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Organisation of Pharmaceutical Producers of India



OPPI Policy for Handling of Complaints

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1. Introduction and Purpose

The Department of Pharmaceuticals ("DoP") has implemented a Uniform Code for Pharmaceutical Marketing Practices 2024 ("UCPMP") that governs ethical marketing practices for pharmaceutical companies.

Organisation of Pharmaceutical Producers of India (OPPI) endeavors to promote the highest professional and ethical standards. OPPI has adopted and implemented the UCPMP to enforce its commitment to conduct drug promotion and marketing activities in the utmost ethical manner and compliance with law in letter and spirit.

Further, to enable a platform to voice concerns and provide clear guidance on reporting procedures, OPPI has developed this Policy for Handling of Complaints ("Policy"). The implementation of this Policy will provide consistent protocols to comply with the UCPMP and provide guidelines and procedures for handling of complaints.

2. Applicability and Eligibility

This Policy applies to OPPI Member Companies and their subsidiary entities, along with their employees, marketing agents and medical representatives (collectively referred hereinafter as "member companies").

This Policy covers concerns related to non-adherence/violation and events of misconduct, as per UCPMP, around marketing and / or promotion of drugs that have taken place or suspected to have taken place by the member companies.

In addition to this Policy, all applicable local laws and regulations should be adhered to, by the member companies. In case any of the requirements of applicable local laws and regulations are more stringent than this Policy, they shall prevail.

3. Formation of the Committee

As directed in the UCPMP, OPPI is required to constitute an Ethics Committee for Pharmaceutical Marketing Practices ("ECPMP"), chaired by Director General, OPPI for or handling complaints. As per the Code, the ECPMP will have three to five members, and its composition will be approved by the Board of the Association and prominently displayed on OPPI's website.

OPPI constituted the ECPMP, following are the members of the Committee:

- **Amitabh Dube**, Country President and Managing Director, Novartis India and President, OPPI
- **Shweta Rai,** Managing Director - India & Country Division Head - South Asia, Pharmaceuticals division of Bayer and President Elect, OPPI
- **Anil Matai,** Director General, OPPI & Chair, ECPMP
- **Meenakshi Nevatia,** Country President & Managing Director, Pfizer India and Chair of the OPPI Ethics and Business Integrity Work Group
- **Dr. Rajesh Chitre,** Senior Compliance & Data Privacy Officer, Merck Life Science Pvt. Ltd and Co-Chair of the OPPI Ethics and Business Integrity Work Group

The Committee will be chaired by Anil Matai, Director General OPPI as per the Code. The ECPMP and persons in-charge of implementation of the Policy are also responsible for addressing issues brought to their attention. The Policy also confirms that OPPI shall remain committed to protecting the complainant.

4. Procedures and Guidelines

4.1. Guidelines for Lodging a Complaint

- All complaints related to the breach of the UCPMP shall be submitted in writing and addressed to the Director General, ECPMP of OPPI in order to be considered as a valid complaint.

- The complaint shall be received by ordinary post, registered post (without AD), by courier, email or by-hand delivery at the following address in order to be considered as a valid complaint:

  Organisation of Pharmaceutical Producers of India,

  C-1620, ONE BKC,

  G Block, Plot No. C-66, Bandra Kurla Complex,

  Bandra East, Mumbai- 400051

- All complaints related to an activity of breach of the UCPMP should, to the extent practicable, be made at one time within six (6) months of the alleged breach, with a maximum of another six months for a reasonable delay for which reason can be mentioned in writing.

- For each concern, the Complainant shall fulfil the following requirements of a valid complaint:

a. The complainant must provide their full name, mailing address with pin code, email address, and a contactable landline or mobile number. Additionally, they must submit documentary proof of their identity and address along with the complaint. If necessitated, OPPIwill assess the authenticity of the provided identity and contact information before registering the complaint.

b. Identify the alleged company and any relevant personnel, products, Third Parties, or agents involved in the suspected breach of the UCPMP

c. Provide full details of the activity alleged to be in breach of the UCPMP, provide date of the breach, clauses of the UCPMP that are alleged to have been breached, and provide supporting/substantiating documents in support of the alleged breach(es)

d. Deposit a non-refundable fee of INR 1,000 including 18% GST with the complaint via bank transfer payable to Organisation of Pharmaceutical Producers of India, following the payment instructions on OPPI's website. Anonymous or pseudonymous complaints, or those without the prescribed fee, will not be accepted by OPPI.

e. In case the complainant is a company or an entity, the complaint shall be signed or authorized in writing by that company's Managing Director ("MD") or CEO or an equivalent officer or any authorized person by the company.

- OPPI shall not be responsible for Enquiry of a complaint not received in writing or not acknowledged to have been received or complaint communicated verbally or over a telephone call.
- If media reports (excluding letters to the editor) suggest a potential breach of the Code by a company, the issue may be considered as a complaint. The Committee may then seek additional information from the relevant publication, and the source or correspondent of the report may be regarded as the complainant.

- Any complaints received by the Department of Pharmaceuticals may also be considered by the Committee for appropriate action. OPPI will then engage with the complainant to address the matter further. Additionally, the Department reserves the right to conduct a special audit if deemed necessary.

4.2. Confidentiality and Protection

- All complaints will be handled in a timely and confidential manner. Information regarding a complaint under Enquiry proceedings will be disclosed on a "need-to-know" basis. OPPI strives, to the extent possible, to consistently complete a thorough and fair Enquiry, and to protect the identity, anonymity, and confidentiality of any individual who reports a complaint.

- All written and oral information and materials disclosed or provided to OPPI in relation to a complaint by a company, its employee, HCP or any relevant stakeholders will be treated confidential except as required to be disclosed as per the law of the land. In case, any disclosure is required to be made, OPPI will ensure confidentiality of personal information to the extent possible and will share the redacted information.

- OPPI is committed to the fair treatment of all its Member Companies and their personnel, agents and healthcare workers and have non tolerance to any retaliation against them.

- Any act of retaliation or discrimination shall be treated as a serious violation of the policy and could result in action, as directed by the ECPMP.

4.3. Guidelines for handling of complaints

- The ECPMP shall initiate and complete the process of Enquiry once a complaint is lodged.

- The ECPMP shall ensure that they are independent and uninvolved in the allegations made and ensure that complaint/concern is addressed by persons with sufficient and appropriate experience and expertise. In instances of conflict of interest, the involved member/s must abstain from participating in the proceedings. In all cases, the quorum for every meeting of the ECPMP will be 3 members present. In case of conflict of 2 or more members in a matter, the Director General will consult OPPI's Executive Committee and nominate requisite members for meeting the quorum for ECPMP with final approval of President, OPPI.

- The decisions of the ECPMP shall be taken by the majority from the initiation stage up to submission of the Report. The decision taken by the ECPMP will be shared with the Department of Pharmaceuticals, and the OPPI Board of Directors will be informed about the decision.

- The ECPMP may require the respondent entity to provide responses, relevant evidence and supporting material for resolution of the complaint within 30 days of receipt of communication from the Committee. The Committee may provide an additional time frame for receiving response, if deemed necessary.

- OPPI may engage the services of professional auditors to facilitate better and independent examination in order to arrive at an informed decision.

- If no appeal is lodged within the specified timeframe, the ECPMP's decision becomes final and binding. Adherence to the decision is mandatory for maintaining OPPI membership. The decisions will also be published on both OPPI's and the Department of Pharmaceuticals' websites.

4.4. Process of Enquiry

- When a complaint is received, the ECPMP will assess its appropriateness, considering factors such as the nature and scope of the complaint, available resources, and internal timelines.

- Any reported concern or complaint will trigger inquiry process and the decision shall be arrived based on the supporting/ substantiating documents by the ECPMP, as detailed below.

- The respondents will normally be informed of the allegations at the outset of an Enquiry and have opportunities to provide their inputs during the proceedings of the Enquiry.

- Evidence shall not be withheld, destroyed, tampered with, and witness shall not be influenced, coached, threatened or intimidated by the respondents.

- All the relevant entities / persons involved in the complaint must fully cooperate with the inquiry process, providing truthful responses during depositions and complying with requests for information and documents. Interference with the inquiry process is prohibited.

4.5. Reporting and Closure of the Enquiry

- After the conclusion of Enquiry and the Report, the ECPMP shall inform/ communicate the decision to the complainant and the respondent in either of the scenarios described below:
    - In case the allegation is established as a breach of the UCPMP:
        - the complainant and the respondent will be informed about the same in writing and advised on the remedial steps to be taken.
        - the subjects shall accept the findings of the ECPMP and undergo the disciplinary action determined by the ECPMP
        - In case the allegation is not established as a breach of the UCPMP, the complainant will be so informed in writing and the Enquiry shall be closed.

- The ECPMP shall maintain a Report in writing that includes the following:
    - Facts of the case.
    - Findings of the ECPMP during the process of Enquiry
    - Recommendations of the ECPMP on disciplinary and remedial or other actions.

- The ECPMP shall provide resolution of the complaint within 90 days of its receipt and promptly notify the parties of its decision, the reasons thereof in writing and send it by recorded mail.

4.6. Penalties and Disciplinary action

- If the Enquiry establishes the allegation of breach of the UCPMP or this Policy, the following disciplinary action(s) may be proposed against the erring entity by the ECPMP.

- Suspension or expulsion of Member Company from OPPI
- Reprimand the Member Company and publish full details of the reprimand
- Require the Member Company to issue a corrective statement in the same media used for unethical promotion. (with the prior approval of the proposed content, time and mode of dissemination of the statement)
- To ask the Member Company to recover money or items given in violation of the UCPMP from concerned persons and submit details of action taken to ECPMP in writing.
- In cases where disciplinary, penal, or remedial action lies within the Government in accordance with the statute, the ECPMP may send its recommendations to such Government agency through the DoP.

- Failure to fully cooperate or any actions hindering the inquiry process, such as concealing or destroying information, providing false answers, deleting documents, or discussing confidential matters, will result in disciplinary action. This may also apply to individuals who are aware of such actions but fail to address or correct them.

4.7. Appeals Against the Decision of the UCPMP

- If either the complainant or respondent is dissatisfied with the ECPMP's inquiry outcome and decision, they may appeal directly to the Apex Committee for Pharma Marketing Practices (ACPMP) headed by the Secretary, Department of Pharmaceuticals, having a Joint Secretary and a Finance Officer dealing with the subject as its members. The decision of the ACPMP is final and binding on both parties.

- The time limit for filing such an appeal will ordinarily be 15 days from the date of decision by the Committee, with an additional 15 days of reasonable time delay permitted for reasons to be recorded in writing.
- The ACPMP will notify both parties and, after providing a reasonable opportunity to be heard, issue a final decision or ruling within six months. The ACPMP may impose penalties or refer the matter to an appropriate government agency, as outlined in para 4.6 above

- Incase no appeal is filed within the stipulated period, the decision of the ECPMP shall be final and binding, and adherence to such decision shall be a condition of continued membership of OPPI. The decisions shall also be uploaded on the website of OPPI and the DoP.

5. Definitions

TERM	DEFINITION OR MEANING
Complaint	Complaint under this Policy includes a concern or grievance reported in writing in good faith that discloses or demonstrates information that may evidence unethical or improper marketing activities involved in drug promotion.
Drug Promotion	Drug promotion is defined under the UCPMP 2024 with reference to the 'Ethical Criteria for Medicinal Drug Promotion' endorsed by the World Health Assembly in 1988 wherein, "Promotion" refers to all informational and persuasive activities by manufacturers and distributors, the effect of

	which is to induce the prescription, supply, purchase and/or use of medical drugs.
Disciplinary action	Disciplinary action means any action that can be taken on the completion of / during the Enquiry proceedings including but not limited to warning, imposition of fine, suspension of membership, expulsion from OPPI.
Enquiry	Enquiry includes the assessment and proceedings conducted after lodging of a concern or complaint with the Ethics Committee of Pharmaceutical Marketing Practices.
Evidence	Any type of proof which tends to establish or disprove a fact material to the case. It includes, but is not limited to, oral testimony of witnesses, including experts on technical matters, documents, electronic, audio, video records and photographs
Member Companies	Member Companies are the pharmaceutical companies and their subsidiary entities including third party, that are members of Organisation of Pharmaceutical Producers of India
Report	A report in writing on the proceedings of the Enquiry and it's outcome.
Third Party	Entities (including their Personnel) or individuals sub-contracted to work for the Member Companies for the provision of goods or services. The following non-exhaustive list sets out categories of third-party relationships designed to apply to the definition:

	1. Consultants, contractors, sub-contractors, or agents engaged by the Member Companies or OPPI to provide advice and/or services to the Member Companies, their clients or OPPI 2. Suppliers or vendors who provide goods and/or services. 3. Agents or representatives including medical representatives, healthcare workers. 4. Recruitment agencies 5. Persons who bring or refer business, if authorized Sponsorship partners who or which represent OPPI or its Member Companies