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Misuse and Abuse of Prescription Drugs: Loopholes in NDPS Regulation

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Abstract
Prescription drug misuse in India is an emerging public health and legal challenge, particularly involving substances such as Tramadol, Alprazolam, and Codeine-based cough syrups. These drugs, while medically essential, are increasingly misused for recreational purposes and easily diverted into the black market due to regulatory loopholes. Despite existing frameworks under the Narcotic Drugs and Psychotropic Substances (NDPS) Act, 1985, and the Drugs and Cosmetics Act, 1940, enforcement remains fragmented and reactive. This paper explores the socio-legal dimensions of prescription drug abuse, identifies weaknesses in current regulation, and suggests actionable reforms. Using case studies, policy analysis, and international comparisons, the study emphasizes the urgent need for integrated monitoring and balanced regulatory mechanisms.

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I. Introduction

The misuse and abuse of prescription drugs have emerged as a complex and under-acknowledged public health and regulatory crisis in India. While prescription medicines are intended for therapeutic use under professional supervision, many of them—especially opioids, sedatives, and cough suppressants—have found their way into patterns of recreational use, dependence, and illicit distribution. Medications such as Tramadol, Alprazolam, and Codeine-based syrups, although legally manufactured and dispensed, are increasingly implicated in episodes of addiction, self-medication, accidental overdose, and organized diversion. These drugs occupy a unique position in drug policy: unlike illicit narcotics, their abuse is facilitated not by clandestine manufacture alone, but by systemic regulatory lapses within the licensed pharmaceutical supply chain.

The global experience of prescription drug abuse, particularly in North America, has shown how pharmaceutical opioids can catalyze public health disasters when regulatory systems fail to distinguish between medical access and diversion risk (Volkow et al., 2011). India, with its vast and diverse pharmaceutical industry, porous regulatory oversight, and inconsistent state-level enforcement, stands particularly vulnerable. According to the AIIMS-MoSJE national survey (2019), nearly 2.26% of the population misuses pharmaceutical opioids, often accessed through over-the-counter sales, informal chemists, and unregulated online platforms. These trends underscore the reality that the conventional dichotomy between legal and illegal drugs no longer holds—prescription drugs occupy a grey zone where law, medicine, and market intersect problematically.

The regulatory response to prescription drug abuse in India is framed primarily through the Narcotic Drugs and Psychotropic Substances (NDPS) Act, 1985, and the Drugs and Cosmetics Act, 1940, along with relevant Schedules (H, H1, X) under the Drug Rules. However, the effectiveness of these laws is undermined by delayed notification of addictive substances (e.g., Tramadol was added to NDPS only in 2018), lack of real-time prescription monitoring systems, fragmented drug control administration, and poor inter-agency coordination between health and law enforcement bodies (Sharma & Gupta, 2020). Moreover, the NDPS Act, designed originally to tackle narcotics and psychotropics in the context of trafficking, has limited mechanisms to monitor legal pharmaceuticals that are diverted post-manufacture.

The paper explores the loopholes in the regulatory system of control of prescription drugs misuse in India. It contends that existing frameworks are not responsive to the complexities of the reality of pharmaceutical abuse and provides a redesign of the enforcement mechanisms that canalizes access, accountability, and harm reduction. The paper will use case studies, policy analysis, and cross-country comparison to contextualize this challenge in India in a larger debate of controlled substances, pharmaceutical politics and government, and the politics of medical regulation.

II. Legal and Regulatory Framework Governing Prescription Drugs in India

The Indian legal framework backing prescription drug control amounts to a dual control system, which consists as the Narcotic Drugs and Psychotropic Substances (NDPS) Act, 1985, and the Drugs and cosmetics Act, 1940, and the Drugs and cosmetics rules, 1945. These regulations were initially developed to reconcile the two priorities, frequently conflicting, one is the access to medicines as a therapeutic agent, and the other danger of diversion, misuse, and trafficking. Nevertheless, the current situation with the pharmaceutical abuse, and especially abuse of the prescription psychoactive drugs has highlighted the shortcomings, and the lapses in these legislative tools.

2.1 The NDPS Act, 1985

The NDPS Act is India's principal law regulating the production, manufacture, possession, sale, and transport of narcotic drugs and psychotropic substances. The Act was enacted in compliance with India's international obligations under UN drug control treaties, such as the 1961 Single Convention on Narcotic Drugs, the 1971 Convention on Psychotropic Substances, and the 1988 UN Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances.

While the NDPS Act is stringent in dealing with illicit narcotics, it was not originally designed to regulate prescription pharmaceuticals. This lacuna delayed the inclusion of several widely misused prescription drugs under the Act. For example, Tramadol, a synthetic opioid known for its abuse potential, was only notified as a psychotropic substance under NDPS in April 2018, following its increasing abuse by terrorists in conflict zones and addicts in Indian metros (Press Information Bureau, 2018). This delay in scheduling reflects a broader institutional inertia in responding to emerging threats within the legal drug supply chain.

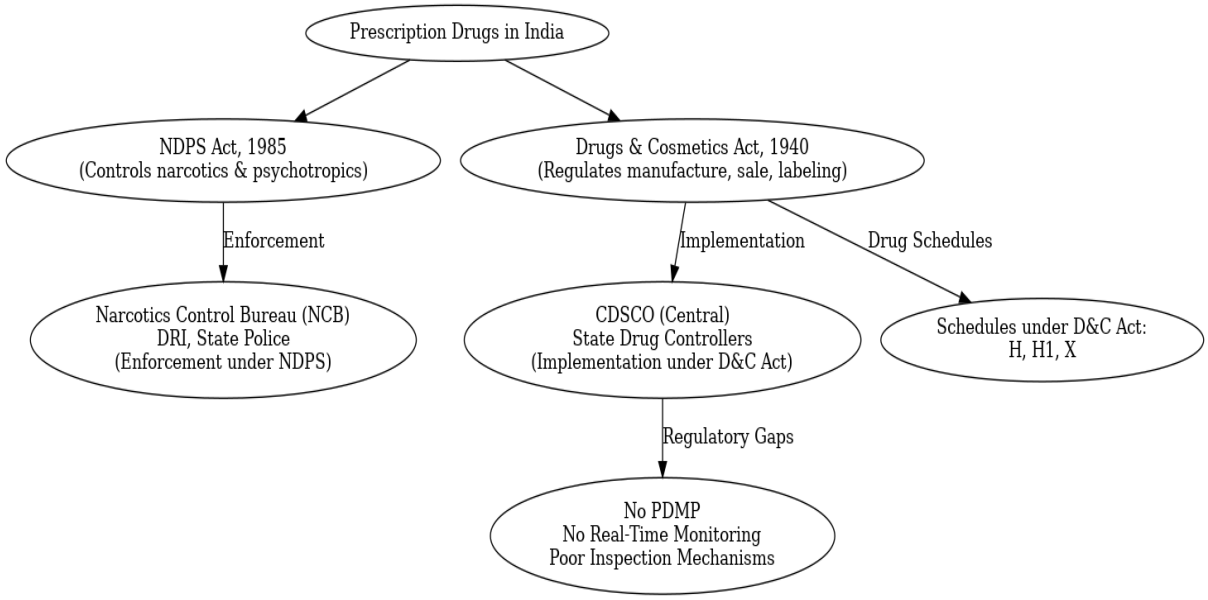
2.2 The Drugs and Cosmetics Act, 1940

The Drugs and Cosmetics Act governs the manufacture, distribution, and sale of drugs in India. The Act categorizes prescription drugs under Schedules H, H1, and X, each with varying degrees of control:

- **Schedule H** drugs require a prescription but are widely sold without one.
- **Schedule H1**, introduced in 2013, mandates pharmacists to maintain detailed registers of sales, including prescriber information, buyer details, and prescription copies for drugs prone to misuse (e.g., Tramadol, Alprazolam).
- **Schedule X** drugs (e.g., morphine, methadone) require both a valid prescription and a retention of records for two years.

Despite these provisions, implementation remains deeply flawed. Regulatory oversight is often limited by:

- A shortage of **drug inspectors** and inadequate inspections,
- Absence of **real-time electronic prescription monitoring systems**, and
- Rampant non-compliance by chemists and wholesale dealers (Dey & Kaur, 2022).



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III. Patterns and Trends in Prescription Drug Misuse in India

Prescription drug misuse in India is no longer a marginal or isolated phenomenon. It has become a mainstream and complex public health concern shaped by socio-economic distress, regulatory lapses, cultural perceptions of pharmaceuticals, and evolving modes of access. Unlike illicit substances such as heroin or methamphetamine, prescription drugs are embedded within the formal medical system, making their misuse more insidious and difficult to detect (UNODC, 2011; Volkow et al., 2011).

3.1 Commonly Misused Prescription Drugs

Several pharmaceutical drugs are consistently reported in abuse cases across India:

- **Tramadol**: A synthetic opioid originally prescribed for moderate to severe pain. Its euphoric effect and low cost have made it a popular choice among youth and manual laborers, especially in North India.
- **Alprazolam and Diazepam**: These benzodiazepines, marketed for anxiety and sleep disorders, are frequently consumed as sedatives, especially in urban settings and party circuits (Dasgupta et al., 2020).
- **Codeine-based syrups**: Intended for cough suppression, these are often misused recreationally, particularly among adolescents in states like Punjab, Assam, and West Bengal.
- **Tapentadol and Pentazocine**: Newer analgesics entering illicit use due to their relative potency and accessibility.

Most of these drugs fall under Schedule H1 or X, but their continued abuse underscores a **regulatory failure in controlling distribution and ensuring prescription compliance**.

3.2 Socio-Demographic Trends

A notable feature of prescription drug misuse in India is the **diverse profile of users**:

- **Youth and Adolescents**: School and college students are often initiated into drug use through easily accessible medications, particularly cough syrups and sedatives, which are wrongly perceived as "safe" alternatives to illicit substances.
- **Labour Class and Migrant Workers**: Many workers consume Tramadol or similar analgesics to suppress fatigue and work longer hours. This pharmacological exploitation is seldom acknowledged as abuse, yet it contributes to dependency (Verma, 2018).
- **Urban Professionals**: Stress-related self-medication with anti-anxiety drugs has become common among white-collar workers, especially post-COVID, leading to overdependence.
- **Women**: Often underreported, women tend to misuse prescription sedatives and painkillers within domestic settings, frequently without medical supervision.

3.3 Distribution Channels Enabling Misuse

The proliferation of prescription drug abuse is closely tied to **loopholes in drug distribution**:

- **Over-the-Counter (OTC) Sales**: Despite regulatory provisions, most Schedule H/H1 drugs are dispensed without prescriptions, especially in small towns and rural areas.
- **Unlicensed Chemists**: Inadequate oversight has led to the growth of informal pharmaceutical vendors operating without valid licenses.
- **Online Pharmacies**: While e-pharmacies offer convenience, many lack proper verification protocols, allowing easy access to habit-forming drugs.
- **"Doctor Shopping"**: Patients visit multiple clinics to obtain overlapping prescriptions, taking advantage of the absence of real-time monitoring.

3.4 Regional Patterns and Hotspots

States like Punjab, Haryana, Uttar Pradesh, and Assam have reported high incidence of prescription drug abuse. In Punjab, for example, opioid substitution therapy clinics have documented significant cases of Tramadol and Buprenorphine misuse (Ray et al., 2017). In North-Eastern states, codeine-based syrups have been banned periodically due to mass misuse among teenagers, despite pushback from pharmaceutical lobbies.

Urban centers such as Delhi, Hyderabad, and Mumbai have seen a rise in benzodiazepine abuse within both recreational and self-medication contexts. These trends indicate that prescription drug abuse is no longer a peripheral issue, but a mainstream public health concern warranting urgent intervention.

3.5 Psychological and Public Health Implications

Prescription drug abuse presents specific risks that are often overlooked due to the legal status of the substances:

- Dependency and Withdrawal: Chronic users develop tolerance, leading to escalated dosage and physical dependence.

- Polydrug Use: Many individuals combine pharmaceuticals with alcohol or illicit drugs, increasing toxicity and overdose risk.
- Delayed Treatment: Because of the misconception that prescription drugs are "less harmful," users often seek help only after severe psychological or physiological damage.
- Stigma and Underreporting: Families are less likely to acknowledge abuse of legal drugs, leading to underreporting and gaps in rehabilitation outreach.

IV. Regulatory Loopholes in Prescription Drug Control in India

The regulatory architecture designed to control the use and distribution of narcotic and psychotropic substances in India rests primarily on two pillars: the Narcotic Drugs and Psychotropic Substances (NDPS) Act, 1985, and the Drugs and Cosmetics Act, 1940, along with its associated rules and Schedules. While these legislations offer a robust legal framework in principle, their implementation, enforcement, and coordination have been marred by critical gaps, rendering the system insufficient to prevent the rampant misuse of prescription pharmaceuticals. This section explores the core structural, administrative, and policy-level loopholes that facilitate the diversion of legally manufactured medicines into illicit use.

4.1 Delayed or Inadequate Drug Scheduling

One of the fundamental issue is the delay in identifying and listing the newly emerging high-risk pharmaceuticals under the NDPS Act. To illustrate, Tramadol, which is an artificially created opioid with known abuse potential the world over was never covered under NDPS until 2018 despite a cautionary note given by the World Health Organization (WHO) and prevalence rates of poor usage in India and other developing nations (Press Information Bureau, 2018). This delay gave it time to legally be distributed on over-the-counter, and underground markets were formed. In addition, the regulatory system in India lacks a coherent system of pharmacovigilance that can be used to assess and schedule newly discovered substances at risk of abuse in a timely manner (Sharma & Gupta, 2020).

4.2 Fragmented Regulatory Jurisdiction

India's drug regulatory system suffers from a diffused and poorly coordinated institutional structure. While the Central Drugs Standard Control Organization (CDSCO) is responsible for approving and regulating drugs nationally, the implementation and enforcement responsibilities lie with state drug control authorities. This federal fragmentation results in inconsistent application of rules, particularly concerning the sale of Schedule H1 and Schedule X drugs. Many state drug controllers lack sufficient manpower, funding, and infrastructure, leading to weak inspections and poor enforcement at the ground level (Dey & Kaur, 2022).

Similarly, enforcement under the NDPS Act is the responsibility of the Narcotics Control Bureau (NCB), but it often lacks real-time coordination with CDSCO or health departments, resulting in blind spots in tracking prescription drug diversion.

4.3 Absence of a Prescription Monitoring Infrastructure

India does not currently operate a Prescription Drug Monitoring Program (PDMP) or any centralized digital system for tracking the prescription, dispensation, and consumption of high-risk medicines. This allows for unchecked practices such as:

- **"Doctor shopping"**, where patients consult multiple physicians to obtain overlapping prescriptions.
- **Pharmacy-hopping**, where the same medicine is bought from several chemists due to the absence of cross-verification protocols.
- **Over-prescription by unethical medical practitioners**, who may be incentivized by pharmaceutical companies or operating with limited awareness of the addictive nature of some drugs.

By contrast, countries such as the United States, Canada, and Australia employ PDMPs to electronically track prescriptions, flag irregular patterns, and prevent diversion (Volkow et al., 2011).

4.4 Ineffective Enforcement of Schedule H1 Regulations

In response to rising abuse, India introduced Schedule H1 in 2013, which mandates that chemists maintain:

- The name and address of the prescriber and patient,
- The quantity of the drug sold,
- A copy of the prescription,
- Retention of records for at least 3 years.

However, studies and field audits have revealed that compliance is rare. According to a 2020 CDSCO internal report, over 70% of pharmacies surveyed across six states failed to maintain mandatory H1 registers, and many sold drugs without prescriptions (Ray & Chatterjee, 2021). Enforcement is weakened further by:

- Lack of digitization, making records easy to manipulate or fabricate.

- Poor auditing and inspection frequency, especially in rural areas.
- Minimal penal consequences for violations, with few successful prosecutions.

4.5 Online Pharmacies and Unregulated E-Commerce

The exponential growth of online pharmacies (e-pharmacies) has introduced new regulatory challenges. While the government has drafted guidelines under the Drugs and Cosmetics Rules (Draft Amendment, 2018) to regulate e-pharmacies, they remain non-binding and not legally enforced. Many platforms allow:

- Purchase of Schedule H1 drugs without uploading prescriptions,
- Bulk purchase of addictive medicines with no upper cap,
- Delivery to minors and unauthorized persons.

Unlike countries such as the UK, which require digital verification of prescriptions and restrict online sale of controlled substances, India's regulatory oversight remains rudimentary. The lack of real-time verification, licensing clarity, and content moderation opens avenues for abuse and black-market proliferation (FICCI Health Report, 2021).

4.6 Loopholes in Pharmaceutical Production and Distribution

The licensing and quota-based manufacturing system intended to limit the production of psychotropic drugs is not foolproof. In practice:

- Pharma companies often exceed production limits, under- or mis-reporting their output to regulatory authorities.
- Bulk distributors divert surplus stock to unauthorized vendors or front companies.
- Inter-state diversion exploits jurisdictional differences in drug enforcement, with high-demand drugs transported to states with lax inspection regimes.

This lack of transparent auditing of production and inventory allows large volumes of drugs like Tramadol, Alprazolam, and Codeine syrups to enter the illicit supply chain under the garb of legitimate commerce (Nair & Rao, 2017). India's existing regulatory apparatus is conceptually strong but structurally fragmented and operationally weak. The absence of real-time prescription tracking, inadequate drug scheduling, poor record maintenance, and the unchecked growth of online pharmaceutical trade have created an enabling environment for the misuse of prescription drugs. These loopholes are not merely administrative oversights; they represent systemic failures with serious public health and legal implications. Addressing them requires coordinated policy reform, technological integration, and inter-agency collaboration at both central and state levels.

V. Black Market Dynamics and Case Studies

5.1 The Economics of Diversion

The existence of a black market where the diversion of lawfully produced drugs is flourishing is one of the most evil of aspects in India regarding prescription drug abuse. Contrary to clandestine production of illegal narcotics, black-market prescription drugs may enter the illicit territory via legal supply companies: pharmaceutical manufacturers, wholesalers, registered chemists, and be diverted to extra-legal or unofficial channels. This system enjoys laxity in regulation, corruption and loopholes in inventory control of substances, especially those most prone to misuse such as Tramadol, Alprazolam and Codeine syrups (Nair & Rao, 2017).

A report by the Narcotics Control Bureau (NCB) in 2022 indicated that at least 4 million tablets of Tramadol were intercepted in four different states including those stored legitimately in warehouses that were misused to distribute the drug in parallel. In these situations, the diversion can be concealed by creating forged invoices, overproduction, or wholesale sales of drugs without receipt in incompliance pharmacies and illegitimate resellers.

5.2 Case Studies

- **Delhi, 2020**: A major bust involved over 10 lakh Alprazolam tablets illegally stored in a warehouse operated by unlicensed suppliers. The consignment was traced back to a licensed manufacturer who failed to report surplus inventory (Hindustan Times, 2020).
- **Mumbai, 2021**: A forensic probe by the Maharashtra FDA revealed that Tramadol was being sold under alternative packaging to avoid NDPS scrutiny, and distributed through e-commerce platforms without prescription verification.
- **Assam, 2023**: Codeine syrups were found circulating among teenagers, prompting local authorities to restrict sales without biometric prescription validation. The syrups were traced to diverted government-subsidized stocks.

These case studies reflect the broader failure of vertical accountability, where drugs escape regulation at multiple points in the supply chain—manufacturing, licensing, sale, and audit.

VI. International Legal and Policy Comparison

To situate India's regulatory approach in a global context, it is useful to compare it with frameworks in countries like the United States, United Kingdom, and Australia, where prescription drug abuse has long been recognized as a public health emergency.

6.1 United States: PDMP and DEA Classification

The U.S. Drug Enforcement Administration (DEA) classifies controlled substances into five schedules based on abuse potential. The U.S. employs a Prescription Drug Monitoring Program (PDMP) in every state, allowing real-time tracking of Schedule II-IV prescriptions and flagging suspicious patterns, such as "doctor shopping" or overlapping prescriptions (Volkow et al., 2011). Enforcement is strict, and prescribers are held legally accountable for overprescription or improper documentation.

6.2 United Kingdom: Controlled Drugs Supervision

In the UK, controlled substances are regulated under the Misuse of Drugs Act (1971) and monitored through the Controlled Drug Regulations, which require prescribers and dispensers to maintain meticulous electronic records. Online sales of controlled drugs are strictly prohibited without registered prescription platforms authorized by the Care Quality Commission.

6.3 Comparison with India

Feature	India	United States	United Kingdom
Digital Prescription Monitoring	Absent	PDMP operational in all states	NHS e-Prescribing system
Real-Time Inventory Tracking	Manual and fragmented	Integrated with PDMP	NHS Controlled Drug Logbooks
Online Pharmacy Regulation	Draft rules (non-binding)	Licensed under DEA regulation	Strict CQC licensing
Legal Enforcement Mechanism	Weak prosecution	High conviction and audits	Strong regulatory culture

India's lack of digital enforcement tools, centralized prescription verification, and interoperable databases places it at a significant disadvantage in mitigating prescription drug misuse.

VII. Recommendations and Policy Reforms

The growing crisis of prescription drug misuse in India requires a multi-pronged and institutional response that moves beyond reactive enforcement and addresses systemic and structural failings.

7.1 Legal and Regulatory Reforms

- Amend the NDPS Act to allow for more dynamic scheduling based on evolving misuse patterns, including a fast-track process for new psychoactive substances.
- Make Schedule H1 compliance mandatory with e-records, with non-compliance resulting in suspension of pharmacy licenses.
- Enforce the pending regulation of e-pharmacies, including licensing, prescription validation protocols, and a central registry of online platforms.

7.2 Technological Integration

- Establish a centralized digital prescription monitoring system (PDMS) akin to PDMP in the U.S., integrating all hospitals, clinics, and pharmacies.
- Use biometric prescription linkage for dispensing high-risk drugs, especially in rural and high-abuse zones.
- Develop AI-based surveillance tools to identify irregular patterns in pharmaceutical transactions.

7.3 Inter-Agency Collaboration

- Strengthen coordination between CDSCO, state FDAs, NCB, and IT cells for real-time tracking and information sharing.
- Set up joint task forces at zonal levels to investigate pharmaceutical abuse networks.

7.4 Awareness, Education, and Harm Reduction

- Launch national campaigns under MoHFW and NCERT to raise awareness about the risks of prescription drug misuse, particularly among youth and caregivers.
- Integrate training on pharmaceutical ethics and addiction risk into medical and pharmacy curricula.
- Expand community-based de-addiction centres focusing on pharmaceutical dependence.

VIII. Conclusion

The misuse and abuse of prescription drugs in India has emerged as a significant public health and legal concern that defies the traditional dichotomy between licit and illicit substances. This study has demonstrated that pharmaceuticals such as Tramadol, Alprazolam, and Codeine-based syrups, though medically essential, have become widely diverted, misused, and trafficked—often through legal channels that have failed in their regulatory mandates. Despite the existence of the Narcotic Drugs and Psychotropic Substances (NDPS) Act, 1985, and the Drugs and Cosmetics Act, 1940, India's current regulatory ecosystem lacks the structural coherence, technological backbone, and inter-agency synergy required to effectively control prescription drug abuse.

Inability to install prescription monitoring in real-time, various forms of drug scheduling flaws, interstate varying enforcement, and uncontrolled growth online drug stores have provided the growth media upon which the misuse of pharmaceuticals proliferated. Even these oversights are purely technical, but in fact a broader institutional complacency and policy obliviousness to the distinctive dangers of prescription drugs, with their cultural approbation and medical halo, that generally obscure their capacity to do harm. Moreover, indicated in the social-economic and demographic construct, the misuse of prescription drugs in India does not subscribe to or modernize along a regional or social demographic frame.

It also targets adolescents, industrial workers, women and even medical professionals, differently weakening them and allowing them different accessibility and vulnerability. What can be observed on the black market dynamic case studies is the inter-reliance of the regulatory lapse at the manufacturing, distribution and retail level to keep a parallel economy of diverted pharmaceuticals.

The comparison of the global best practices, mainly the countries of the United States and the United Kingdom, shows that India has to go towards a more inclusive, technology-oriented, and preventive approach to pharmaceutical regulation. It will involve, not just a change in laws and technological capability, but a paradigm shift in perceiving drug abuse as both a problem of the criminal justice system, but also of a problem of public health.

In sum, prescription drug abuse in India is just but a symptom of more conflict in the intersection of access, accountability and enforcement. This will need an approach involving multi-stakeholders which combine legal reform, regulator innovation, public-awareness efforts, and strengthening of health systems. Then alone India will be able to dream of striking a happy medium between the justifiable demands of access to medicine and the dire need to clamp down on abuse and protect population health.

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