Uniform Code for Marketing Practices in Medical Devices:

Redefining the game for compliance

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Setting the context

The Indian medical device industry has witnessed significant growth through providing cost-effective healthcare solutions and improving healthcare infrastructure contributing to a favourable environment for adoption of medical devices. With a diverse product range, an extensive distribution network, and a strong focus on research and development, the sector has achieved remarkable progress in developing innovative products and solutions over the past decade. This growth is expected to continue, driven by rising per capita consumption, the adoption of digital health technologies, affordable healthcare solutions, and improved access to healthcare.

Medical device sector plays a pivotal role not only to screen or diagnose a disease but to also restore the patients' lives back to normal through pro-active monitoring solutions which aids in preventing health concerns. Besides, the local manufacturers in this sector are heavily reliant on massive imports due to lack of advanced technology solutions, appropriate technical expertise, funds crunch and regulated complex business environment to operate.

The market share of the Indian medical device was estimated as INR90,000 crore, (USD 11 billion) in 2022 and is expected to grow to USD 50 billion by 2030 with a CAGR of 16.4 per cent [1]. To further strengthen the position on a global pedestal, it was a need of hour to devise and implement stringent compliance code to impede the consequences of malpractices and wrong doings which could adversely affect the country's position at global level.

Many countries have laws regulating marketing activities, like the US Physicians Payment Sunshine Act and France's Loi Bertrand, which require transparency in payments to healthcare professionals (HCPs). Similarly, the US FCPA and UK Bribery Act enforce ethical business practices. Until recently, India lacked specific regulations for the medical device industry.

To address this, the Department of Pharmaceuticals introduced the Uniform Code for Marketing Practices in Medical Devices (UCMPMD) 2024. This code applies to all medical device organisations, mandating compliance, and encourages voluntary adherence from non-affiliated organisations.

The code governs product promotion, the conduct of agents and medical representatives, and interactions with HCPs and their families. While multinational and some domestic organisations may already have strict ethical policies, it is crucial to realign these policies as needed and implement proper controls to ensure compliance with the UCMPMD.

This suggests a big change in India's healthcare equipment field. Now, following the rules isn't just about avoiding fines, but also a way to show the industry's promise to be ethical in their marketing, protecting consumers, and building trust in the industry. In this process, the type of leadership becomes very important. In response to this shift, the style of leadership that is promoted becomes critically important.

1. Medical Devices Industry in India, IBEF, 18 October 2024

Key guidelines that have to be adhered to by the organisations are as follows(1/2)

Promotional activities

- Maintain consistency of promotional activities with Instruction for Use (IFU)/Directions for Use (DFU)
- Medical device information must be accurate, balanced, up to date, non – misleading and verifiable.

Brand reminders, evaluation samples, and demonstration products

- Books, calendars, diaries, journals (including e-journals), dummy device models, etc. used in healthcare settings should not exceed INR 1,000 per item.

Evaluation samples:

- Only qualified HCPs (with their names and addresses) should receive samples
- Clearly mark samples as "Evaluation sample - Not for sale"
- The value of distributed samples should not exceed two per cent of the organisation’s annual domestic sales, maintain records for five years.

Demonstration products:

- Use demonstration products to raise awareness, educate patients, and retrieve them after the demonstration period
- Identify and track demonstration products separately
- Maintain details of each demonstration product for at least five years.

Textual and audio – Visual promotion

- Include device's brand name, the manufacturer/importer's details, and warnings in promotional materials
- Mailings and advertisements must clearly show their nature
- Paid promotional material must not resemble editorial content
- Using the names or photos of HCPs is prohibited.

Claims and comparisons

- Efficacy claims must be based on current evidence and relevant IFU/DFU
- Product claims must align with registration or licenses to manufacture, import, or distribute/sell their device with the IFU/DFU/User manual
- Medical device comparisons must be factual and fair, without disparaging competitors or the opinions of HCPs
- Other organisation’s brand names not to be used in comparisons without consent
- Disparaging other organisations and HCPs is prohibited.

Key guidelines that have to be adhered to by the organisations are as follows(2/2)

Medical Representatives (MRs)

- MRs include both employees and third-party contractors
- Inducements or deception not to be used to gain an interview with HCPs
- No payment under any guise, for access to an HCP
- Contracts with MRs must include a clause mandating adherence to the code.

Relationship with HCPs

- Organisation and third parties are restricted to offer gifts or benefits to HCPs and their family members
- Exceptions for travel and hospitality apply to speakers at CME/CPD programmes or training participants with specific approval from the Department of Pharmaceuticals (DoP).

Support for research

- The research should have approval from the competent authority
- HCPs involved must comply with relevant regulations in a consultancy agreement
- Expenditure on research is allowable, subject to the Income Tax Act.

Continuing Medical Education (CME)/ Continuing Professional Development (CPD)

- Medical device industry engagements with HCPs for CME/CPD/training events should follow transparent guidelines
- Foreign events are prohibited except for clinical training in exceptional cases, with justification and relevant details submitted for approval three months in advance
- Publish on organisation's websites - CME/CPD/training events details, and costs.

Significant perils that demand a second glance

Failure to comply with the UCMPMD guidelines may result in the need to implement various corrective measures to prevent legal challenges, financial consequences, and potential damage to the organisation's credibility and trustworthiness. The key approaches available are as follows:

Complaints

- Complaints to be made within six months of the alleged breach of the code with a non-refundable fee of INR 1,000
- The complaint should include details of the complainant, name of the alleged organisation, organisation personnel involved, and details of misconduct
- The complaint must be signed or authorised by the managing director or chief executive of the medical device organisation.

Handling of complaints

- The ethics committee will manage the process of addressing complaints and professional auditors may be engaged to help with the investigations
- The respondent organisation has 30 days to submit its comments
- The committee must resolve the complaint within 90 days of receipt of the complaint.

Appeal

- Dissatisfied parties may appeal before the Apex Committee for Marketing Practices in Medical Device (ACMPMD) within 15 days
- ACMPMD will issue a final decision within six months
- In case of unreasonable delay or inaction by the association for the cases referred by the DoP, ACMPMD may take over the matter themselves.

Penal provisions

- The ethics committee may recommend actions such as suspension or expulsion from the association, reprimands, the issuance of corrective statements, recovery of resources or assets, or regulatory agency action through DoP.

What does UCMPMD mean for the organisation?

The implementation of UCMPMD has amplified the responsibilities of both internal and external stakeholders across the organisation, encompassing those involved in operational management and monitoring. All stakeholders are required to exercise caution and maintain vigilance in all transactions governed by this code.

Key internal stakeholders

- **Chief Executive Officer ("CEO")**
- **Legal & Compliance**
- **Internal Audit / Investigation**
- **Finance**
- **Sales team**
- **MRs**

Actionable as per UCMPMD

- Compliance to the points in the code
- Yearly self-declaration by CEO of the organisation regarding compliance to the UCMPMD
- Furnish return[2] under UCMPMD for disclosing market expenditure incurred
- Appropriate clauses in employment contracts with MRs towards adherence of the code
- Maintain adequate details of the evaluation samples and demonstration products provided to HCPs
- Details of CME/CDP/trainings including expenditure to be published on the organisation website
- Monitor the transactions on a regularly basis
- Response to any complaints received from the ethics committee of the associations in a timely manner
- Adherence to any audit initiated towards compliance to the code.

Key external stakeholders

- **Government & regulatory bodies**
- **Indian Medical Device Associations including their ECMPMD**
- **Channel partners**
- **Healthcare professional**
- **Organizers of CME/CPD/Trainings**

Actionable as per UCMPMD

- Channel partners/third parties must have sound working knowledge of the code
- Associations are responsible to setting up an ethics committee towards compliant redressal
- Associations to conduct audits of the organisations as required
- Organisers of the CME/CPD/trainings should specify procedure followed towards selection of speakers and participants and a statement of their funding sources/expenditure on their website.

2. Source – Form for Disclosure of Marketing Expenditure, UCMPMD, 18 October 2024

What measures must organisations take to comply with the code?

To ensure compliance with the guidelines set forth by the DoP through the UCMPMD, medical device organisations must conduct a comprehensive assessment of their existing framework and implement necessary modifications to their marketing practices. These organisations can undertake the following illustrative activities to achieve compliance:

Established processes/ policies

- Revise existing policies to adhere with the code
- Staff training and accreditation for compliance to the code
- Maintain documentation as required
- Develop a code-compliance monitoring programme
- Deduce a code-related query process for organisation personnel.

Effective control procedures and monitoring system

- Continuous monitoring and proactive audits
- Review and align marketing plan with the code's requirement
- Define a stringent approval matrix towards transactions related to the code
- Update the third-party contracts towards adherence to the code.

How KPMG in India can assist

In light of the recent introduction of rigorous UCMPMD guidelines by DoP, a prompt and thorough evaluation of the existing compliance framework of medical device organisations is essential. This assessment should primarily focus on the efficacy of current mechanisms to ensure adherence to marketing and promotion regulations.

To augment controls and address key areas, the following enhanced practices have been identified: Some of the immediate better practices identified to tighten the controls and address these areas are as follows:

Framework assessment

Assessment of existing framework and designing or revamping of policies and procedures for compliance with UCMPMD.

Independent audits

Onsite organisation and distributor reviews to assess the adherence of UCMPMD guidelines.

Department audits

Assist medical device organisations with special audit and risk-based audits ordered by the DoP.

Awareness session

Design and develop training and awareness sessions and delivery of in-person/virtual as well as web-based sessions to employees (including MRs).

Monitoring mechanism

Establish a continuous monitoring programme in line with the code to identify the red flags and deviations proactively.

Risk assessment

Periodic risk-based assessment to identify potential red flags related to non-compliance of the code.

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