A New Code for Pharmaceutical Marketing Practices: From Symptoms to Diagnosis

KEY TAKEAWAYS

- The New Code applies to both pharmaceutical and medical device companies
- Relative to the Old Code, the New Code has been strengthened, including in respect of penalties, complaints and appeals, along with the possibility of future standing orders
- Several key themes of the Old Code have been retained, including with respect to claims and comparisons, textual and audio-visual promotion, medical representatives, and the relationship with healthcare professionals (*e.g.*, in respect of free samples, gifts, travel, hospitality and monetary grants)
- Nevertheless, the New Code adopts a more balanced approach with respect to educational events and items, including with respect to brand reminders, continuing medical education and professional development, as well as research
- The New Code clarifies what 'promotion' is and provides a framework for conducting promotional events
- It appears that the New Code remains voluntary, although an explicit reference to its voluntary nature has been omitted

INTRODUCTION

Pursuant to a notification dated March 12, 2024 (the "**2024 Notification**"), the Department of Pharmaceuticals ("**DoP**") under the Ministry of Chemicals and Fertilizers, Government of India, issued a new code on pharmaceutical marketing practices called the 'Uniform Code for Pharmaceutical Marketing Practices' (the "**UCPMP 2024**" or the "**New Code**"). The UCPMP 2024 replaces a decade-old version of the same code (the "**UCPMP 2014**" or the "**Old Code**"), which was issued by the DoP pursuant to a notification dated December 12, 2014 (the "**2014 Notification**").

Broadly, like the Old Code, the New Code governs the conduct, and specifically, the marketing and promotional practices of, pharmaceutical (as well as medical device) companies – especially when such conduct or practices involve, and/or otherwise target, healthcare professionals. In this regard, the New Code aims to: (i) clarify the range and limits of permissible marketing/promotional practices; (ii) regulate and/or otherwise prevent unethical marketing/promotional practices; and (iii) establish a framework for ethically marketing/promoting drugs and medical devices in India.

SOME NOTABLE ADDITIONS IN THE UCPMP 2024

'Promotion'

Unlike the Old Code, the New Code specifies that '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/medicinal drugs.

In addition, certain changes and/or clarifications have been introduced in the UCPMP 2024 which distinguish it from the Old Code in significant ways. For instance, the UCPMP 2024 appears to carve out exemptions for educational events and items, including with respect to brand reminders, continuing medical education ("**CME**"), continuing professional development ("**CPD**"), as well as research.

Medical devices

Under the earlier regime, the marketing practices of the medical devices industry were voluntarily regulated through a ministry clarification, pursuant to which medical devices companies, like pharmaceutical products, could voluntarily adopt the Old Code in terms of ethically promoting and marketing their products. Subsequently, in March 2022, acknowledging the distinction between medical devices and pharmaceutical products, the DoP issued a separate draft code (which was in the legislative pipeline since 2017) exclusively for medical devices.

However, the New Code now specifically extends its application to: (i) medical devices, and (ii) companies or entities manufacturing or dealing with the sale and distribution of such products. Given the specific inclusion of medical devices in the New Code, it appears that the DoP may not introduce a separate code in the near future for the purpose of regulating the ethical and fair promotion of medical devices.

UCPMP 2014 VS. UCPMP 2024

Certain key changes are set forth below:

Relaxed timelines and inclusion of government official in apex committee for appeals

Similar to the UCPMP 2014, the UCPMP 2024 requires each Indian pharmaceutical association to have a committee for handling complaints (the 'ethics committee for pharma marketing practices,' or the "**ECPMP**"). However, while the UCPMP 2014 had required all complaints related to the breach of the Old Code to be made within three months of breach, the New Code extends this period to six months, with a further period of a maximum of six months for reasonable delay that can be explained in writing. Such elongation of the available time-window may increase the ability of individuals, companies or other entities to make complaints about alleged breaches of the New Code. Accordingly, pharmaceutical and medical device companies are likely to be rendered more susceptible to complaints in terms of their actions or omissions with respect to the UCPMP 2024.

The New Code also increases the timeline with respect to the lodging of reviews/appeals pursuant to ECPMP rulings. In addition, the UCPMP 2024 contemplates the apex committee for pharma marketing practices (the "**ACPMP**"), which handles appeals from the ECPMP's decisions (including a lack of decision or an inordinate delay in reaching such decisions): (i) to be headed by the Secretary, DoP, and (ii) to further comprise a Joint Secretary and a Finance Officer.

Furthermore, while the Old Code did not clearly stipulate a timeline for the ACPMP's decision, the New Code requires that the ACPMP issue a final decision within six months. The timeline available for the ECPMP to render a decision also stands extended from 30 days to 90 days of receiving the complaint.

The changes described above may bring additional clarity and severity to the complaints and appeals procedure under the UCPMP 2024 relative to the Old Code.

Power to issue standing orders

The UCPMP 2024 grants broad powers to the DoP to issue standing orders from time to time, including: (i) for the furtherance of the New Code's provisions; or (ii) for the purpose of removing difficulties in the code's operation. Further, such standing orders will be considered an integral part of the UCPMP 2024.

This provision has not only increased executive oversight over the subject-matter of the UCPMP 2024 but has also made the New Code more dynamic by explicitly contemplating future adjustments and regulatory course correction.

Brand reminders

While the UCPMP 2014 allowed the giving of free samples (barring anti-depressants and other specified drug categories) subject to certain conditions, the UCPMP 2024 now expressly permits brand reminders not just for (i) free samples provided by pharmaceutical companies to medical professionals (albeit subject to similar conditions as earlier applicable, while presumably permitting free samples of anti-depressant drugs), but also in terms of (ii) 'informational and education items' such as books, calendars, diaries, journals (including e-journals), dummy device models and clinical treatment guidelines for professional use in healthcare settings. However, the value of any such item may not exceed INR 1,000, and such items should not have an independent commercial value for healthcare professionals.

Further, the New Code expressly clarifies that the receipt of brand reminders from pharmaceutical companies by healthcare practitioners may not be construed as an endorsement activity if it does not amount to a recommendation or an issuance of a statement by a healthcare professional with respect to the use of such brand.

However, like in the Old Code, the New Code retains the prohibition on pharmaceuticals companies and/or their agents (including distributors, wholesalers, retailers, etc.) with respect to the offering, providing, supply or promise of gifts or pecuniary advantage or benefit in kind for the personal benefit of any healthcare professional or their family members (both immediate and extended), or to any person qualified to prescribe or supply drugs.

Nevertheless, the explicit permission granted for brand reminders with respect to informational and education items, as well as free samples, is a welcome change. Such changes are likely to avoid confusion and provide added operational clarity. However, pharmaceutical and medical device companies should note the following with respect to the UCPMP 2024:

- the monetary value of free samples distributed by them should not exceed two percent (2%) of the domestic sales of such company per year;
- the giver and recipient of brand reminders should comply with the relevant provisions of the Income Tax Act, 1961, as amended from time to time (the "**IT Act**") with respect to deductions and reporting of income.

Continuing Medical Education/Continuing Professional Development

While the UCPMP 2014 did not contain specific provisions/restrictions on the engagement of the pharmaceutical industry vis-à-vis healthcare professionals with respect to CME, CPD, conferences, seminars, workshops and other similar events (collectively, "**CME Events**"), it had specifically prohibited pharmaceutical companies (including their

associations/representatives or persons acting on their behalf) from extending travel facilities whether within or outside India (including by rail, air or ship, along with cruise tickets, paid vacations, etc.) to healthcare professionals attending the seminar/conference organized by the pharmaceutical company as a delegate.

The UCPMP 2024 sets out a more specific set of guidelines relating to CME Events. In particular, it states that CME Events should only be allowed through a well-defined, transparent and verifiable set of guidelines. Accordingly, the New Code provides a detailed framework within which pharmaceutical and medical device companies may operate for the purpose of conducting such CME Events (such framework, the "**CME Framework**").

The CME Framework

The CME Framework under the New Code specifically allows certain categories of entities, such as pharmaceutical companies (including their trusts/associations, either alone or in collaboration with specified types of professional bodies and institutions), to conduct CME Events provided that such events are not conducted at foreign locations. Further, the CME Framework requires pharmaceutical companies to share the details of CME Events conducted by them on their website, including by (i) explicitly spelling out the procedure followed in the selection of participants and speakers, as well as (ii) displaying a statement of their funding sources and expenditure.

Importantly, the information provided by pharmaceutical and medical device companies in such disclosures may be subject to independent, random, risk-based or special audits. Similar to the provision on brand reminders under the New Code, entities incurring expenditure on CME Events, as well as the participants and speakers themselves, must comply with relevant provisions of the IT Act.

In this regard, the UCPMP 2024 states that the DoP will notify a panel of auditors – which comprises either (i) audit firms of standing which are empanelled by the Comptroller and Auditor General of India; or (ii) reputed commercial audit firms which have experience in dealing with such matters.

Further, the UCPMP 2024 explicitly restricts pharmaceutical and medical device companies (including their representatives or persons acting on their behalf) from extending travel facilities or any hospitality to healthcare professionals (including their immediate and extended family members), unless the person concerned is a speaker for a CME or a CPD program.

Support for research

While the Old Code was silent on research, the New Code specifies that expenses incurred on research by pharmaceutical companies is an allowable expenditure, subject to the provisions of the IT Act. However, the engagement of healthcare professionals in a

consultant-advisory capacity is required to be for *bona fide* research services under a consultancy agreement – involving a consultancy fee or an honorarium-based payment, subject to relevant provisions of the IT Act.

Moving towards stricter enforcement

Unlike the Old Code, the UCPMP 2024 does not start with the words: "this is a voluntary code". The omission of such language is conspicuous and possibly deliberate – given the history of critical stakeholder views (including the government's, from time to time) with respect to making the UCPMP 2014 legally binding (for example, see here and here). Further, the 2024 Notification contemplates wide circulation of the New Code for 'strict compliance', and requests all pharmaceutical associations to take further necessary steps with respect to the code's implementation.

Nevertheless, it appears that the New Code stops short of calling its own requirements 'mandatory,' and in this regard, its potency has been questioned.

In terms of the advisability of making the UCPMP 2024 either a voluntary or mandatory code, the government's stance has been inconsistent. For instance, according to the DoP's Annual Report of 2017-18, pursuant to a review of the Old Code's implementation in consultation with relevant stakeholders (including non-government organizations and civil society), it was felt that the code should be made mandatory in order to implement it more effectively.

With such intent, the DoP had prepared a draft order under the Essential Commodities Act, 1955 ("**EC Act**"), called the Essential Commodities (Control of Unethical Practices in Marketing of Drugs) Order 2017 (the "**CUPMD**") for the purpose of replacing the voluntary Old Code with mandatory legislation. Thus, unlike the UCPMP 2014, the CUPMD was proposed to be a law, seeking to derive its legislative scope under the EC Act – which, in turn, regulates the production, supply, distribution, trade and commerce of 'essential commodities' (including drugs and medical devices).

However, the CUPMD was eventually not brought into force, including on account of issues related to legislative competence. Nevertheless, the UCPMP 2024 attempts to borrow certain elements from the CUPMD, such as the limit of INR 1,000 on freebies and the involvement of government officials with respect to addressing complaints regarding violations.

Importantly, in 2019, despite acknowledging complaints related to unethical marketing practices, the government had noted that the Old Code was being successfully implemented, and by late 2020, the government clarified that it had no intention of making the UCPMP 2014 mandatory. Further, in August and December 2022, the government stated that the existing legal regime was sufficient and enforceable.

However, in September 2022, the government constituted a high-level committee (the "**2022 Committee**") for the purpose of considering various issues related to the Old Code, and examining the requirement of a legally enforceable mechanism to regulate the marketing practices of pharmaceutical companies. Around the same time, a public interest litigation was filed in the Supreme Court praying for the legal enforceability of requirements under the Old Code. According to media reports, the 2022 Committee submitted a report in December 2023 suggesting that, while the Old Code should be strengthened, it ought to remain voluntary. It now appears that several additional elements in the New Code were introduced pursuant to such recommendations of the 2022 Committee.

In this context, it is likely that the decision to *not* make the New Code mandatory was a purposeful move. Moreover, it seems that the government's present stance about the adequacy of the current legal regime, as maintained in recent submissions to the Supreme Court, is here to stay.

CONCLUSION

As opposed to the heavily-regulated regime involving the advertisement of drugs and medical devices with respect to end-users (including the Drugs and Cosmetics Act, 1940; the Drugs & Cosmetics Rules, 1945; the Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954; the Consumer Protection Act, 2019; and the Advertising Standards Council of India's Code for Self-Regulation in Advertising), the promotion and marketing of pharmaceutical products and medical devices by companies vis-à-vis healthcare professionals was only nominally regulated through the UCPMP 2014 – which, despite being considered inadequate (including on account of perceived non-compliances stemming from its voluntary nature), was not made mandatory. While the compliance record and the strength of implementation with respect to the UCPMP 2024 is likely to unfold over the next few months and years, it does appear that the DoP has managed to strengthen the New Code relative to the old regime.

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