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Pharmaceutical Freebies and Medical Ethics: Should India Enact a Binding Statutory Framework to Regulate Pharmaceutical Marketing?

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Abstract

Indian doctors have been barred from accepting gifts, hospitality and cash from pharmaceutical companies since 2009, and companies are subject to a marketing code revised in March 2024. Yet no statute directly prohibits the inducement itself. This article asks whether India should enact a binding statutory framework to regulate pharmaceutical marketing. Using doctrinal and comparative analysis, supported by the medical-ethics and health-policy literature, it examines the professional regulations, the Uniform Code of Pharmaceutical Marketing Practices 2024, the Supreme Court's decision in Apex Laboratories (2022), and the pending petition in which the Court, on 8 October 2026, directed the Union government to constitute a committee on the question. The article argues that the current arrangements leave five gaps: no statutory prohibition on inducements, weak sanctions, fragmented enforcement, no public register of payments, and easy circumvention through indirect channels. It contends that a statute is constitutionally secure under Articles 21 and 19 and is workable in light of experience in the United States, France, the European Union and the United Kingdom. Its contribution is a design for a narrow, proportionate law built on prohibitions with defined exceptions, a searchable payments register, layered enforcement with credible sanctions, and complementary reform of medical education funding.

Keywords: Pharmaceutical Marketing, Medical Ethics, Uniform Code Of Pharmaceutical Marketing Practices, Medical Law, Health Law

1. Introduction

Picture a clinic on an ordinary weekday morning. Patients wait on a bench in the corridor. At the end of the row sits a medical representative, bag of samples at his feet, with a branded pen set and an invitation to a "scientific meeting" at a resort. Nobody in the corridor thinks anything sinister is happening. That, precisely, is the difficulty.[2]

India has formally disapproved of this scene for some time. Since 2009 the professional regulations for doctors have forbidden gifts, hospitality, travel and cash from the pharmaceutical industry (Medical Council of India 2002). The Department of Pharmaceuticals has issued a

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[2] This opening scene is a composite offered for illustration. It is not drawn from any specific clinic, company or individual.

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marketing code for companies, most recently in March 2024 (Department of Pharmaceuticals 2024). Yet the practice endures, and the legal machinery for dealing with it remains oddly lopsided. On 8 October 2026, in a petition that has been pending since 2021, the Supreme Court directed the Union government to constitute a committee to consider whether and how pharmaceutical marketing should be placed on a firmer legal footing, listing the matter again for 29 January 2027 (Choudhury 2026; Verdictum 2026). The question this article addresses is therefore not hypothetical.

1.1. Research Question and Argument

The research question is whether India should enact a binding statutory framework to regulate pharmaceutical marketing, with particular attention to gifts and other inducements offered to prescribers. The article answers yes, but with conditions. A statute is justified because the existing arrangements regulate the recipient through professional discipline and the giver through a code that Parliament has never adopted, leaving no law of general application that directly prohibits the inducement itself. At the same time, a statute would fail if it were drafted as a blunt ban on every interaction between industry and clinicians. The article therefore argues for a narrow, transparent and proportionate law, built on three pillars: clear prohibitions with defined exceptions, a public register of payments, and an enforcement structure with real sanctions.

1.2 Approach and Structure

The analysis is doctrinal and comparative, drawing on the medical-ethics and health-policy literature where the law alone cannot answer the question. One limitation should be stated plainly. Systematic evidence on prescribing behaviour in India is thin, and much of the empirical work cited here comes from high-income countries. The absence of Indian data is itself a symptom of the problem, since a country with no disclosure regime cannot measure what it does not require anyone to report.

Section 2 sets out the ethical problem and the evidence. Section 3 maps the current Indian framework, and Section 4 explains why it falls short. Section 5 takes on the strongest objections to legislation. Section 6 examines constitutional footing, Section 7 draws comparative lessons, and Section 8 sketches the design of a workable statute. Section 9 concludes.

2. Why a Gift Is Rarely Just a Gift

2.1 The Fiduciary Core of the Prescribing Relationship

Medicine is unusual among professions because the person receiving the service cannot meaningfully assess it. A patient does not know whether one antibiotic is better than the cheaper alternative. She relies on the doctor, and in the case of prescription-only drugs she cannot buy the product without the doctor's signature. The physician is, in effect, a gatekeeper who spends other people's money and bears none of the cost. Mainstream bioethics describes the doctor's duties in terms of beneficence, non-maleficence and respect for patient autonomy (Beauchamp and Childress 2019), and the legal literature has long treated the relationship as one of trust close to the fiduciary

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(Frankel 2011). The Supreme Court itself has described the doctor's position as quasi-fiduciary (Apex Laboratories v Deputy Commissioner of Income Tax 2022).

The concern with gifts follows from that structure. The worry is not that every doctor who accepts a lunch is corrupt. It is that a person whose professional judgment is meant to be independent should not be placed in a position where independence is both harder to maintain and harder for patients to trust. Rodwin (1993) made this point in his classic study of physicians' conflicts of interest, and the National Academies report edited by Lo and Field (2009) reached a similar conclusion about the wider field of medical research, education and practice. Conflict of interest, on this view, is a condition to be managed institutionally. It is not a moral failing to be waited out.

There is also a cost dimension that the Indian courts have noticed. As far back as 1987 the Supreme Court observed that pharmaceutical companies spend very large sums on sales promotion to influence doctors and generate prescriptions (Union of India v Cynamide India Ltd 1987). In 2022 the Court returned to the theme, remarking that freebies are not really free, because their cost is built into the price of the drug, producing a cycle that is publicly injurious (Apex Laboratories 2022). Patients, in other words, pay for the inducement offered to their own doctor.

2.2 What the Evidence Shows

The best-known review of the early literature found that contact with industry was associated with favourable attitudes towards the industry, requests to add the sponsor's drugs to hospital formularies, and changes in prescribing (Wazana 2000). Later work has reinforced the pattern. A systematic review and meta-analysis found that interaction with pharmaceutical companies was associated with prescribing that was more frequent, more costly and often of lower quality (Brax et al. 2017), and a separate systematic review reached comparable conclusions on attitudes and prescribing habits (Fickweiler, Fickweiler and Urbach 2017). A large US study of Medicare prescribers found that even modest meals, most costing under US$20, were associated with higher prescribing of the promoted brand (DeJong et al. 2016).

Why would small gifts work? Dana and Loewenstein (2003) draw on social-science research to explain that gifts create a sense of reciprocity, and that the recipient's bias is usually unconscious. Doctors sincerely believe they are immune, which is why education and self-awareness alone do little. Fugh-Berman and Ahari (2007) document how sales representatives deliberately cultivate relationships and tailor attention to each prescriber. As for scale, Gagnon and Lexchin (2008) estimated that United States industry spending on promotion in 2004 reached about US$57.5 billion, far more than the usual figures for marketing would suggest. Companies do not spend at that level unless it pays.

Two cautions are in order. Much of this evidence shows association rather than proof of causation, and most of it comes from other health systems. But the direction of the findings is consistent, and nothing suggests Indian clinicians are exempt from ordinary human psychology. If anything, India's market of many competing branded formulations, with relatively little difference in

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clinical profile between them, is one where the personal relationship with the representative may matter more.

3. India's Current Framework

3.1 Regulating the Doctor

The first layer is professional regulation. The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations 2002, made under the Indian Medical Council Act 1956, were amended in 2009 to add a code of conduct governing the relationship between doctors and the pharmaceutical and allied health sector (Medical Council of India 2002). Regulation 6.8 prohibits gifts, travel facilities, hospitality, and cash or monetary grants from the industry, and it deals separately with medical research and with doctors' associations. Regulation 1.5 encourages prescribing by generic name and rational prescription. Violations are professional misconduct, dealt with by the State Medical Councils and, on appeal, by the national body.

The institutional picture shifted when the National Medical Commission Act 2019 replaced the Medical Council of India with the National Medical Commission (NMC) and created the Ethics and Medical Registration Board to regulate professional conduct (National Medical Commission Act 2019, s 30). The NMC notified fresh professional conduct regulations in August 2023, but placed them in abeyance within weeks (National Medical Commission 2023).[3] The practical result is that the 2002 Regulations remain the operative reference point for most purposes. The public record of disciplinary action under regulation 6.8 is, as far as published sources show, thin.

3.2 Regulating the Company: The Marketing Code

The second layer addresses companies. The Uniform Code of Pharmaceutical Marketing Practices (UCPMP) was issued in December 2014 as a voluntary code. A revised version, UCPMP 2024, was circulated to pharmaceutical associations on 12 March 2024 (Department of Pharmaceuticals 2024). It prohibits companies from offering gifts, travel facilities, hospitality, cash or monetary grants to healthcare professionals or their families, regulates samples, brand reminders, continuing medical education (CME) and research support, and expects the chief executive of each company to file an annual self-declaration of compliance (Trilegal 2024).

The 2024 version is plainly tougher than its predecessor. Each association must set up an Ethics Committee for Pharmaceutical Marketing Practices to hear complaints, and an apex committee under the Secretary of the Department of Pharmaceuticals hears appeals. Companies must disclose spending on CME and similar events. But the sanctions are modest: reprimand, public disclosure, corrective directions, and suspension or expulsion from the association. Where action belongs to some other government authority, the committee may merely forward its recommendation through the Department (Trilegal 2024). Commentators have pointed out that the

[3] The 2023 regulations were reportedly kept in abeyance after objections from the medical profession, including to provisions on conduct and generic prescribing. Readers should verify the current status of the NMC's regulations before relying on this account.

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Code still rests on a policy communication, not on legislation, and that the departmental intention that it be treated as binding does not give it the force of law (Trilegal 2024).

3.3 Courts, Tax and the Pending Petition

The third layer is a patchwork of indirect measures. The most significant is judicial. In *Apex Laboratories*, decided on 22 February 2022, the Supreme Court held that the cost of freebies given to doctors could not be deducted as business expenditure under section 37(1) of the Income Tax Act 1961, because the conduct was "prohibited by law" within the Explanation to that section. The Court rejected the argument that regulation 6.8 binds only doctors and not the companies that induce them (Apex Laboratories 2022). It added that denying the deduction did not amount to penalising the company. The significance of that reasoning is considerable. It confirms that the tax route is a fiscal remedy, and it concedes that no direct penalty in force reaches the company. Parliament has since added a withholding-tax provision on business benefits and perquisites, section 194R of the Income Tax Act 1961, which sits in the same fiscal register (Central Board of Direct Taxes 2022).

The second development is the petition now before the Court. The Federation of Medical and Sales Representatives Association of India (FMRAI), a trade union of sales field workers, asked the Court in 2021 to direct that the UCPMP be given statutory backing with a monitoring mechanism and consequences for violations, or in the alternative, to lay down binding guidelines itself (FMRAI v Union of India 2022). Notice was issued in March 2022 (LiveLaw 2022). On 8 October 2026 a bench of Justices Vikram Nath and Sandeep Mehta, after reserving orders on 8 September, directed the Union to constitute a committee that will consider representations and make recommendations (Verdictum 2026). The order, as reported, did not confer statutory force on the Code, and the petition remains pending (TaxGuru 2026).

Other laws touch pharmaceutical promotion without addressing inducements. The Drugs and Magic Remedies (Objectionable Advertisements) Act 1954 restricts advertisements to the public for specified conditions. The Drugs and Cosmetics Act 1940 is primarily about quality, import and sale. The Consumer Protection Act 2019 deals with misleading advertisements aimed at consumers. Each addresses a different harm. None speaks to the thing that happens in the clinic corridor.

4. Why the Patchwork Falls Short

The existing regime is not worthless. Regulation 6.8 expresses a clear professional norm, the UCPMP 2024 has brought sharper rules and some transparency, and *Apex Laboratories* closed off a tax loophole. The difficulty lies in how these pieces fit together. Five weaknesses stand out.

First, no statute prohibits the giving of inducements. The prohibition on doctors exists in subordinate professional regulation, and the prohibition on companies exists in a code. The Court in *Apex Laboratories* was able to say that the company's conduct was prohibited by law only by reading the doctors' regulation outwards. That was an ingenious piece of interpretation, but a regulatory regime should not depend on ingenuity. A company acting in flagrant violation faces, at most, expulsion from a trade association it can leave.

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Second, the sanctions do not match the stakes. A fine large enough to hurt a major company, debarment from public procurement, or personal liability for the executives responsible would change incentives. A reprimand does not. Association-based enforcement also has an obvious structural problem: the body deciding the complaint is made up of the very firms it polices. The UCPMP's appeal to a departmental committee softens this, but it does not cure it.

Third, enforcement against doctors is weak and isolated from enforcement against companies. State Medical Councils discipline doctors, the Department of Pharmaceuticals oversees the code, and the tax department pursues deductions. These bodies do not share information or coordinate remedies. A single payment may be a professional misconduct issue, a code violation and a tax issue, and nobody holds the whole file.

Fourth, there is no public record of who pays whom. The UCPMP 2024 asks companies to disclose CME expenditure and file self-declarations, which is a start. But there is no register of individual payments that patients, hospitals, journalists or researchers can search. Without it, enforcement depends on whistleblowers and tax raids, and scholarship on Indian prescribing remains starved of data.

Fifth, the rules are easy to route around. Modern pharmaceutical marketing seldom looks like a wrapped gift. It takes the form of sponsored conferences, speaker fees, advisory boards, "research" grants, honoraria and payments through event managers or third-party agencies. A framework built chiefly on lists of prohibited items struggles against these channels, and a framework that relies on voluntary complaint struggles still more.

Taken together, these gaps explain why the Supreme Court's own questions in the FMRAI proceedings have centred on enforcement and legal basis, and not on the content of the rules. The rules are largely agreed. What is contested is who can make them bite.

None of these weaknesses means the UCPMP should be thrown away. They suggest that it is a good first draft of the rules, and that it lacks the legal and institutional footing to deliver them.

5. The Case Against a Statute

Serious objections deserve serious answers. Three are worth considering.

5.1 "Self-regulation Is Enough If It Is Strengthened"

The strongest version of this argument holds that industry knows its own practices, that codes can be updated quickly, and that statutes are slow and rigid. There is something to this. Self-regulation can set a standard faster than Parliament can. But the literature on regulatory design does not support the idea that voluntary systems work on their own. Ayres and Braithwaite (1992) argue that self-regulation performs best at the base of an enforcement pyramid, with persuasion and warnings at the bottom and escalating, credible sanctions at the top. India's pyramid has a base and no apex. The ethical committees can warn and the Department can hear appeals, but there is nothing above them to make a company take the lower tiers seriously.

The strongest comparison cuts the other way too. The United Kingdom's industry code is administered by an industry body, but it operates against the background of statutory prohibitions

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on inducements in the medicines legislation, and it is not the sole barrier (Human Medicines Regulations 2012, Part 14). Co-regulation is therefore a model India could follow. Pure self-regulation is not.

5.2 "A Statute Will Chill Legitimate Education and Research"

This is a real risk. Doctors need to learn about new drugs, and much clinical research is funded by industry. A badly drafted law could shut down genuine continuing education, or push it underground. The answer is to draft the statute around the distinction between inducement and legitimate exchange, and not around contact as such. Samples, reasonable fees for real services at fair market value, support for research through institutions and pooled CME funding can all be permitted, if made transparent and documented. The target is the transfer that has no purpose other than to buy goodwill.

There is a constitutional dimension to this objection as well, which Section 6 takes up. In brief, restrictions on inducements do not limit what companies may say about their drugs. They limit what companies may give to the people who prescribe them.

5.3 "The State Cannot Enforce It"

India's regulators are overstretched, and a statute on paper that is not enforced would add little. That is a fair warning for drafting, and an argument for a design that leans on disclosure rather than inspection. A public register lets many people do enforcement work: hospitals checking their staff, journalists, researchers and patients. Penalties can be graduated so that the regulator's scarce resources are directed at repeat and serious offenders. It is also worth noting that the status quo is not free. Its price is paid every time an expensive brand is prescribed where a cheaper one would do.

6. Constitutional and Legislative Footing

The Supreme Court has long treated health as part of the right to life under Article 21 of the Constitution. It has held that the right to health and medical care is a fundamental right (Consumer Education and Research Centre v Union of India 1995) and that the State has a duty to provide adequate medical facilities (Paschim Banga Khet Mazdoor Samity v State of West Bengal 1996). The FMRAI petition is framed on exactly this basis. A law that protects the integrity of prescribing, and with it affordable and rational access to medicines, advances that duty.

A statute would of course restrict commercial freedom. Article 19(1)(g) protects the right to carry on any trade or business, subject to reasonable restrictions in the public interest under Article 19(6). The Court tests such restrictions through proportionality: a legitimate aim, a rational connection between the measure and that aim, necessity in the sense that no less intrusive measure would do as well, and a proper balance between the benefit and the burden (Modern Dental College and Research Centre v State of Madhya Pradesh 2016; Justice K S Puttaswamy (Retd) v Union of India 2017). A narrowly drawn ban on inducements, with exceptions for legitimate education, research and fair-value services, should satisfy each limb. The aim, protecting patients and the

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integrity of prescribing, is plainly legitimate. The link is supported by the evidence discussed above. And the voluntary regime's history suggests that milder measures have not worked.

Commercial speech is protected under Article 19(1)(a) (Tata Press Ltd v Mahanagar Telephone Nigam Ltd 1995), but the protection attaches to the communication of information. A gift, a paid holiday or a cash grant to a prescriber is a transfer of value and not a statement about a drug. Regulation can leave companies entirely free to explain their products, publish data and advertise to the extent that the law already permits.

On legislative competence, drugs and poisons appear as Entry 19, and the legal, medical and other professions as Entry 26, in List III (the Concurrent List) of the Seventh Schedule. Parliament may legislate on both. A central statute, with room for State Medical Councils to continue their disciplinary role, would sit comfortably within that distribution.

7. Lessons from Other Jurisdictions

Other systems have taken a range of approaches, summarised in Table 1. The aim here is to extract design lessons, and not to import any single model.

Jurisdiction	Principal instruments	Core approach	Enforcement
India	Indian Medical Council Regulations 2002 (reg 6.8); UCPMP 2024	Professional ban on recipients; industry code for companies; no general statute	Medical council discipline; association sanctions; tax disallowance
United States	Sunshine Act (ACA s 6002); Anti-Kickback Statute	Mandatory public reporting of payments; criminal law against kickbacks	Civil monetary penalties; criminal prosecution
France	Law no 93-121 (1993); Loi Bertrand (2011)	Prohibition with authorised exceptions, plus public disclosure	Criminal and professional sanctions
EU and United Kingdom	Directive 2001/83/EC, art 94; Human Medicines Regulations 2012; ABPI Code	Statutory ban on inducements with narrow exceptions; co-regulatory industry code	Medicines regulator; independent industry complaints authority

Table 1: Selected regulatory approaches to pharmaceutical inducements

The United States has chosen transparency in preference to prohibition. The Physician Payments Sunshine Act, enacted as part of the Affordable Care Act, requires manufacturers to report payments and other transfers of value to physicians and teaching hospitals, and the data are published through the Open Payments system (Patient Protection and Affordable Care Act 2010, s 6002). Kickbacks tied to federal healthcare programmes remain criminal under the Anti-Kickback Statute (42 USC § 1320a-7b(b)). The American approach shows how much can be learned once payments are visible, but it leaves a good deal of permitted activity in place.

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France combined an older prohibition with a newer disclosure rule. A law of 1993 forbade benefits to health professionals, subject to hospitality exceptions governed by prior notification or authorisation, and the Loi Bertrand of 2011 added transparency obligations, now implemented through a public database (Loi no 93-121 1993; Loi no 2011-2012 2011). The European Union's medicines directive provides that no gift or pecuniary or in-kind benefit may be supplied or promised to those qualified to prescribe, except for inexpensive items relevant to the practice of medicine (Directive 2001/83/EC, art 94). The United Kingdom implements that rule in its Human Medicines Regulations and layers an industry code and an independent complaints authority on top (Human Medicines Regulations 2012; Association of the British Pharmaceutical Industry 2024).

Three lessons emerge. Disclosure and prohibition work best together: the first makes the second enforceable, and the second gives the first a point. Ban-with-exceptions is a familiar drafting technique, and it allows modest, relevant items without opening the door to resorts and cash. Finally, the most durable systems keep an industry body in the picture, but only beneath a statutory floor. India's task is to build that floor.

8. Designing a Workable Statute

This section sketches the outline of a possible Pharmaceutical Marketing (Regulation and Transparency) Act. It is a proposal for discussion rather than a finished draft, and it is meant to be read alongside the work of the committee the Supreme Court has now directed the Union to constitute.

8.1 Scope and Core Prohibitions

The Act should apply to manufacturers, importers, distributors, marketing agents and medical device companies, and, critically, to intermediaries and third-party event organisers acting on their behalf. It should prohibit any gift, cash, hospitality, travel or other benefit offered to a healthcare professional or a family member, subject to listed exceptions: samples within quantitative limits, inexpensive educational items directly relevant to practice, fair-value payment for genuine services under a written agreement, and research support channelled through institutions. Any benefit linked to prescribing volume or sales should be prohibited without exception.

The offence should be defined by the transfer, and not by proof that it changed any particular prescription. Requiring regulators to show causation would recreate the very evidentiary burden that has made current provisions hard to use. The Act should apply to recipients too, in parallel with the professional regulations, so that both sides of the transaction stand exposed.

Definitions will matter. "Healthcare professional" should cover doctors, dentists, pharmacists and hospital purchasing staff who influence prescribing or procurement, and "benefit" should be defined broadly enough to include sponsored memberships, ghost-written material and sham consultancies. Drafting these terms carefully is what separates a statute that works from one that is merely announced.

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8.2 Transparency

A national, searchable and machine-readable register should record transfers of value above a small threshold, identifying the company, the recipient (by registration number), the amount and the nature of the payment. Companies should file annually, and the regulator should have audit powers. Hospitals and medical colleges should be required to publish the interactions their staff have with industry. The design should be aligned with India's data-protection law, but disclosure imposed by statute for a public-interest purpose is a familiar category, and it should not be allowed to become a pretext for secrecy.

8.3 Enforcement

The enforcement structure should be layered, in the manner suggested by Ayres and Braithwaite (1992). At the base, association ethics committees under the UCPMP can continue to receive complaints and resolve minor matters. Above them, a designated regulator, housed within an existing body such as the Central Drugs Standard Control Organisation or constituted separately, should have powers to investigate, to inspect records, to issue compliance orders and to impose civil penalties scaled to company turnover. At the top should sit tougher sanctions for repeat or serious violations: debarment from government procurement, suspension of marketing permissions and criminal liability for those who knowingly commit or consent to the offence. This follows a pattern familiar from other Indian regulatory statutes.

Disciplinary action against doctors should remain with the Ethics and Medical Registration Board and the State Medical Councils, with a statutory duty on the regulator and the Board to share information. Whistleblower protection matters especially, since medical representatives are often the first to see the practices they are asked to follow. Decisions of the regulator should be subject to appeal to an appellate tribunal and then to the High Courts.

8.4 Complementary Reforms and Phasing

A statute will not succeed in isolation. If industry funds nearly all CME, doctors will keep going to industry-sponsored events regardless of what the law says. A pooled, independently administered CME fund, accredited providers and a stronger culture of generic prescribing would reduce the demand side of the problem. Rational trade margins and price regulation, already part of the Drugs (Prices Control) Order 2013 framework, help reduce the commercial incentive to compete on inducements. Medical education should include teaching on conflicts of interest.

The law could also be phased. An initial period of disclosure and guidance, followed by full enforcement of penalties, would give companies time to adjust, and would give the regulator time to build capacity. A statutory review after a few years, informed by the register's own data, would let Parliament adjust the exceptions and penalties in light of experience. A time-limited pilot with a few large manufacturers could test the reporting templates before the register goes national.

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9. Conclusion

Pharmaceutical freebies are an ethical problem because they place the prescriber's independent judgment under a quiet and constant pressure, and the patient bears the cost in both money and trust. The Indian response so far has been to regulate the doctor by professional rule, to ask companies to follow a code, and to let the tax authorities close one loophole. Each step was sensible. Together they leave a regime in which no statute directly prohibits the inducement, sanctions are weak, there is no public register, and enforcement is fragmented.

The answer to the question posed in the title is yes: India should enact a binding statutory framework. The framework should be modest in aim and firm in method. It should prohibit what is plainly improper, permit what is genuinely useful, make every transfer visible, and back the whole with penalties that a large company cannot treat as a cost of business. It rests on secure constitutional ground, and comparative experience shows that it is practicable.

The Supreme Court's direction of 8 October 2026 gives the government a chance to move beyond debating whether the code should be binding. The committee's task should be to design the law, and to do so with the humility to recognise that no statute can replace professional culture. The law's role is to make it easier for doctors who want to prescribe independently to do so, and harder for anyone else to pretend that a gift is only a gift.

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