The Uniform Code for Pharmaceutical Marketing Practices, 2024 - impact on India's pharma industry

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The Department of Pharmaceuticals (the "**DoP**") recently notified the Uniform Code for Pharmaceutical Marketing Practices 2024 ("**UCPMP 2024**"), in supersession of the UCPMP issued in 2014 ("**UCPMP 2014**").

This article discusses the revisions made and identifies key compliances for pharmaceutical companies ("**Companies**") in relation to marketing their products.

Background

India has various laws to regulate how drugs are advertised and marketed by Companies to end-consumers, including: (i) the Drugs and Cosmetics Act, 1940, and the rules thereunder; (ii) the Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954; (iii) the Consumer Protection Act, 1986; (iv) the Advertising Standards Council of India's Code for Self-Regulation in Advertising; and (v) the Guidelines for Prevention of Misleading Advertisements and Endorsements for Misleading Advertisements, 2022.

Further, the Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002, regulate the relationship between doctors and the healthcare industry. These regulations enforce accountability among registered doctors in accepting gifts and freebies from Companies, with violations potentially resulting in the revocation of their licenses. However, there was a lacuna, in that, Companies were not being penalised in any manner for their actions in giving gifts and freebies to doctors to push their drugs and products.

As per findings published by JAMA Internal Medicine, even a free pizza can influence a doctor's prescription. Contextualizing these findings within India's prevalent industry practice of Companies fostering illicit ties with doctors, the issue becomes concerning. In a recent incident, the maker of Dolo-650 (a painkiller) was alleged to have distributed freebies worth INR10,000 million (approx. US$120 million) to doctors in exchange for doctors prescribing the medicine. In its 2019-20 report, the Public Accounts Committee (PAC) noted that tax assessing officers in seven (7) Indian states had allowed as tax deductible expenses incurred by Companies towards gifts/ freebies to doctors, resulting in a loss to the tune of INR551 million (approx. US$6.6 million) to the exchequer.

Simply put, the drug promoted the most by Companies to doctors becomes the costliest. Further, under the guise of "sales promotion," direct and indirect benefits are offered to doctors, including actual gifts/ freebies, sponsored foreign trips, hospitality, and honorary positions. This affects the prescription habits of doctors and can result in the prescription of drugs: (i) at higher doses or numbers; (ii) for a period longer than required; (iii) in irrational combinations; or (iv) of over-priced brands.

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In 2014, the government introduced the UCPMP 2014, a voluntary code aimed at guiding marketing practices within the industry. However, its adoption was limited as it lacked teeth. In 2017, the Essential Commodities (Control of Unethical Practices in the Marketing of Drugs) Order, 2017 was proposed, but it did not get enacted.

In 2021, a petition was filed in the Supreme Court for directions to the government to give the UCPMP 2014 statutory basis. (*Federation of Medical and Sales Representatives Associations of India v. Union of India*, W.P.(C) No. 323/ 2021.) Further, in 2022, in a tax case, the Supreme Court held that freebies given to doctors by Companies cannot be claimed as a deduction under Section 37(1) of the Income-tax Act, 1961 (the "**Act**"). (*Apex Laboratories Pvt. Ltd. v. Deputy Commissioner of Income Tax*, SLP(C) 23207/ 2019.) Following this ruling, a clarification to this effect was incorporated in the Act by the Finance Act, 2022. In this case, the Supreme Court also noted that the cost of supplying such freebies was generally factored into the drug, which drove up its prices.

In 2022, the draft Uniform Code for Medical Device Marketing Practices (UCMDMP) was published to regulate medical devices separately, albeit again with voluntary compliance. Subsequently, the government constituted a committee to come up with holistic regulations in this area. Pursuant to the committee's recommendations, the government issued the updated UCPMP 2024, which has been brought into law by the DoP to ensure strict implementation.

UCPMP 2024

At the very outset, the UCPMP 2024 demands strict compliance from pharmaceutical associations and its constituent Companies. The key changes are discussed below:

(i) **Scope:** The UCPMP 2024 explicitly clarifies that it applies to drugs as well as medical devices, and it covers Companies and entities manufacturing or dealing with the sale and distribution of such products in India. This eliminates ambiguities relating to its applicability to medical devices.

(ii) **Definition of promotion:** It now defines "promotion" to refer to all informational and persuasive activities by manufacturers and distributors that induce the prescription, supply, purchase and/or use of medical drugs or devices. The definition is broad enough to encompass all illicit activities, whether direct or indirect.

(iii) **General points:** It reiterates certain provisions of UCPMP 2014 and states that drug promotion must adhere to the terms specified in its marketing approval. Moreover, promotion cannot be done before such approval is granted. Further, information about a drug must be balanced, accurate, up-to-date, and not misleading.

(iv) **Claims and comparisons:** It reiterates that the term "safe" in relation to drugs cannot be used without qualification, and that the term "new" cannot describe drugs available or promoted in India for more than one (1) year. Further, using other

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brand names for the purpose of drug comparison requires the consent of such other brands, and disparaging other companies or healthcare professionals is prohibited.

(v) **Textual and audio-visual promotion:** It reiterates compliances related to textual and audio-visual promotion, and mandates adherence to its provisions.

(vi) **Medical representatives:** It reiterates ethical standards for sales representatives of Companies. Importantly, it holds Companies responsible for their employees' compliance with the UCPMP 2024 and states that this should be reinforced through clauses in employment contracts. Further, third parties engaged by Companies in related activities are also required to possess a thorough understanding of the compliances.

(vii) **Brand reminders:** As a key introduction, it permits brand reminders in two (2) categories: (i) informational and education items ("**IEI**"); and (ii) free samples provided by Companies to medical professionals ("**Free Samples**"). Brand reminders through IEI include items such as books, calendars, diaries, etc., that are used for professional purposes in healthcare settings, subject to a monetary limit of INR1,000 (approx. US$12) per item. With respect to Free Samples, the UCPMP 2024 reiterates the compliances and restrictions prescribed under UCPMP 2014, including that Free Samples can only be provided to qualified individuals who can prescribe such products, and that Companies should maintain details of all Free Samples distributed. It also introduces revisions such as: (i) permitting Free Samples for the purpose of creating awareness about treatment options; (ii) capping the number of Free Sample packs per drug per year at twelve (12); (iii) capping the monetary value of distributed Free Samples at 2% of the domestic sales of the Company per year; and (iv) removing anti-depressants from the list of prohibited samples.

Further, it newly clarifies that brand reminders sent to healthcare practitioners will not be considered as endorsement activity if it does not amount to recommendation or issuance of a statement regarding the use of the brand. It also clarifies that both the giver and the recipient of brand reminders are required to comply with the Act, concerning deductions and reporting of income. The clarification regarding what constitutes a brand reminder and its explicit linkage to tax law will give Companies more certainty about their tax liability.

(viii) **Continuing medical education:** This is a new provision which regulates engagements between the pharmaceutical industry and healthcare professionals for Continuing Medical Education ("**CME**"), Continuing Professional Development ("**CPD**"), conferences, seminars, workshops, etc. It provides a framework for activities or events, as per which: (i) conducting events in foreign locations is prohibited; (ii) Companies should share event details and expenditures on their website and these should be subject to independent audits; (iv) organizers must also disclose participant and speaker selection procedures, funding sources, and expenditures on their website, and these should also be subject to special audits; and (v) all entities

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involved must comply with the relevant provisions of the Act. This introduction is significant as, for the first time, formal recognition has been given to the controversial practice of engaging healthcare professionals for conferences or seminars. The provision is equipped with reasonable restrictions, compliance, and enforcement measures, such as mandatory disclosures and independent audits, to prevent indirect influence on doctors through lavish seminars in foreign locations.

(ix) **Support for research:** This is a new provision which provides guidelines for collaboration between Companies and healthcare professionals. In brief: (i) any research must have approval from competent authorities and be conducted at recognized locations; (ii) engagement of healthcare professionals in a consultant-advisory capacity must be for *bona fide* research services, under a consultancy agreement involving a consultancy fee or an honorarium-based payment, subject to compliance with all applicable tax laws; and (iii) expenditure by Companies on research is considered allowable, subject to the provisions of the Act. This addition is critical as it establishes checks on another mode of indirectly influencing doctors, i.e., through the offering of honorary positions.

(x) **Relationship with healthcare professionals:** Many erstwhile provisions have been refurbished, and Companies or their agents are prohibited from offering gifts or benefits to healthcare professionals or even their family members. This includes any form of pecuniary advantage, travel arrangements, hospitality, or monetary grants, unless, as per the newly introduced exception, the healthcare professional is participating as a speaker in a CME/ CPD programme.

(xi) **Ethics committee for pharma marketing practices:** Like its earlier counterpart, the UCPMP 2024 provides that each association will have a committee for handling complaints, namely the Ethics Committee for Pharma Marketing Practices ("**ECPMP**"). It also reiterates that in case of Companies who are not associated with an association, or are associated with multiple associations, the complaint will be handled by the pharma industry association addressed by the complainant in his/her complaint. This means that Companies not affiliated with any associations are also required to ensure compliance with the UCPMP 2024. However, the UCPMP 2024 falls short by not defining the exact constitution of the ECPMP. Notably, the ECPMP is envisioned as the primary enforcing authority under the UCPMP 2024 and is responsible for handling and completing inquiries into complaints. Given the extensive scope of its powers, it is crucial to ensure diversity, impartiality, and independence among its members. The entire enforcement of the UCPMP 2024 hinges on the effective functioning of the ECPMP, especially concerning newly introduced controversial concepts such as CME/ CPD and support for research.

(xii) **Lodging of complaints:** It refurbishes this section and extends timelines to make complaints to six (6) months, from the earlier three (3) months, and provides another window of six (6) months in case of reasonable delay. Unfortunately, the UCPMP 2024 does not entertain any pseudonymous or anonymous complaint. It also prescribes payment of a fee of INR1000 (approx. US$12) at the time of lodging

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complaints. Both provisions act as deterrents for complainants. The UCPMP 2024 should ideally contain a whistle-blowing mechanism as industry insiders are most likely to be complainants in such cases.

(xiii) **Penalties and appeal**: It continues to prescribe penalties and actions, including suspension or expulsion from the association, reprimand, and requirement for the entity to issue a corrective statement through the same media used for promotional material. It also provides for appeal to the Apex Committee for Pharma Marketing Practices (ACPMP). The penalty provision of the UCPMP 2024 undermines its deterrent effect. Due to its failure to introduce stringent penalties, Companies may continue to prioritize commercial interests over ethical considerations.

(xiv) **Miscellaneous:** Under UCPMP 2024, the DoP has the authority to issue standing orders. The DoP is to also designate a panel of auditors to facilitate audits. These provisions give teeth and facilitate its implementation. They are further supplemented by compliance-based requirements. Chief Executive Officers ("**CEO**") of Companies have been made responsible for ensuring compliance with the UCPMP 2024. He/ she is required to submit an annual self-declaration of compliance within two (2) months after the end of each financial year to the association for publication on their website, or directly to the DoP's UCPMP portal, if the CEO is not affiliated to any association or is a member of multiple associations.

Conclusion

The UCPMP 2024 is a crucial step towards regulating the pharmaceutical industry, which currently wields significant influence over public health. Key requirements for Companies include annual filing of a declaration of compliance by the executive head, maintaining databases of Free Samples distributed and CME events, and equipping employees with a thorough understanding of the UCPMP 2024 through training. In addition to meeting its ethics mandates, Companies will now also have to ensure audit readiness. However, no timelines have been specified for Companies to comply with its provisions.

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