

9. Committee for Complaint Handling:

- 9.1 There will be a committee for handling the complaints named as "Ethics Committee for Pharma Marketing Practices (ECPMP)" in each of the associations.
- 9.2 The committee will have 3 members, represented by the Executive Head of the companies or a nominee from the Executive Head, but not below the rank of Director in the Board of Company.
- 9.3 In case of conflict of interest, the Head of the association will decide 3 members, who will handle the complaint.
- 9.4 There will be a review committee for handling the review of the decisions of ECPMP, if any of the parties (complainant or respondent) desire so. This committee will be named as "Apex Ethics Committee for Pharmaceuticals Marketing Practices (AECMP)" and will consist of 5 members, represented by the Executive Head of the companies or a nominee from the Executive Head, but

not below the rank of Director in the Board of Company. The members of the committee will be nominated by the Head of the Association.

10. Procedure of Lodging a Complaint:

- 10.1 All complaints, related to the breach of the code should be addressed to the "Ethics Committee for Pharma Marketing Practices (ECPMP)", Secretary General/Chairman/President, "Name of Association".
- 10.2 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.
- 10.3 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).
- 10.4 A non-refundable amount of Rs.1,000/- is to be deposited by the complainant along with the complaint. The associations will elaborate how this payment is to be made within a month of issue of the code and upload the same on their website.

- 10.5 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.
- 10.6 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.
- 10.7 Any complaint received by the Department of Pharmaceuticals will also be forwarded to the concerned Association for necessary action. In such cases, the concerned association will further take up the matter with the complainant directly.

11..Procedure of Handling of Complaints

- 11.1 Once a complaint is lodged, the process of enquiry shall be completed by the committee even if it is withdrawn.
- 11.2 The Head of the association will personally take note of the complaint.
- 11.3 The Head of the association will refer the complaint to the senior most (by designation) member (Chairman) of ECPMP and also indicate the names of other two members of the committee in case of conflict of interest.
- 11.4 The decision will be made by majority.
- 11.5 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.
- 11.6 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.

- 11.7 The company against which the complaint is made should provide supporting evidence even if it thinks that the Code has not been breached.
- 11.8 The respondent company shall submit its comments and supporting documents to the committee within 10 working days after receipt of information from the committee.
- 11.9 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.
- 11.10 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.
- 11.11 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.
- 11.12 If there is no request of review within the stipulated period (clause 13.4), the decision of ECPMP 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.

12. PENALTY PROVISIONS

Once it is established that a breach of code has been made by a company, the committee can propose one of the following decisions against the alleged company to the Head of the Association 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 as stipulated in clauses 6 and 7; details of the action taken must be provided by the company in writing to the Committee.

13. Review of Decisions of the Complaints:

- 13.1 If a party to the complaint is dissatisfied with the decision of ECPMP, it may request for review of the decision from AECPMP. Any party requesting a review of a decision of ECPMP shall notify the same to the Head of the Association.
- 13.2 The complainant or the respondent company may file a review application for review against a ruling of ECPMP and the ruling of the review committee (AECPMP) shall be final.
- 13.3 A review by the complainant must be notified within five working days of the notification of the ruling of ECPMP and the review should be lodged within ten working days of notification of the ruling of ECPMP.
- 13.4 Where the respondent company appeals for review, it must give notice of appeal within five working days of notification of the ruling of ECPMP and must lodge the review within ten working days of notification of the ruling of ECPMP.
- 13.5 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(AECPMP) and the complainant.
- 13.6 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 (AECPMP).

- 13.7 If AECMP 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.
- 13.8 The final decision of AECMP and the corrective statements/ actions taken by the concerned company shall be uploaded on the website of the Association.
14. 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 the Association for uploading the same on the website of the Association. The same must be uploaded on the website of the company also.

A. Self-Declaration By Executive Head Of The Company Regarding Compliance To The Uniform Code For Pharmaceuticals Marketing Practices, to be made within two months of issue of the code

"This is to declare that(name of the company), Headquarters at, will comply with the provisions laid down in the Uniform Code for Pharmaceuticals Marketing Practices."

Name and Designation
Seal of the company

B. Self-Declaration By Executive Head Of The Company Regarding Compliance To The Uniform Code For Pharmaceuticals Marketing Practices, to be made within two months of end of every financial year:

"This is to declare that(name of the company) , Headquarters at, has complied with the provisions laid down in the Uniform Code for Pharmaceuticals Marketing Practices . This declaration is for the financial year....."

Name and Designation
Seal of the company