India's Pharmaceutical Marketing Regulation in the Global Context: Ethics, Enforcement, and Emerging Norms

Deepak Paliwal[1], Puttanna K. [2]
[1]*Research Scholar, Corresponding Author Department of Business Administration, Mangalore University*
[2]*Professor, Department of Business Administration, Mangalore University*
[1]*https://orcid.org/0009-0000-4417-8853*
[2]*https://orcid.org/0009-0009-7029-7667*
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***Abstract*—As of 2025, India's pharmaceutical marketing landscape is governed by a multifaceted regulatory framework integrating statutory mandates, self-regulatory codes, judicial oversight, and evolving digital compliance norms. This article presents a comprehensive analysis of the key legislative instruments—including the Drugs and Cosmetics Act, 1940; the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954; and the Consumer Protection Act, 2019—alongside the operational roles of regulatory bodies such as CDSCO, DoP, PCI, and State Drug Controllers. It critically examines the transition of the Uniform Code for Pharmaceutical Marketing Practices (UCPMP) from a voluntary to a mandatory regime, highlighting its implications for ethical promotion, CEO accountability, and audit enforcement. The study also explores the intersection of medical ethics, influencer liability, and post-marketing surveillance, supported by recent judicial interventions and industry adaptations. Despite the framework's robustness, enforcement bottlenecks and legislative delays persist, especially in the digital and AYUSH sectors. The article concludes by emphasising the need for sustained vigilance, digital harmonisation, and stakeholder collaboration to uphold ethical standards in India's rapidly evolving pharmaceutical market.**

***Index Terms*—Pharmaceutical marketing regulation, UCPMP 2024, Consumer Protection Act 2019, ethical promotion, medical ethics, ASCI guidelines,**

I. INTRODUCTION

In India, the regulatory landscape governing pharmaceutical marketing is a complex mosaic shaped by historical legislation, evolving government policies, judicial oversight, and a growing emphasis on ethics and compliance. As of 2025, the Indian pharmaceutical industry ranks as the third-largest globally by volume, making the imperative to ensure public health and ethical promotion even more pronounced. The sector's marketing practices are regulated through a confluence of statutory enactments, executive guidelines, codes of conduct developed by both government and industry bodies, and a robust judicial tradition. This report delivers a comprehensive analysis of all core laws, governmental and quasi-governmental agencies' roles, industry self-regulation, recent updates, and the real-world enforcement mechanisms that collectively create India's current approach to pharmaceutical marketing regulation.

Overview of Key Regulatory Authorities and their Mandates

1.1 Central Drugs Standard Control Organisation (CDSCO)

As India's National Regulatory Authority (NRA), the CDSCO acts under the Directorate General of Health Services, Ministry of Health & Family Welfare, and is primarily responsible for the approval of new drugs, monitoring of clinical trials, ensuring the enforcement of quality standards, and overseeing the import and control of drugs[1]. The CDSCO coordinates with State Drug Control Organisations to guarantee uniform application of the Drugs and Cosmetics Act, 1940 and the associated Rules of 1945. The scope of CDSCO oversight fundamentally shapes drug marketing practices by dictating which drugs can be sold and on what terms, and, crucially,

by scrutinising post-marketing activities such as safety monitoring (pharmacovigilance) and approving all associated advertising material involving new products.

Key Functions

- Approval of new drugs and clinical trials
- Enforcement of drug standards and GMP
- Post-marketing surveillance and pharmacovigilance
- Licensing for import of drugs
- Coordination with state licensing authorities for domestic manufacturers
- Issuing guidance documents on distribution practices and quality standards[2]

The CDSCO updates its operational guidance regularly to align with new scientific standards and global best practices, including recent guidelines on risk-based monitoring at ports and Good Distribution Practices (GDP) for pharmaceutical products[3].

1.2 State Drug Controllers

State drug control authorities operate as enforcement arms at the state level, ensuring compliance with the central framework. They license manufacturers, wholesalers, and retailers, conduct inspections, sample testing, and initiate prosecutions for violations such as misbranding or unauthorised sales. They are also the first line of enforcement under the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954, often handling the majority of complaints regarding improper drug promotion[4,5].

1.3 Pharmacy Council of India (PCI)

The PCI, under the Pharmacy Act of 1948, not only prescribes the standards of pharmacy education and practice but exerts an indirect influence on pharmaceutical marketing by ensuring that only registered pharmacists engage in drug dispensing and by issuing circulars and annual handbooks that reinforce ethical promotional practices[6]. The Council's guidelines require compliance with UGC and state norms, highlight the importance of skill development, and celebrate events like Pharmacovigilance Week, reflecting a commitment to pharmaceutical ethics and transparency.

1.4 Department of Pharmaceuticals (DoP)

Functioning under the Ministry of Chemicals and Fertilisers, the Department of Pharmaceuticals sets overarching policy for regulating pharmaceutical marketing and has led the drive towards the Uniform Code for Pharmaceutical Marketing Practices (UCPMP) 2024, giving compliance a more statutory underpinning with robust self-regulatory and reporting compulsion[7].

II. LEGISLATIVE AND REGULATORY FRAMEWORK

2.1 Drugs and Cosmetics Act, 1940 and Rules, 1945

This Act is the foundational statute for India's drug regulation, defining the boundaries of lawful manufacture, sale, and advertisement of drugs.

Key Provisions Related to Marketing:

- Section 18: Prohibits the manufacture/sale of any drug that is not of standard quality, misbranded, or makes unauthorised therapeutic claims.
- Section 29: Penalises use of government analytical reports in advertising[8].
- Labelling and Promotional Claims: Strict requirements as per Rules for correct labelling and prohibitions against false or exaggerated claims.
- Schedules H, H1, X: Prohibit the advertisement of certain drugs without sanction.
- Schedule J: Specifically restricts advertising of drugs as cures for specified diseases.

The Rules are continuously updated, most recently reflecting international harmonisation and addition of GDP and pharmacovigilance requirements for marketing authorisation holders[9,10].

2.2 Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 (DMROA)

This Act specifically targets advertising practices, prohibiting any advertisement of drugs purporting to treat, cure, or prevent diseases listed in its Schedule (which includes cancer, diabetes, sexual ailments, etc.), or making false or misleading claims generally. Notably:

- Section 3: Bans advertisements for over 50 critical conditions.
- Section 4: Forbids false or misleading advertisements.
- Section 7: Stipulates imprisonment and/or fine for violations.
- Section 9: Makes company officers liable for corporate offences[11].

DMROA covers all systems of medicine: Ayurvedic, Unani, Siddha, and allopathic. Importantly, recent years have seen court interventions (notably in the Patanjali and AYUSH advertisement controversies) reinforce the need for stringent enforcement[12,13].

Recent Update:

Draft amendments to increase penalties and expand the list of prohibited disease claims have stalled since 2020, with proposals for sharper punitive measures and enhanced enforcement powers languishing pending legislative approval[14].

2.3 Consumer Protection Act, 2019

The CPA 2019 gives the Central Consumer Protection Authority powers to act against misleading advertisements of pharmaceuticals and holds not only sellers, but also endorsers and influencers, accountable for substantiating claims[15,16].

- Section 2(28): Defines misleading advertisement in detail, including false guarantee, concealment, and misrepresentation.
- Section 21: Central Consumer Protection Authority can order withdrawal or modification of misleading advertisements, and levy fines up to ₹10 lakh (and up to ₹50 lakh for repeat offences).
- Section 89: Allows for imprisonment up to two years, a fine, or both.
- Section 10: Establishes the Central Consumer Protection Authority (CCPA).
- Influencer and Endorser Liability: Uniquely, the CPA 2019 holds influencers/bloggers/social media endorsers personally responsible for substantiating health claims and, if necessary, for paying penalties[15].

2.4 Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002

Though this governs doctors' conduct, it directly intersects with pharmaceutical marketing because:

- Section 6.1 and 6.4: Strictly prohibit doctors from advertising services, endorsing drugs/products, or accepting any gifts, commissions, or benefits from pharmaceutical companies in return for brand endorsement or promotion of particular medicines[17,18].
- Disciplinary sanctions-suspension or removal from the medical register-are imposed on violations, and widely publicised cases attest to these regulations being enforced.

2.5 Uniform Code for Pharmaceutical Marketing Practices (UCPMP) 2024

Legal Status and Recent Amendments

The UCPMP is now mandatory, representing a step-change from the voluntary 2014 code. As per circulars and notifications up to September 2025, all pharmaceutical companies (including medical device firms, unless specifically exempted) are required to comply, and failure to do so can result in public sanction and even expulsion from industry associations[19,20,21].

Key Provisions

- Evidence-based Claims: All advertising and promotional material must be supported by verifiable scientific evidence, with a direct ban on exaggerated or unsubstantiated claims.
- Material Limits: Gifts and promotional incentives, including sample packs, are capped: medical information items (e.g., books/calendars) must not exceed ₹1,000 per item, free samples per brand per doctor cannot exceed twelve packs per year, and the total value of annual samples must not exceed 2% of a company's domestic sales.
- Transparency and Public Disclosure: Companies are compelled to furnish annual declarations of compliance with the Code. CEOs are made personally responsible for this compliance, submitting self-declarations on the association or DoP portal[22].
- Regulation of Continuing Medical Education (CME): Pharma sponsorship for CME and medical research is tightly regulated. Foreign trips are prohibited. Participation/funding must be transparently disclosed and may be subject to audit.
- Gifts, Hospitality, and Sponsorship: Any form of direct or indirect gift, hospitality, or non-bona-fide funding to health professionals, or their family members, is now rigorously banned.
- Complaints Adjudication: Each association must have an Ethics Committee for Pharma Marketing Practices (ECPMP) to expeditiously handle complaints, with appeal provisions at the Apex Committee for Pharma Marketing Practices (ACPMP).

- Sales Team/Representative Conduct: Companies are liable for the actions of their representatives, and third-party agents must also be trained and compliant[23,24].

Enforcement and Penalties

Penalties range from corrective action and exclusion from associations to referral to government authorities in cases of gross or repeated violations. The UCPMP also details explicit audit obligations for record keeping, particularly of samples and CME sponsorships[22].

2.6 OPPI Code of Pharmaceutical Practices 2019

Leading global and domestic pharmaceutical companies in India are also bound by the Organisation of Pharmaceutical Producers of India (OPPI) Code, which is closely aligned with the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) principles[25].

OPPI Code Highlights

- Focuses on patients' welfare, integrity, transparency, and accuracy in all promotional communications.
- Prohibits direct-to-consumer promotion of prescription drugs and bans all personal gifts or cash incentives to healthcare professionals.
- Sets rigorous standards for scientific substantiation and restricts event sponsorships to only bona fide professional gatherings, without any leisure or entertainment components.
- Internal company procedures must ensure compliance with complaint-handling and whistleblower mechanisms.

2.7 Other Industry Codes

- IPA and FICCI: Both the Indian Pharmaceutical Alliance and FICCI are signatories to the UCPMP and maintain liaison with the DoP for handling complaints, member self-declarations, and compliance training[1920].
- IDMA (Indian Drug Manufacturers' Association): Has its own Ethics Committee for enforcement at the national level[26].

2.8 Good Distribution Practices (GDP)

The CDSCO's GDP guidelines are based on WHO technical standards, focusing on the quality and traceability of drugs throughout the supply chain. Points of concern include:

- Preventing spurious, misbranded, or substandard drugs from entering the market
- Requiring documented procedures for storage, handling, and recall
- Mandatory licensing for all supply chain participants
- All distribution activity (including storage and transport) is subject to periodic self-inspection and audit[23].

2.9 Advertising Standards Council of India (ASCI) Guidelines

ASCI, the principal self-regulatory organisation for advertising, issues healthcare-specific guidelines against misleading claims and imposes procedural standards for influencer and social media marketing. Key 2025 amendments require influencers to disclose qualifications and endorsements in technical health or nutrition products; generic (non-technical) promotions are exempt from such disclosures, but all promotional content must carry appropriate disclaimers and not mislead the lay audience[27,28].

III. RECENT JUDICIAL DECISIONS AND REGULATORY ENFORCEMENT

3.1 Supreme Court Oversight

Indian courts, particularly the Supreme Court, have stepped up their direct intervention in pharmaceutical advertising matters in recent years. Notable examples include:

- Indian Medical Association vs. Union of India (2024-2025): The Supreme Court closely scrutinized misleading ads by Patanjali and others, temporarily stayed the removal of Rule 170 of the Drugs and Cosmetics Rules (which had required state pre-approval for Ayush ad claims), and ultimately vacated the stay, allowing Ayush companies to advertise without pre-clearance but with existing statutory controls remaining in force[12,13].
- Apex Laboratories v. DCIT (2022): Supreme Court held that "freebies" to doctors by pharmaceutical companies are not a legitimate tax-deductible expense, strengthening the practical impact of ethical marketing rules.

3.2 Regulatory Actions

- ASCI Investigations: The Advertising Standards Council of India routinely flags and removes misleading advertisements in the healthcare

sector and now actively monitors digital influencer campaigns.

- CCPA Enforcement: The Central Consumer Protection Authority has fined manufacturers, social media influencers, and even platforms for propagating misleading or false medical claims, especially during the COVID-19 pandemic[15].

Table 1:
Summary of Key Regulations and Responsible Authorities

Regulation / Guideline	Key Provisions	Responsible Authority
Drugs and Cosmetics Act, 1940 & Rules, 1945	Drug approval, licensing, labelling, compliance; bans on misbranding, misrepresentation	CDSCO, State Drug Controllers
Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954	Prohibits misleading health claims and advertising for several listed diseases	Ministry of Health & Family Welfare, State Drug Controllers
Uniform Code for Pharmaceutical Marketing Practices (UCPMP) 2024	Mandatory code of ethical pharma promotion, CEO self-declaration, audit, and strict bans on gifts	Department of Pharmaceuticals (DoP), Pharma Associations
OPPI Code of Pharmaceutical Practices 2019	Industry code for India's leading pharma companies: no gifts, strict substantiation, reporting	OPPI
Indian Medical Council Regulations, 2002	The Code of Ethics for Doctors prohibits endorsements, gifts, and rebates from pharma companies	National Medical Commission, State Medical Councils
Consumer Protection Act, 2019	Empowers CCPA to police and penalise misleading pharma ads, including influencer liability	CCPA, Ministry of Consumer Affairs
Advertising Standards Council of India (ASCI) Guidelines	Advertising code: misleading claims, influencer endorsements, health promotions, self-regulation	ASCI
Good Distribution Practices (GDP) Guidelines (CDSCO)	Supply chain integrity, documentation, recalls, and anti-spurious drug measures	CDSCO
State Drug Controller Rules and Licensing	Local inspections, licensing, enforcement of labelling, supply, and sale norms	State Drug Controllers

IV. RECENT AND EMERGING POLICY DEVELOPMENTS (2024-2025)

4.1 UCPMP 2024: Statutory Muscle and Digital Enforcement

The shift from a voluntary to a mandatory UCPMP, backed by CEO declarations and online compliance portals, marks a huge transformation in the regulatory regime. The establishment of Ethics Committees at every pharma association and the mandatory maintenance of detailed records for samples, CME sponsorship, and event expenditures are directly intended to clean up the pharma-HCP interface[22].

Details such as brand reminder, monetary caps, explicit bar on direct or indirect gifts or non-bona fide sponsorship, and reporting guidelines are now strictly enforceable and auditable.

4.2 Expanded Role for the CCPA and Consumer Rights

The Central Consumer Protection Authority has acted assertively against misleading or unsubstantiated health claims, especially prominent during the COVID-19 pandemic, and has begun targeting not just manufacturers but influencers, celebrities, and digital media platforms for noncompliance[29].

4.3 Supreme Court and High Court Vigilance

Judicial oversight-seen in the Supreme Court's monitoring of misleading advertising cases, and in various consumer court orders against companies and endorsers-continues to drive regulatory focus on stricter standards.

4.4 Digital, Social, and Influencer Guidelines

- The ASCI's 2025 update now distinguishes between general product promotions and technical-health claims requiring professional qualifications, reflecting the importance of both consumer protection and the practical realities of digital promotion[27].
- Influencers are required to disclose brand relationships and, when making technical claims, must be qualified health professionals.

4.5 Pharmacovigilance and Post-Marketing Surveillance

Recent CDSCO guidelines require more frequent reporting of safety data, greater transparency, and AI-based monitoring systems for early detection of adverse effects. Companies must have robust pharmacovigilance departments, submit periodic safety update reports (PSURs), and actively report all adverse events to the licensing authorities, impacting the scope of claims that can be made in promotions[9,10].

4.6 Industry Feedback and Compliance Audits

Pharma companies are investing significantly in compliance training, documentation systems, and audit readiness. The capital and administrative burden is offset by reputational gains and risk mitigation in both global and domestic markets.

V. PRACTICAL ENFORCEMENT: STATE AND COMPANY-LEVEL ACTIONS

5.1 Licensing and Inspections

All sales and manufacturing operations must hold valid licenses, subject to periodic inspection by State Drug Controllers. Any promotional infraction unearthed during inspections (e.g., unapproved claims, inadequate labelling, promotional gifts) can result in immediate suspension of licenses and prosecution.

5.2 Complaint Mechanisms and Ethics Committees

- Each major industry association (IPA, FICCI, OPPI) runs a complaint portal, with a public record of compliance declarations and resolved cases[19].
- Unresolved grievances can be escalated to the DoP, the ACPMP, or even the CCPA and courts.

VI. ONGOING CHALLENGES AND UNRESOLVED ISSUES

6.1 Enforcement Bottlenecks

While the regulatory framework is detailed and theoretically robust, in practice, enforcement faces challenges due to the vastness of the Indian market, a proliferation of small and medium manufacturers, inadequate resources and expertise at the local level, and emerging complexities in digital and influencer-driven advertising.

6.2 Pending Legislative Updates

Amendments to the Drugs and Magic Remedies Act aimed at expanding prohibited claims and stiffening penalties remain stalled. The lack of clear, updated rules for digital media and the full integration of Ayush products into the modern compliance framework are still works in progress.

6.3 Industry Adaptation

Many companies, especially multinationals and leading Indian corporates, have proactively remade their marketing, medical affairs, and compliance operations. However, smaller firms and regional players may lag, exposing gaps in market-wide compliance and uniform application of the UCPMP.

VII. CONCLUSION

The regulatory framework governing pharmaceutical marketing in India as of 2025 is, by global standards, extensive and rigorously defined. Anchored by the Drugs and Cosmetics Act, the DMROA, and

enforced through statutory and self-regulatory codes like UCPMP 2024, the system now increasingly leverages digital compliance, CEO accountability, and a multi-tiered complaints handling and enforcement strategy. The continuous evolution of jurisprudence, regulatory circulars, and industry codes signals a maturing landscape where ethical marketing is both a statutory expectation and a strategic business necessity.

Constant vigilance, periodic legislative upgrades, digital adaptation, industry-academia-government collaboration, and judicial intervention will remain the necessary pillars for India to sustain and advance its leadership as a provider of high-quality, ethically promoted medicines in the coming decade. Companies, health professionals, influencers, and consumers alike must adapt to this new era of transparency, substantiation, and accountability.

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