client alert

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ahead of the curve

Uniform Code for Pharmaceuticals Marketing Practices (UCPMP) 2024: Frequently Asked Questions

On March 12, 2024, the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers (**DoP**), unveiled the revised Uniform Code of Pharmaceutical Marketing Practices (**UCPMP 2024**) with a view towards providing a set of guidelines that would mitigate unethical ensure transparency, integrity, and accountability in the marketing of pharmaceutical and medical device products across India. In this regard, UCPMP 2024 is a successor to UCPMP 2014[1], which was the initial attempt made by the Government to enable the industry to self-regulate. While the basic foundation of UCPMP 2024 remains similar to UCPMP 2014, this newer version contains some subtle (and not so subtle) changes which have sparked concerns and questions within the industry.

We attempt to answer some of these FAQs below:

1. Is UCPMP 2024 a voluntary code?

Unlike UCPMP 2014, which was clearly identified as a *voluntary code* in its preamble[2], UCPMP 2024 does not contain any such identification. The tone and tenor of language used in UCPMP 2024 - phrases like "*shall be*", "*must be*" absent a qualification as to the voluntary nature of the code indicate a more directive-oriented rather than a suggestion-oriented approach. The new code comes across as more mandatory than voluntary in nature.

2. What is promotion?

"*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[3].

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

UCPMP 2024 is applicable to promotion and marketing activities undertaken by pharmaceutical and medical device companies[4] (**Companies**). Implementation is overseen by pharmaceutical associations that have

1 Uniform Code of Pharmaceutical Marketing Practices - 2014.
2 https://pharmaceuticals.gov.in/sites/default/files/UCPMP.pdf

3 '*Ethical Criteria for Medicinal Drug Promotion*' as endorsed by the World Health Assembly in 1988.
4 In terms of Provision 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.

industry players as members. The DoP plays a guiding role.

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

Promotion must be consistent with marketing approval. Promotions that are off-label or before the receipt of the required marketing approval[5] are not allowed. 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.[7] No claims of safety without proper qualification.[8] No categoric statement regarding absence of side effects, toxic hazards or risk of addition.[9]

No identification/ description of a drug/ therapeutic intervention as "*New*" if it has been generally available/ promoted in India for more than 1 (one) year.[10]

Drug comparisons must be factual, fair, and verifiable[11]. Avoid misleading information[12]. No comparison between brand names of products of other companies without consent. 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 authorized holder or with the authority of such person. Consistency with the requirements of the code is required.[15]

Promotion for the purposes of providing HCP's (qualified to prescribe) with information that may enable them to make a decision must include the name of the drug along with its generic name, name and address of the authorization holder, list of active ingredients (use generic names), recommended dosage, method of use and administration, adverse reactions, contraindications, warnings and precautions for use and statement as regards the current/ updated nature of information provided and availability of additional information.[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] No use of names and photographs of HCP's.[20] No Imitation (devices, slogans, layouts) of materials used by others, which may result in misrepresentation, or confusion[21]. All information should be up-to-date and dates of review/ updating should be identified accordingly.[22]

Public-facing materials like postcards or envelopes 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 (including personnel retained by way of contract with third parties) and other company representatives who call on HCPs, pharmacies, hospitals, or healthcare facilities in connection with promotion of drugs.

5 Provision 1.2
6 Provision 1.3
7 Provision 2.1
8 Provision 2.2
9 Ibid
10 Provision 2.3
11 Provision 2.4
12 By distortion, by undue emphasis, by omission, or in any other similar way.
13 Provision 2.6
14 Provision 2.7
15 Provision 3.1
16 Provision 3.2
17 Provision 3.3
18 Provision 3.4
19 Provision 3.5
20 Provision 3.6
21 Provision 3.7
22 Provision 3.8
23 Provision 3.9
24 Provision 3.10
25 Provision 4.1

The Medical representatives' (**MR**) must not employ any inducement or subterfuge to gain an interview. They must not pay, under any guise, for access to HCP[26].

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 UCPMP. 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 HCP's.

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

Third parties working for or on behalf of pharmaceutical 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 UCPMP 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 are Brand reminders?

The UCPMP 2024 allows companies to offer brand reminders of their products to HCPs under two categories[29]: (i) Informational and educational items, and (ii) Samples.

10. What qualifies as Informational and educational items?

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. Such items should not have an independent commercial value for HCPs.[30]

11. Whether samples can be provided by companies?

Yes. Samples can be provided by companies to HCPs for the purpose of creating awareness about treatment options and for acquiring experience in dealing with the product[31], subject to certain conditions.

12. What key aspects are to be borne in mind by companies while providing samples to HCPs?

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

i. Samples to be provided for creating awareness about treatment options and for experience in dealing with the product. Should be categorically marked as "Free medical sample not for sale" or bear any other analogous legend.[33] No sampling of drugs that are hypnotics, sedatives or tranquilizers.[34] Monetary value should not exceed 2 (two) percent of annual domestic sales.[35] Both giver and recipient to act in consonance with applicable tax laws.[36]

ii. Do not provide free samples to any person who is not qualified to prescribe.[37] Hand over samples directly to a person who is qualified to prescribe or authorized to receive on their behalf. Note down HCP name and address along with sample details.[38]

26 Provision 4.3
27 Provision 4.4
28 Provision 4.5
29 Provision 5.1
30 Provision 5.1 (i)
31 Provision 5.1 (ii) a
32 Provision 5.1 (ii)
33 Provision 5.1(ii)(c)
34 Provision 5.1 (ii)(f)
35 Provision 5.1(ii)(dot)
36 Provision 5.3
37 Provision 5.1 (ii)
38 Ibid.

iii. Limit sample packs to prescribed dosage course for not more than 3 (three) patients and 12 (twelve) sample packs per drug to any HCP per year[39]. Sample size should not be larger than the smallest pack present in the market.[40]

iv. Company should maintain accurate records containing name of HCP, quantity of samples given, date of supply etc.[41]

13. Would Brand reminders sent by companies to HCPs qualify as endorsements of products?

Brand reminders to the HCP's may not be seen as an act of endorsement, absent any recommendation from the HCP[42].

14. Can Continuing Medical Education (CME)/ Continuing Professional Development (CPD) programs be conducted by companies?

Yes. Engagement of companies with HCPs for CME/ CPD programs/events is allowed subject to well-defined, transparent and verifiable guidelines[43].

15. What is the permitted framework for conducting CME/CPD programs under the UCPMP 2024?

i. In general, permitted organizers of CME/CPD would include, medical colleges and teaching institutions, hospitals, professional associations of doctors, research institutions, pharmaceutical companies (including their trusts/associations), laboratories of ICMR, DBT, CSIR etc. in collaboration with specified bodies.[44]

ii. While undertaking CME/CPD programs, the companies must be mindful of the following[45]:

- Have well-defined, transparent and verifiable guidelines. These guidelines form the basis for permissible expenditure to be undertaken by companies.[46]
- Disclose CME/CPD event details, including expenditure incurred, on their website, which may be subject to audits.
- Disclose participant & speaker selection procedures, funding sources and expenditure incurred in a transparent manner, and which may be subject to audits.
- All entities, including participants and speakers, involved in CME/CPD events must comply with relevant provisions of Income Tax Act, 1961 (**IT Act**).

16. Can companies conduct CME/CPD events outside India?

No. CME/CPD events cannot be conducted by companies at *foreign locations*[47].

17. What aspects are to be kept in mind by companies while collaborating for study and research studies with HCPs?

i. Research collaborations/ studies between companies and HCPs must have prior approval from competent authorities (such as ICMR, DCGI, Ethics Committee, etc.). Such studies should be conducted at recognized sites and adhere to instructions from relevant bodies like NMC, etc.[48]

ii. Engagement of HCPs for research must be for *bonafide purposes, under consultancy agreements*, subject to relevant provisions of IT Act.[49]

iii. Companies can claim expenditure on research as *allowable expenditure*, subject to relevant provisions of IT Act.[50]

18. Can "Gifts" or any pecuniary advantage be provided by companies to HCPs?

No. Companies and their agents (i.e. 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 supply drugs is also prohibited.[51]

39 Provision 5.1(ii)(b)
40 Provision 5.1(ii)(d).
41 Provision 5.1(ii)(dot)
42 Provision 5.2
43 Provision 6.1
44 Ibid.
45 Provision 6.2
46 Provision 6.1
47 Provision 6.2 (i)
48 Provision 7 (i)
49 Provision 7 (ii)
50 Provision 7 (iii)
51 Provision 8.1

19. Can monetary grants be provided to HCPs by companies?

No. Companies or their representatives are prohibited from paying *cash or monetary grant* to any HCPs or their family members (both immediate and extended) under any pretext.[52]

20. Can travel facilities to HCPs be sponsored by companies?

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 can be provided.[53]

21. 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 program can be provided.[54]

22. Whether associations are mandated to upload the UCPMP on their website?

It is mandatory for all Indian Pharmaceutical Associations to upload the UCPMP on their website along with the detailed procedure for lodging of complaints.[55] The UCPMP website of the associations must be linked to DoP's UCPMP portal.[56]

23. Who will oversee the complaints regarding breaches under the UCPMP 2024?

The code provides for constitution of an "*Ethics Committee for Pharma Marketing Practices* (**ECPMP**)", to be chaired by the Chief Executive Officer (**CEO**) of every association.[57] The ECPMP will handle complaints regarding breach of any provisions under the UCPMP 2024. The ECPMP is required to have a strength of *three to five members*[58]. The composition of the ECPMP is to

be approved by the board of the association and be displayed on its website[59].

24. Are pharma associations required to publish details of the complaint received by them?

Yes. Pharma associations are mandated to retain complaint and connected particulars for 5 (five) years on their website[60]. Furthermore, these particulars are also required to be uploaded to DoP's UCPMP portal.[61]

25. 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.[62]

26. What if a company is not a member of any association?

Complaints regarding companies without an affiliation or with multiple affiliations should ordinarily be handled by the specific pharma industry association to whom such complaint is addressed. If needed, the concerned pharma association can seek guidance from the DoP.[63]

52 Provision 8.4
53 Provision 8.2
54 Provision 8.3
55 Provision 9.1
56 Ibid.
57 Provision 9.2
58 Ibid.
59 Ibid.
60 Provision 9.5
61 Ibid.
62 Provision 9.3
63 Provision 9.4

27. Where are complaints in respect of breach of UCPMP 2024 lodged?

The complaints regarding breach of UCPMP to be lodged with the respective association's ECPMP and addressed to its chair - CEO[64].

28. What is the time limit of registering a complaint under the UCPMP 2024?

6 (six) months extendable to a period of another 6 (six) months, wherein the delay can be explained in writing.[65]

29. 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.[66] All complaints should be accompanied by a non-refundable fee of INR 1000.[67] Pseudonymous and anonymous complaints are not allowed.[68] Detailed requirements regarding lodging of complaint are defined under Provision 10 (*Lodging of Complaints*) of the UCPMP 2024.

30. Can a company register a complaint under the UCPMP 2024?

Yes. The complaint must be signed or authorized in writing by the company's MD or CEO or a person at the equivalent level.[69]

31. Can the committee (ECPMP) take *suo moto* cognizance of any complaint?

Yes. Whenever a media report (excluding letters to editors) is treated as a complaint, the ECPMP may ask for more details from the concerned publication, and the source or the correspondent may be considered the complainant.[70]

32. What is the mechanism of handling of complaints under the UCPMP 2024?

The complaints regarding breach of UCPMP are investigated by the ECPMP and decided basis a majority vote.[71] The Managing Director or CEO of the company against whom a complaint is made would be required to provide a complete response to the complaint received by ECPMP[72], and the Respondent company would have 30 (thirty) days to respond.[73] ECPMP has 90 (ninety) days to render its decisions[74]. Detailed requirements regarding handling of complaints are defined under Provision 11 (*Handling of Complaints*) of the UCPMP 2024.

33. What penalties are attracted in case of non-compliance of the UCPMP?

In the event of any non-compliance, the ECPMP can propose the following actions against the erring entity[75]:

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.

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

Appeals against ECPMP decisions are directed to the Apex Committee for Pharma Marketing Practices (**ACPMP**), chaired by the Secretary, DoP, with other

64 Provision 10.1
65 Provision 10.2
66 Provision 10.3
67 Provision 10.4
68 Ibid.
69 Provision 10.5
70 Provision 10.6

71 Provision 11.1
72 Provision 11.2
73 Provision 11.5
74 Provision 11.7
75 Provision 12

members including a Joint Secretary and a Finance Officer.[76] The ACPMP holds the authority to impose penalties or refer matters to relevant governmental bodies, as per the "*Penalties and Reference*" provision.[77] The time limit for appeal or review is 15 (fifteen) days, extendable by another 15 (fifteen) days.[78] The ACPMP is obliged to reach a decision within 6 (six) months[79], which is binding and final on all parties involved.[80] Detailed requirements regarding the mechanism of entertaining and filing appeals are defined under Provision 13 (*Appeal*) of the UCPMP 2024.

35. Who is responsible for adherence of this code?

The CEO of the company is responsible for adherence of the code. In such pursuit, he/she is obligated to submit the self-declaration form (Annexure to UCPMP 2024) regarding the compliance of the code within two months after the end of every financial year to the association, or directly on the UCPMP portal of the DoP, if not a member of such association or any other associations[81].

76 Provision 13.1
77 Provision 13.4
78 Provision 13.2
79 Provision 13.3
80 Provision 13.5
81 Provision 14.4

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