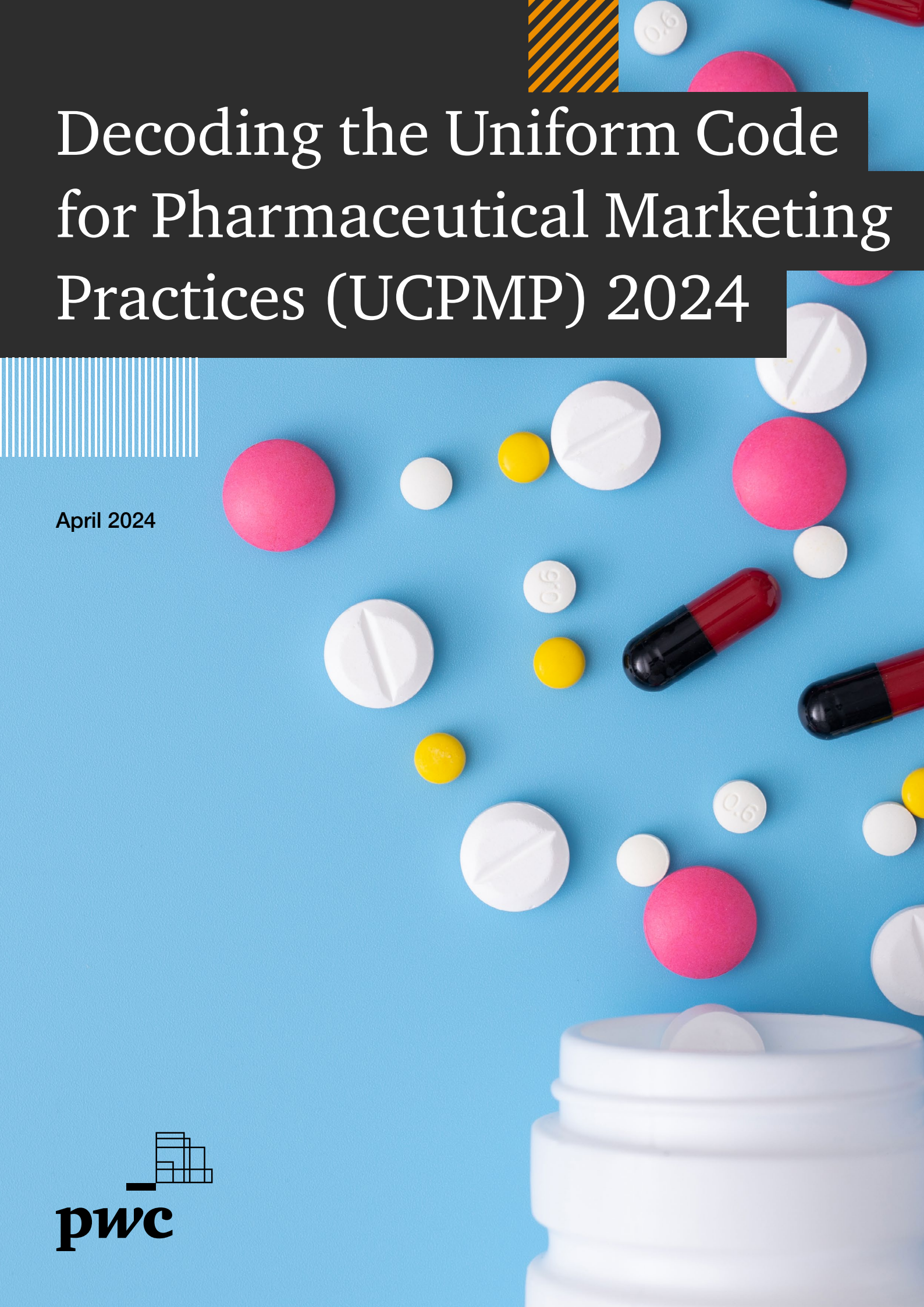
# Decoding the Uniform Code for Pharmaceutical Marketing Practices (UCPMP) 2024

April 2024



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# Decoding UCPMP 2024

## Key tenets

- **Mandatory** for pharmaceutical and 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])

## What's new?

| | |
|---|---|
| Brand reminders defined clearly along with value limit | Samples – limited distribution with maximum limit linked with sales |
| Continuing medical education (CME) guidelines introduced | Research/studies to be pre-approved by a competent authority |
| Specific call-out on ensuring employees are compliant with the code | Disclosure on website – events involving interaction with healthcare professionals (HCPs), including expenditure incurred |
| Annual CEO self-declaration on adherence to the code | |

## Implications of non-compliance

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

# Engagement with HCPs and organisations

## CME

**Can be organised by:**

Pharmaceutical companies alone or in collaboration with institutions, universities, hospitals, medical colleges, professional associations and research institutions

**Nature of events:**

CME, continuing professional development (CPD), seminars, workshops and conferences

**Key requirements:**

- Events at foreign locations are prohibited
- Travel and hospitality for delegates is not allowed
- Details of event and expenditure incurred to be disclosed on the website

## Research support

- Research to be approved by a competent authority (ICMR,DCGI, institutional authority, EC*)
- Consultants or advisors can be appointed through consultancy agreements subject to competent authority approval

**Disclosure on website:**

- Nature of research
- Honoraria to consultant or advisor
- Research-related expenditure

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

## Gifts or monetary grants

- Gifts are prohibited
- Cash or monetary grants to individual HCPs are prohibited

### Income-tax Act:

- Section 37(1) will be attracted in case of non-compliance with the MCI/UCPMP (e.g. travel for delegates or events at foreign locations).
- TDS under section 194R will be attracted is case of any expenses construed as benefit to the HCPs subject to conditions.
- TDS under section 194J will be attracted in case of honorarium payouts to HCPs.

# Engagement with HCPs

**Brand reminders**

## Informational and educational items

- Books, calendars, diaries, dummy device models, journals (including e-journals), clinical treatment guidelines
- Value up to INR 1,000 per item

## Samples

**Samples can be provided to qualified HCPs for:**

- creating awareness
- acquiring experience.

**Value and periodicity:**

- 3 patients per course, maximum of 12 packs per drug per HCP in a year
- Total value should not exceed 2% of domestic sales of the company

**Tracking and monitoring:**

Detailed records with respect to product name, doctor name, quantity, supply date, value

## Promotional materials

**Key guidelines:**

- 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

**Income-tax Act:**

- TDS under 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 CME, research support, brand reminders, etc.
- Design a **spend transparency reporting mechanism** of public disclosures and **annual self-declaration** by CEOs (within 2 months from end of FY).

## 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.

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