F.No.31026/23/2022-Policy
Government of India
Ministry of Chemicals and Fertilizers
Department of Pharmaceuticals
****

Shastri Bhawan, New Delhi
12th March, 2024

To

All Pharmaceutical Associations

Subject: Uniform Code for Pharmaceutical Marketing Practices (UCPMP) 2024 – reg.

Sir / Madam,

Please find enclosed the Uniform Code for Pharmaceutical Marketing Practices (UCPMP) 2024. It may kindly be circulated to all members for strict compliance.

2. All associations are requested to constitute an Ethics Committee for Pharmaceutical Marketing Practices (ECPMP), set up a dedicated UCPMP portal on their website, and take further necessary steps towards implementation of this Code.

Enclosure: as above

Yours sincerely

(Ravindra Pratap Singh)
Joint Secretary (Policy)

Copy to: NIC, DoP – with the request to upload the same on the website of Department of Pharmaceuticals

Uniform Code for Pharmaceuticals Marketing Practices (UCPMP) 2024

1 General Points

1.1 As per the '*Ethical Criteria for Medicinal Drug Promotion*' endorsed by the World Health Assembly in 1988, "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.

1.2 The promotion of a drug must be consistent with the terms of its marketing approval and a drug must not be promoted prior to receipt of its marketing approval from the competent authority, authorizing its sale or distribution.

1.3 Information about drugs must be balanced, up-to-date, verifiable, must not mislead either directly or by implication; accurately reflect current knowledge or responsible opinion; and must be capable of substantiation, which must be provided without delay, at request of the members of the medical and pharmacy professions, including members of other professions employed in the pharmaceutical industry.

2 Claims & Comparisons

2.1 Claims for the usefulness of a drug must be based on up-to-date evaluation of all available 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 any therapeutic intervention which has been generally promoted in India for more than a year.

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, by omission, or in any other similar 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 or scientific opinions of healthcare professionals must not be disparaged either directly or by implication.

3 Textual and Audio-Visual Promotion

3.1 Any 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 the promotional material is to provide persons qualified to prescribe with sufficient information upon which to reach a decision for prescription or for use, the following minimum information must be given legibly and must be an integral part of the promotional material:

i. The relevant drug, the name and address of the holder of authorization for 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, along with a list of 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, its method of administration;
iv. Adverse reactions, warnings, precautions for use and relevant contraindications for the use of the product;
v. A statement that additional information is available on request, and 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 some promotional material in journals, such promotional material must not resemble the editorial matter.

3.4 All promotional materials appearing in journals, the publication of which is paid for, or secured or arranged by a company, referring by brand name to any product of that company must comply with Clause 3.3 of this Code, 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 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 used by other companies in a way that is likely to mislead or confuse.

3.8 Wherever 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 this Code are fully 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 other company representatives who call on healthcare professionals, pharmacies, hospitals, or healthcare facilities in connection with promotion of drugs.

4.2 The 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 The 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 their employees, including the medical representatives, for ensuring compliance of this Code. This should additionally be ensured through an appropriate clause in the employment contract signed between the Company and its Medical Representatives as defined above.

4.5 Third parties working for or on behalf of the pharmaceutical companies, including those acting on their behalf (such as joint ventures and licensees), that are commissioned to engage in activities covered by this Code, should also have a sound working knowledge of this Code.

5 Brand Reminders

5.1 Brand Reminders are permitted in the following two categories, viz., (i) Informational and education items and (ii) Free samples provided by the companies to medical professionals.

i. ***Informational and educational items*** mean books, calendars, diaries, journals (including e-journals), dummy device models and clinical treatment guidelines for professional used in healthcare settings value of which does not exceed *Rs. 1000 per item*. Such items should not have an independent commercial value for the healthcare professionals.

ii. ***Free samples****:*

- Free samples of drugs shall not be supplied to any person who is not qualified to prescribe such a product.
- Where samples of products are distributed by a medical representative, the sample must be handed directly to the person qualified to prescribe such product, or to a person authorized to receive the sample on their behalf, and the name and address of the healthcare practitioner noted for records.
- The following conditions shall be observed while providing samples to a person qualified to prescribe such product:

a. Such samples are provided only for the purpose of creating awareness about treatment options and for acquiring experience in dealing with the product;

b. Sample packs should be limited to prescribed dosage for not more than three patients for the required course of treatment and no company should offer more than twelve such sample packs per drug to any healthcare practitioner per year;

c. Each sample should be marked "free medical sample not for sale" or bear another legend of analogous meaning;

d. Each sample pack should not be larger than the smallest pack present in the market;

e. An adequate system of accountability and control must be maintained in respect of supply of such samples;

f. A pharmaceutical company shall not supply a sample of a drug which is a hypnotic, sedative, or a tranquillizer.

- Each company should maintain details such as product name, doctor name, quantity of samples given, date of supply of free samples to healthcare practitioners etc, and the monetary value of samples so distributed should not exceed two percent of the domestic sales of the company per year.

5.2 Receipt of brand reminders from pharmaceutical companies by healthcare practitioners may not be construed as endorsement activity if it does not amount to recommendation or issuance of a statement by a healthcare professional w.r.t. use of the respective brand.

5.3 The giver and recipient of brand reminders should comply with the relevant provisions of the Income Tax Act, 1961 with respect to deductions and reporting of income.

6 Continuing Medical Education

6.1 Engagement of pharmaceutical industry with the healthcare professionals for Continuing Medical Education (CME), Continuing Professional Development (CPD) or otherwise for conference, seminar, workshop, etc. should only be allowed through a well-defined, transparent, and verifiable set of guidelines based on which the pharmaceutical industry may undertake such expenditures.

6.2 Such activities or events should operate within the following framework:

i. Conduct of such events in foreign locations is prohibited.

ii. The following are allowed to conduct CME/CPD meetings:
   a) Medical Colleges/Teaching Institutions/Universities/Hospitals
   b) Professional Associations of Doctors/Specialists
   c) NIPERs, Laboratories of ICMR, DBT, CSIR etc, Pharma Colleges/other academic and research institutions
   d) Pharmaceutical companies, including their trusts/associations, either alone or in collaboration with professional bodies, institutions as stated in a, b & c above.

iii. All pharmaceutical companies should share the details of such events conducted by them, including the expenditures incurred thereupon, on their website, and may be subject to independent, random, or risk-based audit for this purpose.

iv. All organizers of such events should explicitly spell out the procedure followed in the selection of participants and speakers, display a statement of their funding sources and expenditures on their website, and may be subject to special audit for this purpose.

v. Entities incurring expenditure on such events, as well as participants and speakers, must comply with the relevant provisions of the Income Tax Act 1961 as amended from time to time.

7 Support for Research

To provide rational support and encouragement to research and innovation through the industry-academia linkage, interaction between pharmaceutical companies and healthcare professionals may be subject to the following:

i. The said study or research should be one that has the requisite approval from the competent authority (such as ICMR, DCGI, Ethics Committee, Institutional Authority etc.) and is conducted, where so applicable, at a recognized site or location. Instructions by relevant bodies like NMC, etc., may be complied with.

ii. Engagement of healthcare professionals in consultant-advisory capacity shall be for bona-fide research services, under a consultancy agreement involving a consultancy-fee or an honorarium-based payment, subject to the relevant provisions of the Income-Tax Act, 1961. Such engagements should ensure the patient interest is not compromised and integrity of the healthcare professional is maintained in line with the NMC regulations.

iii. Expenditure on research by pharmaceutical companies is an allowable expenditure subject to the provisions of the Income Tax Act 1961 as amended from time to time.

8 Relationship with Healthcare Professionals

8.1 Gifts: No gift should be offered or provided for personal benefit of any healthcare professional or family member (both immediate and extended) by any pharmaceutical company or its agent i.e. distributors, wholesalers, retailers, etc. Similarly, no pecuniary advantage or benefit in kind may be offered, supplied, or promised to any person qualified to prescribe or supply drugs, by any pharmaceutical company or its agent i.e. distributors, wholesalers, retailers, etc.

8.2 Travel: Companies or their representatives, or any person acting on their behalf, should not extend travel facilities inside or outside the country, including rail, air, ship, cruise tickets, paid vacations, etc., to healthcare professionals or their family members (both immediate and extended) for attending conferences, seminars, workshops etc., unless the person is a speaker for a CME or a CPD Program.

8.3 Hospitality: Companies or their representatives, or any person acting on their behalf, should not extend hospitality like hotel stay, expensive cuisine, resort accommodation etc., to healthcare professionals or their family members (both immediate and extended) unless the person is a speaker for a CME or a CPD program.

8.4 Monetary Grants: Companies or their representatives should not pay cash or monetary grant to any healthcare professional or their family members (both immediate and extended) under any pretext.

Where any item missing, the Code as per the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulation, 2002, as amended from time to time, will prevail.

9 Ethics Committee for Pharma Marketing Practices

9.1 All the Indian Pharmaceutical Associations will upload the UCPMP on their website along with the detailed procedure for lodging of complaints which will be linked to the UCPMP portal of the Department of Pharmaceuticals.

9.2 There will be a committee for handling complaints named as "Ethics Committee for Pharma Marketing Practices (ECPMP)" in each Association, chaired by its Chief Executive Officer. The Committee will have three to five members, and its composition will be approved by the Board of the Association and prominently placed on its website.

9.3 If a complaint received in a particular association is not concerned with its members, the receiving association will input the abstract of the complaint and will duly transfer the complaint to such other association where the respondent company is a member of the other association.

9.4 In case of companies, who are not members of any Association, or member of more than one Association, the complaint should ordinarily be handled by the Pharma Industry Association to whom the complainant has addressed the complaint; and where necessary, it will seek guidance from the Department of Pharmaceuticals.

9.5 All pharma associations will share on their website the details of complaints received i.e. the nature of complaint, the company against whom the complaint has been made, the present status of the complaint, including action taken by the ECPMP, and such details should remain uploaded for five years. Such details should also be uploaded on the UCPMP portal of the Department of Pharmaceuticals.

10 Lodging of Complaints

10.1 All complaints, related to the breach of the Code should be addressed to the "Ethics Committee for Pharma Marketing Practices (ECPMP)", "Chief Executive Officer", "Name of Association".

10.2 All complaints related to an activity of breach of the Code should, to the extent practicable, be made at one time. The complaint must be made within six months of the alleged breach of the Code, with a maximum of another six months for reasonable delay that can be explained in writing. Related complaints may be clubbed together by the Ethics Committee to save time and expedite disposal.

10.3 Complaints must be in writing and for each case *The Complainant* should:

i. identify himself (whether a company, entity or an individual) with a full mailing address (email and mobile telephone no).

ii. identify the company, which is alleged to have breached the Code, including 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, give the date of the alleged breach, clauses of the Code which are alleged to have been breached, and 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 respective association will elaborate on their website how this payment is to be made. No pseudonymous or anonymous complaints or those made without the prescribed fee will be entertained.

10.5 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 officer or a person at an equivalent level.

10.6 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 may be treated as complaint, and the committee may request the concerned publication for further information, and the source or the correspondent may be treated as the complainant.

10.7 Any complaint received by the Department of Pharmaceuticals may also be forwarded to the concerned Association for necessary action. In such cases, the concerned Association will take up the matter further with the complainant concerned. The Department may order a special audit for the purpose.

11 Handling of Complaints

11.1 Once a complaint is lodged, the process of enquiry should be taken up and completed by the ECPMP. The decision of the Committee will be made by majority. In case of conflict of interest, the member/s concerned should recuse themselves from the proceedings.

11.2 When the Committee receives information from which it appears that a company may have contravened the Code, the managing director or chief executive officer of the company concerned will be asked to provide a complete response to the matter.

11.3 To assist companies in ensuring that a complete response is submitted, the Committee may suggest to the respondent company the relevant supporting material to be supplied, and it shall be the responsibility of the respondent company to ensure that a full response is submitted within the stipulated timeframe.

11.4 Associations may engage the services of professional auditors to facilitate better and independent examination towards arriving at an informed decision.

11.5 The respondent company shall submit its comments and supporting documents to the Committee in not more than 30 days after receipt of notice from the Committee.

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

11.7 The Committee should render a decision within 90 days of the receipt of complaint, and having done so, it should promptly notify the parties of its decision, the reasons thereof in writing and send it by recorded mail.

11.8 Where the Committee decides there is no breach of the Code, or that matter of complaint is not within the scope of the Code, the complainant will be so advised in writing, including advice on the appropriate forum to approach in such cases.

11.9 Where the Committee, after enquiry, decides that there is a breach of the Code, the complainant and the respondent company will be so advised in writing, including the remedial steps that need to be taken in this regard.

11.10 If 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 the Association. The decisions shall also be uploaded on the website of the Association and the Department of Pharmaceuticals.

12 Penalties and Reference

Once it is established that a breach of the Code has been made by an entity, the Committee can propose one of the following actions against the erring entity:

i. To suspend or expel the entity from the Association.
ii. To reprimand the entity and publish full details of such reprimand.
iii. To require the entity to issue a corrective statement in the same media (and other suitable media) which was used to issue promotional material, textual or audio-visual (details of the proposed content, mode and timing of dissemination of the corrective statement must be provided by the entity to the Committee for prior approval).
iv. To ask the entity to recover money or items, given in violation of the Code, from the concerned person/s, and details of the action taken in this regard must be submitted by the entity to the Committee in writing.
v. In cases where disciplinary, penal, or remedial action lies within the domain of any agency or authority of the Government in accordance with the statute, the Committee may send its recommendations to such agency or authority through the Department of Pharmaceuticals.

13 Appeal

13.1 If a party to the complaint is dissatisfied with the decision of the ECPMP, it may file an appeal before an 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.

Explanation: The expression 'party to the complaint' means the complainant or the respondent entity, and the expression 'decision of the ECPMP' includes a lack of decision thereof, or inordinate delay in reaching such a decision.

13.2 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.

13.3 The ACPMP will give a notice to both the parties, and after giving a reasonable opportunity of being heard, give a final decision or ruling within six months.

13.4 The ACPMP may prescribe any penalties or make a reference to an appropriate agency or an authority of the Government in accordance with para-12 above.

13.5 The decision in appeal shall be final and binding on both the parties.

14 Miscellaneous

14.1 The Department of Pharmaceuticals may, for furtherance of the provisions of this Code, or for removal of difficulties in its operation, may issue standing orders from time to time which will be considered an integral part of this Code.

14.2 The provisions of this Code, unless exempted, or to the extent modified by standing orders, shall apply mutatis mutandis to medical devices and companies or entities manufacturing or dealing with the sale and distribution of such products.

14.3 The Department of Pharmaceutical will notify a panel of auditors, either audit firms of standing empanelled by the CAG or commercial audit firms of repute having an experience of dealing with such matters.

14.4 Finally, the Chief Executive Officer of the company itself is responsible for adherence to this Code, and a self-declaration in the format given in the annexure shall be submitted by the executive head of the company within two months of the end of every financial year to the Association for uploading on their website, or directly on the UCPMP portal of the Department of Pharmaceuticals in case he is not a member of such a body, or a member of more than one such bodies.

Sd/-

(Arunish Chawla)
Secretary to Government of India,
Department of Pharmaceuticals,
Ministry of Chemicals and Fertilizers,
Shastri Bhawan, New Delhi
12th March 2024

Annexure

Self-Declaration by the Executive Head of the Company Regarding Compliance to the Uniform Code for Pharmaceuticals Marketing Practices, to be made within two months of the 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 for the financial year....."

"This is to further undertake that ..... (name of the company), headquarters at ..... will continue to abide by the provisions of the Uniform Code for Pharmaceuticals Marketing Practices and with extend all required assistance to authorities for the enforcement of this Code."

[Name and Designation]
[Seal of the Company]