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FROM VOLUNTARY CODE TO STATUTORY REGULATION: RETHINKING THE REGULATION OF PHARMACEUTICAL MARKETING IN INDIA

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ABSTRACT

Pharmaceutical marketing occupies a distinctive position within commercial regulation because the consequences of promotional practices extend beyond ordinary consumer choice and can directly influence medical decision-making and public health. In India, the regulation of pharmaceutical marketing has primarily developed through the Uniform Code for Pharmaceutical Marketing Practices (“UCPMP”), which has historically operated as a voluntary framework. Although the UCPMP 2024 strengthened and expanded the regulatory standards applicable to pharmaceutical companies, its voluntary character raises fundamental questions concerning enforcement, accountability and the availability of effective remedies for violations. The Supreme Court’s decision in *Federation of Medical Representatives Association of India v Union of India* (“FMRAI”) brings these concerns into sharper focus and provides an opportunity to reconsider whether pharmaceutical marketing can adequately be regulated through voluntary industry standards. This paper examines the evolution of pharmaceutical marketing regulation in India and evaluates the structural limitations of the existing voluntary framework. It argues that the central weakness of the UCPMP is not merely the absence of statutory force, but the absence of an independent and effective enforcement architecture. Accordingly, simply granting statutory status to the existing Code would not, by itself, resolve the regulatory deficit. The paper proposes a broader statutory framework combining clearly defined prohibited practices, independent regulatory oversight, accessible complaint and investigation mechanisms, proportionate sanctions and mandatory transparency requirements. At the same time, it argues that regulation must distinguish between legitimate scientific and commercial communication and practices capable of improperly influencing medical decisions. The paper therefore advocates a model of regulated self-regulation in which industry expertise may contribute to standard-setting, while enforcement remains subject to independent statutory supervision. It concludes that an effective pharmaceutical marketing

regime must move beyond voluntary ethical guidance towards a system of regulatory accountability capable of protecting the integrity of medical decision-making and, ultimately, patient interests.

INTRODUCTION

The pharmaceutical industry occupies a peculiar position within the market economy. Pharmaceutical companies operate as commercial entities seeking to promote and sell their products, but the consumption of those products is ordinarily mediated by healthcare professionals whose prescribing decisions have direct consequences for patients. This makes pharmaceutical marketing fundamentally different from conventional commercial promotion. The manner in which medicines are promoted can influence not only the commercial success of a pharmaceutical product but also prescribing practices, healthcare expenditure and, ultimately, the quality and accessibility of healthcare. The possibility that commercial incentives may influence medical decision-making therefore creates a regulatory concern that extends beyond the relationship between a company and its customers.¹

Pharmaceutical marketing in India has historically been regulated through a combination of statutory provisions, professional regulations and industry-led codes. The Uniform Code for Pharmaceutical Marketing Practices (“UCPMP”) was introduced in 2015 as a voluntary framework intended to regulate promotional practices adopted by pharmaceutical companies and medical-device manufacturers. It was subsequently revised through the UCPMP 2024. The framework addresses practices such as the provision of gifts and hospitality to healthcare professionals, travel facilities, monetary grants, continuing medical education and the distribution of free samples. However, its voluntary character has remained a significant limitation. While the UCPMP establishes standards of conduct, questions concerning the binding nature of those standards, the independence of enforcement mechanisms and the consequences of non-compliance have continued to raise concerns regarding the effectiveness of the regulatory framework.²

These concerns have acquired greater significance in *FMRAI v Union of India*, in which the Supreme Court was confronted with allegations concerning unethical pharmaceutical marketing practices and the adequacy of the existing regulatory framework. The proceedings have brought renewed attention to the question whether pharmaceutical marketing can

¹ World Health Organization, ‘Ethical Criteria for Medicinal Drug Promotion’ (WHO, 1988) 1–3.

² Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India, ‘Uniform Code for Pharmaceutical Marketing Practices (UCPMP) 2015’ (2015).

effectively be governed through voluntary industry standards or whether the nature of the public-health interests involved requires a legally enforceable statutory framework. The significance of *FMRAI*, therefore, extends beyond the particular practices challenged before the Court³. It raises a broader regulatory question: **whether an industry should be permitted to substantially regulate its own promotional practices where the consequences of those practices may extend to patients and the wider healthcare system.**

The case also exposes a more fundamental distinction between **regulation on paper and regulatory accountability in practice**. Merely identifying prohibited or undesirable conduct does not necessarily ensure compliance. An effective regulatory framework must also determine who can investigate violations, who can initiate proceedings, what sanctions may be imposed, whether affected persons can access an effective complaint mechanism and whether the body responsible for enforcement possesses sufficient independence from the industry it regulates. Consequently, the central weakness of the existing framework may not lie solely in the absence of statutory force, but also in the institutional architecture through which pharmaceutical marketing is regulated.⁴

This paper argues that India requires a shift from voluntary pharmaceutical marketing standards towards a **statutory and independently enforceable regulatory framework**. However, simply granting statutory status to the UCPMP would not, by itself, resolve the underlying regulatory deficiencies. A meaningful statutory regime must combine clearly defined substantive prohibitions with independent enforcement, accessible complaint mechanisms, proportionate sanctions and greater transparency concerning financial and other relationships between pharmaceutical companies and healthcare professionals. The objective should not be to prohibit legitimate scientific communication or pharmaceutical promotion, but to distinguish such legitimate activity from practices capable of improperly influencing prescribing decisions.⁵

The paper proceeds in five broad stages. First, it examines the evolution of pharmaceutical marketing regulation in India and the regulatory framework established under the UCPMP 2015 and UCPMP 2024. Second, it analyses *FMRAI v Union of India* and the concerns it raises regarding the voluntary nature of the existing framework. Third, it examines the enforcement deficit and structural limitations associated with industry self-regulation. Fourth, it evaluates whether merely giving statutory force to the existing UCPMP would be sufficient and proposes

³ Federation of Medical and Sales Representatives Association of India v Union of India, Writ Petition (Civil) No 323 of 2021 (SC, 8 October 2026) paras 1–5.

⁴ *ibid* paras 15–19.

⁵ *ibid* paras 20–22.

elements of a more effective statutory framework. Finally, the paper considers whether transparency and mandatory disclosure of pharmaceutical companies' relationships with healthcare professionals should complement substantive prohibitions. Through this analysis, the paper seeks to demonstrate that the transition from voluntary regulation to statutory regulation should not be understood merely as a change in legal status, but as an opportunity to construct a more accountable, transparent and effective system of pharmaceutical marketing regulation in India.

THE EXISTING REGULATORY FRAMEWORK: FROM UCPMP 2015 TO UCPMP 2024

The regulation of pharmaceutical marketing in India has developed through a combination of statutory regulation, professional standards and industry-led mechanisms. Unlike sectors where commercial conduct is governed predominantly through a single comprehensive statute, pharmaceutical promotion is subject to several overlapping regulatory instruments. The UCPMP represents the principal framework specifically directed towards the marketing practices of pharmaceutical companies. Its development from a voluntary code in 2015 to the revised UCPMP 2024 reflects the government's continuing attempt to address concerns surrounding the promotion of medicines and the relationship between pharmaceutical companies and healthcare professionals. However, the regulatory significance of the UCPMP cannot be assessed merely by examining the conduct it seeks to regulate. Its institutional design and enforcement mechanism are equally important in determining whether the standards it establishes can operate effectively.

A. Evolution of Pharmaceutical Marketing Regulation in India

The UCPMP was introduced in 2015 against the backdrop of persistent concerns regarding the use of gifts, hospitality and other benefits to influence the prescribing practices of healthcare professionals. The Code sought to establish ethical standards for pharmaceutical companies in their interactions with healthcare professionals and to discourage promotional practices that could compromise professional independence. Importantly, however, the 2015 Code was voluntary. Its effectiveness consequently depended to a substantial extent upon the willingness of pharmaceutical companies and industry associations to comply with the standards that it prescribed.⁶

⁶ UCPMP 2015 (n 3).

The voluntary nature of the framework became particularly significant because pharmaceutical marketing frequently involves conduct that may be commercially advantageous to both the company and, in certain circumstances, the recipient of the benefit. A regulatory framework that relies principally upon voluntary compliance therefore faces an inherent difficulty: the regulated entities have an economic interest in the conduct that the framework seeks to constrain. The problem is not necessarily that every interaction between pharmaceutical companies and healthcare professionals is improper. Rather, it is that the absence of sufficiently binding standards and effective sanctions may make it difficult to distinguish legitimate scientific and commercial engagement from inducements capable of influencing prescribing decisions.

The UCPMP 2024 represented an attempt to strengthen and update this framework. It retained restrictions on several forms of promotional activity while providing more detailed standards concerning the interaction between pharmaceutical companies and healthcare professionals. The revised Code therefore reflects a recognition that pharmaceutical marketing requires more specific regulatory standards. Nevertheless, its basic character as an industry-oriented code remains central to the debate concerning its effectiveness.⁷

B. Substantive Regulation under the UCPMP 2024

The UCPMP 2024 regulates a range of practices through which pharmaceutical companies may promote their products or interact with healthcare professionals. Among the principal areas addressed by the Code are gifts, travel facilities, hospitality, monetary grants and the provision of pharmaceutical samples. The underlying regulatory objective is to prevent commercial benefits from becoming instruments through which pharmaceutical companies obtain an improper influence over medical decision-making.⁸

The regulation of gifts is particularly important in this context. Benefits provided to healthcare professionals may appear individually insignificant, but their regulatory significance lies in the possibility that such benefits may create an obligation, expectation or commercial relationship that affects prescribing behaviour. The Code therefore seeks to draw a boundary between legitimate professional interaction and benefits that may operate as inducements.⁹

Similar concerns arise in relation to travel and hospitality. Pharmaceutical companies frequently participate in conferences, educational programmes and professional events

⁷ UCPMP 2024 (n 2) paras 4–8.

⁸ *ibid* paras 4–8.

⁹ *ibid* para 4.

involving healthcare professionals. Such activities may serve legitimate educational purposes and contribute to the dissemination of scientific information. At the same time, the financing of travel, accommodation or other expenses can create opportunities for commercial influence. The regulatory challenge is consequently not simply to prohibit all interaction between the pharmaceutical industry and healthcare professionals, but to determine when such interaction crosses the line from legitimate professional engagement into improper inducement.¹⁰

The Code also addresses monetary grants and continuing medical education. Medical education occupies a particularly sensitive position because pharmaceutical companies can legitimately contribute to the dissemination of scientific and clinical information, while simultaneously possessing an incentive to promote their own products. The regulatory framework must therefore ensure that educational activities remain genuinely educational rather than becoming indirect mechanisms for product promotion or the cultivation of prescribing relationships.¹¹

The provision of free samples presents another regulatory concern. Samples can have legitimate purposes, including enabling healthcare professionals to familiarise themselves with a new medicine. However, the uncontrolled distribution of samples may also operate as a promotional device. Regulation of sampling is therefore intended to prevent a legitimate marketing practice from becoming an avenue for excessive or inappropriate promotion.

Taken together, these provisions demonstrate that the UCPMP does not seek to prohibit pharmaceutical marketing as such. Its objective is to regulate the methods through which pharmaceutical products are promoted and to prevent commercial incentives from improperly influencing healthcare professionals. The distinction is important because an effective regulatory framework must preserve legitimate communication concerning medicines while restricting practices that undermine professional independence.

C. Institutional and Enforcement Architecture

The effectiveness of any regulatory code depends not only upon the substantive standards that it establishes but also upon the institutions responsible for implementing them. Under the UCPMP framework, industry associations and their designated mechanisms have an important role in receiving and addressing complaints concerning alleged violations. The Ethics Committee for Pharma Marketing Practices (“ECPMP”) functions within this framework as a mechanism for examining complaints relating to pharmaceutical marketing practices.¹²

¹⁰ ibid para 5.

¹¹ ibid para 6.

¹² ibid paras 9–11.

This institutional arrangement reflects the broader reliance of the UCPMP on self-regulation. Pharmaceutical industry associations participate significantly in the implementation and enforcement of the Code, rather than enforcement being placed exclusively in the hands of an independent statutory regulator. Such an approach has certain advantages. Industry bodies possess technical knowledge of pharmaceutical marketing and may be able to identify problematic practices more efficiently than a general regulatory authority. Self-regulation can also provide flexibility and allow industry standards to respond more rapidly to changing promotional practices.¹³

However, the same arrangement creates questions concerning independence and accountability. Where the entities subject to regulation participate substantially in the administration of the regulatory framework, the possibility of conflicts of interest cannot be ignored. The effectiveness of self-regulation therefore depends upon the credibility of the enforcement process, the transparency of decisions, the availability of meaningful sanctions and the ability of affected parties to obtain effective remedies.¹⁴

This institutional dimension becomes particularly important when the UCPMP is compared with a statutory regulatory framework. A statutory regime would not merely transform the Code's substantive standards into legally binding obligations. It could also establish an independent authority, prescribe investigation and adjudication procedures, provide statutory penalties and create avenues for appeal and judicial review. The distinction between these two models forms the basis for assessing whether India's existing approach is capable of adequately addressing unethical pharmaceutical marketing.

The evolution from UCPMP 2015 to UCPMP 2024 therefore demonstrates both progress and limitation. India has developed increasingly detailed standards governing pharmaceutical promotion, but the existence of substantive standards does not necessarily guarantee effective compliance. The central regulatory question is consequently no longer simply **what pharmaceutical companies should or should not do**, but **who should enforce those standards and what consequences should follow when they are violated**. It is against this background that *FMRAI v Union of India* assumes significance.¹⁵

FMRAI V UNION OF INDIA: THE JUDICIAL CHALLENGE TO

¹³ Julia Black, 'Constitutionalising Self-Regulation' (1996) 59 Modern Law Review 24, 25–27.

¹⁴ Ian Ayres and John Braithwaite, *Responsive Regulation: Transcending the Deregulation Debate* (Oxford University Press 1992) 4–7.

¹⁵ *FMRAI* (n 4) paras 1–4.

VOLUNTARY REGULATION

The debate surrounding the regulation of pharmaceutical marketing acquired renewed significance in *Federation of Medical Representatives Association of India v Union of India*. The litigation brought before the Supreme Court concerns the manner in which pharmaceutical companies market their products and the potential consequences of promotional practices that may influence the prescribing decisions of healthcare professionals. More importantly, the proceedings place the legal status and institutional effectiveness of the UCPMP at the centre of the regulatory debate. The case therefore provides an important point of departure for examining whether voluntary industry regulation is adequate where the conduct being regulated may affect public health.

A. Background to the Litigation

The concerns raised in *FMRAI* arise from the broader relationship between pharmaceutical companies and healthcare professionals. Pharmaceutical companies necessarily engage with doctors and other healthcare professionals to disseminate information about their products. Such interaction is not inherently problematic and may serve a legitimate scientific purpose. However, the relationship becomes legally and ethically problematic when promotional activities involve financial or non-financial benefits that may influence prescribing decisions.¹⁶ The petitioners raised concerns regarding practices such as the provision of gifts, hospitality, travel facilities and other benefits to healthcare professionals. The underlying concern was that such practices could transform the prescribing decision from one based primarily upon clinical considerations into one influenced, at least in part, by commercial incentives. The issue is particularly significant in the pharmaceutical sector because the person who makes the prescribing decision is often not the person who ultimately bears the financial and health consequences of that decision.¹⁷

The litigation consequently raises a broader public-interest concern. Pharmaceutical marketing does not merely determine which company sells a particular product. Where promotional practices influence prescribing behaviour, they may affect the choice, quantity and cost of medicines consumed by patients. Unethical marketing can therefore have consequences extending beyond commercial competition and into the functioning of the healthcare system itself.¹⁸

¹⁶ FMRAI (n 4) paras 1–4.

¹⁷ *ibid* paras 2–4.

¹⁸ Rupali Mukherjee, ‘Can India stop drug companies giving gifts to doctors?’ (2013) 346 *BMJ* f2635.

B. The Challenge to the Existing Regulatory Framework

A significant aspect of the proceedings concerns the adequacy of the UCPMP as a mechanism for controlling such practices. The existence of a detailed code does not necessarily resolve the regulatory problem if compliance with the code is not supported by sufficiently binding legal obligations and effective enforcement mechanisms.

This distinction is central to the challenge. A voluntary code can establish standards of desirable conduct, but its effectiveness ultimately depends upon compliance by the entities to whom those standards are directed. Where the regulated entities have significant commercial incentives to engage in promotional practices, voluntary compliance may be insufficient to deter conduct that produces economic benefits.¹⁹

The issue is therefore not simply whether the UCPMP contains adequate substantive restrictions. Even a comprehensive prohibition on gifts or inducements may have limited practical effect if there is no sufficiently independent authority capable of investigating violations and imposing meaningful consequences. The litigation thus exposes the difference between **norm-setting** and **enforcement**. The former concerns the rules governing pharmaceutical marketing; the latter concerns the institutional capacity to ensure that those rules are observed.²⁰

The question assumes particular importance in the context of industry self-regulation. Under the existing framework, industry associations play a significant role in implementing and enforcing the Code. While industry participation can provide technical expertise and regulatory flexibility, it also raises concerns regarding institutional independence. A regulatory system must retain public credibility, particularly where the regulated industry has a direct economic interest in the practices under examination.

C. The Supreme Court and the Question of Statutory Regulation

The proceedings before the Supreme Court have brought the voluntary nature of the UCPMP into sharper focus. The Court's engagement with the regulatory framework reflects an underlying concern that pharmaceutical marketing practices affecting public health cannot necessarily be addressed through a system that relies predominantly upon voluntary compliance.²¹

¹⁹ Julia Black (n 15) 25–27.

²⁰ Robert Baldwin, Martin Cave and Martin Lodge, *Understanding Regulation: Theory, Strategy, and Practice* (2nd edn, Oxford University Press 2012) 105–09.

²¹ FMRAI (n 4) paras 15–19.

The significance of the Court's intervention lies less in prescribing a particular regulatory model and more in compelling attention to the institutional question that has remained at the heart of the debate: **whether the regulation of pharmaceutical marketing should continue to depend upon voluntary industry standards or should instead be supported by statutory authority.**

The distinction is consequential. A statutory framework would potentially provide pharmaceutical marketing regulations with binding legal force and could establish clearer procedures for investigation, adjudication and enforcement. It could also determine the consequences of non-compliance in a manner that does not depend upon the willingness of industry bodies to discipline their members.²²

At the same time, statutory regulation should not automatically be equated with effective regulation. A poorly designed statutory framework may reproduce many of the weaknesses of the existing system. If the same industry bodies retain primary responsibility for investigating violations, if sanctions remain inadequate, or if complaints cannot be effectively pursued, converting the UCPMP into a statutory instrument would provide only a formal solution to a structural problem.²³

This distinction is important to the present paper. The question raised by *FMRAI* is not simply whether the UCPMP should become legally enforceable. It is whether India should use the present regulatory moment to reconsider the architecture through which pharmaceutical marketing is governed.

D. Significance of *FMRAI* for Pharmaceutical Regulation

FMRAI is significant because it places pharmaceutical marketing within a broader conception of public-interest regulation. The case demonstrates that the regulation of pharmaceutical companies cannot be assessed solely through the lens of commercial freedom or industry ethics. The interests of patients, healthcare professionals and the public must also form part of the regulatory equation.²⁴

The proceedings also expose a structural tension inherent in self-regulation. Pharmaceutical companies possess substantial expertise concerning their products and marketing practices, making industry participation valuable. At the same time, the commercial incentives of the industry make complete reliance upon self-regulation difficult to justify. The challenge,

²² *Tata Cellular v Union of India* (1994) 6 SCC 651, 679–80.

²³ *FMRAI* (n 4) paras 20–22.

²⁴ *Consumer Education and Research Centre v Union of India* (1995) 3 SCC 42, 46–47.

therefore, is not necessarily to eliminate industry participation but to ensure that such participation operates within a framework of independent oversight and legally enforceable standards.²⁵

The case accordingly provides an opportunity to reconsider the regulatory model itself. The transition from the UCPMP's voluntary framework to statutory regulation should not be viewed merely as an exercise in changing the legal status of an existing code. It should involve a reassessment of the institutions responsible for enforcement, the transparency of pharmaceutical–healthcare professional relationships, the accessibility of complaint mechanisms and the proportionality of sanctions.

The importance of *FMRAI* consequently extends beyond the immediate allegations before the Supreme Court. It represents a broader regulatory question concerning the appropriate relationship between the State, the pharmaceutical industry and healthcare professionals. The answer requires an assessment of whether voluntary self-regulation can adequately protect public-health interests or whether the nature of pharmaceutical marketing requires a system in which substantive obligations are accompanied by independent enforcement and meaningful accountability. The next section examines this enforcement deficit and the structural limitations of the existing self-regulatory model.

WHY VOLUNTARY REGULATION FALLS SHORT: THE ENFORCEMENT AND ACCOUNTABILITY DEFICIT

The principal weakness of India's existing pharmaceutical marketing framework lies not necessarily in the absence of substantive standards, but in the limited ability of those standards to generate effective compliance. The UCPMP identifies several practices that pharmaceutical companies should avoid, yet its voluntary character creates a gap between the articulation of regulatory norms and their enforcement. This gap becomes particularly significant where the regulated conduct involves commercial incentives that may directly benefit the entities expected to comply with the Code.

A. The Enforcement Deficit

A regulatory framework is effective only when violations produce meaningful consequences. Voluntary regulation, however, relies substantially upon the willingness of regulated entities

²⁵ Julia Black (n 15) 25–27.

to conform to prescribed standards. In the pharmaceutical sector, this creates a structural difficulty because marketing expenditure is intended to advance commercial interests. Where promotional practices provide a company with a competitive advantage, the deterrent effect of a voluntary code may be limited unless non-compliance carries sufficiently serious and credible consequences.²⁶

The problem is therefore not merely whether the UCPMP prohibits a particular benefit or promotional practice. It is whether a violation can be reliably detected, investigated and sanctioned. An effective regulatory system requires a clear chain of accountability: a mechanism through which complaints can be made, violations investigated, findings determined and penalties imposed. Where these stages lack sufficient legal force or institutional independence, substantive prohibitions risk becoming aspirational rather than regulatory.

B. The Problem of Industry Self-Regulation

The reliance on industry bodies to administer significant aspects of the UCPMP raises a second concern: the potential conflict between regulatory responsibility and commercial interest. Industry participation can undoubtedly provide valuable technical expertise. Pharmaceutical marketing involves complex scientific, commercial and professional relationships that may be difficult for an external regulator to understand fully. Self-regulation can also be more flexible than legislation and can adapt to emerging promotional practices.²⁷

However, these advantages must be balanced against the inherent difficulty of an industry substantially regulating its own members. Pharmaceutical companies have a commercial interest in effective promotion, while industry associations are constituted, at least in significant part, to represent the interests of those companies. This does not mean that industry-led mechanisms are necessarily ineffective or incapable of acting independently. It does, however, create a perception and accountability problem: a regulatory system must be sufficiently independent to command confidence among patients, healthcare professionals and the wider public.

C. The Accountability Gap

The limitations of voluntary regulation become particularly apparent when responsibility for pharmaceutical marketing is distributed across multiple institutional actors. Different aspects

²⁶ Ian Ayres and John Braithwaite (n 16) 4–7.

²⁷ Baldwin, Cave and Lodge (n 23) 105–09.

of pharmaceutical conduct may fall within the domains of government departments, professional regulators, industry associations and other statutory authorities. Such fragmentation can make it difficult to identify who bears ultimate responsibility for preventing and responding to unethical marketing.

An effective framework should answer four basic questions: **who can complain, who investigates, who decides, and what remedy follows?** If these questions cannot be answered through a clear and accessible process, the existence of regulatory standards alone provides limited protection.

The problem is also compounded by the position of the patient. Pharmaceutical marketing primarily operates through relationships between companies and healthcare professionals, while patients are often indirect participants in those relationships. Yet patients ultimately bear the consequences when prescribing decisions are distorted by commercial incentives, whether through higher expenditure, inappropriate medication or reduced access to affordable treatment. A regulatory framework that does not provide sufficient consideration to this downstream impact risks treating pharmaceutical marketing as an internal industry issue rather than a matter of public interest.²⁸

D. From Self-Regulation to Shared Accountability

The shortcomings of voluntary regulation do not necessarily require the complete elimination of industry participation. Industry expertise can remain valuable in identifying emerging marketing practices and developing technical standards. The more appropriate objective is therefore to place industry participation within a framework of **independent statutory oversight**.

The State should establish the substantive obligations, investigation powers and minimum sanctions, while industry bodies may continue to contribute technical expertise and compliance guidance. Such an approach would preserve the advantages of self-regulation without allowing the regulated industry to exercise predominant control over enforcement.²⁹

The experience of the UCPMP therefore demonstrates that the central regulatory problem is one of accountability. The question is not simply whether pharmaceutical companies have been told what constitutes ethical marketing, but whether there exists a credible mechanism capable of ensuring that they comply. This distinction provides the basis for examining whether simply

²⁸ Consumer Education and Research Centre (n 27) 46–47.

²⁹ OECD, 'Reinforcing Regulatory Frameworks through Standards, Measurements and Assurance' (OECD Publishing, 2025), section on the spectrum of regulatory approaches.

granting statutory force to the UCPMP would be sufficient, or whether India requires a more fundamental redesign of its pharmaceutical marketing regulatory framework.

SHOULD INDIA MAKE THE UCPMP A STATUTE?

The shortcomings of voluntary regulation make a strong case for statutory intervention. However, the proposition that the existing UCPMP should simply be given statutory force requires closer examination. Converting a voluntary code into a legally binding instrument would undoubtedly strengthen the enforceability of its provisions, but legal enforceability alone does not guarantee effective regulation. If the institutional architecture, investigative process and enforcement mechanisms remain substantially unchanged, statutory status may address the formal weakness of the UCPMP without resolving its underlying structural deficiencies.

A. The Case for Statutory Regulation

The principal advantage of statutory regulation is that it would transform pharmaceutical marketing standards from voluntary expectations into legally enforceable obligations. Pharmaceutical companies would no longer be able to treat compliance as a matter of industry ethics alone. Statutory obligations could establish clear duties, create defined consequences for violations and provide a legal basis for regulatory intervention.³⁰

Statutory regulation would also promote greater uniformity. At present, reliance on industry-led mechanisms may result in variations in the manner in which complaints are addressed and standards are applied. A statutory framework could establish common procedures for investigation, adjudication and appeals. It could also provide proportionate penalties capable of creating a meaningful deterrent against unethical marketing practices.

More importantly, statutory regulation would strengthen public accountability. A statutory regulator would be required to exercise powers within a defined legal framework and would remain subject to administrative and judicial review. This would provide greater transparency than a system in which regulatory responsibility is substantially exercised through voluntary industry mechanisms.

B. Why Statutory Force Alone May Not Be Enough

Despite these advantages, simply converting the UCPMP into a binding code would be an incomplete response. The first difficulty concerns enforcement. A statutory prohibition has

³⁰ Drugs and Cosmetics Act 1940, long title and ss 18–27.

little practical value if the regulator lacks adequate investigative powers, resources or institutional independence. The central question would therefore remain: **who will enforce the statutory code?**³¹

If enforcement continues to depend predominantly upon industry associations, statutory status may merely place binding obligations within an essentially self-regulatory structure. The conflict between commercial interests and regulatory responsibility would consequently remain. The problem identified in the existing framework would have been transformed legally but not institutionally.

The second difficulty concerns the precision of the regulatory standards themselves. Pharmaceutical marketing encompasses a wide range of activities, from scientific communication and clinical education to sponsorships, samples and promotional interactions. A statutory framework that relies on vague concepts such as “ethical” or “appropriate” conduct without defining prohibited practices could create uncertainty for both pharmaceutical companies and regulators. Conversely, excessively rigid rules could prevent legitimate scientific communication and impose disproportionate restrictions on pharmaceutical businesses.³²

The third issue concerns sanctions. Effective regulation requires penalties that are sufficiently serious to outweigh the commercial benefits of non-compliance, while remaining proportionate to the nature and gravity of the violation. A framework that provides only weak or rarely imposed sanctions may fail to create meaningful deterrence. At the same time, indiscriminate criminalisation could result in over-regulation and discourage legitimate industry activity.³³

C. From a Statutory Code to a Statutory Regulatory Framework

The appropriate response is therefore not merely to give the UCPMP statutory status, but to develop a **statutory regulatory framework for pharmaceutical marketing**. Such a framework should contain at least four interconnected elements: clearly defined substantive standards, an independent enforcement mechanism, accessible complaint and investigation procedures, and meaningful sanctions.

The distinction is important. A statutory code primarily answers the question of **what conduct is prohibited**. A statutory regulatory framework must additionally answer **who regulates that conduct, how violations are established, what consequences follow and how affected**

³¹ Julia Black (n 15) 25–27.

³² Drugs and Magic Remedies (Objectionable Advertisements) Act 1954, ss 3–7.

³³ Modern Dental College and Research Centre v State of Madhya Pradesh (2016) 7 SCC 353, 412–14.

parties can challenge regulatory decisions. The latter approach would address the institutional weaknesses that have limited the effectiveness of voluntary regulation.

The framework should also avoid treating every interaction between pharmaceutical companies and healthcare professionals as inherently improper. Pharmaceutical companies have a legitimate interest in communicating scientific information, introducing new medicines and supporting genuine educational activities. Regulation should therefore distinguish between legitimate professional engagement, activities requiring disclosure or safeguards, and conduct that constitutes an inducement and should be prohibited outright.³⁴

Such differentiation would allow statutory regulation to pursue public-health objectives without unnecessarily restricting legitimate commercial activity. It would also provide clearer guidance to pharmaceutical companies and healthcare professionals regarding the boundaries of permissible conduct.

D. The Need for an Independent Enforcement Architecture

The most significant institutional question is whether enforcement should remain within the industry or be entrusted to an independent statutory authority. Complete exclusion of industry expertise may be impractical, given the technical nature of pharmaceutical marketing. However, industry participation should occur within a framework in which final investigative and adjudicatory authority rests with an independent body.³⁵

Such an arrangement could combine regulatory oversight with industry expertise. Industry bodies could assist in developing technical guidance and compliance standards, while an independent statutory authority could receive complaints, conduct investigations, determine violations and impose sanctions. This would preserve the benefits of specialised industry knowledge while preventing the regulated industry from exercising predominant control over enforcement.

Accordingly, the transition contemplated after *FMRAI* should not be understood as a binary choice between voluntary regulation and government control. The more appropriate model is **regulated self-regulation under independent statutory oversight**. The objective should be to retain useful elements of industry participation while ensuring that the ultimate responsibility for accountability rests outside the commercial interests being regulated.

The central lesson is therefore that statutory status should be regarded as the beginning, rather

³⁴ ABPI, 'Code of Practice for the Pharmaceutical Industry 2024' (Association of the British Pharmaceutical Industry, 2024).

³⁵ Ayres and Braithwaite (n 16) 4–7.

than the end, of pharmaceutical marketing reform. The effectiveness of the proposed regime will ultimately depend upon the quality of its substantive rules and, more importantly, the independence, transparency and enforcement capacity of the institutions responsible for implementing them.

DESIGNING AN EFFECTIVE STATUTORY FRAMEWORK FOR PHARMACEUTICAL MARKETING

If the limitations of the existing framework arise from both the voluntary nature of the UCPMP and the weaknesses of its enforcement architecture, statutory reform must address both dimensions simultaneously. The objective should not be to create a regime that indiscriminately restricts pharmaceutical promotion, but one that clearly identifies unacceptable forms of influence while preserving legitimate scientific communication. A workable statutory framework should therefore combine substantive prohibitions with independent enforcement, accessible complaint mechanisms and proportionate sanctions.

A. Clearly Defining Prohibited Conduct

The first requirement of statutory regulation is certainty. Pharmaceutical companies and healthcare professionals should be able to determine with reasonable clarity which forms of conduct are prohibited, restricted or permissible. The legislation should specifically address gifts, hospitality, travel benefits, monetary inducements and other benefits provided in connection with the promotion or prescription of pharmaceutical products.³⁶

Particular attention should be given to the connection between a benefit and prescribing behaviour. Not every interaction between pharmaceutical companies and healthcare professionals should be treated as an inducement. Scientific conferences, genuine educational programmes and the dissemination of accurate information about medicines can serve legitimate purposes. The relevant distinction should therefore be whether the benefit is capable of creating an improper commercial influence over professional decision-making.

A statutory framework should also provide safeguards against circumvention. Restricting direct payments while permitting substantially similar benefits through third parties, event organisers or intermediary arrangements would leave significant gaps in regulation. The legislation should therefore regulate the substance of the benefit rather than merely its formal method of delivery.

³⁶ UCPMP 2024 (n 2) paras 4–8.

B. An Independent Enforcement Mechanism

Substantive rules will have limited value unless supported by an institution capable of enforcing them independently. The proposed framework should therefore assign primary enforcement responsibility to an independent statutory authority or to an appropriately empowered existing regulator.³⁷

The authority should possess powers to receive complaints, demand relevant records, conduct investigations and determine violations. It should also be able to examine not merely individual transactions but broader patterns of promotional conduct where necessary. Independence is particularly important because the pharmaceutical industry possesses substantial commercial and technical expertise, while regulators may face information asymmetry when investigating sophisticated promotional practices.

Industry bodies should nevertheless not be excluded entirely. Their technical expertise may be valuable in developing industry guidance and identifying emerging promotional practices. Their role, however, should remain advisory or participatory rather than determinative. The final decision regarding whether a violation has occurred should rest with an independent statutory authority.

C. An Accessible Complaint and Investigation Mechanism

The effectiveness of enforcement will also depend upon who is permitted to initiate regulatory action. A narrow system in which only industry competitors or professional bodies can lodge complaints would fail to reflect the public-health dimension of pharmaceutical marketing.

The statutory framework should therefore permit complaints from a broad range of stakeholders, including healthcare professionals, employees of pharmaceutical companies and, where appropriate, patients or patient organisations. Whistleblowing mechanisms should also provide confidentiality and protection against retaliation where individuals disclose credible evidence of unethical promotional practices.³⁸

Once a complaint is received, the framework should establish clear procedural stages for preliminary assessment, investigation, adjudication and appeal. Time limits should be prescribed where appropriate so that complaints do not remain unresolved for extended periods. Procedural safeguards would simultaneously protect pharmaceutical companies against arbitrary enforcement and ensure that genuine violations are not left without an effective remedy.

³⁷ Modern Dental College (n 36) 412–14.

³⁸ FMRAI (n 4) para 23(C)–(E).

D. Proportionate and Meaningful Sanctions

Sanctions are central to the credibility of any regulatory framework. If the financial or commercial benefit derived from an unlawful promotional practice substantially exceeds the expected penalty, the regulatory system may fail to create an adequate deterrent.³⁹

The statutory framework should therefore provide a graduated range of sanctions. Minor or inadvertent violations could attract warnings or corrective directions, while serious or repeated violations could result in substantial monetary penalties. In appropriate circumstances, regulators could also require corrective disclosures or publicise violations to create reputational consequences.

At the same time, sanctions should remain proportionate. Not every technical breach should attract the same penalty as deliberate inducement or systematic manipulation of prescribing practices. The seriousness of the conduct, its frequency, the benefit obtained, the involvement of senior management and the impact on patients could be relevant factors in determining the appropriate sanction.

E. Transparency as an Element of Accountability

An effective statutory framework should also consider transparency as a regulatory tool. The difficulty in identifying improper relationships between pharmaceutical companies and healthcare professionals is partly an information problem. Financial and other interactions may occur without meaningful public visibility, making external scrutiny difficult.

The law could therefore require disclosure of specified categories of payments, sponsorships, travel support and other benefits provided to healthcare professionals or healthcare institutions. A publicly accessible disclosure mechanism could supplement substantive prohibitions by allowing regulators, professionals and the public to identify patterns of industry–professional relationships.⁴⁰

Transparency should not, however, become a substitute for prohibition. Disclosure may be appropriate for legitimate relationships that create potential conflicts of interest, but conduct involving direct inducements linked to prescribing should remain prohibited irrespective of whether it is disclosed. The two mechanisms should therefore operate together: **prohibition for unacceptable conduct and disclosure for relationships that are legitimate but potentially capable of creating conflicts of interest.**

³⁹ Tata Cellular (n 25) 679–80.

⁴⁰ Centers for Medicare & Medicaid Services, ‘Open Payments’ (US Department of Health and Human Services, 2026).

A statutory framework incorporating these elements would represent a significant departure from the present model. Its purpose would not simply be to make the UCPMP legally binding, but to create a coherent system in which substantive standards, institutional independence, procedural accountability and transparency reinforce one another. Such a model would better address the central concern raised by *FMRAI*: that effective pharmaceutical marketing regulation requires not only rules governing conduct, but institutions capable of ensuring that those rules have practical effect.

BEYOND PROHIBITION: TRANSPARENCY AS A REGULATORY TOOL

The regulation of pharmaceutical marketing has traditionally focused on identifying and prohibiting conduct considered capable of improperly influencing healthcare professionals. While such prohibitions are necessary, they cannot by themselves address every form of potential conflict of interest. Pharmaceutical companies routinely interact with healthcare professionals through legitimate activities such as scientific conferences, educational programmes, research collaborations and professional sponsorships. The regulatory challenge is therefore not simply to eliminate industry–professional relationships, but to ensure that such relationships remain transparent and do not compromise independent medical judgment. Transparency can supplement substantive regulation by making potentially significant relationships visible to regulators, professionals and the public.

A. Mandatory Disclosure of Industry–Professional Relationships

A statutory framework could require pharmaceutical companies to disclose specified categories of benefits provided to healthcare professionals and healthcare institutions. These could include payments for consultancy, speaking engagements, travel, accommodation, conference sponsorships, educational grants and other financial or non-financial benefits above a prescribed threshold.⁴¹

The purpose of disclosure would not be to presume that every financial relationship is improper. A healthcare professional may legitimately provide expert advice to a pharmaceutical company or participate in a scientific conference supported by industry funding. The concern arises when such relationships remain entirely opaque and therefore prevent meaningful scrutiny of potential conflicts of interest. Disclosure would make it possible

⁴¹ Medicines Australia, ‘Section 14: Transparency Reporting’ (Code of Conduct, 2026).

to distinguish legitimate professional relationships from patterns of conduct that warrant regulatory attention.

A disclosure requirement could also improve the quality of enforcement. Regulators would have access to information that may otherwise be difficult to obtain during an investigation. Patterns of repeated payments, unusually concentrated relationships or substantial benefits directed towards professionals prescribing particular products could provide useful indicators for further examination.

B. A Public Disclosure Database

Disclosure would have greater regulatory value if the information were consolidated in a publicly accessible database. Rather than requiring regulators or individual patients to obtain information through separate proceedings, a central database could allow relevant stakeholders to examine relationships between pharmaceutical companies and healthcare professionals.

Such a system would also introduce an element of reputational accountability. Pharmaceutical companies and healthcare professionals would know that specified financial relationships could be subject to public scrutiny. Transparency can therefore operate as a form of preventive regulation even where no direct prohibition is triggered.

However, public disclosure must be carefully designed. Excessive disclosure requirements may impose unnecessary administrative burdens and could expose commercially sensitive information that has little relevance to the regulatory objective. The legislation should therefore identify the categories of information that are genuinely relevant to conflicts of interest and establish appropriate thresholds for reporting.

C. Transparency and the Patient

The case for transparency is particularly strong because patients are ordinarily removed from the commercial relationship between pharmaceutical companies and healthcare professionals. A patient may know which medicine has been prescribed but may have little information regarding the financial or professional relationships that could potentially influence that decision.⁴²

Greater transparency would not, by itself, enable patients to determine whether a prescription is medically appropriate. Medical treatment remains a matter requiring professional judgment. However, transparency can improve the conditions under which that judgment is exercised by

⁴² International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 3 January 1976) 993 UNTS 3, art 12.

making significant conflicts of interest visible. It may also strengthen public confidence in the healthcare system by demonstrating that relationships between industry and healthcare professionals are subject to oversight.

The patient should therefore not be treated merely as the indirect beneficiary of pharmaceutical marketing regulation. The patient is ultimately the person whose health and financial interests are affected by prescribing decisions. A regulatory model that incorporates transparency recognises this wider public dimension.

D. The Limits of Disclosure

Transparency should nevertheless not be treated as a substitute for substantive regulation. Disclosure cannot legitimise conduct that should be prohibited in the first place. If a pharmaceutical company provides a healthcare professional with a benefit specifically to influence prescribing behaviour, requiring the company to disclose that benefit would not adequately address the underlying harm.

The appropriate approach is therefore to create different regulatory categories. Conduct that constitutes a direct or improper inducement should be prohibited and penalised. Legitimate relationships that may nevertheless generate potential conflicts of interest should be subject to disclosure. Ordinary scientific and professional interactions that present minimal risk should remain permissible without excessive regulatory intervention.

This approach would allow regulation to move beyond an overly binary distinction between “permitted” and “prohibited” conduct. Instead, pharmaceutical marketing could be governed through a combination of **prohibition, disclosure and oversight**, depending upon the nature and risk of the activity.

E. Towards a Transparency-Based Regulatory Culture

The introduction of mandatory disclosure would also mark a broader shift in India's regulatory philosophy. Instead of relying exclusively upon regulators to identify violations after they occur, transparency would create conditions in which questionable relationships could be identified earlier by multiple stakeholders. Regulators could use disclosed information for risk-based investigations, professional bodies could identify potential conflicts, and healthcare institutions could strengthen their internal compliance mechanisms.

Transparency is therefore best understood as complementary to statutory regulation rather than an alternative to it. A strong pharmaceutical marketing regime should prohibit conduct that is inherently unacceptable, require disclosure where relationships create potential conflicts, and

subject both categories to independent regulatory oversight where necessary.

The transition from the voluntary UCPMP to statutory regulation consequently presents an opportunity to move beyond a purely prohibition-based model. By combining legally enforceable standards with transparency and disclosure, India could create a regulatory framework that not only responds to violations but also reduces the informational and institutional conditions in which unethical pharmaceutical marketing can flourish.

RECONCILING PUBLIC HEALTH, COMMERCIAL FREEDOM AND PHARMACEUTICAL INNOVATION

A stronger regulatory framework for pharmaceutical marketing must recognise that regulation serves two competing interests. On one hand, pharmaceutical marketing can create incentives that distort medical decision-making and adversely affect patients. On the other, pharmaceutical companies have a legitimate interest in communicating information about their products, introducing new medicines and engaging with healthcare professionals. The objective of statutory regulation should therefore not be to eliminate pharmaceutical promotion, but to establish a principled boundary between legitimate commercial communication and impermissible influence.

A. Pharmaceutical Marketing as a Legitimate Commercial Activity

Pharmaceutical companies require mechanisms through which they can communicate information concerning the composition, efficacy, safety and appropriate use of their medicines. Healthcare professionals, in turn, require access to accurate and updated information to make informed clinical decisions. Scientific conferences, medical education, clinical discussions and product information can therefore serve an important function within the healthcare system.⁴³

An excessively restrictive regulatory framework could undermine these legitimate objectives. If every interaction between pharmaceutical companies and healthcare professionals were treated as inherently suspect, companies could face difficulties in communicating scientific information or supporting genuine educational activities. Such an approach could ultimately affect the dissemination of information concerning new treatments and medical developments. The regulatory objective should consequently be to distinguish **information from influence**. The dissemination of accurate scientific information should ordinarily remain permissible,

⁴³ ABPI Code (n 37) clauses 19–21.

while benefits or promotional practices designed to create an improper obligation or commercial preference should attract greater scrutiny.

B. Commercial Freedom and the Need for Regulation

Pharmaceutical companies may also contend that restrictions on marketing practices interfere with their ability to conduct legitimate business. Commercial activity enjoys legal protection, and regulatory restrictions must therefore be justified by a legitimate public interest and structured in a proportionate manner.

The public-health consequences of pharmaceutical marketing provide a particularly strong justification for regulation. Unlike many ordinary consumer products, medicines are frequently purchased or consumed on the basis of professional advice. The prescribing decision therefore creates a relationship in which commercial influence can have consequences extending beyond the immediate transaction.

The State consequently has a legitimate interest in ensuring that prescribing decisions are guided primarily by clinical considerations rather than commercial inducements. The existence of such an interest, however, does not justify unrestricted regulatory intervention. Restrictions should remain sufficiently precise to target conduct that creates a genuine risk of improper influence while avoiding unnecessary interference with legitimate pharmaceutical activity.

C. Protecting the Independence of Medical Decision-Making

The most appropriate regulatory principle is therefore the protection of independent professional judgment. A healthcare professional should be able to evaluate a medicine based upon its clinical characteristics rather than the personal or financial benefits associated with prescribing it.

This principle provides a useful basis for distinguishing permissible and impermissible conduct. A pharmaceutical company may provide scientific information about a medicine because doing so serves a legitimate informational purpose. However, when that interaction is accompanied by a benefit that is contingent upon, or reasonably capable of influencing, prescribing behaviour, the regulatory concern becomes substantially stronger.

The same principle can guide the treatment of educational programmes and professional conferences. Industry participation should not automatically be prohibited merely because pharmaceutical companies provide financial support. Instead, safeguards can be imposed to ensure that educational content, participant selection and professional decision-making remain independent of commercial interests.

D. The Role of Proportionality

The statutory framework should therefore adopt a proportionate regulatory approach. The severity of regulatory intervention should correspond to the risk posed by the conduct.⁴⁴

Activities involving direct financial inducements or benefits expressly linked to prescribing should attract the strongest restrictions. Relationships that are legitimate but capable of generating conflicts of interest may instead be subjected to disclosure requirements and institutional safeguards. Ordinary scientific communication, by contrast, should generally remain permissible provided that it satisfies requirements of accuracy, transparency and professional integrity.

Such a differentiated approach would prevent the regulatory framework from becoming unnecessarily broad. It would also provide greater certainty to pharmaceutical companies and healthcare professionals regarding the consequences of particular forms of conduct.

E. Drawing the Regulatory Line

The central challenge for Indian pharmaceutical regulation is therefore not whether pharmaceutical marketing should be permitted, but **where the boundary between legitimate promotion and improper influence should be drawn**. A useful regulatory framework should ask whether a particular practice primarily facilitates the communication of legitimate scientific information or instead creates an incentive capable of distorting independent medical judgment.

This distinction also reinforces the need for a combination of regulatory tools. Absolute prohibitions are appropriate for conduct that presents an inherently high risk of improper influence. Disclosure can address relationships that are legitimate but capable of creating conflicts of interest. Independent oversight can ensure that the boundary between the two is not determined solely by the industry itself.

The objective of statutory regulation should consequently be neither to suppress pharmaceutical marketing nor to preserve the existing system in the name of commercial freedom. It should establish conditions in which pharmaceutical companies can compete through the quality and scientific value of their products, while healthcare professionals remain free to make independent clinical decisions. Such a balance would allow pharmaceutical innovation and legitimate commercial activity to coexist with the State's responsibility to protect public health.

⁴⁴ Modern Dental College (n 36) 412–14.

The challenge, therefore, is to design a regulatory framework that is sufficiently strong to deter improper influence but sufficiently precise to avoid treating legitimate pharmaceutical engagement as unethical conduct. Achieving this balance is essential if statutory regulation is to command both legal legitimacy and practical effectiveness.

THE WAY FORWARD: TOWARDS A COHERENT PHARMACEUTICAL MARKETING REGIME

The preceding analysis demonstrates that the principal weakness of India's pharmaceutical marketing framework is not simply the voluntary status of the UCPMP. The larger problem is the absence of an integrated regulatory architecture combining clear substantive standards, independent enforcement and meaningful transparency. Statutory regulation therefore presents an opportunity to move beyond the existing code without abandoning the aspects of industry participation that remain useful. The objective should be to establish a framework in which pharmaceutical companies remain free to engage in legitimate scientific and commercial activity, while practices capable of improperly influencing medical decision-making are effectively regulated.

A. A Layered Regulatory Model

India should adopt a layered approach in which different forms of pharmaceutical marketing are subjected to different levels of regulatory intervention. Conduct involving direct or indirect inducements linked to prescribing should be prohibited and subject to meaningful sanctions. Relationships that are legitimate but capable of creating conflicts of interest should be subject to mandatory disclosure and appropriate safeguards. Ordinary scientific communication and professional engagement should remain permissible, provided that they satisfy standards of accuracy and transparency.⁴⁵

Such differentiation would prevent the regulatory framework from becoming either excessively permissive or unnecessarily restrictive. It would also allow regulators to concentrate enforcement resources on conduct presenting the greatest risk to patients and the integrity of medical decision-making.

B. Independent Statutory Oversight

The proposed framework should place ultimate enforcement responsibility with an independent

⁴⁵ Medicines Australia (n 44) ss 5, 14.

statutory authority or an existing public regulator possessing appropriate powers. The authority should have the capacity to receive complaints, conduct investigations, require production of relevant records and impose proportionate sanctions.

Industry bodies should continue to play a role where their technical expertise is useful, particularly in developing compliance guidance and identifying emerging promotional practices. However, industry participation should operate under independent oversight rather than constitute the final layer of enforcement. This would preserve the benefits of specialised industry knowledge while addressing the conflict inherent in allowing regulated entities to substantially control their own regulation.

C. Transparency and Public Accountability

Mandatory disclosure should form a complementary component of the statutory regime. Pharmaceutical companies should be required to disclose specified payments and benefits provided to healthcare professionals and healthcare institutions, subject to appropriate thresholds and safeguards.

A central disclosure mechanism would allow regulators to identify patterns that may warrant investigation while also enabling greater public scrutiny. Transparency would not replace substantive prohibitions; rather, it would operate alongside them. The resulting framework would distinguish between conduct that must be prohibited and relationships that may remain lawful but require visibility because of their potential to generate conflicts of interest.

D. Effective Remedies and Proportionate Sanctions

A credible regulatory framework must also provide meaningful consequences for non-compliance. Sanctions should be graduated according to the seriousness, frequency and consequences of the violation. Minor breaches may justify warnings or corrective directions, while deliberate or repeated inducements should attract substantially stronger monetary and regulatory penalties.

The framework should additionally provide clear avenues of appeal and judicial review. This would ensure that pharmaceutical companies are protected against arbitrary regulatory action while maintaining the regulator's ability to act decisively where violations are established.

E. Periodic Review and Regulatory Adaptability

Pharmaceutical marketing practices are not static. Promotional strategies can evolve rapidly through digital platforms, social media, virtual conferences, data-driven advertising and new

forms of interaction between companies and healthcare professionals. A statutory framework that is overly prescriptive may consequently become outdated.

The legislation should therefore establish mechanisms for periodic review of regulatory standards. An independent regulator could issue subordinate rules or guidance, within the limits prescribed by the parent legislation, to address emerging practices. Such flexibility would allow the regulatory system to respond to technological and commercial developments without repeatedly requiring comprehensive legislative amendments.⁴⁶

F. A Shift from Ethical Guidance to Regulatory Accountability

The central reform should ultimately involve a change in regulatory philosophy. The UCPMP represents an important articulation of ethical standards, but effective regulation requires more than identifying desirable behaviour. It requires institutions capable of translating those standards into enforceable obligations.

The model proposed in this paper can therefore be understood as a progression:

Voluntary standards → statutory obligations → independent oversight → transparency → meaningful enforcement.

This progression does not require the complete rejection of self-regulation. Instead, it places self-regulation within a broader system of statutory accountability. Industry expertise can inform the regulatory process without determining its ultimate outcome; pharmaceutical companies can continue legitimate promotion without being permitted to use commercial benefits as instruments of influence; and healthcare professionals can maintain relationships with industry while remaining accountable for conflicts of interest.

Such a framework would better respond to the regulatory concerns highlighted by *FMRAI*. It would also ensure that the transition from the UCPMP's voluntary model to statutory regulation is not merely a change in legal form. The real objective should be to create a system in which the rules governing pharmaceutical marketing are clear, their enforcement is independent, and the interests of patients remain central to the regulatory process.

CONCLUSION

The regulation of pharmaceutical marketing presents a difficult regulatory problem because it lies at the intersection of commercial activity, professional independence and public health. Pharmaceutical companies have a legitimate interest in promoting their products and

⁴⁶ OECD (n 32).

communicating scientific information to healthcare professionals. At the same time, promotional practices involving gifts, hospitality, financial benefits and other inducements can create incentives that compromise independent medical judgment and ultimately affect patients who have no direct involvement in the commercial relationship. The regulation of such practices must therefore extend beyond the conventional concerns of commercial competition and recognise their wider consequences for the healthcare system.

India's experience with the UCPMP demonstrates the limitations of relying primarily upon voluntary regulation to address this problem. Although the UCPMP 2015 and UCPMP 2024 have established increasingly detailed standards governing pharmaceutical marketing, substantive rules cannot ensure effective compliance in the absence of credible enforcement. The reliance on industry participation also raises questions concerning independence, accountability and the ability of affected stakeholders to obtain meaningful remedies. *FMRAI v Union of India* has brought these concerns to the forefront and created an important opportunity to reconsider the regulatory architecture governing pharmaceutical marketing in India.⁴⁷

This paper has argued that India should move towards a statutory framework, but that statutory status alone would not provide an adequate solution. Simply transforming the UCPMP into a binding instrument could leave unresolved the institutional weaknesses that have limited the effectiveness of the existing framework. The more appropriate approach is to establish a comprehensive regulatory system comprising clearly defined substantive prohibitions, independent statutory oversight, accessible complaint and investigation mechanisms, proportionate sanctions and meaningful avenues of appeal.

The proposed framework should also move beyond a purely prohibition-based approach. Mandatory disclosure of specified financial and professional relationships between pharmaceutical companies and healthcare professionals can provide an additional layer of accountability. Transparency would allow regulators and other stakeholders to identify potential conflicts of interest while preserving legitimate scientific and educational relationships. At the same time, disclosure cannot substitute for prohibition where conduct constitutes a direct or improper inducement. The two mechanisms must therefore operate together.

Ultimately, effective pharmaceutical marketing regulation requires a balance between competing interests. Regulation should not prevent legitimate scientific communication,

⁴⁷ FMRAI (n 4) paras 15–24.

professional education or pharmaceutical innovation. Its purpose should instead be to ensure that commercial incentives do not undermine the independence of medical decision-making. The appropriate regulatory question is therefore not whether pharmaceutical marketing should be permitted, but under what conditions it can occur without compromising patient interests and professional integrity.

The significance of *FMRAI* consequently lies beyond the immediate question of whether the UCPMP should acquire statutory force. It provides an opportunity to reconsider how pharmaceutical marketing should be regulated altogether. India must move from a model centred primarily upon voluntary ethical standards towards one based upon **statutory accountability, independent enforcement and transparency**. The transition from a voluntary code to statutory regulation should therefore not be treated as a change in legal form alone. It should represent a broader shift towards a regulatory system in which pharmaceutical companies remain free to compete through legitimate scientific and commercial means, while the integrity of medical decision-making and the interests of patients remain the ultimate benchmarks of regulatory success.

