

SPEED POST

No. 5/3/2009-PI-II
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals
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Dated the 19th March, 2012

To

IPA / OPPI / IDMA / CIPI / FOPE / SPIC

Subject: Uniform Code of Pharmaceuticals Marketing Ethics (UCPMP).

Sir,

I am directed to enclose a copy of the Uniform Code of Pharmaceuticals Marketing Practices (UCPMP) prepared by the Department of Pharmaceuticals based on the comments / inputs received from various stakeholders on the draft UCPMP. The above UCPMP is to be adopted in the first instance voluntarily for a period of six months.

You are requested to provide your comments urgently so that further action can be taken in the matter.

Yours faithfully


(Ram Chander)

Under Secretary to the Govt. of India
Telefax: 23385765

Encl. : as above.

UFC

Uniform Code for Pharmaceuticals Marketing Practices (UCPMP)

This is a voluntary code of Marketing Practices for Indian Pharmaceutical Industry for the present and its implementation will be reviewed after a period of six months from the date of its issue. If it is found that it has not been implemented effectively by the Pharma Associations/Companies, the Government would consider making it a statutory code.

1. General Points

- 1.1 A drug must not be promoted prior to receipt of the marketing approval by the competent authority, authorizing its sale or supply.
- 1.2 The promotion of a drug must be consistent with the terms of the marketing approval.
- 1.3 Information about drugs must be up-to-date, verifiable and accurately reflect current knowledge or responsible opinion.
- 1.4 Information about drugs must be accurate, balanced, fair, objective, and must not mislead either directly or by implication.
- 1.5 Information must be capable of substantiation.
- 1.6 Substantiation that is requested pursuant to para 1.5 above must be provided without delay at the request of members of the medical and pharmacy professions including the members of those professions employed in the pharmaceutical industry.

2. Claims & Comparisons

- 2.1 Claims for the usefulness of a drug must be based on an up-to-date evaluation of all the evidence.
- 2.2 The word "safe" must not be used without qualification and it must not be stated categorically that a medicine has no side effects, toxic hazards or risk of addiction.
- 2.3 The word "new" must not be used to describe any drug which has been generally available, or therapeutic indication which has been generally promoted, in India for more than 12 months.
- 2.4 Comparisons of drugs must be factual, fair and capable of substantiation. In presenting a comparison, care must be taken to ensure that it does not mislead by distortion, by undue emphasis, omission or in any other way.
- 2.5 Brand names of products of other companies must not be used in comparison unless the prior consent of the companies concerned has been obtained.
- 2.6 Other companies, their products, services or promotions must not be disparaged either directly or by implication.
- 2.7 The clinical and/or scientific opinions of members of healthcare professionals must not be disparaged either directly or by implication.

3. Textual and Audio-Visual Promotional Material

- 3.1 All promotional material issued by an authorized holder or with his authority, must be consistent with the requirements of this Code.
- 3.2 Where the purpose of promotional material is to provide persons qualified to prescribe or supply with sufficient information upon which to reach a decision for prescribing or for use, then the following minimum information, must be given clearly and legibly and must be an integral part of the promotional material:

- (i) The relevant drug, the name and address of the holder of the authorization of the drug or the business name and address of the part of the business responsible for placing the drug on the market;
- (ii) The name of the drug and a list of the active ingredients using the generic name, placed immediately adjacent to the most prominent display of the name of the drug;
- (iii) Recommended dosage, method of use and where not obvious, method of administration;
- (iv) Adverse reactions, warnings and precautions for use and relevant contraindications of the product;
- (v) A statement that additional information is available on request;
- (vi) The date on which the above particulars were generated or last updated.

3.3 Promotional material such as mailings and journal advertisements must not be designed to disguise their real nature. Where a pharmaceutical company pays for or otherwise secures or arranges the publication of promotional material in journals, such promotional material must not resemble editorial matter.

3.4 All promotional materials appearing in journals, the publication of which is paid for or secured or arranged by a company and referring by brand name to any product of that company, must comply with Clause 3.3 of this Code as appropriate, irrespective of the editorial control of the material published.

3.5 Promotional material must conform, both in text and illustration, to canons of good taste and must be expressed so as to recognize the professional standing of the recipients and not be likely to cause offence.

- 3.6 The names or photographs of healthcare professionals must not be used in promotional material.
- 3.7 Promotional material must not imitate the devices, copy slogans or general layout adopted by other companies in a way that is likely to mislead or confuse.
- 3.8 Where appropriate (for example, in technical and other informative material), the date of printing or of the last review of promotional material must be stated.
- 3.9 Postcards, other exposed mailings, envelopes or wrappers must not carry matter which might be regarded as advertising to the lay public or which could be considered unsuitable for public view.
- 3.10 Audio-visual material must be supported by all relevant printed material so that all relevant requirements of the Code are complied with.

4. Medical Representatives

- 4.1 The term "medical representative" means sales representatives, including personnel retained by way of contract with third parties and any other company representatives who call on healthcare professionals, pharmacies, hospitals or other healthcare facilities in connection with the promotion of drugs.
- 4.2 Medical representatives must at all times maintain a high standard of ethical conduct in the discharge of their duties. They must comply with all relevant requirements of the Code.
- 4.3 Medical representatives must not employ any inducement or subterfuge to gain an interview. They must not pay, under any guise, for access to a healthcare professional.
- 4.4 Companies are responsible for the activities of all their employees including Medical Representatives for ensuring compliance of the Code. This would be additionally ensured by the companies through appropriate clause in the contract

of the employment between the companies and its employees/Medical Representatives.

- 4.5 Other third parties working for or on behalf of pharmaceutical companies, and those that do not act on behalf of companies (such as joint ventures and licensees) commissioned to engage in activities covered by the Code should also have a good working knowledge of the Code.

5. Samples

- 5.1 Free samples of drugs shall not be supplied to any person who is not qualified to prescribe such product.
- 5.2 Where samples of products are distributed by a medical representative, the sample must be handed directly to a person qualified to prescribe such product or to a person authorized to receive the sample on their behalf.
- 5.3 The following conditions shall be observed in the provision of samples to a person qualified to prescribe such product:
 - (i) Such samples are provided on an exceptional basis only (see (ii) to (vii) below) and for the purpose of acquiring experience in dealing with such a product;
 - (ii) Such sample packs shall be limited to prescribed dosages for three patients for required course of treatment;
 - (iii) Any supply of such samples must be in response to a signed and dated request from the recipient;
 - (iv) An adequate system of control and accountability must be maintained in respect of the supply of such samples;
 - (v) Each sample pack shall not be larger than the smallest pack present in the market;

- (vi) Each sample shall be marked "free medical sample – not for sale" or bear another legend of analogous meaning;
 - (vii) Each sample shall be accompanied by a copy of the most up-to-date version of the Product Information (As required in Drug and Cosmetic Act, 1940) relating to that product.
- 5.4 A pharmaceutical company shall not supply a sample of a drug which is an anti-depressant, hypnotic, sedative or tranquillizer.
- 5.5 The companies will maintain details, such as product name, doctor name, Quantity of samples given, Date of supply of free samples distributed to Healthcare practitioners etc.

6. Gifts

- 6.1 No gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to persons qualified to prescribe or supply drugs, by a pharmaceutical company or any of its agents i.e. distributors, wholesalers, retailers etc.
- 6.2 Gifts for the personal benefit of healthcare professionals and family members (both immediate and extended) (such as tickets to entertainment events) also are not to be offered or provided.

7. Relationship with Healthcare Professionals

- 7.1 **Travel facilities:** Companies or their associations/representatives or any person acting on their behalf shall not extend any travel facility inside the country or outside, including rail, air, ship, cruise tickets, paid vacations, etc., to HealthCare Professionals and their family members for vacation or for attending conference, seminars, workshops, CME programme etc. as a delegate. It is hereby clarified that in any seminar, conference or meeting organized by a pharmaceutical company for promoting a drug or disseminating information, if a medical practitioner participates as a delegate, it will be on his/her own cost.

- 7.2 **Hospitality:** Companies or their associations/representatives shall not extend any hospitality like hotel accommodation to Healthcare Practitioners and their family members under any pretext.
- 7.3 **Cash or monetary grants:** Companies or their associations/representatives shall not pay any cash or monetary grants to any healthcare professional for individual purpose in individual capacity under any pretext. Funding for medical research, study etc., can only be extended through approved institutions by modalities laid down by law/rules/guidelines adopted by such approved institutions, in a transparent manner. It shall always be fully disclosed.

Where there is any item missing, the code of MCI as per "Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulation, 2002 as amended time to time, will prevail.

8. Mode of Operation

- 8.1 All the Indian Pharmaceutical Manufacturer associations will have UCMP uploaded on their website.
- 8.2 All the associations will upload the detail procedure (as stated in Para 10) of lodging complaints.
- 8.3 All the associations will also have a provision on their website for uploading the details of complaints received i.e. the nature of complaint, the company against whom the complaint has been made, the action taken by the committees under the association including the present status in the complaint and such details of a complaint should remain uploaded for three years. The details of proceedings in a complaint and decisions thereafter will be sent by the concerned Association on Quarterly basis, to National Pharmaceutical Pricing Authority, on following address:

**Member Secretary, NPPA,
3rd Floor,
YMCA Cultural Centre Building,
1, Jai Singh Road,
New Delhi- 110001.**

- 8.4 If a complaint received in a particular association is not concerned with its members, the receiving association will input the details of the complaint but in the column of action taken, it will mention that the complaint has been transferred to such and such association as the respondent company is member of the other association.
- 8.5 In case of companies, who are not a member of any Association or member of more than one Association, the complaint will be handled by the Pharma Industry Association to whom the complainant has addressed the complain. The Association will then, take up the complaint for the required course of action as stipulated in UCPMP.

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 (AECPMP)**" 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 AECMP. 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 (AECMP) 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(AECMP) 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 (AECMP).

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- 13.7 If AECMPMP 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 AECMPMP 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