Regulatory Hotline

March 15, 2024

CODE FOR PHARMACEUTICAL MARKETING PRACTICES REFURBISHED: NO ROOM FOR NON-COMPLIANCE

- Refurbished code to regulate pharmaceutical marketing practices
- Pharmaceutical companies to ensure compliance through self-declaration
- Transparency in interaction of the industry with healthcare professionals
- DoP to appoint independent panel of auditors

INTRODUCTION

The Department of Pharmaceuticals ("**DoP**") has notified the Uniform Code for Pharmaceutical Marketing Practices ("**UCPMP**") 2024,[1] in supersession of the UCPMP issued by the Government in 2014. Companies have been provided a runway for undertaking marketing activities directed towards healthcare professionals, in compliance with certain conditions prescribed under the code, to ensure checks are maintained in the industry.

The UCPMP is addressed to all pharmaceutical associations and the intention of the DoP in notifying the refurbished code is to provide clarity on permissible marketing practices, curbing the unethical marketing practices prevalent in the pharmaceutical industry and to guide the interactions between the industry and the healthcare professionals in the country by bringing about transparency requirements. The UCPMP is required to be implemented by the pharmaceutical associations of which pharmaceutical companies are a part, through the Ethics Committee for Pharmaceutical Marketing Practices ("**ECPMP**").

The 2014 draft expressly stated the voluntary nature of applicability of the code to pharmaceutical companies while the present version of the UCPMP has omitted such statement. UCPMP has been structured in a manner that the DoP intends to ensure conformity with the provisions of the code by the pharmaceutical companies. The notification of the DoP fails to provide the date of coming into effect of the UCPMP and the timeline within which the companies must ensure compliance with the stipulated provisions under the code.

ANALYSIS OF THE UCPMP PROVISIONS

The DoP has placed reliance on the 'Ethical Criteria for Medicinal Drug Promotion' endorsed by the World Health Assembly in 1988 to provide guidance on the activities that may constitute 'promotion' for the purposes of the UCPMP to provide guidance to the industry.

While the general provisions pertaining to promotional materials, claims and comparisons of drugs, interaction with medical representatives, lodging and handling of complaints remain the same as the 2014 draft, provisions pertaining to brand reminders, hospitality, engagement of healthcare professionals in education programs and the complaint handling timelines have witnessed a change.

Some of the key changes in the acceptable marketing practices and new provisions under the UCPMP are analysed below:

Applicability of UCPMP

The UCPMP applies to all pharmaceutical manufacturing companies in India. The provisions of the UCPMP continue to be implemented by the associations of which pharmaceutical companies are a part.

The UCPMP further provides that the provisions under the code would be applicable to medical devices companies or entities manufacturing or dealing with the sale and distribution of such products, unless exempted, thereby widening the scope of its applicability.

Definition for Promotion

The definition for the term 'promotion' was previously absent and was open for interpretation by the assessing authorities. The definition for 'promotion' adopted under the UCPMP is broad in its ambit and all informational and persuasive activities by manufacturers and distributors to induce the prescription, supply, purchase and or use of medical drugs would constitute promotion.

Auditor Panel of DoP

The DoP has proposed to notify a panel of auditors/firms for assisting the DoP in dealing with matters pertaining to the UCPMP and conducting audits as may be necessary. While the role of the auditor panel is not clearly spelt out under the UCPMP, DoP is likely to oversee the implementation of the UCPMP as well as take assistance from the

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auditor panel in assessing complaints received by it regarding the expenses being incurred by pharmaceutical companies in engaging with the healthcare sector.

Provision of Brand Reminders

The dilemma faced by the pharmaceutical companies in providing brand reminders to healthcare professionals is resolved in a manner where the provisions under the UCPMP have been harmonised with the provisions of the Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002 ("**MCI Code**") which provides the permissible limits for brand reminders and other items. The UCPMP has provided further clarity on the number of times such brand reminders may be provided to healthcare professionals in a given year, which is absent in the MCI Code.

The UCPMP allows companies to provide informational and education items and free samples to medical professionals, subject to certain conditions.

Informational and educational items have been defined under the UCPMP to include books, calendars, diaries, journals (including e-journals), dummy device models and clinical treatment guidelines for professional use in healthcare settings. The UCPMP provides that the value of such informational and educational items should not exceed INR 1000 per item and should not have an independent commercial value for the healthcare professionals. The provision provides clarity on the nature of items that may be supplied to the healthcare professionals and removes the ambiguity in the amount that may be spent on each item by the companies.[2]

Companies may continue to provide free samples to persons qualified to prescribe the product for creating awareness about treatment options and for providing medical professionals information on dealing with the product. No written request or exceptional case basis are required to be provided by the healthcare professional for the provision of free samples, as required under the previous draft. The UCPMP requires the companies to maintain records of the name and address of the healthcare practitioner to whom such samples are provided and only twelve sample packs (pack consisting of prescribed dosage for not more than three patients) per drug may be provided to the healthcare professional in a year. An important clarity on the amount that may be spent by companies in providing samples to medical professionals is that the monetary value of samples should not exceed two percent of the domestic sales of the company per year. While the limit may be ordinary for small to medium scale companies, it provides ample room for the big pharmaceutical companies to strategize and undertake the marketing activity.

Conducting Continuing Medical Education Programs

Engagement of the healthcare professionals in Continuing Medical Education ("**CME**"), Continuing Professional Development ("**CPD**"), conferences, seminars, workshops, etc. is permitted to be undertaken by companies through a well-defined, transparent and verifiable set of guidelines, in the absence of which, we expect the DoP to provide further clarity.

Various entities including medical colleges/professional associations of doctors or specialists, etc. may conduct the programs. Companies may also conduct CME/CPD either alone or in collaboration with such entities. The companies would be required to share the details of the events including expenditures incurred on their websites and are subject to independent/random/risk-based audit. Thereby increasing the accountability and risk on the companies in undertaking the proposed activities either directly or through third parties, involving healthcare professionals. However, the nature, format and timeline for transparency disclosures required to be made by the company have not been provided in the UCPMP.

The much-undertaken practice of conducting such activities in foreign locations is now prohibited and companies would be required to remodel their proposed activities in line with the provisions of the UCPMP.

Relationship with Healthcare Professionals

Gifts: Companies or their representatives continue to be prohibited from offering or providing gifts for personal benefit of any healthcare professional or family member (both immediate and extended).

Travel: Companies should not extend travel facilities inside or outside the country to healthcare professionals or their family members for attending conferences, seminars, workshops, etc. where they are acting in the capacity of a delegate, similarly provided under the MCI Code. A leeway has been provided to companies to offer travel facilities to healthcare professionals where they are engaged as a speaker for a CME/CPD program.

Hospitality: UCPMP has provided certain guidance in interpreting the term 'hospitality', where it restricts the companies from extending hospitality like hotel stay, expensive cuisine, resort accommodation, etc. to healthcare professionals in the capacity of a delegate. Such hospitality may be offered to healthcare professionals in the capacity of a speaker for a CME/CPD program.

Monetary Grants: Companies and their representatives are prohibited from paying any cash or monetary grant to healthcare professionals or family members under any pretext.

Support for Research

Expenditure incurred by companies on research involving healthcare professionals would be considered acceptable if it is undertaken in compliance with the applicable laws. Support may be provided by the company for a study or research that has the requisite approval from the competent authority or under a consultant-advisory capacity under a consultancy agreement where a fee or honorarium may be paid to the healthcare professional for providing bona-fide research services.

Responsibility of the companies

The UCPMP imposes the responsibility of implementation of the UCPMP on the Chief Executive Officer ("**CEO**") of the company itself and requires him to submit a self-declaration in the format provided under the UCPMP to the association, similar to the previously imposed responsibility under the 2014 draft of the UCPMP. The self-declaration is required to be submitted by the CEO within two months of the end of every financial year and would be uploaded by the association on their website or directly on the UCPMP portal of the DoP where the company is not a member of any association or is a member of more than one such body.

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The self-declaration format prescribed under the UCPMP requires the CEO of the company to declare present compliance with the UCPMP along with the declaration to continue compliance with the UCPMP, an addition to the declaration requirement in comparison to the earlier draft. Companies are likely to face the consequences of non-compliances with the code where they fail to implement the provisions of the UCPMP or to submit the self-declaration. This has the potential to hamper the promotional activities undertaken by the company or their membership with the pharmaceutical associations.

Complaint Lodging and Handling

The ECPMP, headed by the Chief Executive Officer of the Association is responsible for handling of complaints lodged with the committee by any person (company, entity or individual). The structure of the ECPMP is refurbished under the UCPMP and is required to be approved by the board of the association.

A complaint pertaining to an alleged breach of the UCPMP may be made within six months as against the previous timeline of three months from the date of alleged breach. The timeline may be extended by the ECPMP by a period of six months in case of reasonable delay. The respondent company (company against whom the complaint has been filed with the ECPMP) may submit its response and supporting documents within thirty days of receipt of the notice from the ECPMP as against the ten days timeline previously prescribed under the UCPMP, providing the companies ample opportunity to take cognizance of the complaint and provide the required supporting documents to the ECPMP.

The timeline within which the ECPMP is required to render its decision has been extended to a period of ninety days (previously thirty days) from the date of receipt of the complaint. An appeal from the decision of the ECPMP may be filed before the Apex Committee for Pharma Marketing Practices ("**ACPMP**") headed by the Secretary, DoP, within fifteen days of the decision of the ECPMP.

The duration of retaining complaint related information (including the nature of the complaint, status, action taken by ECPMP) uploaded on the website of the association has been extended from three to five years and are also required to be uploaded on the UCPMP portal of the DoP.

POTENTIAL HURDLES

The UCPMP seeks to regulate pharmaceutical marketing practices undertaken by the company in harmony with the other applicable guidelines issued by the respective authorities and has provided numerous linkages to encourage compliance indirectly, given that the UCPMP has not been made mandatory.

A key pressure point for pharmaceutical companies remains to be the re-enactment of the National Medical Commission Registered Medical Practitioner (Professional Conduct) Regulations, 2023 ("**NMC Code**") which were notified on August 9, 2023, and were subsequently put in abeyance on August 23, 2023, pursuant to representations made by various stakeholders. While the UCPMP provides companies with a freeway to undertake certain marketing activities, the NMC Code places restrictions on healthcare professionals from partaking in such activities. For example, while providing travel facility to healthcare professionals acting in the capacity of a speaker engaged by the company is permitted by the UCPMP, the NMC Code prohibited the former from accepting any such facilities from the companies. The NMC Code provides stricter penalties and consequences of non-compliance on the healthcare professionals, thereby creating a hurdle for their potential engagements with companies.

While the NMC Code does not prescribe a direct penalty on pharmaceutical and medical device companies, there could be tax implications in claiming deductions and may face hesitation in participation by healthcare professionals. Companies would be required to adopt creative and foolproof marketing practices in line with the UCPMP and prepare for the re-enactment of the NMC Code or a similar code which may introduce further hurdles.

ACTION POINTS FOR COMPANIES

Key action points arising out of the UCPMP for the pharmaceutical companies in undertaking marketing practices are:

- Records regarding the brand reminders provided to healthcare professionals to be maintained;
- Transparent set of guidelines to be put in place by the company to regulate the conduct of CME/CPD programs;
- Transparency disclosures containing details of the CME/CPD events including expenditures incurred to be published on company website;
- Any engagement with healthcare professionals should be under valid agreements;
- Self-declaration to be submitted by the CEO regarding compliance with UCPMP to the association.

CONCLUDING REMARKS

The UCPMP is a measure adopted by the DoP to regulate the interactions of the industry with the healthcare professionals and to maintain the integrity of the industry. The compliance requirements under the UCPMP and the subsequent requirement of submission of a self-declaration by the company is a means for ensuring and encouraging compliance with the UCPMP. Companies would need to ensure that the relationship with the healthcare professionals is transparent and within the bounds of the UCPMP. Given the implications that the company may face in claiming deductions under the Income Tax Act, 1961 for incurring expenses in violation of the UCPMP and other applicable laws.

The UCPMP provides clarity on various aspects of marketing practices undertaken by companies and may require companies to remodel their structure and promotional activities to be in compliance with the code. The implementation of the provisions of the UCPMP remain to be seen.

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You can direct your queries or comments to the authors.

[1]Accessible at: https://pharmaceuticals.gov.in/important-document/uniform-code-pharmaceutical-marketing-practices-ucpmp-2024-reg

[2]A similar value limit was proposed to be placed by the Medical Council of India on the healthcare professionals in restricting them from accepting items of value more than INR 1000 under the Indian Medical Council (Professional Conduct, Etiquette and Ethics) (Amendment) Regulations, 2015 proposed the amounts for various brand reminders including gifts, travel facilities, hospitality, etc.