



CIVIL

Pharmacy Council of India (Manner of Holding Inquiry and Imposition of Penalty) Regulations, 2025 Notified

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On June 10, 2025, the Pharmacy Council of India (PCI) notified the “Pharmacy Council of India (Manner of Holding Inquiry and Imposition of Penalty) Regulations, 2025.” These regulations, effective from the date of publication in the Gazette, aim to streamline the process of conducting inquiries and imposing penalties under the Pharmacy Act, 1948. This initiative is a significant step towards enhancing regulatory oversight and ensuring compliance within the pharmacy sector.

Key Terms Defined

The regulations define key terms to ensure clarity and uniformity. The “Act” refers to the Pharmacy Act, 1948, while the “adjudicating officer” is an officer authorized under Section 43A of the Act. An “appellant” is a person aggrieved by an order of the adjudicating officer who files an appeal, and the “appellate authority” is the President of the Central Council. These definitions form the foundation for understanding the procedural aspects outlined in the regulations.

Filing Complaints

Complaints regarding any contravention of the Act can be filed by any person through electronic means, speed post, or in person using Form-I. This provision ensures that grievances can be raised conveniently and efficiently, promoting active participation from stakeholders in the pharmacy sector.

Conducting Inquiries

The process of conducting inquiries is carefully detailed. Upon receiving a complaint, the adjudicating officer issues a notice (Form-II) to the person against whom the complaint is filed, requiring them to show cause within a specified period (not less than seven days) why an inquiry should not be held. The notice specifies the nature of the alleged contravention. After considering the response, if any, the adjudicating officer decides whether to proceed with the inquiry. If an inquiry is to be held, the officer issues a notice requiring the person to appear personally or through a representative on a specified date. On the specified date, the officer explains the alleged contravention and gives the person an opportunity to present documents or evidence (Form-III). The officer may also require and enforce the attendance of any person acquainted with the case to give evidence or produce documents. If the person fails to appear, the officer may proceed with the inquiry in their absence after recording the reasons. If the officer is satisfied that a contravention has occurred, they may impose a penalty by a written order, specifying the reasons and the provision of the Act contravened.

Appeal Process

The regulations also provide a detailed appeal process. Any person aggrieved by an order of the adjudicating officer can file an appeal to the appellate authority using Form-IV within 45 days of receiving the order. The appeal may be admitted after this period if the appellant shows sufficient cause for the delay. The appeal must be accompanied by a copy of the adjudicating officer’s order and a clear statement of the facts, grounds for appeal, and relevant sections of the Act. The appeal must be filed in triplicate by the appellant or their authorized representative through electronic means, registered post, or speed post. The appellate authority serves a copy of the appeal on the respondent, who may file a reply within 30 days of service. The appellate authority may call for records and pass orders after hearing the parties. The appellate authority must dispose of the appeal within 90 days of filing.

Orders and Penalties

Orders and penalties are also regulated. Every order made under these regulations must be dated, signed, and communicated to all parties. Penalties realized under these regulations are credited to the respective state pharmacy council’s account. These provisions ensure that the process is transparent and that penalties are managed appropriately.

Issuing Authority and Legal Basis

The regulations were issued by the [Pharmacy Council of India](#) under the powers conferred by Section 18(1) and Section 18(2)(i) of the Pharmacy Act, 1948, with the approval of the Central Government. This notification was published in the Gazette of India, Extraordinary, Part III—Section 4, on June 10, 2025. The issuance of these regulations marks a significant step towards

enhancing regulatory oversight and ensuring compliance in the pharmacy sector.

Conclusion

The new regulations by the Pharmacy Council of India provide a comprehensive framework for conducting inquiries and imposing penalties, ensuring that the pharmacy sector operates within the bounds of the law. These measures are expected to promote accountability and transparency, ultimately benefiting patients and healthcare providers alike.

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