client alert

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ahead of the curve

Uniform Code for Marketing Practices in Medical Devices (UCMPMD) 2024: Frequently Asked Questions

On September 6, 2024, the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers (**DoP**), unveiled the Uniform Code for Marketing Practices in Medical Devices, 2024 (**UCMPMD 2024**) with a view towards providing a set of guidelines that would mitigate unethical practices, and ensure transparency, integrity, and accountability in the marketing of medical devices across India. In this regard, UCMPMD 2024 is an addition to the Uniform Code for Pharmaceuticals Marketing Practice, 2024 (**UCPMP 2024**)[1]. While the foundation of UCMPMD 2024 and UCPMP 2024 have similarities, this new code for medical devices stands out with some subtle and not so subtle distinctions.

We attempt to answer some of these in the FAQs below:

1. Is UCMPMD 2024 a voluntary code?

The UCMPMD 2024 echoes similar language to the UCPMP 2024, which we previously assessed as more mandatory than voluntary in nature[2]. Much like the UCPMP 2024, the tone and tenor of the language in UCMPMD 2024 - characterised by the omission of terms such as "*shall be*" or "*must be*," which would otherwise imply a voluntary framework—reflect a more authoritative, directive-oriented approach rather than a suggestive one.

2. What is promotion under UCMPMD?

The UCMPMD 2024 does not define "*Promotion*" as endorsed by the World Health Assembly in the UCPMP 2024. Instead, the contours of promotion are limited to (i) no medical device may be promoted before the receipt of product approval by the authority[3], and (ii) ensuring promotions align with the terms of documents submitted for obtaining approval for manufacture, import, distribution or sale[4]. The remaining provision is consistent with UCPMP 2024.

3. What does UCMPMD 2024 cover? Who oversees the implementation?

UCMPMD 2024 is applicable to promotion and marketing activities undertaken by medical device companies[5] (**Companies**). Implementation is overseen by pharmaceutical associations that have industry players as members. The DoP plays a guiding role in enforcement of the code.

1 Uniform Code of Pharmaceutical Marketing Practices - 2024.

2 Question 1. Uniform Code for Pharmaceuticals Marketing Practices (UCPMP) 2024: FAQs dated March 21, 2024

3 Provision 1.1

4 Provision 1.2

5 In terms of Provision 3 which highlights that medical device companies are required to comply with the provisions of the code and file their disclosures.

4. What aspects are to be kept in mind while promoting medical devices?

Medical device cannot be promoted prior to receipt of the approval by the regulatory authority. Promotions must be consistent with terms of document submitted by the company for obtaining requisite approvals (licenses or registrations) for manufacture, import, distribution, etc. Promotions, including making claims, must be specifically consistent with Instruction for Use (**IFU**) and/or Direction for Use (**DFU**). Information provided should be accurate balanced, up-to-date, verifiable, and readily available, and not misleading[6].

Claims for usefulness must be based on up-to-date evaluation of available evidence including IFU and/or DFU[7]. No claims of safety without proper qualification[8]. No categoric statement regarding absence of adverse consequences.[9]

Medical device comparisons must be factual, fair, and verifiable[10]. Avoid misleading information[11]. No comparison between brand names of products of other companies is permitted without consent[12]. No product disparagement[13]. No disparagement of clinical or scientific opinions of healthcare professional (**HCP**).[14]

5. What aspects should be considered while designing promotional campaigns?

All promotional material must be issued in conformity with the code by the proper and authorised holder or with authority of such person. Consistency with the requirements of the code is required[15].

Promotions aimed at giving HCP's (qualified to prescribe/ use) information that could allow them to make a decision must include the name of the medical device along with its generic and/or brand name, manufacturer/importer of the medical device along with business name and address of the entity responsible for labelling the device, usage warnings and precautions, and relevant product contraindications. They also need a statement that additional information is available on request, and the date on which the particulars stated in this paragraph were generated or updated[16].

Promotional materials in print - mailing and journal advertisements, publications should not resemble editorial matter.[17] Journal ads referencing a company's branded product must follow the same guidelines, regardless of editorial control.[18]

All text and illustrations must be in good taste and representative of high professional standards to which the recipients of such information adhere to.[19] Using names and photographs of HCPs[20] are prohibited and imitating (devices, slogans, layouts) materials used by others, which may result in misrepresentation, or confusion[21] is barred. All information are required to be up-to-date and dates of review/ updating should be identified accordingly.[22]

Public-facing materials like postcards, envelopes, wrappers and other exposed mailings should not contain advertising content or be unsuitable for public view.[23]

Audio-visual material must be supported by all relevant printed material that comply with this code.[24]

6. Who is a Medical Representative? Can Medical Representatives induce or pay for access to HCPs?

"*Medical representative*" [25] means sales representatives (medical affairs or marketing professionals, clinical specialist including personnel retained through contract with third parties) and other company representatives who call on HCPs, pharmacies, pathology labs, research labs, hospitals, or healthcare facilities in connection with promotion of medical devices. Much like, UCPMP 2024, medical representatives' (**MRs**) must not employ any inducement or subterfuge to gain an interview, including pay, under any guise, for access to HCPs[26].

6 Provision 1.3 & 1.4
7 Provision 2.1
8 Provision 2.2
9 Ibid
10 Provision 2.4
11 By distortion, by undue emphasis, by omission, or in any other similar way.
12 Provision 2.5
13 Provision 2.6
14 Provision 2.7
15 Provision 3.1
16 Provision 3.1
17 Provision 3.2
18 Provision 3.3
19 Provision 3.4
20 Provision 3.5
21 Provision 3.6
22 Provision 3.7
23 Provision 3.8
24 Provision 3.9
25 Provision 4.1
26 Provision 4.3

7. What obligations do the companies have towards acts committed by their MRs?

Companies are responsible for the activities of their employees, including MRs for ensuring compliance of UCMPMD 2024. To ensure absolute compliance in this regard, companies should include appropriate covenants in their employment contract with their MRs[27]. It is advisable that Companies hold regular training sessions on the code for their HCPs.

8. Is the code applicable to third parties that work on behalf of the Companies?

Third parties working for or on behalf of medical device companies including JV partners and licensees, and agents commissioned to engage in activities covered by the code are required to have a sound working knowledge of the UCMPMD 2024[28]. It is advisable that wherever companies engage in the above, appropriate training should be conducted to ensure compliance. Covenants in this regard may also be considered in contracts that cover such relationships.

9. What qualifies as brand reminders?

This would include reminders for professional use in healthcare settings, including books, calendars, diaries, journals including e-journals, dummy device model and clinical treatment guidelines, with value of such items capped at INR 1,000 per item and should not have an independent commercial value for HCPs[29]. In the UCPMP 2024, these were covered under the category of "Information and educational items" under Brand Reminders.

10. Whether medical device samples can be provided by the Companies?

Yes. Medical device samples can be provided by the Companies to HCPs in form of evaluation samples for the limited purpose of acquisition of hands-on experience in using medical device products, subject to certain conditions[30]. The "Evaluation Samples" are different from "Demonstration Products", which is dealt separately under the code[31].

11. What are the key distinguishing features between 'Evaluation samples' and 'Demonstration products'?

The key differences between the two are as follows:

Point of Distinction	Evaluation Samples	Product Demonstration
Purpose	Evaluation samples are provided for the purpose of providing hands on experience in using the medical device product to HCPs.	Demonstration of products is carried out by MRs to explain the functioning and/ or features of the medical device to HCPs.
Limit in monetary value	Monetary value of samples distributed should not exceed two percent of the domestic sales of the company per year.	No such limit prescribed.
Return period	No such period is prescribed. Samples are given to the HCPs for evaluation purposes.	Provided for definite period.
Patient Use	Silent on this aspect.	Not meant for patient use.
Sale	Not meant for sale.	Not applicable. Product needs to be returned after the demo period.

27 Provision 4.4
28 Provision 4.5
29 Provision 5.1
30 Provisions 5.2 and 5.3
31 Provision 5.3

12. What key aspects should the companies borne in mind while providing Evaluation samples to HCPs?

The Companies must be mindful of the below-mentioned key considerations, while providing Evaluation samples to HCPs [32]:

i. They should be provided for the purpose of acquisition of hands-on experience on the product[33].

ii. They should be supplied with the latest version of products IFU and/or DFU and either be marked as "Evaluation sample - Not for sale" or bear any other analogous legend.[34]

iii. These cannot be provided to any person who is not qualified to prescribe[35]. Such sample ought to be handed over directly to a person who is qualified to prescribe or authorised to receive on their behalf, with the name of the HCP and address receiving such sample be recorded[36].

iv. These should be limited to the quantity that is reasonably necessary for evaluation of that product[37].

v. Monetary value of these samples should not exceed 2 (two) percent of annual domestic sales[38]. Both given and recipient to act in consonance with applicable tax laws[39].

vi. The Company providing the samples should maintain accurate records containing the name of the HCP, quantity and value of samples given, and other relevant details for traceability purposes. This information should be maintained for a period of 5 (five) years[40].

13. What should be borne in mind while undertaking the activity of demonstration of medical device products?

The Companies must be mindful of the below-mentioned key considerations, while providing demonstration of medical device products to HCPs[41]

i. Demonstration products are intended for the use by MRs to explain functioning/ features of the medical device to HCPs.

ii. Such products could be single-use products, mock-ups, temporary software, or equipment that may be used for patient awareness and education[42].

iii. These are not meant for patient use and the Companies must take them back after the demonstration period[43]

iv. Ought not to be provided to any person other than qualified HCPs[44]. Such samples ought to be handed directly to the person qualified to prescribe or authorised to receive on their behalf, with the name of the HCP and address receiving such sample be recorded[45].

v. Th Company should maintain accurate records of the HCP, quantity and value of as per the MRP of device or demonstration product given, date of supply to HCPs, and date of taking back the product and other relevant details for traceability purposes. Such information is required to be maintained for 5 (five) years[46].

14. Would Brand reminders, Evaluation samples and Product demonstration by companies to HCPs qualify as endorsements of products?

Brand reminders, Evaluation samples and Product demonstration to the HCPs may not be seen as endorsement acts, absent any recommendation or issuance of statement from the HCP for use of products from any such respective brand[47].

32 Provision 5.2.2
33 Provision 5.2
34 Provision 5.1 (ii)(c)
35 Provision 5.2.1
36 Ibid.
37 Provision 5.2.2 (ii)
38 Provision 5.2.2 (iii)
39 Provision 5.5
40 Provision 5.2.2 (ii)
41 Provision 5.3.1
42 Ibid.
43 Ibid.
44 Provision 5.2.1
45 Ibid.
46 Provision 5.3.2
47 Provision 5.4

15. Can Continuing Medical Education (CME)/ Continuing Professional Development (CPD) programs be conducted by the Ccompanies?

Yes. Engagement of companies with HCPs for CME/ CPD programs/events/trainings is allowed subject to well-defined, transparent and verifiable guidelines[48].

16. What framework for conducting CME/CPD/training programmes under the UCMPMD 2024?

i. In general, medical colleges and teaching institutions, hospitals, professional associations of doctors/specialist, research institutions, medical device companies (including their trusts/ associations), ICMR, DBT, CSIR, etc., working in collaboration with specified bodies[49], are allowed to conduct CME/CPD/trainings.

ii. While undertaking CME/CPD/training programs, the companies must be mindful of the following[50] :

a. Establish well-defined, transparent and verifiable procedures. These procedures form the basis for permissible expenditure to be undertaken by the Companies[51].

b. Disclose CME/CPD/training event details, including expenditure incurred, on their website, which may be subject to audits[52].

c. Disclose participant and speaker selection procedures, funding sources and expenditure incurred in a transparent manner, all of which may be subject to audits.

d. All entities, including participants and speakers, involved in CME/CPD/training events must comply with relevant provisions of Income Tax Act, 1961 (**IT Act**)[53].

17. Can the Companies conduct CME/CPD or training events outside India?

No. CME/CPD events cannot be conducted by the Companies at *foreign locations*[54]. However, there is a slight deviation regarding the prohibition on conducting

events in foreign locations. Unlike the UCPMP 2024, the UCMPMD 2024 permits conduct of foreign events for the limited purposes of advanced clinical trainings[55] if there is non-availability of trainers, equipment or products within the country. However, such events are permitted only upon furnishing necessary details and particulars to the DoP 3 (three) months before the scheduled date of the event, and upon the receipt of approval from the DoP.[56], Pursuant to examination of the conditions, DoP may approve such events on a case-to-case basis.

18. What considerations should Companies take into account when determining the speaker-to-participant ratio for CME/CPD events?

Based on the information received regarding the DoP circular dated October 4, 2024[57], companies organizing CME/CPD events within India must ensure that the speaker-to-participant ratio does not exceed 1:10. This means event organizers should carefully balance the number of speakers to maintain this ratio, ensuring compliance with the UCMPMD 2024 and fostering an effective learning environment. The formal circular release is anticipated soon.

48 Provision 6.1
49 Provision 6.2(ii).
50 Provision 6.2
51 Provision 6.1
52 Provision 6.2(iii) & (iv)
53 Provision 6.2(v)
54 Provision 6.2 (i)
55 Ibid.
56 Provision
57 Circular No. 2 of 2024 - F. No. 31026/44/2024-MD dated October 4, 2024

19. What aspects should Companies bear in mind while collaborating for study and research studies with HCPs?

i. Research collaborations/ studies between the Companies and HCPs must have prior approval from competent authorities (such as ICMR, DCGI, Ethics Committee, etc.). Such studies should be conducted at recognised sites and adhere to instructions from relevant bodies like the NMC, etc.[58]

ii. Engagement of HCPs for research must be for *bonafide purposes, under consultancy agreements*, subject to relevant provisions of IT Act.[59]

iii. Companies can claim expenditure on research as *allowable expenditure*, subject to relevant provisions of IT Act.[60]

20. Can Companies offer gifts or any pecuniary advantage to the HCPs?

No. The Companies and their agents (distributors, wholesalers, retailers, etc.) are strictly prohibited from offering or providing *Gifts* to any HCPs, including their family members (both immediate and extended). Similarly, any *pecuniary advantage or benefit in kind* to any person qualified to prescribe or use medical devices is also prohibited.[61]

21. Can companies provide monetary grants be the HCPs?

No. Companies or their representatives are prohibited from paying *cash or monetary grant* to the HCPs or their family members (both immediate and extended) under any pretext.[62]

22. Can companies sponsor travel facilities to HCPs?

Travel facilities regardless of form or substance, for purposes of attending conferences, seminars workshops, etc., or paid vacations inside or outside the country, should not be extended to HCPs or their family members (immediate and extended). Travel facilities for individuals who are speakers for a CME/ CPD program or participants in training program can be extended. For travel facilities being provided to participants of training programs, specific approval has to obtained from the DoP.[63]

23. Can companies sponsor any hospitality facilities to HCPs?

Hospitality facilities, regardless of form or substance, should not be extended. Hospitality facilities for individuals who are speakers for a CME/ CPD programme or participant in training programs can be provided. However, for the latter, specific approval has to obtained from the DoP.[64]

24. Whether associations are mandated to upload the UCMPMD 2024 on their website?

It is mandatory for all Indian Medical Device Associations to upload the UCMPMD 2024 on their website along with the detailed procedure for lodging of complaints.[65] The UCMPMD website of the associations must be linked to DoP's UCPMP portal.[66]

25. Who will oversee the complaints regarding breaches under the UCMPMD 2024?

The code provides for constitution of an "*Ethics Committee for Marketing Practices in Medical Devices* (**ECMPMD**)", to be chaired by the Chief Executive Officer (**CEO**) of every association.[67] The ECMPMD will handle complaints regarding breach of any provisions under the UCMPMD 2024. The ECMPMD is required to have a strength of *three to five members*[68]. The composition of the ECMPMD is to be approved by the board of the association and be displayed on its website[69].

26. Are medical device associations required to publish details of the complaint received by them?

Yes. Medical device associations are mandated to retain complaint and connected particulars for 5 (five) years on their website[70]. Furthermore, these particulars are

58 Provision 7 (i)
59 Provision 7 (ii)
60 Provision 7 (iii)
61 Provision 8.1
62 Provision 8.4
63 Provision 8.2
64 Provision 8.3
65 Provision 9.1
66 Ibid.
67 Provision 9.2
68 Ibid.
69 Provision 9.2
70 Provision 9.5

also required to be uploaded to DoP's UCPMP portal. There is a slight deviation from UCPMP 2024 wherein the details of complaints are required to be published after disposal of the complaint by the association.[71]

27. What happens if a complaint is received by a wrong association?

If an association receives a complaint unrelated to its members, it will summarise the complaint and forward it to another association where the respondent company holds membership. Unlike the UCPMP 2024, the UCMPMD 2024 clarifies that in case the Company is not a member of any association, the complaint shall be forwarded to the DoP.[72]

28. What if a Company is not a member of any association or member of multiple associations?

Complaints against Companies with multiple affiliation would be handled by specific medical device association to which the complaint is addressed. If necessary, the concerned association may seek guidance from the DoP.[73] This marks a slight departure from the UCPMP, 2024 where complaints involving Companies not affiliated with any association could be referred to a relevant industry association. This provision has been removed in the UCMPMD 2024 creating a gap in addressing such complaints.

29. Where are complaints in respect of breach of UCMPMD 2024 lodged?

The complaints regarding breach of UCMPMD 2024 to be lodged with the respective association's ECMPMD and addressed to its chair - CEO[74].

30. What is the time limit for registering a complaint under the UCMPMD 2024?

The limit is of 6 (six) months, extendable to a period of another 6 (six) months, wherein the delay can be explained in writing.[75]

31. What details should be included in a complaint?

A complaint must be in writing and contain details about the complainant (address, email, telephone

number), details about the company that is alleged to have committed a breach, details about the products pertaining to such breach, activities that are in breach of the code, clauses that have been breached along with evidence of such breach.[76] All complaints should be accompanied by a non-refundable fee of INR 1000.[77] Pseudonymous and anonymous complaints are not allowed.[78] Detailed requirements regarding lodging of complaint are defined under Provision 10 (*Lodging of Complaints*) of the UCMPMD 2024.

32. Can a Company register a complaint under the UCMPMD 2024?

Yes. The complaint must be signed or authorised in writing by the Company's Managing Director (**MD**) or CEO or a person at the equivalent level.[79]

33. Can the committee (ECMPMD) *take suo moto* cognizance of any complaint?

Yes. Whenever a media report (excluding letters to editors) is treated as a complaint, the ECMPMD may ask for more details from the concerned publication, and the source or the correspondent may be considered the complainant.[80]

71 Ibid.
72 Provision 9.3
73 Provision 9.4
74 Provision 10.1
75 Provision 10.2
76 Provision 10.3
77 Provision 10.4
78 Ibid.
79 Provision 10.5
80 Provision 10.6

34. What is the mechanism of handling of complaints under the UCMPMD 2024?

The complaints regarding the breach of UCMPMP 2024 are investigated by the ECMPMD and decided basis a majority vote. The MD or CEO of the company against whom a complaint is made must respond to all aspects of the complaint that the ECMPMD has received. The Respondent company would have 30 (thirty) days to respond and the ECMPMD has 90 (ninety) days to render its decisions. Detailed requirements regarding handling of complaints are defined under Provision 11 (*Handling of Complaints*) of the UCMPMD 2024.[81]

35. What penalties are attracted in case of non-compliance of the UCMPMD 2024?

In the event of any non-compliance, the ECMPMD can propose the following actions against the erring entity:[82]

i. Suspend or expel such an entity from the association.
ii. Reprimand such entity and publish full details of the reprimand.
iii. Require such entity to issue a corrective statement in the same media.
iv. To ask such entity to recover money or items given in violation of the code.
v. Where it deems any disciplinary, penal, or remedial action falls within the domain of any agency or authority of the Government in accordance with statutory provisions, it may send its recommendations to such agency or authority through the DoP.

36. What is the mechanism for appeal in the UCPMP 2024?

Appeals against the ECMPMD decisions are directed to the Apex Committee for Marketing Practices in Medical Devices (**ACMPMD**), chaired by the Secretary, DoP, with other members including a Joint Secretary and a Finance Adviser. The ACMPMD holds authority to impose penalties or refer matters to relevant governmental bodies, per the "*Penalties and Reference*" provision. The time limit for appeal or review is 15 (fifteen) days, extendable by another 15 (fifteen) days. The ACMPMD is obliged to reach a decision within 6 (six) months, which is binding and final on all parties. Detailed requirements for entertaining and filing appeals are defined under Provision 13 (*Appeal*).[83] The Appeal provision adds a nuanced layer absent in UCPMP 2024, where if a case is referred by DoP to an association and there is delay or inaction, the ACMPMD may proceed as per the provisions of the code.

37. Who is responsible for adherence of this code?

The CEO of the company is responsible for the adherence of the code. In such pursuit, he/she is obligated to submit the self-declaration form (Annexure to UCMPMD 2024) regarding the compliance of the code within two months after the end of every financial year (**FY**) to the association, or directly on the UCPMP portal of the DoP[84].

38. Are there any other additional requirements under the UCMPMD?

The UCMPMD 2024 mandates the continuous disclosure of expenses related to Evaluation samples, CME/CPD/ training or any other events. These disclosures must be uploaded within two months after the end of each FY on the UCPMP portal of the DoP[85]. The disclosure format of these submissions is placed at the end of the code.

Based on information received regarding the DoP circular dated October 4, 2024[86], companies are required to submit their self-declaration for FY 2024-2025. This information must be communicated to all members by October 31, 2024, and the formal circular release is anticipated soon.

81 Provision 11
82 Provision 12
83 Provision 13
84 Provision 14.3
85 Preamble/Introduction point 3
86 Circular No. 1 of 2024 - F. No. 31026/44/2024-MD dated October 4, 2024

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