Pharma and medtech marketing: Navigating the imminent disclosure deadline

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In 2024, the Indian government instituted new mandatory benchmarks for marketing practices applicable to pharmaceutical and medical device companies (involved in manufacturing, importing, selling and/or distribution) with the introduction of the Uniform Code for Pharmaceutical Marketing Practices, 2024 (UCPMP) and the Uniform Code for Marketing Practices in Medical Devices, 2024 (UCMPMD), respectively. The key areas of compliance under these codes include ethical conduct regarding brand reminders, the regulated distribution and accountability of free/evaluation samples, and stringent rules governing interactions with healthcare professionals (HCPs), including limitations/prohibitions regarding gifts, travel facilities, hospitality, and monetary grants to HCPs.

While the financial year 2024-25 marks the first full financial year requiring adherence to these codes, a critical compliance deadline is now just hours away. By May 31, 2025, companies must submit their mandatory self-declarations of compliance with the applicable code and detailed disclosures of marketing expenditures for the aforementioned financial year. Given the proximity of this deadline, we analyse the specifics of what must be disclosed, the persons responsible for compliance, the prescribed submission procedures, and the potential consequences of non-compliance.

Essentially, companies are obligated to submit two key components. *Firstly*, the codes require a formal declaration by the company's Executive Head (CEO or equivalent), affirming the company's complete compliance with all provisions of the applicable code for the financial year 2024-25. *Secondly*, a detailed account of all marketing-related expenses must be disclosed in a specific format for this period. The key categories for this disclosure include expenditure details regarding the distribution of free or evaluation samples, engagement in continuing medical education (CME) or continuing professional

development (CPD), and involvement in conferences, workshops, training, and seminars, regardless of whether these events are organised directly by the company or through third-party entities.

That said, cautious preparation is paramount for both the self-declaration and the expenditure disclosure, especially with the deadline being immediate. For instance, before issuing the required declaration, the Executive Head must ensure strict adherence to all restrictions under the codes throughout the year, such as the INR 1,000 cap per item for brand reminders or the 2 per cent of domestic sales limit for free/evaluation samples. Similarly, for disclosures concerning marketing expenditures, it is important to have compiled all necessary data according to the prescribed format. This includes company information (such as Corporate Identification Number/Foreign Company Registration Number, name, address, email, and Permanent Account Number), the monetary value of free samples, and comprehensive details of CME/CPD events, including the number of events, total expenditure for direct events, and specific details such as date, location, organiser, and expenditure for third-party events.

Regarding submission channels, the requirements for self-declarations differ. Under the UCPMP, pharmaceutical companies can submit their self-declaration to their Industry Association (for uploading on their website) or, if the company is not a member of any such body or is a member of more than one, directly to the UCPMP portal of the Department of Pharmaceuticals (DoP). In contrast, the UCMPMD mandates that medical device companies submit their self-declaration both to their association (for website uploading) and directly on the UCPMP portal of the DoP. For both pharmaceutical and medical device companies, the marketing expenditure disclosure is required to be submitted directly on the UCPMP Portal of the DoP.

On the enforcement front, the UCPMP and the UCMPMD are primarily enforced through industry associations. These associations are mandated to establish an Ethics Committee for Pharmaceutical Marketing Practices or an Ethics Committee for Marketing Practices in Medical Devices. These committees are responsible for addressing any breaches of the applicable code. Failure to comply with the codes, such as not making the required disclosures by the deadline, can lead to various actions based on the recommendations or proposals of these Ethics Committees. Potential consequences may range from the committee reprimanding the entity and publishing full details of such reprimand, to requiring the entity to recover money or items found to have been provided in violation of the applicable code, or referring cases to other government authorities for appropriate action. Furthermore, Section 405 of the Companies Act, 2013, stipulates a penalty of up to INR 3,00,000 for the company and the officer in default if any information furnished is incorrect or incomplete in any material respect.

With the May 31, 2025, deadline looming, the companies must act swiftly if they have not already. Rigorous tracking of all compliance measures and marketing expenditures throughout the year is essential. Before submitting the self-declaration and expenditure disclosure, the Executive Head must be fully informed to ensure accuracy and alignment

with regulatory expectations. If any ambiguities in interpreting the codes or disclosure requirements persist, immediate consultation with legal and regulatory experts is strongly advised.