



PHARMACY COUNCIL OF INDIA

POLICY ON MONITORING THE PRESENCE OF REGISTERED PHARMACIST IN PHARMACY ESTABLISHMENT

1. Title, Applicability and Commencement:

- i) This policy shall be called the **“Policy on Monitoring the Presence of Registered Pharmacist in Pharmacy Establishment”**.
- ii) It is applicable to all licensed retail and wholesale pharmacy establishments within the jurisdiction of the Regulatory Authority.
- iii) It shall come into force from the date of its notification by the Pharmacy Council of India, New Delhi.

2. Legal Framework:

This policy is framed under the Pharmacy Act, 1948, considering the following provisions:

- i) Mandatory Registration of Pharmacists with the State Pharmacy Council.
- ii) Regulation of Professional Conduct and Practice of Pharmacy.
- iii) To ensure that only duly Registered Pharmacists engage in Dispensing and Compounding of Drugs in the premises.

3. Objectives:

The objectives of the Policy are:

- i) To uphold the standards of professional practice as envisaged under section 42 of the Pharmacy Act, 1948.
- ii) To ensure continuous physical presence of duly Registered Pharmacist during operating hours of pharmacy premises.
- iii) To strengthen regulatory compliance and patient safety.
- iv) To prevent unauthorized practice of pharmacy by unqualified persons.
- v) To introduce biometric attendance as a reliable and verifiable mechanism for monitoring physical presence.
- vi) To operate in harmony with applicable provisions of the Drugs and Cosmetics Act, 1940 and Rules, 1945, without prejudice to any statutory requirements there under.

4. Definitions:

4.1 “Registered Pharmacist” means a person whose name is entered in the register of pharmacists maintained by the State Pharmacy Council under the Pharmacy Act, 1948, and whose registration is valid and in force.

4.2 “State Pharmacy Council” means the statutory body constituted under section 19 of the Pharmacy Act, 1948.

4.3 “Pharmacy Establishment” means any premises licensed for the compounding, sale, stocking, exhibition, distribution or dispensing of drugs.

4.4 “Biometric Attendance System” means an electronic system that records attendance using fingerprint, iris, or facial recognition technology.

4.5 “Regulatory Authority” means the Authority of State Pharmacy Council / Pharmacy Council of India responsible for the enforcement of the mandates of the Pharmacy Act, 1948 or any Rules or any Regulations made there under.

5. Mandatory Presence of Registered Pharmacist:

5.1 No person other than a Registered Pharmacist shall compound, prepare, mix, or dispense any medicine on the prescription of a Registered Medical Practitioner.

5.2 Every pharmacy establishment shall ensure the physical presence of at least one Registered Pharmacist during all hours of operation.

5.3 The Registered Pharmacist shall:

- a) Personally supervise dispensing of medicines.
- b) Provide patient counseling where necessary.
- c) Ensure compliance with ethical and professional standards prescribed by the State/Central Pharmacy Council.

6. Biometric Attendance System:

6.1 Every pharmacy establishment shall install and maintain a functional Aadhaar Enabled Biometric Attendance System (AEBAS) approved by the authority of Pharmacy Council of India.

6.2 The biometric system shall:

- a) Record real-time attendance i.e. entry and exit of Registered Pharmacists in the premise.
- b) Be tamper-resistant and auditable.
- c) Maintain date and time-stamped logs.

6.3 The system shall be integrated with a centralized digital monitoring platform accessible to the Regulatory Authority of the Pharmacy Council of India.

6.4 Biometric data shall be stored securely and used only for regulatory purposes in compliance with data protection laws.

7. Biometric System Maintenance and Compliance:

7.1 Device Standards: Only STQC-certified AEBAS devices (finger print/ IRIS/ Face recognition) are permitted.

7.2 Connectivity: The pharmacy must maintain stable Wi-Fi or optical fibre internet for real-time synchronization with the PCI Portal.

7.3 Power Backup: Devices should be connected to a UPS to prevent bypass due to power failure.

8. Attendance Recording and Data Maintenance:

8.1 Registered Pharmacists shall mandatorily mark biometric attendance at the commencement and end of duty hours.

8.2 Attendance records shall be:

- a) Daily attendance record shall be maintained electronically. In case of technical failure, a physical attendance register must be maintained as a supplementary record.
- b) Preserved for a minimum of 03 (three) years.
- c) Establishments shall produce the attendance report before the inspecting and Regulatory Authorities.

8.3 Any discrepancy between recorded attendance and physical presence shall be treated as a violation of the Pharmacy Act, 1948.

9. Display of Valid Registration Certificate:

9.1 The original or a certified copy of the Registration Certificate issued by the State Pharmacy Council shall be prominently displayed in the pharmacy premises.

9.2 The Registration Number issued by the State Pharmacy Council shall be reflected in all official records, prescriptions dispensed, and inspection registers.

9.3 The pharmacy establishment shall maintain updated records of the validity and renewal status of the Pharmacist's Registration.

10. Inspections and Enforcement:

10.1 The State Pharmacy Council shall appoint Pharmacy Inspectors in accordance with Section 26A of the Pharmacy Act, 1948, to monitor compliance with the provisions of the Act and the regulations made thereunder.

10.2 The appointed Pharmacy Inspectors shall have the power to:

- a) Inspect any premises where drugs are compounded or dispensed.
- b) Examine registration credentials and validity of the Pharmacist.
- c) Verify biometric attendance records and the physical attendance register, if necessary.
- d) Ascertain the physical presence of the Registered Pharmacist.
- e) Examine logs, audit trails and system integrity.
- f) Investigate any complaint made in writing in respect of any contravention of the Pharmacy Act, 1948.
- g) Exercise such other powers as may be necessary for carrying out the purpose of Chapters III, IV and V of the Pharmacy Act, 1948 or any Rules or any Regulations made there under.

11. Reporting to State Pharmacy Council:

In cases of impersonation, proxy attendance, or unauthorized use of Pharmacist's registration, the Pharmacy Inspecting Officer shall submit such report to the Registrar of the State Pharmacy Council for further course of action.

12. Non-Compliance and Penalties:

12.1 Failure to ensure the presence of a Registered Pharmacist shall be deemed as contravention to the provisions of the Pharmacy Act, 1948 and may attract disciplinary action as per the provisions of the Pharmacy Act, 1948.

12.2 The following actions may be taken:

- a) Issuance of show-cause notice.
- b) Imposition of monetary penalties as per the Jan Vishwas (Amendment of Provisions) Act, 2023.
- c) Suspension or removal of name from the register as per the Pharmacy Act, 1948.

12.3 Proxy attendance, biometric manipulation, or allowing unregistered persons to dispense medicines shall attract strict penal action and may also be referred to the State Pharmacy Council for disciplinary action as per the provisions of the Pharmacy Act, 1948 and as per the Jan Vishwas (Amendment of Provisions) Act, 2023.

13. Data Protection and Privacy:

13.1 Biometric data shall be collected and processed strictly for regulatory compliance.

13.2 Unauthorized access, sharing, or misuse of biometric data shall be punishable.

14. Savings and Overriding Effect:

In case of any inconsistency, the provisions of the Pharmacy Act, 1948 shall prevail. This Policy shall supplement and not derogate from statutory provisions like Pharmacy Practice Regulations, 2015 & 2021 and Jan Vishwas (Amendment of Provisions) Act, 2023.