Decoding the Uniform Code for Marketing Practices in Medical Devices (UCMPMD) 2024

October 2024

pwc

Decoding UCMPMD 2024

Key tenets

- **Mandatory** for medical device companies
- **Quasi-judicial** code with complaint and appeal ecosystem
- Heightened **scrutiny and stricter** enforcement actions
- Enhanced **governance and monitoring framework**
- **Convergence with other applicable laws** and regulations (Income-tax Act, Medical Council of India [MCI], Medical device Rules)

What's new?

Training and educational programmes introduced (overseas location allowed with exceptional approvals)	Guidelines for evaluation samples along with overall threshold limit
Broadened scope of medical representatives*	Retention of demonstration samples
Research/studies to be pre-approved by a competent authority	Annual self-declaration by CEO on adherence to the code with a defined annexure
Disclosure on expenditure incurred	

* Sales representatives, medical affairs or marketing professionals, clinical specialists or contractors)

Implications of non-compliance

- Suspension/expulsion from association
- Disciplinary action
- Public disclosure of corrective actions

Engagement with healthcare professionals (HCPs) and organisations

CMEs/CPDs/training

Can be organised by:

Medical device companies alone or in collaboration with institutions, universities, hospitals, medical colleges, professional associations and teaching/ research institutions

Nature of events:

Continuous medical education (CMEs), continuing professional development (CPD), training, conferences, seminars, workshops, etc.

Key requirements:

- Events at foreign locations are prohibited except in case of advanced clinical trainings in exceptional circumstances (non-availability of trainer or product in the country)
- Department of Pharmaceuticals (DOP) approval required three months in advance. Details below to be submitted:
  - details of participating HCPs and trainers
  - location, duration and rationale
  - expenditure on travel and boarding for speaker and participants
  - equipment and facilities to be used.
- Details of events and expenditure incurred to be disclosed in defined format on website and along with annual certification

Research support

- Research to be approved by a competent authority (ICMR,DCGI, institutional authority, EC*)
- Instructions of National Medical Commission must be complied with
- Consultants or advisors can be appointed through consultancy agreements subject to competent authority approval

(*ICMR – Indian Council of Medical Research, DCGI – Drug Controller General of India, EC – Ethics Committees)

Gifts or monetary grants

- Personalised gifts and benefits are prohibited to be distributed to HCPs, distributors, agents, wholesalers, retailers, etc.
- Cash or monetary grants to individual HCPs, including distributors, agents, wholesalers and retailers, are prohibited

Income-tax Act:

- Section 37(1) will be attracted in case of non-compliance with the MCI/UCMPMD (e.g. unapproved event at foreign locations).
- TDS section - 194R will be attracted is case of any expenses construed as a benefit to the HCPs subject to conditions.
- TDS section - 194J will be attracted in case of honorarium payouts to HCPs.

Engagement with HCPs and organisations

Brand reminders and promotional materials

Brand reminders:

- Can provide books, calendars, diaries, dummy device models, journals (including e-journals), etc., for professional use in healthcare settings
- Value up to INR 1,000 per item
- Items should not have independent commercial value to HCPs

Promotional materials:

- Minimum information (as defined) must be part of the promotional material
- Market authorisation should be in place prior to promotion
- Avoid using the words ‘safe’ and ‘new’
- Should not contain the name or photograph of an HCP
- Date of printing or of the last review of promotional material shall be stated

Evaluation sample

Brand reminders:

- Provided to qualified HCPs for acquiring experience
- Samples should be supplied with instructions for use (IFU), directions for use (DFU), electronic instructions for use (eIFU) or user manual
- Should not exceed the quantity reasonably necessary for evaluation
- Total value should not exceed 2% of domestic sales
- To be labelled as ‘evaluation samples – not for sale’

Demonstration samples

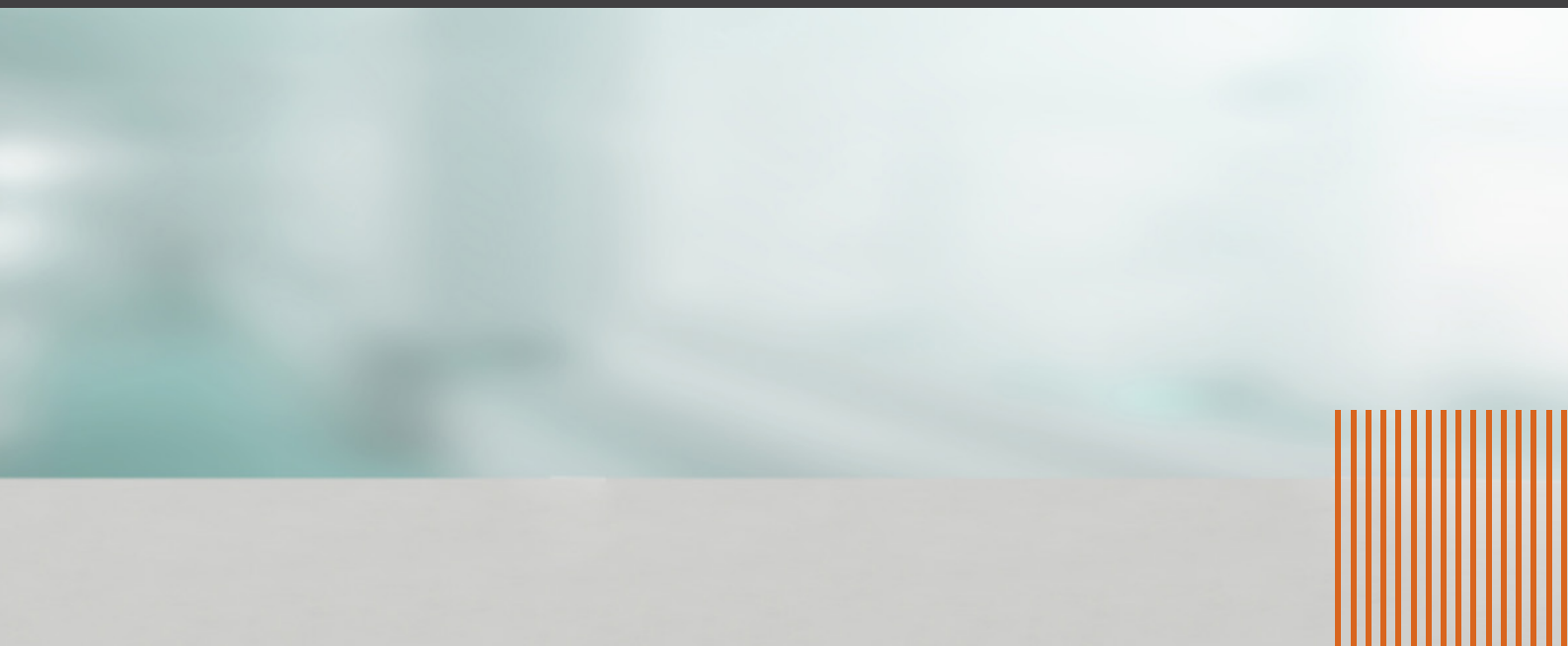
- Can be single-use products, mock-ups, temporary software or equipment for patient awareness/ education
- Possession of such samples should be with the company
- The demonstration equipment must be returned to the company after the demonstration period is over

Tracking and monitoring

- Detailed records with respect to product name, doctor name, address, quantity, supply date, value to be maintained
- Additionally, date of collection from HCPs and MRP to be captured for demonstration samples
- Evaluation and demonstration samples should be differentiated
- Records should be maintained for five years

Income-tax Act:

- TDS section - 194R will be attracted in case of any expenses construed as a benefit to the HCPs subject to conditions.
- Section 37(1) will be attracted in case of non-compliance with the MCI or UCPMP.



How to approach adherence to this new change?

Revisit/redesign the compliance framework

- **Revisit existing policies and procedures** to incorporate the key requirements around new changes for CMEs, training, research support, brand reminders, samples, etc.

Design transparency programme

- Design a **spend transparency reporting mechanism** of public disclosures on website.
- **Annual self-declaration** by CEOs (within two months from end of FY) in the defined format.

Reinforce systems to enhance control and monitoring

Enhance system controls around:

- audit trail around HCP interaction related spends
- dispatch and distribution monitoring
- value thresholds and triggering alerts for samples/brand reminders.

Promote adherence to the code and related laws/regulations

- Reinforce awareness through **workshops and training for medical representatives (MRs).**
- **Revisit contractual obligations** with MRs to ensure compliance with the code.

Notes

Notes

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