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Navigating the new regulatory terrain

Uniform Code of Pharmaceuticals Marketing Practices: What lies ahead?

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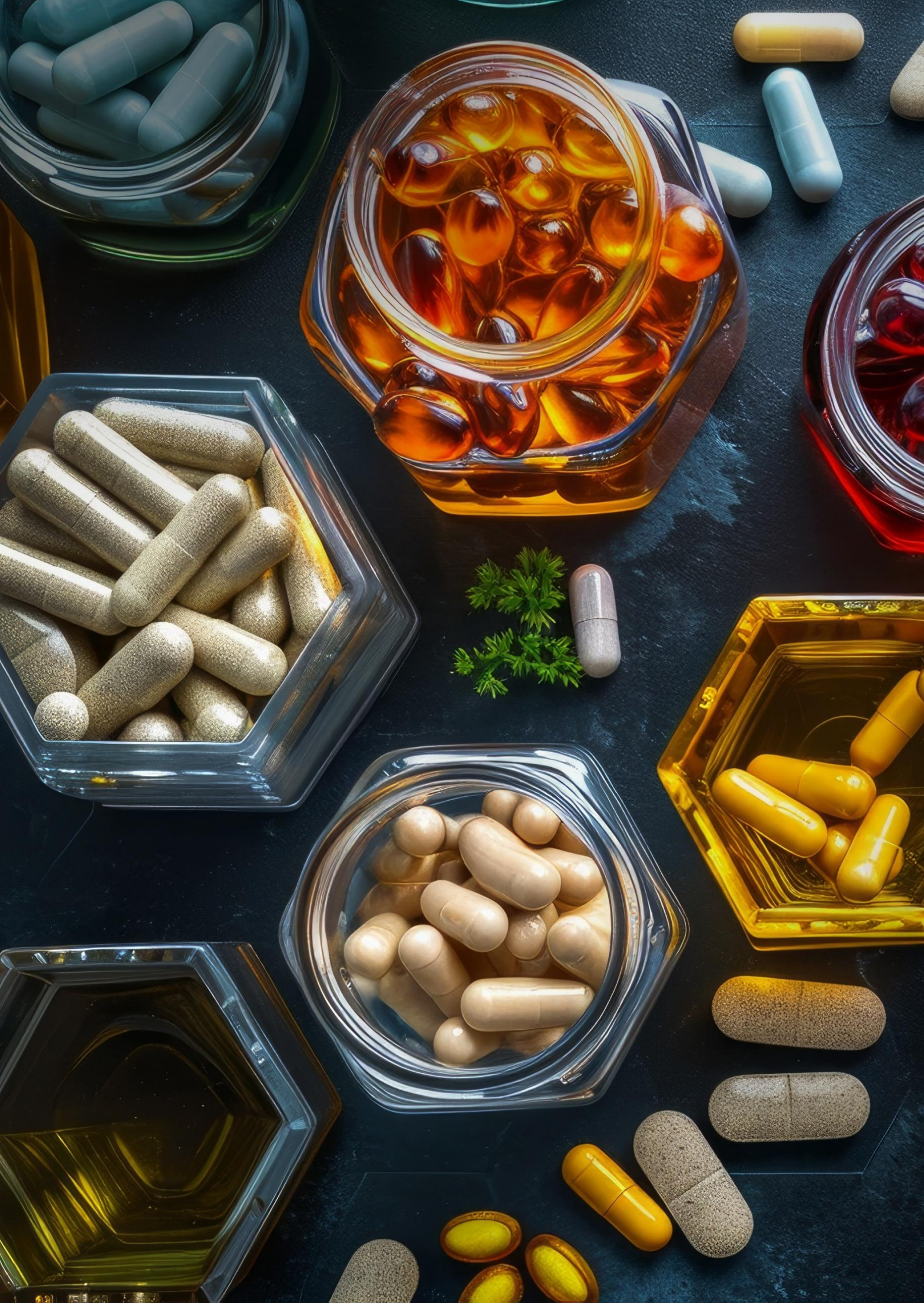
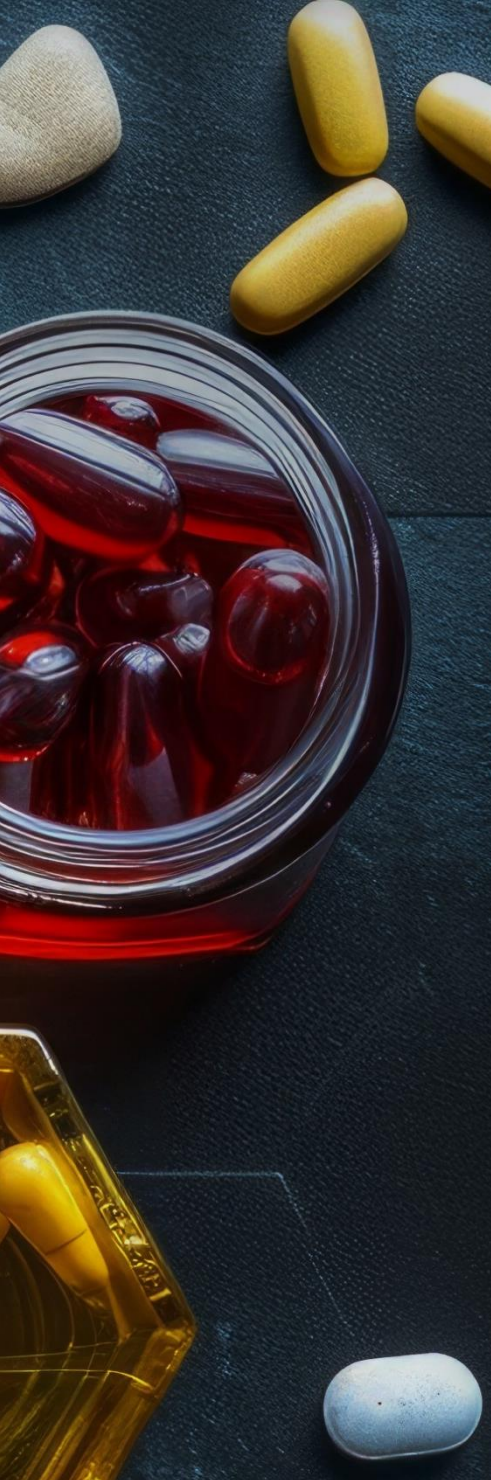




Setting the context

With a varied range of products, extensive distribution network and a sharp focus on research and development, the Indian pharmaceutical industry has experienced significant growth over the past decade and made strides in the creation of cutting-edge products and solutions. The industry is expected to continue its growth trajectory, driven by factors such as increasing population, rising income levels and improved access to healthcare.

As a result, organisations are looking to scale up and achieve a larger share of the market through multiple promotional and marketing strategies. It is crucial to recognize that the organisations and their sales and marketing functions confront various ethical predicaments as they strive to achieve their objectives.

Many countries across the globe have specific laws and regulations that regulate the promotional and marketing activities like the Physicians Payment Sunshine Act (US), Association of the British Pharmaceutical Industry (ABPI) Code of Practice and French Sunshine (Loi Bertrand) Act that require transparency in reporting payments made to healthcare professionals or the US FCPA and UKBA which mandates ethical business practices. There are publicly accessible databases for disclosing details of payments and other benefits in kind made to Healthcare Professionals (HCP)s like the Open Payments Data in the U.S. and Disclosure UK by ABPI.

With the objective of ensuring ethical marketing practices, the Department of Pharmaceuticals has notified the Uniform Code for Pharmaceutical Marketing Practices 2024 (UCPMP or 'The Code') to all Pharmaceutical Associations for circulating the same to their members for strict compliance to the Code. The provisions of this Code, unless exempted, shall also apply to Medical Device organisations. Further, the Code also prompts compliance by the organisations who are not members of any association.

The Code regulates inter-alia product promotion, conduct of agents as well as medical representatives and interaction with healthcare professionals or their family members (both immediate and extended). Organisations who are part of global groups and some domestic organisations might have their own strict ethical policies, but it is imperative to restructure the policies, as required, and maintain adequate controls to ensure adherence to UCPMP.

This is a monumental change in the Indian pharmaceutical landscape. Hence, adherence to the Code should not be considered as just a regulatory obligation to avoid penalties and damages but a unique opportunity to showcase the industry's commitment to ethical and responsible market practices, ensuring the protection of consumers and the credibility of the industry. Consequently, the tone the leadership sets is of paramount importance.

Did you know?

The executive head of every pharmaceutical / medical device organisation has to submit a self declaration in a prescribed format, confirming their organisation's adherence to UCPMP for the financial year 2024-25.

- DOP Circular no 01 dated 28 May 2024

Key UCPMP guidelines that have to be adhered to by the organisations (1/2)

1. Promotional activities

- Promotional activities must be consistent with its marketing approval and should not be promoted prior to receiving its approval
- These activities should not induce inappropriate prescription, purchase, or use of drugs
- Information about drugs must be accurate, balanced, up to date, must not mislead and should be verifiable.

2. Claims & Comparisons

- Claims about drug efficacy must be based on up-to-evaluation of evidence
- Comparisons of drugs must be factual and fair, without disparagement of competitors, clinical or scientific opinions of healthcare professionals
- Brand names of products of other organisations should not be used in comparison without prior consent
- Other organisations and opinions of HCPs must not be disparaged.

3. Textual and Audio – Visual

- Promotional material must include essential information about the drug, dosage, adverse reactions, etc. so to be consistent with the requirements of the Code
- Mailings and journal advertisements must not be designed to disguise their real nature
- Promotional material must not resemble editorial matter when a pharmaceutical organisation pays for its publication
- The use of healthcare professionals' names or photographs in promotional material is prohibited.

4. Medical Representatives (MRs)

- MRs have been defined to include personnel on organisation's payroll and those retained via contract with third parties
- MRs should maintain high standard of ethical conduct in discharge of their duties
- Must not employ any inducement or subterfuge to gain an interview
- No payment under any guise, for access to a healthcare professional
- Ensure appropriate clause in the contract of the MRs for compliance to the Code.

Key UCPMP guidelines that have to be adhered to by the organisations (2/2)

6. Continuing Medical Education/ Professional Development

- Pharmaceutical engagement with healthcare professionals for CME should follow transparent guidelines
- Conducting events in foreign locations is prohibited
- Details of CME/CPD events including expenditures, must be shared on organisation's website
- Expenditure incurred on such events is subject to the provisions of Income Tax Act, 1961.

5. Brand Reminders

(Educational items and Free samples)

- Informational and educational items used in healthcare settings should not exceed INR 1,000 per item
- Samples shall be marked as "free medical sample not for sale" and distributed for creating awareness. They are not to be supplied to any person who is not qualified to prescribe such a product.
- Each sample pack should not be larger than smallest pack in market
- organisations must maintain records of sample distribution, and sample packs limited to three patients with limits set at twelve sample packs per drug per year per healthcare professional. The monetary value of samples distributed should not exceed two percent of the domestic sales of the organisation per year.
- The giver and recipient of brand reminders should comply with the provisions of Income Tax Act, 1961.

7. Support for Research

- The research should have requisite approval from the competent authority
- Engagement of healthcare professionals in research should adhere to relevant regulations under a consultancy agreement
- Expenditure on research by pharmaceutical organisation is allowable, subject to the provisions of Income Tax Act, 1961.

8. Relationship with HCPs

- No gifts, no benefits in kind, no travel facilities, no hospitality, no cash and monetary grants to healthcare professionals or their family members by organisations or their third parties
- Exceptions related to travel and hospitality exist for speakers at CME/CPD programme.

Indicative perils which should not be ignored (1/2)

A great incentive to give importance to UCPMP is the potential risk of non-compliance brings to the organisation. Depicted below are some of the indicative perils which should not be ignored:

A. Direct repercussions as per the Code

Complaints

- Complaints to be made within six months of the alleged breach of the Code. Related complaints maybe clubbed together
- A Non-refundable fee of INR 1,000 to be deposited for complaints along with the details of the Reporter, name of the alleged organisation and the organisation personnel involved, details of misconduct, etc.
- The complaint must be signed or authorized by organisation's managing director or chief executive officer or at an equivalent level if reported by pharmaceutical organisation.

Handling of complaints

- The enquiry process and decision-making should be taken up by the Ethics Committee of the particular association. Professional auditors may be engaged by associations to assist in investigations
- The respondent organisation shall submit its comments and supporting documents in not more than 30 days after receipt of notice from the Committee
- The Committee should render a decision within 90 days of the receipt of complaint.

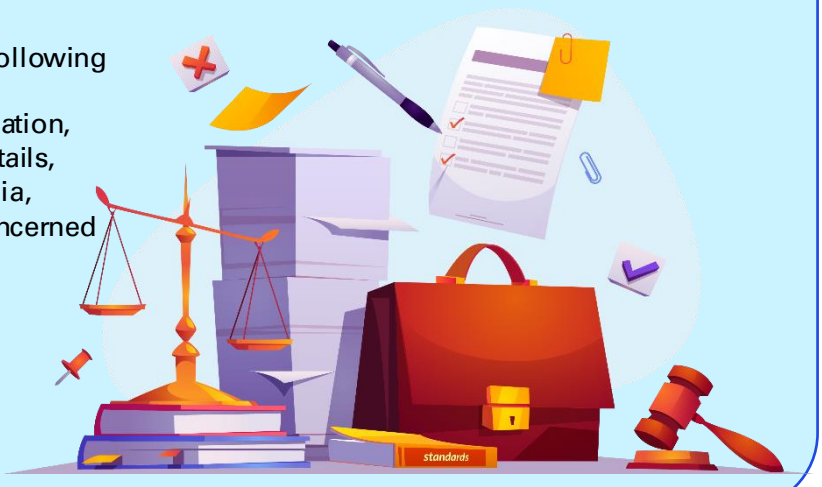
Appeal

- Appeal can be made before an Apex Committee for Pharmaceutical Marketing Practices (ACPMP) if a party to the complaint is dissatisfied
- Time limit to file an appeal will ordinarily be 15 days and a final decision or ruling by the Committee within six months.

Penal provisions

Ethics committee can propose one of the following actions once breach is identified:

- Suspension or expulsion from the association,
- Reprimand including publishing such details,
- Issuance of corrective statements in media,
- Recovery of money or items from the concerned person, or recommendation actions to regulatory agencies through the DoP.



Indicative perils which should not be ignored (2/2)

B. Trickle effect

Lapses on account of inability to comply with the UCPMP guidelines may lead to adoption of various routes of action including legal crisis and financial repercussions, undermining organisational credibility and trust. This may also impact:

- Relationship with the Association and regulatory body
- Monetary and reputational loss
- Employee morale and loss of talent
- Loss of customers and missing revenue targets
- Coming in notice of the Global agencies of similar repute

- Ineligibility to claim deduction of expenses incurred in contravention to the UCPMP guidelines as per the provisions of Section 37(1) / any other provisions of the Income Tax Act, 1961*
- Ineligibility to claim input tax credit of Goods and Service Tax ('GST') paid. (Currently, input tax credit eligibility is not linked with UCPMP)

**It is to be noted that deduction of expenses, under the Income Tax Act, 1961 incurred by a Pharmaceutical Company on HCPs in violation of Medical Council of India ('MCI') guidelines, have always been a matter of litigation and accordingly claim of deduction of such expenses also requires a separate evaluation*

What does UCPMP mean for the organisation?

Implementation of UCPMP has enhanced the obligation for internal and external stakeholders across the organisations whether they have been engaged in managing operational or monitoring aspect of the organisation. They are required to maintain caution and be vigilant while entering into transactions covered under this Code.

A. Key internal stakeholders

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

Actionable as per UCPMP

- Compliance to the points in the Code
- Yearly self-declaration by CEO of the organisation regarding compliance to the UCPMP
- Appropriate clauses in employment contracts with MRs towards adherence of the Code
- Maintain adequate details of the free samples provided to HCPs
- Details of CMEs/CPDs 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 review initiated towards compliance to the Code

B. Key external stakeholders

- Government and regulatory bodies
- Indian Pharma Associations including their Ethics Committee for Pharma Marketing Practices ('ECPMP')
- Channel partners including distributors, liasoning agents etc.
- Organizers of CMEs

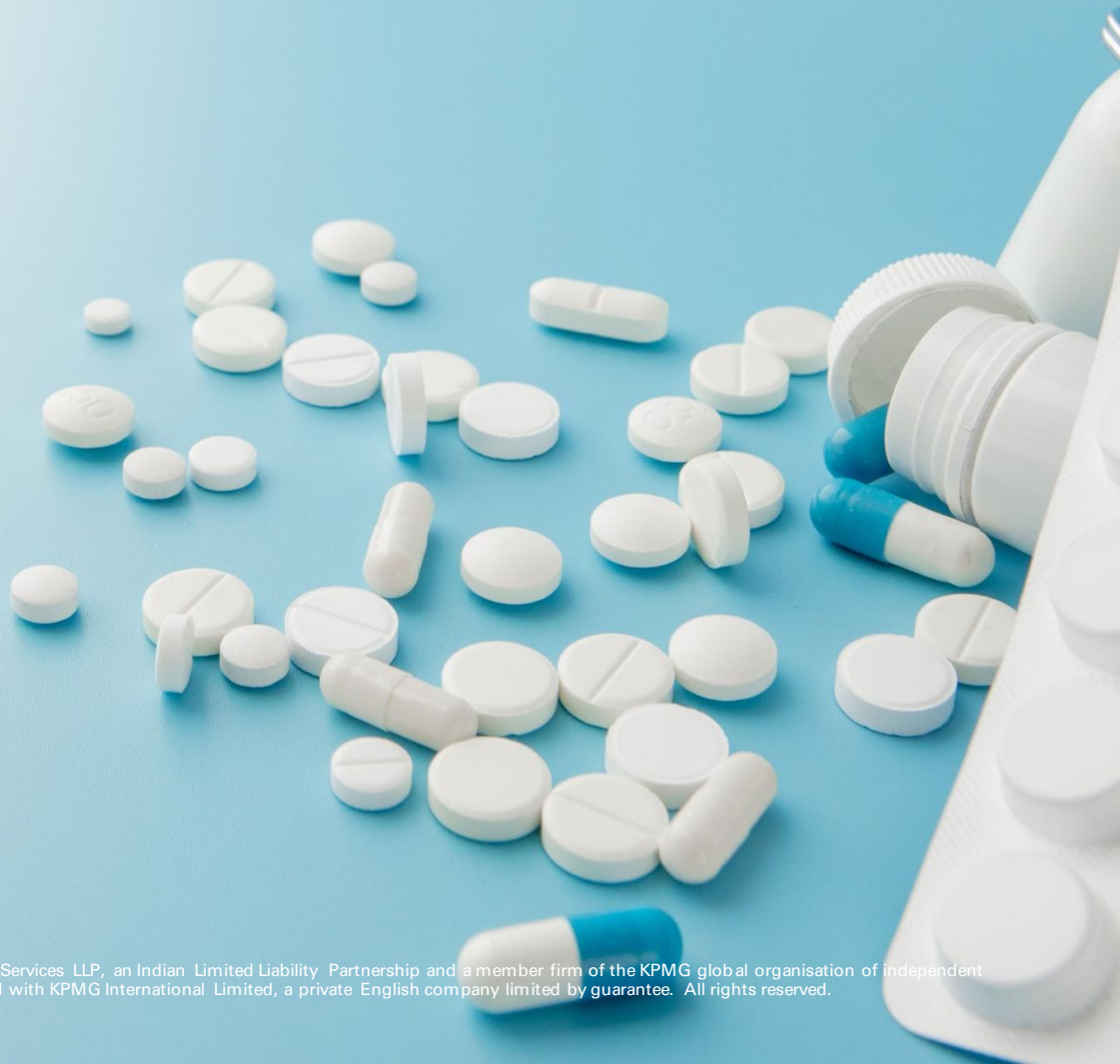
Actionable as per UCPMP

- 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
- Organizers of the CMEs should specify procedure followed towards selection of speakers and participants and a statement of their funding sources / expenditure on their website

What do the organisations need to do to be compliant towards the Code?

In order to adhere with the guidelines prescribed by the DoP through UCPMP, pharmaceutical organisations have to assess their existing framework and implement the changes required in the marketing practices to comply with the Code. Listed below are some illustrative activities can be implemented by pharmaceutical organisations.

Area	Activity
Defined processes / policies	• Revise their policies in line with the Code • Trainings / certification by the employees towards adherence to the Code • Maintain documentation as required.
Adequate controls and monitoring	• Continuous monitoring and proactive reviews • Review the marketing plan in line with the Code • Define a stringent approval matrix towards transactions related to the Code • Update the third party contracts towards adherence to the Code.



How can KPMG in India assist

Considering this recent implementation of stringent UCPMP guidelines by DoP, the immediate step is to assess and evaluate the efficacy of the existing compliance mechanism of the pharmaceutical organisations with respect to marketing and promotion activities.

Some of the immediate better practices identified to tighten the controls and address these areas are as follows:

Policy framework assessment

Assessment of existing framework and designing or revamping of policies and procedures for compliance with UCPMP including any existing policies towards whistleblower mechanism, anti-bribery and corruption, code of conduct

Health check of the various expenses along with the withholding compliances if any to ensure allowability of expenses under the provisions of the Act and review input tax credit eligibility under GST provisions.

Independent reviews

Proactive reviews of the organisation to assess the compliance to UCPMP and Anti bribery and Corruption (ABC) framework. These reviews can also be performed periodically.

Third party risk assessment

With increased emphasis on third parties such as distributors, liaison agents, consultants, etc. being employed by the organisations for transactions related to UCPMP, perform a risk assessment of these parties towards their compliance to the Code.

Training and awareness session

Design and develop training and awareness sessions and delivery of in-person/virtual as well as web-based sessions.

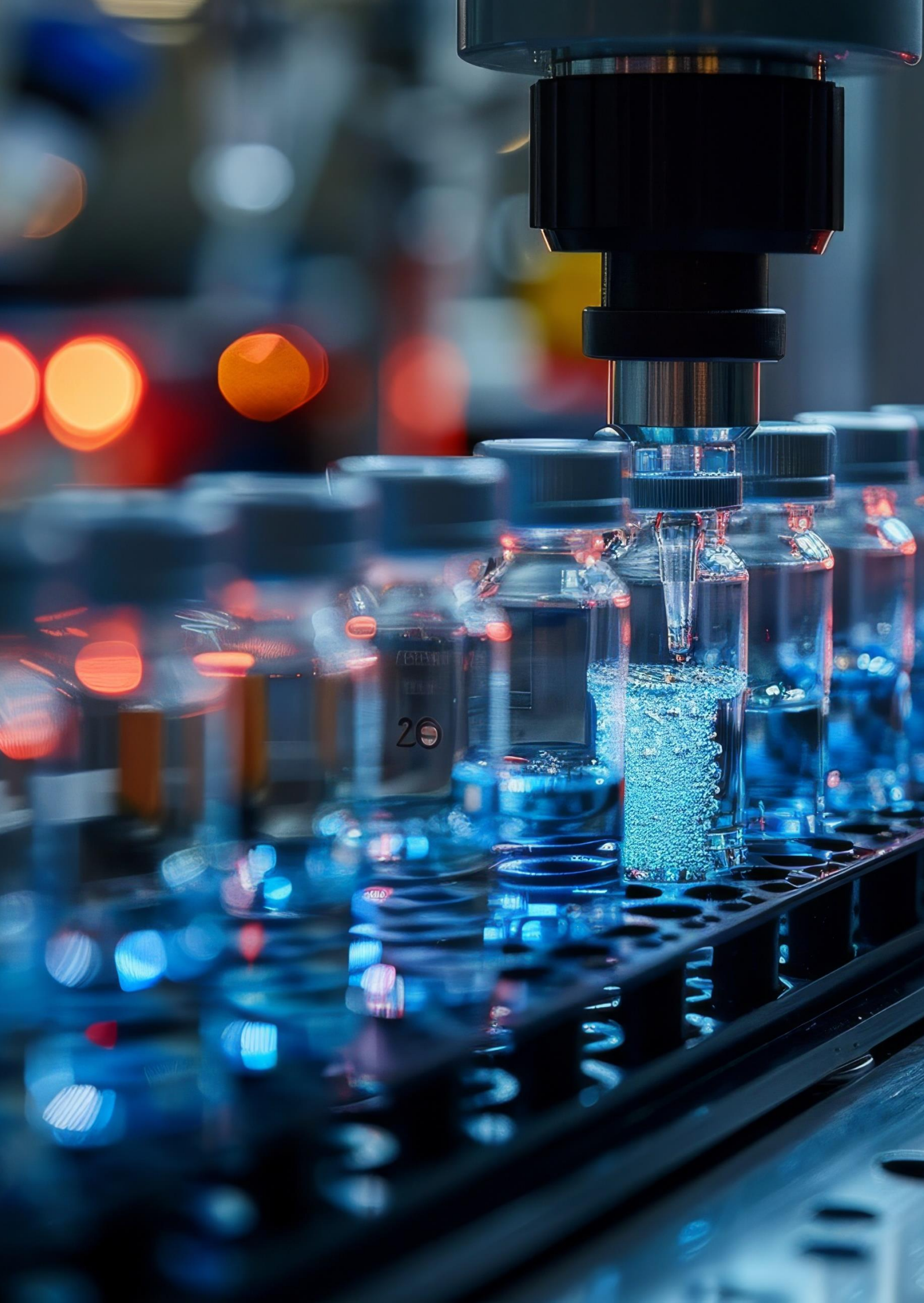
Monitoring mechanism

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

Assist in complaint/ notice

Work with the organisation to assist them in the complaint process to provide the required supporting and perform a risk-based review as necessary to validate the claims

Assist in maintaining list of documents expected to be maintained by the organisation in order to demonstrate/support the claim of expenses under the provisions of the Act.



KPMG in India contacts:

Akhilesh Tuteja
Head
Clients & Markets
E: atuteja@kpmg.com

Manoj Kumar Vijai
Office Managing Partner, Mumbai
Head Risk Advisory
E: mkumar@kpmg.com

Vijay Chawla
Partner and Chief Operating Officer – Consulting
E: vschawla@kpmg.com

Santosh Dalvi
Partner
Tax Head, Life Sciences
E: sdalvi@kpmg.com

Suveer Khanna
Partner and Head
Forensic Services
E: skhanna@kpmg.com

Sudesh Anand Shetty
Partner
Risk Advisory, Life Sciences
E: sashetty@kpmg.com

Pranav Sarvaiya
Technical Director
Forensic Services
E: pranavs1@kpmg.com

kpmg.com/in

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KPMG Assurance and Consulting Services LLP, Lodha Excelus, Apollo Mills Compound, NM Joshi Marg, Mahalaxmi, Mumbai - 400 011 Phone: +91 22 3989 6000, Fax: +91 22 3983 6000.