Division is enclosed as **Appendix-I** for ready reference.

In this connection, it is stated that -

- The Pharmacy Council of India (PCI) is a statutory body working under the Ministry of Health and F.W., Government of India, New Delhi. It is constituted under the Pharmacy Act, 1948 and is responsible for regulation of -
  - pharmacy education for the purpose of registration as a pharmacist.
  - practice of profession of pharmacy in the country.
- As per section 42 of the Pharmacy Act, no person other than a registered pharmacist shall compound, prepare, mix, or dispense any medicine on the prescription of a medical practitioner and whosoever contravenes this provision 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.

c) For registration as a Pharmacist under the Pharmacy Act, a candidate should have passed the "Diploma in Pharmacy" or "Degree in Pharmacy" from an institution recognised under section 12 of the Pharmacy Act. "Diploma in Pharmacy" is a two years course after 10+2, followed by 500 hours practical training spread over a period of not less than 3 months and "Degree in Pharmacy" is a 4 years course after 10+2. The registration of pharmacist is done by the State

Pharmacy Councils constituted by the State Govts. under section 19 of the Pharmacy Act. The registration is done under section 33 read with 32(2) of the Pharmacy Act, according to which minimum statutory requirements for registration are as under -

- (a) applicant should have attained the age of 18 years & pay the prescribed fee.
- (b) applicant should reside or carry on the business or profession of Pharmacy, in the State.
- (c) applicant should have passed an approved examination or he should possess a qualification approved under section 14 of the Pharmacy Act or is a registered pharmacist in another state.

Regarding sub-para (c), it is most respectfully submitted that u/s 10 of the Pharmacy Act, the PCI is empowered to prescribe the minimum standard of education required for qualification as a pharmacist and as per regulation 2 of the Education Regulations, 1991, an approved course and examination for registration as a pharmacist is "a pass in diploma or degree course in Pharmacy" from an institution approved by the PCI u/s 12 of the Pharmacy Act.

d) Under the Pharmacy Act, 1948, only the following qualifications from an institution approved by the PCI u/s 12 of the Pharmacy Act are approved for the purpose of registration as a pharmacist to practice the profession -

Course	Duration (Years)	Admission Qualification
Diploma in Pharmacy (D.Pharm)	2 yrs. & 500 hrs. practical training	- 10+2 science academic stream with Physics, Chemistry, Mathematics or Biology.
Bachelor of Pharmacy (B.Pharm)	4 yrs.	- 10+2 science academic stream with Physics, Chemistry, Mathematics or Biology. <b>OR</b> - Diploma in Pharmacy from PCI approved institution.
Doctor of Pharmacy (Pharm.D.)	6 yrs.	- 10+2 science academic stream with Physics, Chemistry, Mathematics or Biology. <b>OR</b> - Diploma in Pharmacy from PCI approved institution.

e) As per the guidelines of WHO, Pharmacy education is a health oriented subject and requires special technical skill. During the course of study of pharmacist, the student is given a vigorous training on all facets of drug i.e. reading of prescription, type of dosage forms, drug formulations, uses, compatibility, in-compatibility, drug interactions, side effects, storage, indications, contra-indications, etc. Such a vigorous and detailed training makes a pharmacist an expert of drugs.

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With his special and in-depth knowledge about drugs which he attains during a course of study, he is in a unique position in counselling the society and community on drugs i.e. how much doses are to be taken, how the drug is to be taken, timings are to be taken care of in case of antibiotics therapy in order to have optimum blood level concentration, how the drug are to be stored in his own shop to prevent drug deterioration due to atmospheric conditions etc.

The Pharmacist acts as an important member of "Health Care Team" to function as a perfect material media for a physician in combating diseases. This academic training in an institution approved by the PCI enables the student pharmacist to become eligible for registration as a pharmacist.

Special skill and scientific knowledge is required to sell medicines because any lapse at the retail sale level can adversely affect the public health. An unqualified seller may not know the effect of atmospheric reaction on medicines during storage if exposed to light, air or moisture which can all together alter the properties of the medicines leading to availability of substandard drugs to the patient. With the development of the potent and synthetic drugs, the handling of drugs has become highly crucial as well as complex to safeguard the public health, which is of prime importance. Sometimes the Pharmacist who knows the composition of the medicine may even refuse to sell the drug and advise the patient to consult medical practitioner again if the composition of the drug may not suit the patient along with other medicines.

It cannot be denied that the health of the members of the society is of vital importance. With the industrial and technological development, health hazards have gained new and serious dimensions. To save citizens from these hazards, very efficient and suitable medical facilities are required which include the selling of medicines with appropriate knowledge about medicines and in cautious manner. The age old long practice of selling and consuming medicines without much care cannot now be followed and has rightly been given up. Services of qualified persons are not only for the retail sale of the medicines in proper and just manner but it will also work as a check against unauthorized sale of medicines for purposes other than treatment.

It is well known to every body that a large number of medicines are now being used for purposes of intoxication. If a qualified person is present in the shop at the time of sale, it may provide a check against such improper use of the medicines. The supply of medicines against a prescription essentially requires certain skill for correct interpretation of generally illegible routine prescriptions, checking the doses prescribed and detailing the same properly to the patient. It is also stated that frequently certain Latin terms are also used in the prescriptions detailing about drugs and food items which is only possible to follow through a qualified person. Such kind of job cannot be left open to be performed by an unqualified person who has not undergone an approved course of study.

Further D.Pharm/B.Pharm and Pharm.D. course is a Public Health oriented course. Over the past decades, the role of pharmacist has evolved and shifted beyond merely dispensing of medicines to provider of patient care. Now the role of the pharmacists is to ensure that patient's drug therapy is appropriately indicated, the most effective available, the safest possible and convenient for the patient. The role of the pharmacist has become even more important as he is the common point of contact between the patient and doctor and is trained to play a key role both in disease prevention and drug safety.

New drug discovery/research has led to introduction of new drug molecules and novel drug delivery systems. The prescribing pattern has changed. Multi drug regimen is the way of treatment leading to lot of cases of not only drug-drug interactions and adverse drug reactions but also drug induced diseases putting the life of patient at risk.

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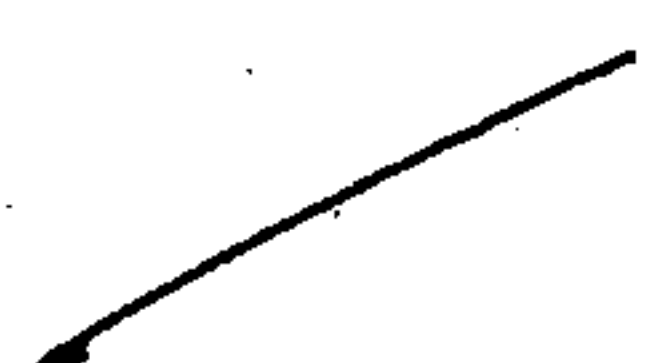
It is further stated that the pharmacy education requires special technical skill. With the development of potent and synthetic drugs, the handling of drugs has become highly crucial and complex. Any lapse in handling medicines can adversely affect the public health. The pharmacist is an expert of drugs and with his special and in-depth knowledge of all facets of drugs, he is in a unique position in counseling the society and community on drugs. His role in Health Care Team is that of a perfect material media between the Physician/Counselor and his patients. The candidate who is not properly trained may not know the effect of atmospheric reaction to light, air or moisture which can all together alter the properties of the medicines leading to availability of substandard drugs to the patient. To safeguard the public health, very efficient and suitable medical facilities are required which include the selling of medicines with appropriate knowledge about medicines and in cautious manner.

- f) The above statutory provisions have been upheld by the Hon'ble Supreme Court and various High Courts also.
- g) There is no dearth of Pharmacists in the country. As on today there are approximately 10 lakhs registered pharmacists and approx. one lakh pharmacists are coming out of the pharmacy institutions per annum in the country.

In view of above it is stated that -

- a) dispensing of medicines cannot be done by a person other than a registered Pharmacists holding approved pharmacy qualification under the Pharmacy Act in the interest of public health failing which it will have disastrous effects on the health of the society. Hence kind support of the Ministry is solicited to ensure the presence of registered pharmacist in all areas where medicines are dispensed.
- b) Health Ministry is requested to impress upon the State Govts. for appointment of inspectors u/s 26 (A) of the Pharmacy Act for strict implementation of section 42. Section 26(A) of the Pharmacy Act empowers the State Pharmacy Councils to appoint inspectors with the previous sanction of the State Govt. to inspect any premises where drugs are dispensed and to enquire whether a person who is engaged in dispensing of drugs is a registered pharmacist. The PCI has been taking up the matter with the State Govts. for the appointment of inspectors but the same is not done by majority of the State Govts.

Yours faithfully

  
(ARCHNA MUDGAL)  
Registrar-cum-Secretary

✓ Cc to -

1. All Drugs Controllers.
2. CDSCO
3. All State Govts. / Union Territories
4. All State Pharmacy Councils / Registration Tribunals.

  
(ARCHNA MUDGAL)  
Registrar-cum-Secretary

does take place to variable extents by unqualified persons including Jawans/attendants/sweepers/peons etc. but not by Pharmacists.

Besides being a breach of law, dispensing of prescriptions and medicines in the absence or without supervision of the pharmacist is a serious health risk, which unfortunately the public is exposed to across the country - day in and day out. Medicines have to be used responsibly for best outcomes. They may have side effects and misuse of potent medicines may lead to harm, and serious health consequences.

In spite of stiff opposition from various interested stakeholders, some of the states like Maharashtra, Gujarat, Tamil Nadu, Andhra Pradesh, Karnataka, Goa etc. the FDA Commissioners and Drug Controllers are making a difference. They are trying their best to implement the law. The outcome of their efforts has improved the presence of pharmacists at the Pharmacy counters. This is indeed a significant step towards better public health.

**IT IS RESOLVED THAT** the Ministry of Health should take up this issue seriously with the CDSCO, State Health Secretaries, State Drug Controllers/FDA Commissioners, Pharmacy Council of India and State Pharmacy Councils so that Drugs & Cosmetics Act & Rules and The Pharmacy Act are implemented uniformly throughout the country. This will ensure that medicines are always dispensed only by or under the supervision of a Registered Pharmacist in the best interest of the public health.

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