INDIAN PHARMACOPOEIA COMMISSION Materiovigilance Programme of India (IPC-MvPI)



Dealing with Complaints and Appeals.

1.0 Purpose

To provide an overview of IPC-MvPI's complaints and appeals handling process.

2.0 Scope

This process applies to complaints and appeals related to IPC-MvPI's certification services, and complaints and appeals against certified clients made to IPC-MvPI.

3.0 Definition

Complaints:- Expression of dissatisfaction made to IPC-MvPI with regards to its certification/ auditing services or its certified/audited clients (as it relates to the implementation of the clients' management systems), where a response or resolution is explicitly or implicitly expected.

Appeals:- Appeals refer to the formal process by which a party, often dissatisfied with a decision made by certification body, or authority, seeks a review and reconsideration of that decision by another competent body. The purpose of an appeal is to ensure that the original decision was made in accordance with the law and proper procedures, and to provide a mechanism for correcting errors or ensuring fairness in legal proceedings or administrative determinations. Appeals typically involve a presentation of legal arguments, evidence, and relevant facts to support the contention that the original decision should be modified, reversed, or remanded for further consideration. The outcome of an appeal could result in the affirmation, modification, or reversal of the original decision.

4.0 Process

- 4.1. All complaints and appeals lodged through telephonically, e-mail (mvpi-ipc@gov.in) or posted to the CEO of IPC-MvPI at the office address shall be received by the designated person. All the complaints & and appeals shall be recorded.
- 4.2 All the complaints shall be allocated a unique number.
- 4.3 IPC-MvPI shall acknowledge the receipt of the complaint or appeal and shall provide a progress report to the complainant or appellant.
- 4.4 The complaint & and appeals handling process is subject to the requirements for confidentiality.
- 4.5 The submission, investigation, and decision on complaints or appeals shall not result in any discriminatory actions against the complainant.
- 4.6 After making the necessary entry, the complaint or appeal shall be handed over to the technical manager.

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- 4.7 Technical manager shall conduct a preliminary investigation to determine the nature and scope of the complaint or appeal. If necessary, the certification body may request additional information from the client, complainant, or other relevant parties to facilitate a comprehensive investigation.
- 4.8 The investigation process for addressing complaints and appeals pertaining to certified or audited clients typically involves a comprehensive evaluation of the effectiveness of the client's management system. In certain cases, it may also require the implementation of a specialized audit. If the complaint or appeal is found directly linked to a certified client, this meticulous investigation may result in the temporary suspension of their certification.
- 4.9 The process of establishing validity of the complaint shall generally involve processes like conduct of additional surveillance activities visit to certified client's premises for special evaluation, testing and evaluation of the manufacturing process. All the necessary information shall be gathered and verified to validate the complaint or appeal.
- 4.10 The designated person in consultation with the technical manager shall review the complaint or appeal for its root cause analysis in an unbiased manner.
- 4.11 Data obtained shall be scrutinized and correction and corrective action shall be taken appropriately. The effectiveness of corrective action taken shall be reviewed and recorded.
- 4.12 The decision related to the complaint or appeal shall be made by or approved by the individual(s) not previously involved in the subject of the complaint or appeal and shall be independent of the persons involved in certification related recommendations and decision and their position in the IPC-MvPI shall be such that it shall not be possible to influence their decisions with respect to the subject of the appeal.
- 4.13 The final report of the outcome of the complaint or appeal shall be presented to the complainant or appellant and also communicating to the appellant about the provision for giving an opportunity to formally present his case.
- 4.14 Based on the presentation made, the final decision shall be taken on the appeal, and a formal notice of the outcome and the end of the appeal process shall be given to the appellant.
- 4.15 IPC-MvPI shall take any subsequent action needed to resolve the complaint or appeal.
- 4.16 The IPC-MvPI shall determine, together with the certified client and the complainant, whether and if so to what extent, the subject of the complaint and its resolution shall be made public.

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- 4.17 When the complaint is against a certified/audited client, the subject of the complaint is usually not to be made public. IPC-MvPI shall also notify the client of the receipt of a complaint against their certified/audited system at an appropriate time.
- 4.18 The timeline for the closure of complaints and appeals are 90 days.

REVISION LOG		
Version	Description of Change	Release Date
00	New document for posting on IPC's website	11-OCT-2023
01	Addition of the clause 4.18	07-MAR-2024

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