

Pharma & Healthcare Update

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NEW PROMOTION CODE RELEASED: MEDICAL DEVICE INDUSTRY TO BREATHE EASY

- The DoP has released a separate marketing code which accounts for the distinct nature of the activities undertaken by medical devices companies
- Companies are required to adhere to certain transparency requirements
- The enforcement of UCMPMD will be through industry associations

BACKGROUND

The Department of Pharmaceuticals ("DoP") has released the much-awaited Uniform Code for Marketing Practices in Medical Devices ("UCMPMD") which, going forward, will govern the promotional activities of the industry, including engagements with healthcare professionals.

Earlier this year, the DoP had released the Uniform Code for Pharmaceutical Marketing Practices ("UCPMP") which was made expressly applicable to medical devices as well. While it had been stated that the UCPMP will be applicable *mutatis mutandis* for medical devices, there was no additional clarity on the manner in which it may be altered for medical devices. As a result, there was widespread panic across the industry, since several inalienable practices of the medical devices industry either did not find mention or did not conform to the UCPMP.

KEY DEVELOPMENTS

The UCMPMD is substantially similar to the UCPMP, particularly in terms of promotional materials and promotion through medical representatives (our hotline providing an overview of the UCMPMD may be accessed [here](#)). We have discussed some of the relevant additions below.

Broadened scope of Medical Representatives

The scope of medical representatives has been expanded to include not only sales representatives but also medical affairs or marketing professionals and clinical specialists who call on HCPs, pharmacies, pathology labs, research labs, hospitals or other healthcare facilities to promote medical devices.

Companies would be required to ensure that all their medical representatives (including those retained through agencies) comply with the UCMPMD. Appropriate clauses must be included in the agreements with such personnel.

Evaluation Samples

Similar to the samples under UCPMP, evaluation samples may be provided to HCPs for the purpose of acquiring hand-on experience in using the medical device. The UCMPMD allows for "a quantity that is reasonably necessary for evaluation of that product" of free evaluation samples to be provided to HCPs. Pertinently, only single-use products may be provided.

Companies are required to maintain details including: product name, HCP's name and contact information, date of supply, quantity and value, and relevant product traceability information in relation to evaluation samples. The information must be retained for a minimum period of five years.

Demonstration Products

Distinct from evaluation samples, demonstration products are intended for use by medical representatives to explain the functioning/features of the medical device to the HCP. These may be single use products, mock-ups, temporary software, or equipment. Demonstration products must be taken back by the company after the demonstration period is over. They may be used for patient awareness and education, but cannot be used for patients in the course of treating.

Companies are required to maintain details such as: product name, HCP name and contact information, quality and value of demonstration products given (in terms of MRP), date of supply, date of taking back, and the relevant traceability information.

Overseas Clinical Training

Recognizing that the blanket ban on conduct of educational events overseas was not feasible for medical devices companies, the UCMPMD provides an exception for advanced clinical trainings that cannot be conducted domestically owing to restraints such as unavailability of trainers, equipment or products in India.

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Companies are required to seek prior approval from the DoP prior to conducting such events. A detailed report containing the justification for conducting the event overseas, as well as details of participating HCPs, duration and location of the training, trainers, equipment and facilities used, expenditure to be incurred on travel and accommodation, etc must be submitted at least three months prior to the scheduled date of the event.

Companies are permitted to bear the expenses of participants in approved clinical training programs, as well as speakers at CME and CPD programs.

Product Training

The draft version of the UCPMP that was circulated for public consultation in 2022 contained a requirement that companies provide hands-on training on the effective use of the device. Notably, the UCPMD excludes this provision. The intent of excluding this obligation, however, does not appear to be to preclude such training, but merely to enable companies to take reasoned decision on whether or not it is necessary.

Transparency Requirements and Declaration of Compliance

The requirement under UCPMP to disclose details of the events conducted and the expenses incurred in connection therewith on the company website has been retained in the UCPMD as well.

In addition, the obligation to submit returns in a prescribed format of the expenses incurred towards providing samples, organizing events and sponsoring events was introduced into the UCPMP earlier this week. The same has been incorporated into the UCMDMP as well.

Pertinently, the DoP has expressly stated that the information submitted in the return will be handled in accordance with the provision for disclosure of third-party information provided under the Right to Information Act, which means that the information contained therein could potentially be disclosed in response to a request after providing the company chance to make a representation. The DoP has also stated that action may be initiated under the Companies Act, 2013 where a company provides incorrect or incomplete information within the disclosure. The company would be liable to a penalty ranging between from INR 20,000 to INR 3,00,000.

This return must be submitted on the DoPs UCPMP portal by June 30 of every financial year, along with the declaration to be submitted by the executive head of the company certifying compliance in the preceding financial year and committing to continued compliance in that financial year.

ACTION ITEMS

The crux of the UCPMD remains that companies should undertake promotions and engage with HCPs in an ethical and transparent manner. The purpose should be to educate HCPs and maximise patient welfare, and there should be no attempt to influence an HCPs independent clinical decision.

For medical devices companies, the key action items arising from the UCPMD would be:

- Put in place internal policies to ensure transparency and non-arbitrariness in the decision-making process for promotional activities
- Follow stringent documentation practices to ensure that actions taken may be justified.
- Undertake an assessment of their product portfolio to identify the events would mandatorily have to be conducted in a foreign location. Since the application for approval must be sought at least three months in advance, companies may keep the shell of the report handy.
- Maintain records of all evaluation samples and demonstration products provided to HCPs
- Details of events and the expenditure incurred thereon must be uploaded the website. In the absence of clarity from the DoP, companies may devise an internal format for making such disclosures.
- Annual returns in respect of UCPMP to be uploaded to the DoP portal.
- Declaration of compliance with the UCPMD to be submitted through the DoP portal

CONCLUSION

The UCPMD has brought about some relief from the tussle between compliance with UCPMP and distinct requirements of medical devices companies. The *modus operandi* remains self-governance, and implementation through industry association. From a broader regulatory perspective, it also signals that the DoP is making active strides towards a separate framework for medical devices, which will go a long way towards establishing a conducive environment for medical devices companies to operate in India.

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You can direct your queries or comments to the relevant member.

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