FICCI's Policy for Handling of Complaints

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1. Introduction and Objectives:

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

The Federation of Indian Chambers of Commerce and Industry strives to uphold the highest professional and ethical standards. FICCI has embraced and put into practice the UCPMP to reaffirm its dedication to conducting drug promotion and marketing activities with the utmost ethical integrity and adherence to both the letter and the spirit of the law.

Further, to enable a platform to voice concerns and provide clear guidance on reporting procedures, FICCI 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 the FICCI Member companies and their personnel, marketing agents, medical representatives and healthcare workers and their subsidiary entities, if any.

This Policy covers concerns related to malpractices and events of misconduct around marketing and / or promotion of drugs that have taken place or suspected to have taken place.

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

3. Establishment of the Committee

As directed in the UCPMP, FICCI would be required to constitute an Ethics Committee for Pharmaceutical Marketing Practices ("ECPMP") and the Ethics committee for Medical Devices chaired by its Chief Executive Officer ("CEO")[1] for handling complaints. As per the Code the ECPMP / Ethics Committee for Medical Devices will have three to five[2] members, and its composition will be approved by the Board of the Association and prominently displayed on FICCI's website.

FICCI will be constituting the ECPMP and an Ethics committee for Medical Devices.

The Committee will be chaired by the Advisor of the FICCI Health Services committee.

The ECPMP / the Ethics committee for medical devices and persons in-charge of the committee will be responsible for addressing issues brought to the attention. The Policy also confirms that the FICCI ethics committee (under Pharmaceuticals & Medical Devices Sector) remain committed to protecting the complainant.

[1] Chief Executive Officer of the company those are a member of Ethics Committee (under Pharmaceuticals & Medical Devices Sector
[2] Number of the ECPMP/ Ethics committee for Medical Devices may change as deemed fit by FICCI.

4. Procedures and Guidelines

4.1 Procedures for Submitting a Complaint

All complaints related to the breach of the UCPMP shall be submitted in writing and addressed to the Chief Executive Officer ("CEO"), ECPMP of the FICCI/ Ethics committee for Medical Devices to be considered as a valid complaint.

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

FICCI Health Division (Pharma/Medical Devices)
Federation of Indian Chambers of Commerce and Industry
Federation House, 1, Tansen Marg,
New Delhi 110001, INDIA

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:

- 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. FICCI will verify the authenticity of the provided identity and contact information before registering the complaint.
- Identify the alleged company and any relevant personnel, products, Third Parties, or agents involved in the suspected breach of the UCPMP.
- Please furnish comprehensive information regarding the activity purportedly violating the UCPMP, including the date of the alleged breach, the clauses of the UCPMP suspected to have been violated, and supply supporting evidence for the alleged breach(es).
- Deposit a non-refundable fee of INR 1,000 with the complaint via demand draft/Bank Transfer payable to FICCI Pharma Ethics Sub-Account (Information will be shortly added), following the payment instructions on FICCIs website/Pharma microsite. Anonymous or pseudonymous complaints, or those without the prescribed fee, will not be accepted by the FICCI.
- 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.
- The FICCI 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 or through an email.
- 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. The FICCI 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 managed in a timely and confidential manner. Information regarding a complaint under Enquiry proceedings will be disclosed on a "need-to-know" basis. The FICCI 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.

Any written or verbal information and materials shared with FICCI concerning a complaint from a company, its employees, healthcare professionals, or other pertinent stakeholders will be managed confidentially, unless mandated otherwise by the applicable laws. Should any disclosure become necessary, FICCI will strive to fully maintain the confidentiality of personal information possible and will provide redacted information when shared.

The FICCI is committed to the fair treatment of FICCI Member companies and their personnel, marketing agents, medical representatives and healthcare workers and their subsidiary entities and protects them against retaliation. The FICCI will take steps to minimize difficulties, which the Complainant may experience because of lodging a complaint.

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/Ethics Committee for Medical Devices.

4.3. Guidelines for handling of complaints

The ECPMP/ Ethics Committee for Medical Devices shall initiate and complete the process of Enquiry once a complaint is lodged.

The ECPMP/ Ethics Committee for Medical Devices 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/ Ethics Committee for Medical Devices will be 3 to 5 members present.

In case of conflict of two or more members in a matter, the Advisor will consult the quorum of the ECPMP / Ethics Committee of Medical Devices.

The decisions of the ECPMP / Ethics Committee for Medical Devices shall be taken by majority from the initiation stage up to submission of the Report. The ECPMP / Ethics Committee for Medical Devices will make recommendation to the ECPMP Committee of FICCI and forward it to the Department of Pharmaceuticals.

The ECPMP / Ethics Committee for Medical Devices may require the respondent entity to provide responses, relevant evidence and supporting material for resolution of the complaint within a time bound manner as will be set out in its communication.

The FICCI may engage the services of professional auditors to facilitate better and independent examination to arrive at an informed decision.

If the Committee finds no breach of the Code or if the complaint is beyond its scope, the

complainant will be informed in writing, with guidance on further steps.

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

4.4. Process of Enquiry

When a complaint is received, the ECPMP / Ethics Committee for Medical Devices 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 a formal preliminary assessment and inquiry process by the ECPMP / Ethics Committee for Medical Devices, 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 personnel and Third Parties 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

Upon completion of the process of Enquiry and the Report, the ECPMP/ Ethics Committee for Medical Devices shall discuss the concern or subject-matter with 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 / Ethics Committee for Medical Devices and undergo the disciplinary action determined by the ECPMP / Ethics Committee for Medical Devices

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 / Ethics Committee for Medical Devices shall maintain a report in writing that includes the following:

- Facts of the case.
- Findings of the ECPMP/ Ethics Committee for Medical Devices during the process of Enquiry
- Recommendations of the ECPMP/ Ethics Committee for Medical Devices on disciplinary and remedial or other actions.

The ECPMP/ Ethics Committee for Medical Devices 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 or Ethics Committee for Medical Devices:

- Suspension or expulsion of Member Company from the FICCI
- 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)
- 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/ Ethics Committee for Medical Devices in writing.
- In cases where disciplinary, penal, or remedial action lies within the Government in accordance with the statute, the ECPMP/ Ethics Committee for Medical Devices 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 decision of the ECPMP/ Equivalent Committee for Medical Devices

If either the complainant or respondent is dissatisfied with the ethics committee'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, 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.

In case no appeal is filed within the stipulated period[3], the decision of the ECPMP/ Ethics Committee for Medical Devices shall be final and binding, and adherence to such decision shall be a condition of continued membership of the FICCI The decisions shall also be uploaded on the website of the FICCI and the DoP.

[3] Time limit for filing such an appeal will ordinarily be 15 days, with additional 15-day delay permitted for reasons recorded in writing.

5. Glossaries

Term	Definitions
Complaint	A complaint under this Policy encompasses a concern or grievance reported in writing, in good faith, which reveals or indicates information that may suggest unethical or improper marketing activities associated with 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 the FICCI.
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 & Medical Devices companies, who are members of the Federation of Indian Chambers of Commerce and Industry.
Report	A report in writing on the proceedings of the Enquiry and it is 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 the FICCI to provide advice and/or services to the Member Companies, their clients, or the FICCI 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 6. Sponsorship partners who or which represent the FICCI or its Member Companies