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Tax alert: Uniform Code for Pharmaceutical Marketing Practices (UCPMP) 2024

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The Department of Pharmaceuticals ('DoP') has issued a policy communication to all pharmaceutical associations on March 12, 2024, enclosing the Uniform Code for Pharmaceutical Marketing Practices 2024 (referred to as 'UCPMP 2024' or 'the Code') for dissemination among members, urging strict adherence.

In a nutshell

UCPMP 2024 covers critical areas such as conduct of medical representatives, the provision of brand reminders and free samples, CME, and relationships with HCPs

UCPMP 2024 permits brand reminders categorized as informational and educational items and free samples subject to limits and conditions specified

UCPMP 2024 prohibits conduct of CME, CPD conference, workshop, etc. in foreign locations. Further, it addresses the interaction between pharmaceutical companies and HCPs for research purposes.

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Background:

- On December 12, 2014, the central government released the Uniform Code of Pharmaceutical Marketing Practices to be voluntarily adopted and complied by pharma industries with respect to marketing practices. It was mentioned that if the code is not found to be effectively implemented by pharma associations/ companies, the government may consider making it a statutory code.
- On March 12, 2024, the Department of Pharmaceuticals ('DoP') issued a policy communication to all pharmaceutical associations, enclosing the Uniform Code for Pharmaceutical Marketing Practices 2024 (referred to as 'UCPMP 2024' or 'the Code') for dissemination among members, urging strict adherence.
- Through this communication, the DoP requested all associations to establish an Ethics Committee for Pharmaceutical Marketing Practices ('ECPMP'), create a dedicated UCPMP portal on their website and initiate necessary steps toward implementing the Code.
- UCPMP 2024 delineates permissible and impermissible activities for ethically promoting drugs and addressing complaints regarding unethical marketing practices by pharmaceutical companies. It covers critical areas such as the conduct of medical representatives ('MRs'), the provision of brand reminders and free samples, Continuing Medical Education ('CME'), and relationships with Healthcare Professionals ('HCPs').

Key highlights:

Brand reminders

- UCPMP 2024 permits brand reminders categorized as:
  - Informational and educational items: The Code permits items such as books, calendars, diaries, journals (including e-journals), dummy device models and clinical treatment guidelines for professional use in healthcare settings, capped at a value of Rs. 1,000 per item. Such items should not have an independent commercial value for HCPs.
  - Free samples: The Code prohibits supplying free drug samples to any person who is not qualified to prescribe such products. It outlines conditions for providing samples, including the purpose of distribution, the size of sample pack, limits on quantity offered to HCP per year, the instructions on packaging and specifies the items for which samples cannot be supplied.
- Furthermore, the Code mandates pharmaceutical companies to document details such as product name, doctor name, quantity of samples provided, and date of distribution to HCPs. Notably, the monetary value of distributed samples should not exceed 2% of the company's domestic sales per year.
- The Code specifies that receipt of brand reminders from pharmaceutical companies by the HCPs may not constitute endorsement activity if it does not amount to recommendation or issuance of a statement by the HCPs, regarding the use of the respective brand. Additionally, giver and recipient of brand reminders should comply with relevant provisions of the Income Tax Act, 1961 ('the Act') concerning deductions and reporting of income.

Continuing Medical Education

- The Code mandates that expenditure by the pharmaceutical industry on Continuing Medical Education ('CME'), Continuing Professional Development ('CPD'), conference, workshop, etc., should only be through a well-defined, transparent and verifiable set of guidelines. Pharmaceutical companies, including their Trusts/ associations, either alone or in collaboration with professional bodies, institutions as specified, are inter alia permitted to engage in such activities/ events. Notably, the conduct of such events in foreign locations is prohibited.
- Furthermore, pharmaceutical companies are required to disclose event details, including incurred

expenditures, on their websites. Similarly, all event organizers must transparently outline participant and speaker selection procedures, as well as disclose funding sources and expenditures on their websites. Pharmaceutical companies, event organizers may be subject to risk-based or special audits for this purpose. Additionally, entities incurring expenses on such events as well as participants and speakers, must adhere to the relevant provisions of the Act.

Support for research

- The Code addresses the interaction between pharmaceutical companies and HCPs for research purposes. It mandates that engagements of HCPs, in consultant-advisory capacities shall be for bona fide research services, under consultancy agreements involving a consultancy fee or an honorarium-based payment, subject to the relevant provisions of the Act. These engagements must prioritize patient interests and maintain the integrity of the HCP in alignment with NMC regulations. The study or research should be one that has the requisite approval from a competent authority and is conducted, where so applicable, at a recognized site or location.

Relationship with HCPs

- The Code strictly prohibits pharmaceutical companies and their agents (i.e. distributors, wholesalers, retailers, etc.) from offering or providing gifts for personal benefit of any HCPs or their family members (both immediate and extended). Similarly, it prohibits the offering, supplying, or promising of any pecuniary advantage or benefit in kind to any person qualified to prescribe or supply drugs.
- Additionally, the Code specifies that pharmaceutical companies or any person acting on their behalf should not extend travel facilities or hospitality to HCPs or their family members, unless the person is a speaker for a CME or a CPD program.
- Companies or their representatives should not pay cash or monetary grant to any HCP or their family members under any pretext.
- In instances where the Code does not address matters concerning relationship with HCPs, the guidelines outlined in the Indian Medical Council (Professional Conduct, Etiquette, and Ethics) Regulation of 2002, as amended periodically, will prevail.

Other directives

- The Code incorporates directives for lodging complaints; handling of unaddressed issues, complaints, penalties, reference and appeals, along with delineating responsibilities of pharmaceutical company CEOs.
  - The ECPMP in each association can take appropriate action, including suspension or expulsion of the entity from the Association, and other remedial actions once it is established that a breach of the Code has been made by an entity. In cases where disciplinary, penal or remedial action falls under the jurisdiction of government agencies, the Committee may forward its recommendations to the relevant authorities through the DoP.
  - The Code introduces a new appeal mechanism allowing parties to the complaint to file an appeal with the Apex Committee for Pharma Marketing Practices ('ACPMP') in cases of disagreement with the decision of the ECPMP[1]. The ACPMP may prescribe any penalties or make reference to an appropriate government agency or authority. The decision in appeal, shall be final and binding on both the parties.
  - The Chief Executive Officers of pharmaceutical companies bear responsibility for ensuring compliance with the Code and are required to submit a self-declaration in the prescribed format 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 DoP, in case he is not a member of such a body , or a member of more than one such bodies.

[1] Decision of ECPMP includes a lack of decision or inordinate delay in reaching a decision.

- Unless explicitly exempted or modified by standing orders, the provisions of the Code extend mutatis mutandis to medical devices and companies or entities engaged in the manufacturing or dealing with the sale, and distribution of such products.

Comments:

While the Code largely retains the contents of the previous code with certain modifications, it additionally addresses crucial topics such as brand reminders, CMEs, and support for research. Nonetheless, further clarity may be necessary regarding its interplay with other regulations.

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