

Uniform Code of Marketing Practices in Medical Devices (UCMPMD)

1. Acceptance of UCMPMD:

Association of Diagnostics Manufacturers of India (ADMI) hereby accepts Department of Pharmaceuticals (DoP) prescribed Uniform Code of Marketing Practices in Medical Devices (UCMPMD) enclosed and request all its members to follow the same scrupulously or keep us informed where they seek amendment with justification or they find it difficult to follow and reasons thereof.

2. Committee for Complaint Handling:

2.1 If any complaint received against any member, then it will be handled by the "Ethics Committee for Medical Devices Marketing Practices (ECMDMP).

The members of the **ECMDMP Committee** are:

Sl. No	Name	Company position & name	Committee Designation
1	Mr. Jatin Mahajan	Managing Director, J.Mitra & Co (P) Ltd	President
2	Mr. Sanjeev Lala	Sr. Strategic Advisor, Advy Chemical Pvt. Ltd.	Vice President
3	Dr. Rajesh Patel	CEO, AGD Biomedicals Pvt. Ltd.	Secretary

In case of potential conflict of interest, the President - ADMI will decide alternate members who will handle the complaint.

2.2 There will be a review committee for handling the review of the decisions of the ECMDMP, if any of the parties (complainant or respondent) desire so, named as Apex Ethics Committee for Medical Devices Marketing Practices (AECMDMP).

The members of the **AECMDMP Committee** are:

Sl. No	Name	Company position & name	Committee Designation
1	Mr. Chirag Joshi	Managing Director, Beacon Diagnostics (P) Ltd.	Treasurer
2	Ms. Veena Kohli	CEO, Vanguard Diagnostics (P) Ltd.	Member
3	Mr. Suresh Ghatalia	Managing Director, Biolab Diagnostics (I) Pvt.Ltd.	Member
4	Mr. Sanjeev Lala	Sr. Strategic Advisor, Advy Chemical Pvt.Ltd.	Vice President
5	Mr. Prateek Mittal	Managing Director, Medsource Ozone Bio Medicals Pvt.Ltd.	Member

Mr. Jatin Mahajan, Managing Director of J.Mitra & Co (P) Ltd. will act as the Secretary of the above two committees.

3. Procedure of Lodging a Complaint:

3.1 All complaints related to the breach of the code should be addressed to:

Secretariat - ADMI
Ethics Committee for Medical Devices Marketing Practices (ECMDMP)
Association of Diagnostics Manufacturers of India (ADMI)
TR-217, 2nd Floor, AltF 101 Okhla, NH-19, CRRI,
Ishwar Nagar, New Delhi-110044
Ph. + 91 95993 58095
E-mail: secretariat@admi-india.org

3.2 All complaints about any one activity of breach of code should to the extent practicable be made at one time. The complaint must be made within three month of breach of code.

3.3 Complaints must be in writing and for each case THE COMPLAINANT should:

- i) Identify himself (whether a company or an individual) with a full mailing address (fax number, if possible, mobile telephone nos.). When the complaint is from a pharmaceutical company, the complaint must be signed or authorized in writing by the company's managing director or chief executive or equivalent and must state those clauses of the Code which are alleged to have been breached.
- ii) Identify the company which is alleged to be in breach of the Code, and the name of any company personnel, product or products which are specifically involved.
- iii) Give the details of the activity which is alleged to be in breach of the Code.
- iv) Give the date of the alleged breach of the Code.
- v) Provide supporting evidence of the alleged breach(es).

3.4 A non-refundable amount of Rs.1,000/- is to be deposited by the complainant along with the complaint. The said amount shall be paid in the form of a demand draft drawn on any bank in India in favour of Association of Diagnostics Manufacturers of India or the Payment may be made through NEFT /online payment option given over website.

Bank account No.01351070010335

MICR Code : 396240061

IFSC Code : HDFC0000135

Bank/Branch Name : HDFC Bank Ltd., Navsari.

3.5 When it appears from media reports (other than letters to the editor of a publication) that a company may have breached the Code, the matter will be treated as a complaint and the committee may request the concerned publication for further information.

3.6 A published letter, from which it appears that a company may have breached the Code, will be dealt with as a complaint with the author being treated as the complainant.

3.7 Any complaint received from the Department of Pharmaceuticals will further be taken up with the complainant directly.

4. Procedure of Handling of Complaints

4.1 Once a complaint is lodged, the process of enquiry shall be completed by the committee even if it is withdrawn.

4.2 The President-ADMI will personally take note of the complaint. He/She will refer the complaint to the Chairman of ECMDMP and also indicate the names of other two members of the committee in case of conflict of interest

4.3 The decision will be made by majority.

4.4 When the committee (ECPMP) receives information from which it appears that a company may have contravened the Code, the managing director or chief executive or equivalent of the company concerned will be requested to provide a complete response to the matters of complaint.

4.5 To assist companies in ensuring that a complete response is submitted, the committee may suggest to the respondent company about the relevant supporting material to be supplied. It is the responsibility of the respondent company to ensure that a full response is submitted.

4.6 The company against which the complaint is made should provide supporting evidence even if it thinks that the Code has not been breached.

4.7 The respondent company shall submit its comments and supporting documents to the committee within 10 working days after receipt of information from the committee.

4.8 The Committee shall render a decision within 30 days of receipt of the complaint with supporting documentation and shall promptly notify the parties of its decision, and the reasons therefore, in writing and by registered mail.

4.9 Where the committee decides no breach of the Code because it considers the matter of complaint is not within the scope of the Code, the complainant will be so advised in writing.

4.10 Where the committee, after enquiry decides that there is breach of the Code, the complainant and the respondent company are so advised in writing and are given the reasons for the decision.

4.11 If there is no request of review within the stipulated period (clause 6.3), the decision of ECMDMP shall be final and binding, and adherence to the decision shall be a condition of continued membership of the Association. The decisions shall be uploaded on the website of the Association.

5. Penalty Provisions

Once it is established that a breach of code has been made by a company, the ECMDMP can propose one of the following decisions against the alleged company to the President - ADMI for action.

- i. To suspend or expel the company from the Association.
- ii. To reprimand the company and publish details of that reprimand.
- iii. To require the company to issue a corrective statement in the media (covering all media) which was used to issue promotional material textual & audio visual; details of the proposed content and mode and timing of dissemination of the corrective statement must be provided by the company to the committee for approval.
- iv. To ask the company to recover items from the concerned persons, given in violation of the code ; details of the action taken must be provided by the company in writing to the Committee.

6. Review of Decisions of the Complaints:

- 6.1 If a party to the complaint is dissatisfied with the decision of ECMDMP, it may request for review of the decision from AECMDMP. Any party requesting a review of a decision of ECMDMP shall notify the same to the President - ADMI.
 - 6.2 The complainant or the respondent company may file a review application for review against a ruling of ECMDMP and the ruling of the review committee (AECMDMP) shall be final.
 - 6.3 A review by the complainant must be notified within five working days of the notification of the ruling of ECMDMP and the review should be lodged within ten working days of notification of the ruling of ECMDMP.
 - 6.4 Where the respondent company appeals for review, it must give notice of appeal within five working days of notification of the ruling of ECMDMP and must lodge the review within ten working days of notification of the ruling of ECMDMP.
 - 6.5 Where review is asked by the complainant, the respondent company shall give comments on the reasons given by the complainant for the review within ten working days and these comments will be circulated to the members of the review committee (AECMDMP) and the complainant.
 - 6.6 Where review is asked by the respondent company, the complainant shall give comment on the reasons given by the respondent company for the review within ten working days and these comments will be circulated to the respondent company and to the members of the review committee (AECMDMP).
 - 6.7 If AECMDMP decides that there is a breach of code, the respondent company will provide a written undertaking within five working days that the promotional activity or use of the material in question and any similar material (if not already discontinued or no longer in use) will cease forthwith and that all possible steps will be taken to avoid a similar breach of the Code in the future. If the decision of the committee is about the recovery of items given in violation of the code, the company will inform the action taken in this regard within fifteen (15) working days. This undertaking must be signed by the managing director or chief executive or equivalent of the company or with his authority and must be accompanied by details of the actions taken by the company to implement the undertaking, including the date on which the promotional material was finally used or appeared and/ or the last date on which the promotional activity took place.
 - 6.8 The final decision of AECMDMP and the corrective statements/ actions taken by the concerned company shall be uploaded on the website of ADMI.
7. Finally, the Managing Director/CEO of the company is ultimately responsible for ensuring the adherence to the code and a self-declaration, in the format given in annexure shall be submitted by the executive head of the company within two months of date of issue of UCPMP and thereafter within two months of end of every financial year to ADMI for uploading the same on the website of the Association. The same must be uploaded on the website of the company also.