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

Shastri Bhawan, New Delhi
6th September, 2024

To

All Medical Devices Associations

Subject: Uniform Code for Marketing Practices in Medical Devices (UCMPMD) 2024 - reg.

Sir / Madam,

Please find enclosed the Uniform Code for Marketing Practices in Medical Devices (UCMPMD) 2024 which may be circulated to all members for strict compliance.

2. All associations should constitute an Ethics Committee for Marketing Practices in Medical Devices (ECMPMD), upload the UCMPMD 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.

3. Additionally, in exercise of the powers conferred by Para 14.1 of the Uniform Code for Marketing Practices in Medical Devices (UCMPMD) 2024, the Department requires disclosure from Medical Devices companies of particulars related to distribution of evaluation samples and expenses incurred on Continuing Medical Education/ Continuing Professional Development/ Conferences/ Workshops/ Trainings/ Seminars etc. The format for such disclosure is also enclosed. The particulars are to be filled on an ongoing basis and mandatorily within two months of the end of every financial year on the UCPMP portal of the Department within the time limit fixed for submitting self- declaration under Para 14.3 of the Code.

Enclosure: As above

Yours sincerely

(Ravindra Pratap Singh)
Joint Secretary (MediTech Policy)

Uniform Code for Marketing Practices in Medical Devices (UCMPMD) 2024

1 General Points

1.1 A Medical Device must not be promoted prior to receipt of the product approval (wherever applicable) by the Regulatory Authority, authorizing its sale or distribution as per the provisions of the Medical Device Rules, 2017.

1.2 The promotion of a Medical Device must be consistent with the terms of documents submitted by the Companies for obtaining product registration or licenses to manufacture, import, distribute or sell these Devices in India; and more specifically, with the Instructions for Use (IFU)/Directions for Use (DFU) of the relevant product.

1.3 Product Information about Medical Devices must be up-to-date, verifiable and accurately reflect current knowledge or responsible opinion.

1.4 Product Information about Medical Devices must be accurate, balanced, must not mislead either directly or by implication, and must be capable of substantiation.

1.5 Substantiation that is requested pursuant to para 1.4 above must be provided within a reasonable time frame, by the authorized sources of the Company at the request of Health Care Professionals (HCPs).

2 Claims & Comparisons

2.1 Claims for usefulness of a Medical Device must be based on evaluation of available and published evidence and/or IFU/ DFU of the relevant product.

2.2 The word "safe" or “safety” must not be used without qualification and it must not be stated categorically that a Medical Device has no adverse consequences.

2.3 All product claims should be in accordance with the terms of documents submitted by the Companies for obtaining product registration or licenses to manufacture, import, distribute or sell the Device in India and the IFU/DFU/User Manual for the same.

2.4 Comparisons of Medical Devices must be factual, fair and capable of substantiation by way of available data. 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 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 must be consistent with the requirements of this Code. Where the purpose of promotional material is to provide persons qualified to prescribe or use with sufficient information upon which to reach a decision for prescribing or for use, the following minimum information, must be given clearly and legibly and must be an integral part of the promotional material:

a. Generic name and/or brand name of the Medical Device;

b. The name and address of the manufacturer/importer of the Medical Device and the business name and address of the entity responsible for marketing the Device;

c. Warnings and precautions for use and relevant contraindications of the product;

d. A statement that additional information is available on request; and

e. The date on which the above particulars were generated or last updated.

3.2 Promotional material such as mailings and journal advertisements must not be designed to disguise their real nature. Where a 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.

3.3 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 this Code, irrespective of the editorial control of the material published.

3.4 Promotional material must conform, both in text and illustration, to canons of good taste and must be expressed to recognize professional standing of the recipients.

3.5 The names or photographs of healthcare professionals must not be used in the promotional material.

3.6 Promotional material must not imitate the medical devices, copy slogans, or general layout used by other companies in a way that is likely to mislead or confuse.

3.7 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.

3.8 Postcards, envelopes, wrappers, and other exposed mailings, must not carry matter which might be regarded as advertising to the lay public, or otherwise unsuitable for public view.

3.9 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 representatives" means sales representatives, medical affairs or marketing professionals, clinical specialists including personnel retained by way of contract with third parties or any other company representatives who call on HCPs, pharmacies, pathology labs, research labs, hospitals, or other healthcare facilities in connection with the promotion of Medical Devices.

4.2 The medical representatives must at all times maintain a high standard of ethical conduct in the discharge of their duties and comply with all relevant requirements of this 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 Medical Device Companies, that are commissioned to engage in activities covered by this Code (including those acting on their behalf such as joint ventures or licensees), must have a sound working knowledge and must comply with all provisions of this Code.

5 Brand Reminders, Evaluation Samples and Demonstration Products

5.1 **Brand Reminders** means books, calendars, diaries, journals (including e-journals), dummy device models etc. for professional use in healthcare settings. Such items are permitted provided their value does not exceed Rs. 1000 per item and the items do not have an independent commercial value for the healthcare professionals.

5.2 **Evaluation Samples** are provided for the purpose of acquiring hands on experience in using the medical device product.

5.2.1 Free evaluation samples of Medical Devices must not be supplied to any person other than the qualified healthcare professionals (HCPs). Where samples of products are distributed by a medical representative, the sample must be handed directly to the person qualified to prescribe or use such product, or to a person authorized to receive the same on their behalf, and the name and address of the healthcare professional must be noted for records.

5.2.2 The following conditions shall be applicable to the provisions of evaluation samples:

(i) Each sample should be supplied with latest version of the Product's IFU/DFU/e-IFU or User Manual, wherever applicable.

(ii) The number of evaluation samples (single use products) provided at no charge shall not exceed the quantity that is reasonably necessary for evaluation of that product.

(iii) The Companies should maintain the details, such as product name, HCP's name & contact information, date of supply of evaluation samples, quantity and value of evaluation samples given, and other relevant product traceability information, for a minimum period of five years.

(iv) The monetary value of samples so distributed should not exceed two percent of the domestic sales of the company per year.

(v) Each evaluation sample should be marked "Evaluation Sample- Not for Sale" or bear another legend of analogous meaning.

5.3 **Demonstration Products:**

5.3.1 Demonstration Products are different from Evaluation Samples and intended for use by medical representatives to explain the functioning/features of the medical device to the HCPs. Demonstration Products can be single use products, mock-ups, temporary software, or equipment that may be used for patient awareness & education. They are, however, are not intended for patient use and such demonstration equipment should be taken back by the Company after the demonstration period is over. Demonstration Products must be separately identified and tracked by the Company in all cases.

5.3.2 The Companies should maintain details, such as product name, HCP's name & contact information, quantity and value as per the MRP of the Device or Demonstration Product given, Date of supply to HCPs, and the date of taking back of such products, and maintain the relevant product identification and traceability information for a minimum period of five years.

5.4 Receipt of Brand Reminders or Evaluation Samples or Demonstration Products from 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 of such products.

5.5 The giver and recipient of Brand Reminders or Evaluation Samples or Demonstration Products must 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 Medical Device Industry with Healthcare Professionals for Continuing Medical Education (CME), Continuing Professional Development (CPD), Training, or otherwise for conference, seminar, workshop, etc. should only be through a well-defined, transparent and verifiable set of procedures based on which the Medical Device 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, except for advanced clinical trainings in exceptional circumstances like non-availability of trainers or equipment and products within the country. For trainings to be conducted at foreign locations, detailed justification, along with details of participating HCPs, duration and location of training, trainers, equipment and facilities to be used, expenditure to be incurred on travel and boarding etc. should be submitted to the department at least three months in advance before the scheduled date, and only on specific approval of the department such foreign trainings may be permitted.

ii. The following are allowed to conduct CME/CPD/Trainings:
   a) Medical Colleges/Teaching Institutions/Universities/Hospitals
   b) Professional Associations of Doctors/Specialists

c) NIPERs, ICMR, DBT, CSIR Laboratories, other academic and research institutions
d) Medical Device Companies, their trusts/associations, either alone or in collaboration with professional bodies, institutions as stated in a, b & c above.

iii. All Medical Device 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. 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 Medical Device 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 Medical Device 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 Medical Device Company or its agent viz. 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 use Medical Devices, by any Medical Device Company or its agent viz. 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 or a participant in a training program for which specific approval has been obtained from the Department as per clause 6.2 above.

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 or a participant in a training program for which specific approval has been obtained from the department as per clause 6.2 above.

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 Marketing Practices in Medical Devices

9.1 All the Indian Medical Device Associations will upload the UCMPMD 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 Marketing Practices in Medical Device (ECMPMD)" 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 record the abstract of the complaint and will transfer the complaint to such other association where the respondent company is a member, or to the Department of Pharmaceuticals in case the company is not a member of any association.

9.4 In case of companies who are members of more than one Association, the complaint should ordinarily be handled by the Medical Device Association to whom the complaint is addressed, and where necessary, it may seek guidance from the Department of Pharmaceuticals.

9.5 After disposal all Medical Device Associations should share on their website the details of complaints received, the company against whom the complaint was received, the action taken on the complaint 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 Marketing Practices in Medical Device (ECMPMD)", "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 for the same.

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 Medical Device 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) that a company may have breached the Code, the matter may be treated as a complaint, and the Department or the Committee may request the concerned publication for further information. In such cases, 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 further necessary action. The Department may also order a special audit and/or deal with the complaint directly.

11 Handling of Complaints

11.1 Once a complaint is lodged, the process of enquiry should be taken up and completed by the ECMPMD. 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 chief executive officer of the company concerned should be asked to provide a complete response to the matter.

11.3 To ensure that a complete response is submitted, the Committee may suggest to the respondent company the relevant supporting material that needs to be supplied, and it shall be the duty 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 ECMPMD 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 UCPMP portal of 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 textual or audio-visual promotional material (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 ECMPMD, it may file an appeal before an Apex Committee for Marketing Practices in Medical Devices (ACMPMD) headed by the Secretary, Department of Pharmaceuticals, having a Joint Secretary and a Finance Adviser 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 ECMPMD' 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 In cases referred by the Department to the Association in accordance with para 10.6 and 10.7 above, if inordinate delay or lack of action thereof is observed, the ACMPMD may itself proceed further in the matter in accordance with the provisions of this Code.

13.4 The ACMPMD 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.

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

13.6 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. The standing orders may include formats for data that needs to be submitted in compliance of this Code.

14.2 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.

14.3 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 and also directly on the UCPMP portal of the Department of Pharmaceuticals.

Sd/-
Arunish Chawla
Secretary to Government of India,
Department of Pharmaceuticals,
Ministry of Chemicals and Fertilizers,
Shastri Bhawan, New Delhi.
6th September, 2024

UCMPMD 2024 – Form for Disclosure of Marketing Expenditure

Form for furnishing return in respect of the Uniform Code for Marketing Practices in Medical Devices (UCMPMD) 2024

All fields are mandatory

Company Information

1. (a) Corporate Identity Number (CIN)/Foreign Company Registration Number (FCRN)

   (b) Name of the Company

   (c) Address of the registered office of the company

   (d) Email ID of the company

   (e) Permanent Account Number (PAN) of the company

2. Return for the Financial Year

3. Particulars to be filled by Companies in pursuance to UCMPMD 2024:

(A) Free Evaluation Samples Distributed

Month/Year	Monetary Value of Evaluation Samples (in ₹)	Number of Recipient Healthcare Professionals	Domestic Sales Revenue (in ₹ Crores)

(B) Continuing Medical Education/ Continuing Professional Development/ Conferences/Workshops/ Trainings/Seminars etc. organized directly by the medical devices company.

Month/Year	Total no. of events	Expenditure* incurred (in ₹ lakhs)

(C) Continuing Medical Education/ Continuing Professional Development/ Conferences/ Workshops/ Trainings/Seminars etc. organized through third party including associations/bodies etc.

Date of the Event (dd/mm/yyyy)	Location of the Event	Name of the Organizers	Expenditure* incurred (in ₹ lakhs)

** Note: Expenditure includes all expenses incurred for the event including sponsorship, travel, lodging, hospitality, advertisements, stalls, souvenirs, etc.*

Declaration:

1. I have read UCMPMD Code-2024 and the information furnished is in compliance of the Code.
2. It is hereby declared that the information given in the form and attachments is true to the best of my knowledge and belief.

To be digitally signed by DSC Box

Designation

Director Identification Number (DIN) or PAN of the Executive Head of the Company

Note: Information submitted will be handled in accordance with the provision for disclosure of third-party information as provided under the RTI Act.

Mobile: **Email id:**

Note: Attention is drawn to the provisions of section 405 of the Companies Act, 2013 which provides for punishment for any information which is incorrect or incomplete in any material respect.

For office use only:

eForm Service request number (SRN)

eForm filling date (DD/MM/YYYY)