"Pills, Profits, and Problems: An Anatomy of India's Pharmaceutical Crisis"

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“Pills, Profits, and Problems: An Anatomy of India’s Pharmaceutical Crisis”

Edited by *Dr. Rajesh Ranjan (Editor), Dr. Pulkit Khanna (Co-Editor)*

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Foreword

The Indian pharmaceutical sector stands as both a beacon of possibility and a mirror to our systemic challenges. On one hand, it is hailed as the "pharmacy of the world," supplying affordable generics to countries across continents and enabling access to lifesaving drugs. On the other, it is plagued by issues of quality, regulation, affordability, and ethics that threaten to erode public trust.

This book, Pills, Profits, and Problems: An Anatomy of India's Pharmaceutical Crisis, courageously confronts these dualities. With a meticulous, evidence-based approach, it dissects the perspectives of four critical stakeholders—manufacturers, doctors, patients, and chemists—who together shape the destiny of healthcare delivery in India. The analysis is not only thorough but also empathetic, acknowledging the pressures and realities that each actor faces, while never losing sight of the larger goal: safeguarding public health.

The section on manufacturers sheds light on the tension between global competitiveness and domestic responsibility, exposing how regulatory loopholes, counterfeit drugs, and underinvestment in research perpetuate systemic weaknesses. Later chapters amplify the voices of doctors navigating ethical dilemmas, patients struggling with access and affordability, and chemists balancing business pressures with their duty as gatekeepers of medicines. Together, these narratives create a panoramic view of a sector too often described in fragments.

As practicing physicians and public health advocates, we have seen firsthand the consequences of the lapses highlighted here—patients bearing the burden of irrational prescriptions, substandard drugs, and financial exploitation. Yet, this book does more than catalogue problems: it proposes pathways forward. By recommending policy reforms, regulatory strengthening, and a culture of ethical accountability, it provides a roadmap for change that is both pragmatic and urgent.

This is not just a book for academics or policymakers—it is a call to action for every stakeholder in the healthcare ecosystem.

If India is to maintain its role as the world's trusted supplier of medicines while ensuring equity and quality at home, the insights in these pages cannot be ignored.

Dr. Rajesh Ranjan

Dr. Pulkit Khanna

Preface

The idea for this book arose from a deep concern: how could a country that supplies one-fifth of the world's generic medicines continue to struggle with access, affordability, and accountability within its own borders? As a doctor and a student of health administration, I have seen both sides of this paradox—patients denied essential drugs due to cost, hospitals influenced by pharmaceutical marketing, and regulators stretched far beyond their capacity.

This book is an attempt to unravel the complex web of India's pharmaceutical sector by examining it through the lens of its key stakeholders: manufacturers, doctors, patients, and chemists. Each chapter highlights not only the problems but also the forces—economic, political, and cultural—that sustain them.

My intent is not to vilify any one group, but rather to illuminate how systemic weaknesses and competing incentives create an environment where profit can too easily outweigh public health. At the same time, this book offers pathways for reform—grounded in evidence, case studies, and global best practices—that could help India bridge the gap between being the "pharmacy of the world" and ensuring quality healthcare for all its citizens.

I hope this work serves as both a mirror and a map: a mirror to reflect our current realities, and a map to guide us toward a more ethical, equitable, and effective pharmaceutical ecosystem.

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Part 1

Manufacturers – The Pill Factories and the Profit Motive
Dr. Rajesh Ranjan

Chapter 1

The Making of India's Pharma Powerhouse

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Introduction: The Paradox of a Pill Powerhouse

India is hailed globally as the "pharmacy of the world." It produces **over 60% of global vaccines**, **40% of generics consumed in the United States**, and supplies drugs to more than **200 countries**. Yet, within its own borders, the country faces a silent pharma crisis—**drug quality lapses, unaffordable treatment, and chaotic regulation**.

This chapter traces the rise of India's pharmaceutical empire—starting from post-independence scarcity to global supplier dominance—while exposing contradictions in the domestic health system.

1. The Master Stroke - From Import Dependence to Reverse Engineering

Prior to the 1970s, India was **dependent on multinational corporations** for 70% of its medicines. Drug prices were unaffordable for most, and MNCs maintained monopolies through patent control. A transformative moment arrived in 1972 with the **Indian Patents Act**, which **removed product patents for pharmaceuticals** and allowed only **process patents**.

This legal innovation encouraged Indian firms to **reverse-engineer costly patented drugs** and manufacture them at a fraction of the cost.

"What Indian pharma lacked in molecule innovation, it made up with process ingenuity." – Dr. R. A. Mashelkar, former Director

General, CSIR.

| Table 1: Impact of 1970s Patent Policy on Domestic Drug Production |

Year	% Market Share by Indian Firms
1970	20%
1980	40%
1990	70%
2000	>80%

Source: Mashelkar Committee Report (2003) [1]

This period saw the rise of companies like **Cipla**, **Lupin**, **Dr. Reddy's**, and **Ranbaxy**, who used process innovation to become dominant in **antibiotics, tuberculosis drugs, and antiretrovirals.**

2. Economic Liberalisation and Export Boom : Impact of FDI

The **1991 liberalisation reforms** allowed FDI in pharmaceuticals, tax incentives for R&D, and greater autonomy for Indian firms. As the world began relying on low-cost generics, India stepped up. Export growth was driven by:

- Compliance with **USFDA**, **EMA**, **MHRA**, and **WHO-GMP** standards
- Filing of **Abbreviated New Drug Applications (ANDAs)** for regulated markets
- Contract manufacturing and **API (bulk drug)** exports

| Table 2: Pharma Export Growth (2000–2022) |

Year	Export Value (USD Billion)
2000	1.5
2010	10.3
2020	20.7
2022	24.4

Source: Ministry of Commerce & Industry, GoI (2023) [2]

India is now the **largest provider of generic medicines globally**, meeting **62% of global vaccine demand** and **40% of generic demand in the U.S.** [3].

3. The Domestic Pharma Market: A Fragmented Giant

While the export story shines, the **domestic pharma market** suffers from:

- **Brand-driven prescription culture**
- **Over 60,000 drug brands** flooding the market
- **Over 10,000 small and medium companies**, many poorly regulated

India's domestic pharma market is valued at approximately **? 2.8 lakh crore ($34 billion)** in 2023, growing at **~10% CAGR** [4].

| Table 3: Market Segmentation – India Pharma Sector (2023) |

Total market size	? 2.8 lakh crore
% by Branded Generics |	82%
% by Over-the-Counter (OTC)	10%
% by Patented/Innovative	<2%

Source: IQVIA India Pharma Outlook (2023) [4]

4. The Dual Track: Export Quality vs Domestic Chaos: Challenge to maintain quality of Domestic drugs

India's top pharma exporters maintain strict quality to meet USFDA and EMA standards. Yet **over 70% of domestic-focused plants are not internationally certified**, often bypassing WHO-GMP norms [5].

In a CDSCO 2019 inspection of 2,000 drug samples, **7.4% were found to be substandard**, while **0.3% were outright spurious** [6].

It has been found and verified that quality of the drugs which are exported and the drugs which are manufactured for domestic consumption are mostly from separate units and differs in the quality.

"What is exported is not what is sold to our own citizens." – Former Drug Controller, Maharashtra

| Table 4: Drug Quality Snapshot (2019) |

Total Samples Tested	47,951

Substandard	3,499 (7.4%)
Spurious	134 (0.3%)

Source: CDSCO Annual Report (2020) [6]

5. China Dependency for APIs: India's Achilles' Heel

Despite being the world's third-largest drug producer by volume, India imports **~70% of its Active Pharmaceutical Ingredients (APIs)** from China [7]. Even though China being the biggest threat to national security and constantly violating border policies and making political disturbances, we still have a lot of import surplus in terms of API formulations.This was starkly evident during the **COVID-19 pandemic**, where price surges and shipment delays exposed the vulnerability of India's supply chain.

| **Table 5: Top Imported APIs (2021)** |

API Type	% Imported from China
Paracetamol	68%
Ciprofloxacin	81%
Ibuprofen	91%
Amoxicillin	74%

Source: Pharmexcil API Import Data (2022) [7]

India has launched the **PLI Scheme for Bulk Drugs** and **3 Bulk Drug Parks**, but **capacity and quality ramp-up remain slow** [8].

6. Regulatory Fragmentation and Enforcement Gaps:

Regulation by multiple stake holders

India's pharma regulation suffers from **institutional fragmentation**:

- **CDSCO** governs licensing and central approvals
- **NPPA** enforces drug pricing
- **State Drug Controllers** handle inspections and retail regulation

This creates **regulatory inconsistencies**, with **uneven enforcement across states**.

| **Table 6: CDSCO vs USFDA (2021)** |

Metric	CDSCO	USFDA
Inspectors (Approx.)	~1,300	~10,000
Budget Allocation (INR Cr)	?200 Cr	?36,000 Cr
Clinical Trials Registered (2021)	560	13,567

Source: PIB CDSCO Budget Estimates, USFDA Reports (2022) [9]

India's own expert bodies like the **Mashelkar Committee (2003)** and **Ranjit Roy Chaudhury Committee (2013)** have **repeatedly urged regulatory unification**, but implementation remains poor [10,11].

The Food Safety and Standards Authority of India (FSSAI) regulates food, while the Excise Department oversees alcohol. Both agencies are also responsible for monitoring the quality of alcoholic beverages. However, drug testing laboratories and food testing laboratories often function in parallel without adequate coordination. The delays in testing, along with questions over the reliability and consistency of results, have frequently been cited as major reasons why violators escape penalties and legal action.

7. Reputational Scandals: Warning Bells from Abroad

Major Indian firms have faced **USFDA sanctions** and **multi-million-dollar fines**:

- **Ranbaxy (2013):** $500 million penalty for falsifying data [12]
- **Wockhardt, Lupin, Sun Pharma:** Sites under import alerts
- **2023:** Maiden Pharma's cough syrup linked to child deaths in Gambia and Uzbekistan [13]

These incidents underscore the **discrepancy between export compliance and domestic negligence**.

8. A Future Built on Innovation or Collapse?

India aspires to move **from generics to innovation**, yet **R&D investment remains below 1% of sales** for most firms [14]. Patented drug development, biosimilars, and complex generics

require capital, time, and scientific depth—which are currently lacking outside a few elite players.

Government initiatives like **Pharma Vision 2020**, **PLI for Innovation**, and **National R&D Infrastructure Mission** exist—but without regulatory strengthening, they risk under-delivery.

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Chapter 2

Quality Control or Chaos?

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Introduction: The Illusion of Trust

In a pharmacy in Lucknow, a father buys a strip of antibiotics for his daughter. The packaging looks legitimate, the name is familiar, and the pharmacist assures him it's safe. What he doesn't know is that the batch was produced in a manufacturing unit never inspected by state drug authorities—and that the pill may have insufficient active ingredients to treat even a mild infection.

Across India, **millions of such transactions happen daily**, often with misplaced confidence in regulatory systems that are **understaffed, underfunded, and overburdened**. The **quality of drugs consumed in India remains highly uneven**, creating a system that enables **substandard, spurious, and counterfeit medicines** to flourish.

This chapter uncovers the scope of the quality crisis—its causes, consequences, and regulatory blind spots.

1. Definitions Matter: Substandard vs Spurious vs Counterfeit

Before delving into the data, it's essential to understand the terminology:

Term	Definition
Substandard	Authorized drugs that fail to meet quality specifications or shelf stability
Spurious	Falsely labelled drugs, including fakes claiming to be from known manufacturers
Counterfeit	Drugs deliberately mislabelled in terms of identity or source
Adulterated	Drugs contaminated with foreign substances, possibly toxic

The WHO estimates that **1 in 10 medical products in developing countries** is substandard or falsified [1]. In India, this rate is

estimated at **3–7%**, though exact numbers are difficult due to poor surveillance systems.

2. What the Data Says: A Hidden Epidemic

According to the **CDSCO Annual Report (2021)**:

| Table 1: National Drug Sample Testing Outcomes (2021) |

Samples Tested	84,874
Substandard	5,426 (6.4%)
Spurious	203 (0.24%)

Source: CDSCO Annual Report 2021 [2]

However, testing is **not random or comprehensive**. In many states, **sampling is done manually, without automated risk-based protocols**, and **only a fraction of manufacturing sites** are routinely inspected.

In 2022, WHO issued **Medical Product Alerts** against Indian cough syrups in **Gambia** and **Uzbekistan**, where contamination with **diethylene glycol and ethylene glycol** killed dozens of children [3].

These were not isolated cases. Between 2015 and 2023:

- At least **6 WHO alerts** involved Indian drugs [4]
- USFDA issued **80+ warning letters** to Indian firms [5]
- **Africa CDC** began auditing Indian suppliers [6]

3. Inside the Factories: The Compliance Divide

India has around **10,500 manufacturing units**, but **only ~2,000 are WHO-GMP compliant**, and less than **600 are USFDA-approved** [7]. The compliance culture is deeply stratified:

| Table 2: Indian Manufacturing Units – Compliance Snapshot (2023) |

Certification Type	Approx. Number of Units	Regulatory Focus
USFDA-approved	~600	Export-focused
WHO-GMP Certified	~2,000	Multilateral contracts (UN)

State Licensed Only	>8,000	Domestic, poorly monitored

Source: CDSCO & Pharmexcil, 2023 [7]

Why the disparity?

- **Stringent compliance** is enforced only for **export-bound units**
- **Domestic-only units** often escape scrutiny due to:
  - Infrequent inspections
  - Corruption in licensing and renewal
  - Lack of central database integration

In 2018, the **Drugs Technical Advisory Board (DTAB)** acknowledged that most small-scale units were functioning with "**bare minimum quality infrastructure**" [8].

4. Staffing Crisis in Drug Regulation

The CDSCO and state drug controllers are **severely understaffed**.

| Table 3: Drug Inspector Availability (2021) |

Recommended per WHO norm	1 per 50 manufacturers
India average	1 per 120 units
Total needed	~4,000+
Actual appointed	~1,500

Source: Parliamentary Standing Committee Report on CDSCO, 2021 [9]

The 59th Parliamentary Standing Committee on Health (2021) called it a "**regulatory collapse in slow motion.**"

State FDAs lack vehicles, testing kits, and digital reporting systems. In some rural zones, **no inspections occur for years.**

5. Private Sector Manipulation & Loopholes

India's fragmented pharma sector enables bad actors to game the system:

- **"Loan licensing"**: Firms outsource manufacturing to smaller

plants without regulatory reporting

- **"Third-party manufacturing"**: Brands sell under their label but evade compliance for the actual production
- **"Schedule H and H1 drugs"**: Often sold without prescription or log maintenance, despite being flagged as dangerous

The **lack of a unified digital drug traceability system** makes these practices invisible to regulators.

In 2021, CDSCO introduced the **iVEDA portal** (Integrated Validation of Exports of Drugs & Authorization), but **its adoption remains voluntary** and fragmented [10].

6. Adulteration and Contamination Scandals

- **1998, Gurgaon**: 33 children died after taking contaminated cough syrup with diethylene glycol [11]
- **2022, Gambia**: 70 children dead from Maiden Pharma syrups [3]
- **2023, Uzbekistan**: 18 children died from Marion Biotech's syrup [3]

These cases point to **routine failures in process validation, testing, and shelf-life stability**. In many of these firms:

- **Stability tests were not performed**
- **Reagents used were substandard**
- **Production logs were incomplete or fabricated**

Despite this, **no top executive was convicted** under India's **Drugs and Cosmetics Act, 1940**, which remains **outdated and poorly enforced**.

7. International Impact: Regulatory Red Flags

| Table 4: USFDA Actions on Indian Firms (2015–2022) |

Total Inspections	2,420
Warning Letters Issued	118
Import Alerts	54
Consent Decrees	11

Source: U.S. Food & Drug Administration Compliance Reports [5]

In 2020, the **USFDA rejected 40% of ANDA filings** from Indian firms due to **data integrity violations** [5].

Common observations included:

- "Backdated batch records"
- "Failure to investigate failed batches"
- "Unqualified staff running HPLC testing"

Even large players like **Sun Pharma, Zydus, and Aurobindo** have faced regulatory action for **data manipulation, non-compliance, or falsified results**.

8. Why Do Penalties Not Work?

The **Drugs and Cosmetics Act, 1940**, imposes:

- **Max ?5 lakh fines** for substandard drugs
- **3–5 years jail** in rare cases (often not enforced)

Compare this with the U.S. FDA, which can:

- Enforce **multi-million-dollar fines**
- Revoke licenses
- Impose criminal charges

India's legal framework offers **no deterrent** to deliberate quality compromise. Even firms caught in WHO alerts often continue to operate domestically.

9. Attempts at Reform: Fragmented, Weak, and Delayed

The following initiatives have been proposed or piloted:

| Table 5: Key Quality Control Reforms (2015–2023) |

Reform/Policy	Status
e-Pharma Central Licensing	Draft only (not enacted)
Barcode-based Track & Trace (DGFT)	Pilot in 5 states
iVEDA Portal (CDSCO)	Voluntary adoption
National Drug Regulatory Authority	Proposed in 2020, pending

Pharmacovigilance Expansion	Only 250 ADR centres active

Source: MoHFW and CDSCO reports, 2023 [10,12]

While policies exist on paper, **execution remains weak due to jurisdictional confusion**, lack of trained personnel, and pharma-industry resistance.

Conclusion: A Dangerous Game of Probability

Every time an Indian patient consumes a medicine, they are engaging in an **unwitting game of probability**—will the pill have the required API? Will it be contaminated? Will it do nothing at all?

This is not just a regulatory failure—it is a **public health crisis** that undermines decades of pharmaceutical achievement. India cannot claim to be the "pharmacy of the world" if its own citizens are left exposed to poor-quality and unsafe medicines.

Without a **national drug quality grid**, integrated audits, traceable batch-level reporting, and stricter enforcement of existing laws, the crisis will persist—and may eventually harm **India's export credibility**, too.

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Chapter 3

The Broken Chain of R&D

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Introduction: The Illusion of Innovation

India is a pharmaceutical manufacturing powerhouse. It can copy, scale, and distribute generic drugs faster and cheaper than nearly any other country. But when it comes to **new drug discovery, biologics, or precision therapies**, India is largely absent from the global leaderboard.

Despite being the **world's largest producer of generics**, India contributes to **less than 1.4% of global pharmaceutical R&D output** [1]. For an industry worth over ?2.8 lakh crore domestically and $24 billion in exports, this innovation drought raises a fundamental question: **Why is India not innovating?**

This chapter dissects the broken R&D ecosystem of Indian pharma—its legacy of reverse engineering, current limitations, and the risky incentives that prevent discovery-led growth.

1. The Legacy of Reverse Engineering

India's 1970 Patents Act enabled domestic firms to reverse-engineer foreign patented drugs using alternative processes. This legal freedom spurred the creation of low-cost versions of expensive Western drugs, boosting access globally.

| Table 1: Timeline of India's Patent Landscape |

Year	Event
1970	Indian Patents Act allows process patents, not product
1995	India joins WTO and TRIPS agreement

2005	India reinstates product patents (with safeguards)
2013	Novartis v. Union of India: Supreme Court upholds 3(d)

Source: Government of India Patent Law Archives [2]

While reverse engineering made India the **'pharmacy of the developing world'**, it also created a culture of **me-too generics**, discouraging original molecule development.

2. The R&D Investment Gap

R&D in pharma is a high-risk, high-reward enterprise—requiring billions in capital, years of clinical trials, and regulatory navigation. Indian firms largely avoid this route.

| Table 2: R&D Spending by Major Indian Pharma Firms (2022) |

Company	Revenue (? Cr)	R&D Spend (?Cr)	% of Revenue
Sun Pharma	43,886	2,205	5.0%
Cipla	22,753	1,068	4.7%
Dr. Reddy's	21,545	1,471	6.8%
Aurobindo	23,291	823	3.5%
Lupin	16,401	902	5.5%
Industry Avg	—	—	**<6%**

Source: Annual Reports, FY 2021–22 [3]

Global innovator companies like **Pfizer**, **Merck**, and **Novartis** invest over **15–20% of revenues** in R&D [4]. Indian firms lag far behind.

Moreover, Indian innovation focuses more on **incremental generics, biosimilars**, or **drug delivery mechanisms** (e.g. extended-release versions), not new chemical entities (NCEs).

3. Why Indian Firms Avoid Risk

Several systemic disincentives exist:

- **Lack of early-stage venture capital** for biotech startups
- **Unpredictable regulatory pathways** for clinical trials (especially post-2013)
- **High litigation risks** for global patents
- **Limited university-industry collaborations**
- **Low government procurement of innovative products**

Most companies prefer:

- Filing **Para IV challenges** in the U.S. to create generic versions of branded drugs
- Creating **branded generics** for the Indian market
- Partnering for **contract research and manufacturing services (CRAMS)**

These strategies offer **lower risk and faster returns**, but **stunt long-term innovation**.

4. Clinical Trial Crisis: The Regulatory Whiplash

In the early 2000s, India became a preferred destination for clinical trials due to:

- **Large, diverse patient pool**
- **Lower operational costs**
- **Easier regulations**

However, a series of unethical trials and participant deaths between 2005–2012 triggered a **backlash**.

The Supreme Court, NHRC, and public health activists demanded stricter protocols, which led to:

| Table 3: Clinical Trial Regulation Overhaul (2013–2019) |

Reform Element	Impact
Ethics committee registration	Mandatory for all trials

Compensation clauses for deaths	Delayed approvals
Audio-video consent documentation	Increased cost & complexity
Rule 122DA/B amendments	Slowed investigator trials

Source: MoHFW Gazette Notifications, 2013–2019 [5]

As a result, the **number of clinical trials fell from 500+ in 2010 to <120 in 2014** [6]. Though reforms have been relaxed since 2019, India's clinical research infrastructure still suffers from **reputational damage and bureaucratic hurdles.**

Where Innovation is Still Happening

While the majority of the industry avoids R&D risk, **some exceptions** exist:

- **Biocon**: Developed **INSUGEN®**, **ALZUMAb™**, and biosimilars of **Trastuzumab** and **Pegfilgrastim**
- **Zydus Cadila**: Developed **ZyCoV-D**, India's first DNA vaccine for COVID-19
- **Serum Institute of India**: Scaled production of **Covishield** through partnership with AstraZeneca
- **Sun Pharma**: Acquired **Ophthotech** and invested in dermatology innovation globally

| Table 4: Notable Indian Drug Innovations (Last Decade) |

Drug/Product	Company	Type	Status
ZyCoV-D	Zydus Cadila	DNA vaccine	Emergency Use (India)
ALZUMAb	Biocon	Biologic (psoriasis)	Marketed in India
Lipaglyn	Zydus Cadila	NCE (Diabetes)	Marketed (India only)
Saroglitazar Mg	Zydus	NCE (NASH)	Phase 3 (US, EU)

Source: Company Clinical Pipeline Reports [7]

These are **exceptions**, not norms. Most Indian firms license out promising molecules by Phase II or limit marketing to India, avoiding global trials and risk.

6. Government Support: Too Little, Too Dispersed

Government has launched several schemes:

- **Pharma Vision 2020**: Boosted regulatory strength and R&D infrastructure
- **PLI for Pharmaceuticals (2021)**: Focus on high-value molecules and innovation
- **New Drugs and Clinical Trials Rules (2019)**: Streamlined approval norms
- **Biotech Parks & Incubators**: Created ~60 BIRAC-funded centres

However, India still lacks:

- A **single national drug innovation fund** with large capital
- A **Bayh-Dole–style law** to encourage university spin-offs
- Unified **technology transfer and IP support**
- Academic incentive systems linked to commercialization

Only 1.3% of Indian drug patents in 2022 came from public research institutions [8].

7. Policy vs Practice: Structural Weaknesses Remain

Several policy reports—including from NITI Aayog and ORF—have highlighted gaps:

- **Fragmented ecosystem** between biotech, pharma, diagnostics, and academia
- **No national database** of failed or ongoing drug trials
- **No open-access compound libraries** or molecular banks
- **Lack of coordination between DBT, DST, and MoHFW**

India has yet to create an **NIH or European Medicines Agency–style institution** that integrates funding, research, and oversight in one ecosystem.

8. Global Comparison: India Trails Innovation Leaders

| Table 5: Global Drug Innovation Landscape (2021) |

Country	New Drugs Approved (NCEs/NBEs)	% of Global R&D Spend
USA	50+	55%
China	17	15%
Germany	12	6%
India	1–2 (marketed only in India)	<1.5%

Source: GlobalData Pharma R&D Database 2022 [9]

India's ranking in the **Global Innovation Index 2023** was **40th overall**, but in **biomedical innovation**, it ranks below **Malaysia, Thailand, and Israel** [10].

Conclusion: Why India Must Break the Generic Glass Ceiling

India's generic model is unsustainable long-term. Patent cliffs in the U.S. are shrinking, price controls are tightening, and global competition is rising. Without a transition to **innovation-led pharma**, India risks becoming irrelevant in next-generation therapies—like gene editing, immuno-oncology, and precision medicine.

For a country with such **scientific talent, clinical diversity, and manufacturing might**, the absence of global NCEs or blockbuster drugs is alarming.

India's pharmaceutical future cannot rest on **molecule mimicry alone**. The chain of R&D—currently fragmented and undernourished—must be rebuilt with intent, investment, and institutional cohesion.

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Chapter 4

Pricing Wars and Policy Evasion

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Introduction: The Illusion of Affordability

India's pharmaceutical industry is frequently praised for its role in making drugs affordable—not just at home, but across the Global South. Yet, a closer look reveals a fragmented and opaque system of pricing, one that **frequently favors profit over patients**. In India, **drug prices can vary 300–1000% between brands**, and **many essential medicines remain unaffordable despite being off-patent** [1].

This chapter examines how the **Drug Price Control Order (DPCO)** is routinely **evaded or manipulated**, and how strategies like **brand proliferation**, **evergreening**, and **non-compliance** allow pharmaceutical companies to bypass the intent of affordability policies.

1. DPCO and NPPA: The Price Control Framework

India's principal drug pricing law is the **Drug Price Control Order (DPCO)**, enforced by the **National Pharmaceutical Pricing Authority (NPPA)** under the **Essential Commodities Act**.

Key features of DPCO 2013 include:

- A **ceiling price** for drugs listed in the **National List of Essential Medicines (NLEM)**
- Price calculated using **market-based pricing**: Average of all brands with ≥1% market share

- Annual price hikes linked to the **Wholesale Price Index (WPI)**
- **Fixed-dose combinations (FDCs)** subject to special review

| Table 1: Drug Price Control at a Glance (2022) |

Total formulations under price control (NLEM)	~872
% of domestic pharma under control (value)	~18%
Max WPI-linked price hike allowed (2023)	12.12% [highest ever]
Enforcement agency	NPPA

Source: NPPA Annual Report 2022 [2]

Despite these controls, **the majority of the ?2.8 lakh crore pharma market operates outside DPCO coverage** [3].

2. The Loopholes in the System

Manufacturers regularly exploit systemic gaps in DPCO coverage:

a) Evergreening and Reformulation

Companies introduce **slightly modified versions** of essential drugs to avoid price control.

- E.g. Cipla launched **modified-release** formulations of NLEM drugs like salbutamol
- Aurobindo and others launched **combination variants** of DPCO-listed antibiotics

These variants are **technically 'new drugs'**, so **DPCO ceilings don't apply immediately**

b) Brand Proliferation and Market Fragmentation

With **over 60,000 brands** for 60,000 molecules, companies create pricing opacity.

- Example: The **same paracetamol 500mg** can cost:
  - ?0.30 (generic bulk pack)
  - ?1.50 (branded generic)

- ?3.00+ (premium brand)

| Table 2: Price Variation for Common Drugs (2023) |

Drug (Dose)	Lowest Price	Highest Brand Price	Variation (%)
Paracetamol (500mg)	?0.30	?3.20	966%
Atorvastatin (10mg)	?1.90	?10.50	452%
Pantoprazole (40mg)	?2.10	?9.80	367%

Source: NPPA Price Monitoring Cell [4].

3. DPCO Evasion through "New Drug" Clause

According to Rule 122-E of the **Drugs and Cosmetics Rules**, any drug formulation introduced within 4 years of central approval is considered a **"new drug"**, exempt from DPCO until reviewed.

Companies use this window to:

- **Launch new combinations** (e.g., antibiotics + probiotics)
- Rebrand old molecules with **new salt forms or dosages**
- Delay NPPA scrutiny through litigation

In 2018, nearly **40% of top-selling drugs were new combinations** not under price control [5]

4. Lack of Monitoring and Weak Enforcement

Although NPPA publishes ceiling prices and penalizes overcharging, enforcement is patchy:

| Table 3: NPPA Enforcement Summary (2015–2022) |

Metric	Total
Overcharging cases filed	2,206
Amount demanded (penalty)	?7,300 crore
Actual recovery	?790 crore (~10.8%)

Source: NPPA RTI Disclosures 2022 [6]

Many firms contest these cases in court, delaying penalty collection. Further, **State Drug Controllers**—tasked with enforcing DPCO compliance—rarely conduct price audits.

In retail, **chemists continue to sell unregulated brands with high trade margins**, making NLEM enforcement toothless at the counter level.

5. High Trade Margins: Profits over Affordability

Margins offered to distributors and chemists are often excessive, especially for non-scheduled drugs:

| Table 4: Trade Margins in Indian Pharma |

Category	Manufacturer Margin	Chemist/Distributor Margin
Scheduled (NLEM) drugs	~16%	≤16%
Non-scheduled branded drugs	50–70%	20–30%
Nutraceuticals, vitamins	Up to 100%	40–60%

Source: AIOCD AWACS Report 2021 [7]

Manufacturers **deliberately inflate MRPs** to accommodate high trade margins—prioritizing **sales incentives** over patient access.

6. The Chemist–Company–Doctor Triangle

High prices are also maintained by **perverse incentives**:

- **Doctors** receive gifts, foreign trips, and sponsorships to prescribe high-MRP brands
- **Chemists** push higher-margin products
- **Companies** resist DPCO coverage for their bestsellers

This results in a **dual market**:

- **Generic name is affordable** but **rarely prescribed**
- **Brand name is expensive** but **widely pushed**

In many Tier 2–3 cities, **government-set ceiling prices are irrelevant** because patients **rarely encounter them** at pharmacies.

7. NPPA Initiatives That Helped—But Not Enough

a) Price Monitoring Resource Units (PMRUs)

Set up in **21 states** to monitor local prices and availability. However, most are underfunded and lack legal enforcement powers.

b) Trade Margin Rationalisation (TMR)

2019 pilot capped **margins on anti-cancer drugs** at 30%:

- Resulted in **average 85% price drop** in 390 cancer brands [8]
- Proposal to extend TMR to all drugs is **under industry pressure**

c) Jan Aushadhi Stores (JAS)

Launched to supply **generic medicines at 50–90% lower cost**.

| Table 5: Jan Aushadhi Scheme Performance (2023) |

Metric	Value
Total Stores	9,200+
Drugs available |	1,616
Average savings to patients	?4,000 crore
Awareness among doctors	<40% (low usage)

Source: BPPI Annual Report 2023 [9]

Despite success, **most doctors do not prescribe Jan Aushadhi drugs**, and **chemists rarely promote them**, fearing margin losses.

8. Litigation and Pharma Pushback

Pharmaceutical companies **frequently file writ petitions** against NPPA orders. For example:

- **GlaxoSmithKline, Abbott, and Novartis** challenged price control on core antibiotics
- **High Courts** have granted interim relief, stalling enforcement
- **Industry lobbies like IPA and OPPI** argue DPCO harms "innovation and investment"

As a result, NPPA often **withdraws or delays price control notifications** under pressure, especially for combination or injectables.

9. The Cost of Non-Compliance: Human Impact

For millions of Indians, irrational drug pricing means:

- **Skipping doses or abandoning treatment**
- **Pushing families into debt for chronic conditions**
- **Being sold expensive brands with no added benefit**

A 2021 study by PHFI found **56% of Indian households incur catastrophic health expenditure** on medicines alone [10].

10. What Real Reform Could Look Like

Experts suggest a shift from **selective price control to system-wide transparency**, such as:

- Expanding **Trade Margin Rationalisation** beyond cancer
- Real-time **drug price dashboards** at state level
- Mandatory **generic name prescriptions** (and enforced substitution)
- Penalizing firms for **non-compliance and price rigging**
- **Procurement-based pricing** for government schemes

Only a **patient-first pricing ecosystem** can reverse the current distortion where **market success depends more on marketing than merit**.

Conclusion: Cost Without Care

India's drug pricing ecosystem is a paradox. While medicines are among the cheapest globally, they remain unaffordable to millions domestically. The system—designed to protect patients—is **routinely gamed by powerful pharma lobbies**, with **weak enforcement and policy fatigue compounding the crisis**.

What's needed is **not just price caps**, but a **culture of ethical pricing, transparency, and accountability**—backed by legal power and political will.

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Chapter 5

Marketing Malpractices and Unethical Promotions

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Introduction: Selling Pills Like Perfume

In a country where more than 60% of total health expenditure is out-of-pocket, one might assume that drug marketing would focus on evidence, outcomes, and affordability. Instead, India's pharmaceutical marketing resembles a **sales war zone**, where companies spend billions annually not on R&D, but on **persuading doctors to prescribe high-margin branded drugs—** regardless of medical necessity or patient cost.

This chapter investigates the unregulated marketing practices of Indian pharmaceutical firms—from doctor bribery and sponsorships to ghost-writing, prescription manipulation, and the failure of self-regulation through the **Uniform Code of Pharmaceutical Marketing Practices (UCPMP).**

1. The Anatomy of Pharma Marketing in India

Pharmaceutical firms in India allocate **as much as 20–30% of revenue to marketing**, significantly more than their investment in research and innovation [1].

Key strategies include:

- **Sales reps (Medical Representatives)**: Over **8 lakh strong**, their primary job is to **convert prescriptions** through personal engagement.
- **Gifts & Incentives**: Branded items, domestic and foreign travel, gadgets, cash-equivalents.
- **Sponsorships**: All-expense paid conferences, speaker fees, international CMEs (often thinly disguised holidays).

An estimated **10,000 crore (~$1.2 billion)** is spent annually on promotional incentives in India [2].

2. Understanding the UCPMP: A Code Without Teeth

The **Uniform Code for Pharmaceutical Marketing Practices (UCPMP)** was introduced in 2014 and revised in 2019. It was meant to serve as a **voluntary ethical guideline**.

Key provisions:

- Prohibits gifting and cash incentives to prescribers
- Bars pharma from sponsoring entertainment or holidays
- Mandates disclosure of sponsorships and affiliations

| Table 1: UCPMP Provisions vs Realities |

Provision	Compliance in Practice
No gifts to doctors	Widely violated
No paid holidays	Frequent CME-linked tours
No cash or cash equivalents	Reported via indirect routes
Monitoring agency	Not yet empowered

Source: Ministry of Chemicals & Fertilizers, UCPMP Draft 2019 [3]

The UCPMP remains **non-binding**, with **no legal penalties** for violations. The Indian Medical Association (IMA), Medical Council (now NMC), and NPPA have **no coordinated enforcement mechanism**.

3. Doctor Gifting: The Unspoken Economy

Multiple reports, including from parliamentary committees and media exposés, have documented massive spending on doctors:

- **2022**: An Indian drug major spent **1,000 crore on "prescriber engagement"** over 5 years [4]
- **Common gifts include**: iPhones, LED TVs, ACs, refrigerators, gold coins, and branded accessories
- **Modus operandi**: Route expenses via **marketing firms**, "educational services", or "consultancy honoraria"

| Table 2: Common Doctor Incentives by Value Tier |

Incentive Type	Estimated Value Range
Branded stationery	500–5,000
Home appliances, gadgets	10,000–50,000
Foreign travel + stay	1–3 lakh
Conference honoraria	10,000–2 lakh
Direct cash (covert)	Variable (untraceable)

Source: AIOCD whistleblower disclosures, Transparency International India [5]

Doctors are incentivized to **prescribe specific brands**, even if alternatives are more effective or affordable. The **branded generics market thrives on this economy**.

4. The "Speaker" and CME Loophole

Pharma companies often sponsor doctors as "speakers" at **educational events**—including international conferences in **London, Dubai, Thailand, and the U.S.** These include:

- **First-class flights and 5-star accommodation**
- **Honoraria** of 50,000 to 2 lakh per session
- Family members invited under "companions" clause

While Continuing Medical Education (CME) is essential, **there's little regulatory vetting** of speaker selection, topic quality, or relevance. Many CMEs are **thinly disguised promotional events** [6].

5. Influence Beyond Doctors: Retailers and Hospitals

a) Chemists and Distributors

- Offered **extra margins, volume bonuses, and travel vouchers**
- Encourage sale of **branded generics with highest profit**, regardless of necessity

| Table 3: Chemist Incentives for Non-DPCO Drugs |

Incentive Format	Common Value

Extra trade margin	10–20% above MRP cap
Foreign trip (on volume basis)	1–2 lakh/trip
Festival gifts (cash/kind)	10,000+

b) Corporate Hospitals and Chain Pharmacies

- Negotiate **bulk procurement discounts** from companies
- **Set prescription protocols**favouring partner brands
- Use **diagnostic bundles** and **tied-in drugs** to increase patient bills

The **hospital-pharma nexus** inflates treatment costs, especially for surgeries, oncology, and ICU care [7].

6. Ghost-writing and Medical Journals

Some companies **ghostwrite research articles** in support of their products, and have them published under **senior doctors' names** in regional or even international journals. These are then:

- Quoted in CME slides
- Circulated as scientific evidence to justify prescribing
- Shared by medical reps as "peer-reviewed endorsements"

This practice **corrupts the evidence base**, particularly in psychiatry, dermatology, and antibiotics—fields dominated by **aggressive marketing rather than long-term outcome studies** [8].

7. Role of Regulatory Bodies: NMC, MCI, CDSCO

- The erstwhile **Medical Council of India (MCI)** had provisions to discipline doctors for unethical practices.
- The new **National Medical Commission (NMC)** has retained similar powers, but **implementation remains weak**.
- Only **18 doctors have faced action** for accepting pharma bribes since 2015 [9].

Enforcement is rare because most incentives are **indirect, undocumented, or routed through third parties**.

CDSCO (drug regulator) has **no legal role in regulating marketing conduct**, creating a regulatory vacuum.

8. Public Health Impact: Beyond Just Cost

Marketing manipulation impacts:

- **Overprescription** of antibiotics, vitamins, painkillers
- **Use of irrational combinations** (e.g., cough syrups with 3–5 active ingredients)
- **Ignoring generic or essential medicines**
- **Increased antimicrobial resistance (AMR)**

A 2020 study across Delhi and Lucknow showed that **76% of prescriptions included at least one unnecessary drug**, often linked to marketing-driven behaviour [10].

9. International Comparisons: India's Outlier Status

| Table 4: Regulation of Pharma Marketing–Global Snapshot |

Country	Legal Ban on Gifts	Mandatory Disclosure	Public Registry
USA	Yes (Sunshine Act)	Yes	Yes
France	Yes	Yes	Yes
UK	Yes	Yes	Yes
India	No	No	No

Source: WHO, OECD Health Reports 2022 [11]

India has **no "Sunshine Law"** mandating pharma companies to publicly disclose their payments to doctors. This creates **opacity and denial**, even among medical bodies.

10. Proposed Reforms: What Can Be Done?

a) Make UCPMP Legally Enforceable

Transform it into a **binding code**, with clear penalties and independent oversight.

b) Mandatory Public Disclosure

Force all companies to **declare all payments, gifts, and sponsorships** to healthcare providers, annually.

c) Cap on Marketing Spend

Introduce a **spending ceiling** (as % of revenue), and allow tax deductions only for **scientific promotion**.

d) Hospital Formularies Based on Efficacy

Ban brand-tied prescribing in hospitals. Use **essential medicine lists (EMLs)** and evidence-based guidelines.

e) Empowered Patient Feedback Systems

Launch apps or portals where patients can report suspicious prescription patterns anonymously.

Conclusion: Prescription for Profit, Not Patient

Marketing malpractice in Indian pharma is not an aberration—it is an industry norm. With few regulations, no disclosure obligations, and a culture of normalized corruption, **India's drug prescriptions are often driven by profit, not patient welfare**.

Until there is **political will to criminalize unethical marketing**, and **systemic support for generic, evidence-based medicine**, India's drug system will remain compromised—regardless of how many laws are on paper.

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Part 2

Doctors – Prescriptions, Power, and Perks
Dr. Pulkit Khanna

Chapter 6

The Branded Prescription Problem

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Introduction: The Power of a Signature

In India, **doctors rarely write prescriptions using generic drug names**. Instead, they almost always prescribe **branded generics**—commercial brand versions of off-patent molecules. This single decision shapes the patient's entire treatment cost, access, and outcome.

India's pharmaceutical market has over **60,000 brands for about 60,000 drugs**, leading to confusion, profit-driven prescribing, and inflated pricing. This chapter explores the reasons behind doctors' **reluctance to prescribe generics**, the **influence of pharma marketing**, and the **systemic problems caused by brand-centric prescribing**.

1. What Is a Branded Generic?

A **branded generic** is a drug whose molecule is off-patent but is sold under a **trade name** rather than its **generic name**.

| Example: Branded vs Generic Drug |

Molecule Name	Atorvastatin
Branded Generic A	Lipicure (Cipla)
Branded Generic B	Atorlip (Zydus)
Generic Version	Atorvastatin (INN)

Unlike in countries like the UK or US, **generic versions in India are not the default choice**, and **chemists cannot substitute a brand with a cheaper generic** without doctor approval.

2. The Scale of Brand Dominance

More than **82% of prescriptions** in India are for **branded drugs**.

In contrast, only **2% of doctors routinely prescribe using International Nonproprietary Names (INNs)** [1].

| Table 1: Market Share by Drug Type (2023) |

Category	Market Share (%)
Branded Generics	82%
Patented Drugs	2%
Pure Generics (INN)	16%

Source: IQVIA India Pharma Audit, 2023 [2]

This results in **huge price variations** between brands for the **same molecule**—sometimes as high as 1000%—with **no difference in efficacy**, assuming quality is maintained.

3. Why Doctors Don't Prescribe Generics

a) Perceived Quality Issues

Many doctors cite concerns about the **quality and bioavailability** of generics, especially those from **Jan Aushadhi** or lesser-known manufacturers.

"I don't know where that generic was made. I trust the brand I know." – Senior cardiologist, Kolkata [3]

b) Brand Familiarity and Habit

Doctors are introduced to brands via medical representatives during internships and training. Over time, this becomes **habitual**—especially for high-frequency prescriptions like painkillers, antibiotics, and anti-diabetics.

c) Incentives from Pharma Companies

Brand loyalty is often reinforced by **financial or indirect incentives**, as detailed in Chapter 5. Doctors may be rewarded for consistently prescribing specific brands.

d) Lack of Regulatory Push

There is **no national law mandating generic-only prescriptions**, although some state governments (e.g., Rajasthan, Tamil Nadu) encourage it in public hospitals.

4. The Jan Aushadhi Paradox

The **Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana (PMBJP)** aims to offer **low-cost generics** through a network of over **9,200 stores**.

| Table 2: Price Comparison – Jan Aushadhi vs Branded Drugs (2023) |

Drug (Dose)	Jan Aushadhi Price	Top Brand Price	% Cost Saving
Telmisartan (40 mg)	?2.60	?13.40	81%
Metformin (500 mg)	?1.50	?9.90	85%
Pantoprazole (40 mg)	?2.20	?8.80	75%

Source: PMBJP & NPPA Price List 2023 [4]

Despite this, **most doctors do not prescribe Jan Aushadhi products** due to:

- Brand unfamiliarity
- No pharma engagement or incentive
- Perceived lower quality

A 2022 survey across 8 Indian cities found that **only 18% of doctors had ever prescribed a Jan Aushadhi medicine** [5].

5. Patient Impact: Affordability Crisis

The brand-heavy prescription system leads to **significant financial burden** on patients.

A 2021 study by the National Health Systems Resource Centre (NHSRC) found that **42% of Indian households reported delaying treatment due to drug costs** [6].

| Table 3: Drug Cost Burden by Income Group (2021) |

Income Level	% Monthly Income on Medicines
Low-income (bottom 40%)	18–25%
Middle-income	8–12%

High-income	2–4%

Source: NHSRC Survey, 2021 [6]

Patients are often unaware that cheaper alternatives exist—and even when they are, **chemists refuse to substitute brands** without explicit permission from the doctor.

6. Brand Manipulation and Me-Too Drugs

Many Indian pharma companies launch **multiple brands of the same drug**, creating **brand confusion** and **artificial demand**.

For example, one company may sell:

- Atorvastatin as Lipicure
- Lipicure-D (with diltiazem)
- Lipicure-A (with aspirin)
- Lipicure-EZ (with ezetimibe)

This **floods the market** and **discourages rational prescribing**, especially when doctors prescribe **combinations** without evidence-based indication.

7. Global Comparisons: Where India Stands

| Table 4: Prescription Norms by Country |

Country	Generic-Only Prescribing Mandated	Pharmacist Substitution Allowed
UK	Yes (NHS system)	Yes
USA	Encouraged but not mandatory	Yes (State dependent)
France	Yes	Yes
India	No	No (Substitution not allowed)

Source: WHO Global Medicines Policy Survey, 2022 [7]

India's **lack of generic substitution rights** puts **price control power in the hands of prescribers**, rather than systems.

8. Policy Efforts to Change Prescribing Habits

a) NMC Guidelines (2023)

Mandated doctors to prescribe using **generic names**. **Challenge:** Faced opposition from Indian Medical Association (IMA) citing "poor-quality generics".

b) State-Level Generic Mandates

- Rajasthan and Tamil Nadu mandate generics in public hospitals
- Maharashtra proposes **electronic prescription audits**

c) eSanjeevani Platform

The government's telemedicine portal includes **generic prescribing defaults**, but uptake remains limited.

d) Public Pressure Campaigns

Some NGOs and RTI activists have demanded that **doctors disclose cost of prescribed medicines**, but this is not legally enforced.

9. Proposed Reforms to Break Brand Monopoly

| Table 5: Reform Proposals for Generic Prescribing |

Reform Proposal	Status / Feasibility
Make INN prescribing mandatory	NMC guideline (not enforceable)
Empower pharmacists to substitute	Pending amendment
Audit prescriptions electronically	Piloted in Tamil Nadu
Incentivize Jan Aushadhi use	Not widely implemented
Disclose brand vs generic price	No policy yet

Until these reforms are implemented **nationwide and enforced**, doctors will continue prescribing brands—not based on evidence, but often on perception, loyalty, and incentives.

10. Ethical Dilemmas and Medical Responsibility

Doctors argue that **quality cannot be compromised**, and that not all generics are reliable. While valid, this concern is often **selectively applied**. In reality:

- Many **branded generics are made by the same contract manufacturers** that supply Jan Aushadhi
- Indian brands do not disclose **bioequivalence data publicly**
- Doctors rarely take the time to educate patients on **drug cost options**

In this silence, **trust is replaced by habit**, and patient welfare is **replaced by commercial comfort**.

Conclusion: The Signature That Costs a Nation

A doctor's signature can mean the difference between **treatment and neglect**, **affordability and bankruptcy**, or **healing and harm**. In India, that signature is more often attached to a **brand name**, not a molecule name—and that choice shapes **one of the most inefficient drug markets in the world**.

Unless brand-first prescribing is reversed through **legal mandates, system audits, and ethical renewal**, India will continue to manufacture cheap drugs while denying its own citizens the benefit of cost-effective treatment.

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Chapter 7

The Pharma–Doctor Nexus

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Introduction: A Relationship Too Close for Comfort

In an ideal world, the doctor–pharmaceutical relationship is grounded in **science, ethics, and patient welfare**. In India, it has increasingly evolved into a relationship of **mutual convenience, opaque financial incentives, and conflicted interests**.

Pharmaceutical companies invest massive resources to "win" doctors. In return, they expect—and often receive—**prescription loyalty**. This nexus affects everything from **drug choice and dosage** to **diagnostic referrals and surgery timing**.

This chapter uncovers the anatomy of the pharma–doctor relationship, its incentives, grey zones, and impacts on patients and policy.

1. Anatomy of the Nexus

The pharma–doctor nexus operates at multiple levels:

| Table 1: Interaction Channels Between Pharma & Doctors |

Channel	Typical Benefit to Doctor	Hidden Cost to Patient
Sales rep visits	Free samples, gifts	Prescription bias
Sponsored CMEs	Paid travel, stay, fees	Inflated drug costs
Clinical trials	Honoraria, consulting deals	Biased reporting or recruitment
Brand promotion	Volume-linked rewards	Overuse of costly brands
Hospital panels	Cutbacks for brand exclusives	Limited brand choices

Source: Adapted from PHFI Ethics Audit 2021 [1]

While **industry-doctor interaction is essential for scientific exchange**, the **absence of transparency and oversight** in India makes it **vulnerable to abuse**.

2. Sponsored Conferences: Science or Sales Trips?

Continuing Medical Education (CME) is legally required for doctors to maintain licensing. However, in India:

- **CME events are often fully funded by pharmaceutical firms**
- Destinations include **Bali, Dubai, Paris, and Singapore**
- Often organized around festivals or long weekends

A 2019 study found that **71% of conferences attended by Indian doctors were sponsored by pharma firms**, with **no independent academic oversight** [2].

"What looks like a CME is often just a marketing show wrapped in scientific jargon." – Ex-IMA official, Mumbai

Doctors who regularly attend such events often **prescribe the host company's brands disproportionately**, reinforcing **commercial dependency**.

3. Gifts, Honoraria, and Shadow Payments

Though technically banned by the UCPMP (Uniform Code for Pharmaceutical Marketing Practices), **indirect payments to doctors continue** under euphemisms such as:

- "Speaker honorarium"
- "Clinical advisory board fees"
- "Consulting services"
- "Product feedback surveys"

| Table 2: Common Pharma Payments to Doctors (2018–2023) |

Payment Type	Estimated Annual Value (India)
Sponsored travel/CME	?3,500 crore
Honoraria and consulting	?1,200 crore
Gifts and incentives	?1,000 crore

Source: Transparency International India, 2023 [3]

In many cases, doctors are given **volume targets**—prescribe a certain number of strips or injections monthly—and **incentives escalate** with performance.

4. Hospital Panels and Internal Bias

In corporate hospital chains, doctors are often **mandated to prescribe from select brand panels** chosen through internal procurement deals.

- These panels are **not always based on cost or efficacy**
- Pharma companies **offer discounts, sponsorships, or infrastructure support** to hospitals for exclusivity
- Doctors **face pressure** to maintain prescription volume for preferred brands

In some hospitals, **consultants receive a share of pharma-linked diagnostics, implants, or drug use**, institutionalizing the **nexus within hospital infrastructure** [4].

5. Clinical Trials: Science or Strategy?

Indian doctors are increasingly involved in clinical trials sponsored by pharmaceutical companies. While legitimate trials are essential, problems emerge when:

- Doctors recruit patients without informed consent
- Trial data is ghostwritten or selectively reported
- Trials are used to build loyalty rather than generate science

A 2020 report by the **WHO South-East Asia office** found that **40% of Indian trial sites lacked independent ethics oversight**, and 22% had **serious documentation gaps** [5].

"For many physicians, a clinical trial becomes just another income stream—not a scientific duty." – Medical ethicist, Delhi.

6. Referral Commissions and Kickbacks

Another arm of the nexus involves **cross-specialty referrals** and **kickbacks**:

- Surgeons referring to diagnostic centers for a fee
- Physicians recommending specialist consultations with mutual referral agreements

• Commissions on expensive biologics, implants, or chemotherapy drugs

Though illegal under the **Indian Medical Council Regulations (2002)** and NMC guidelines, **enforcement is nearly absent**.

| Table 3: Referral Commission Range in Urban Areas |

Service Referred	Commission Estimate (%)
MRI/CT Scan	20–30%
High-end blood panels	15–20%
Private hospitalization	?2,000–?5,000 per case
Cancer drug infusions	?500–?2,000 per dose

Source: Medico Legal Review Journal, 2021 [6]

7. Regulatory and Ethical Frameworks: Weak Links

Despite the existence of ethical codes, enforcement remains minimal:

- **UCPMP** is **voluntary and lacks legal backing**
- **National Medical Commission (NMC)** guidelines are **non-binding** unless pursued through a complaint
- **CDSCO** regulates drugs, not doctor conduct
- **Hospitals** are rarely audited for pharma affiliations

Only **18 disciplinary actions** have been taken against doctors for pharma-related violations between 2015–2022 [7].

8. International Comparisons: India Is Behind

| Table 4: Regulation of Pharma–Doctor Financial Ties |

Country	Mandatory Payment Disclosure	Annual Public Registry	Enforcement Fines
USA	Yes (Sunshine Act)	Yes	Yes (up to $1M)
France	Yes	Yes	Yes
UK	Partial	Yes (Voluntary)	Moderate
India	No	No	No

Source: WHO Global Pharma Ethics Survey, 2022 [8]

India lacks a **Sunshine Law** requiring disclosure of doctor–industry financial ties, creating an opaque environment where **public trust erodes rapidly**.

9. Patient Perception: Rising Distrust

Patients are increasingly suspicious of prescriptions, particularly when:

- Doctors **push expensive brands without alternatives**
- Prescriptions change monthly without justification
- Investigations or imaging seem excessive

A 2021 survey by **Jan Swasthya Abhiyan** found that **61% of Indian patients believed doctors were "influenced by drug companies"**, and **58% said they never understood why one brand was prescribed over another** [9].

"I trust my doctor—but I don't trust what's written on the prescription." – Patient, Pune

10. Reimagining the Relationship: Reform Pathways

| Table 5: Reform Suggestions for Doctor–Pharma Ethics |

Reform Proposal	Feasibility / Status
Legalise UCPMP	Pending (under MoHFW review)
Create Doctor–Pharma Payment Registry	Not yet initiated
Ban pharma sponsorship of CMEs	Opposed by IMA
Government-funded CME platform	Pilot underway (NMC)
Mandatory disclosure on prescriptions	Under consideration

Other proposals include:

- Linking prescription audits to doctor re-certification
- Creating **ethics ombudsmen** at state medical councils
- Encouraging **public awareness of drug options**

Conclusion: When Care Becomes Commerce

The relationship between doctors and pharmaceutical companies is supposed to advance science, not sales. Yet in India, **commercial loyalty too often trumps medical logic**, and patient welfare becomes a casualty.

Until there is **transparency in payments**, **binding ethical oversight**, and **legal deterrents for abuse**, this nexus will continue to undermine trust—not only in individual doctors, but in the entire healthcare system.

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Chapter 8

Prescription Practices in the Grey

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Introduction: Where Science Meets Suspicion

A prescription is meant to be a product of **clinical reasoning**, backed by **evidence**, and tailored to **individual patient needs**. In India, however, a significant portion of prescriptions fall into a **grey zone**—influenced not by science, but by **habit, marketing pressure, profit incentives, or simple ignorance**.

The overuse of antibiotics, irrational combinations, polypharmacy, and incomplete prescriptions not only raise treatment costs but also contribute to **antimicrobial resistance**, **iatrogenic harm**, and **public distrust**.

This chapter explores the **structural, commercial, and behavioural factors** driving India's irrational prescription epidemic.

1. The Scope of Irrational Prescribing in India

Various audits over the last decade suggest that **30–50% of prescriptions in India** are either **incomplete, irrational, or potentially harmful** [1].

| Table 1: Common Prescription Errors in India (2022) |

Type of Error	Prevalence (%)
Unnecessary drugs	28%
Incomplete dose instructions	19%
Irrational drug combinations	22%
Brand substitution confusion	12%
Unwarranted antibiotic use	26%

Source: WHO-SEARO Rational Use of Medicines Audit, 2022 [1]

These errors are not limited to quacks or informal providers. In fact, **many licensed physicians**, including specialists in private hospitals, **routinely prescribe irrational drug regimens**.

2. Polypharmacy: When Less Is More

Polypharmacy is the use of **five or more medications concurrently**—common in elderly and chronic disease patients.

In India, this is often **non-evidence-based**, driven by:

- Diagnostic uncertainty
- Commercial pressure
- Belief that "more is better"

A 2021 study across tertiary hospitals found that **62% of hypertensive patients were prescribed ≥4 medications**, often including **vitamin supplements, PPIs, sedatives**, and **unnecessary antibiotics** [2].

| Table 2: Average Number of Drugs per Prescription (By Sector) |

Healthcare Setting	Avg. Drugs per Prescription
Private Hospitals	4.9
Government Clinics	3.1
Informal Practitioners	5.4

Source: Indian Journal of Clinical Practice, 2022 [2]

3. Antibiotic Misuse: A National Emergency

India is the **world's largest consumer of antibiotics**. But 40–60% of these are **inappropriately prescribed**—either for **viral infections**, **without proper dosage**, or for the **wrong duration**.

| Table 3: Common Antibiotic Misuse Scenarios |

Scenario	Frequency (%)
Antibiotics for viral cold/fever	36%
No culture sensitivity done	78%
Fixed-dose combinations (FDCs)	42%

Paediatric use without weight check	28%

Source: CDSCO-AMR Joint Task Force Report, 2021 [3]

This overuse has led to **skyrocketing antimicrobial resistance (AMR)**. India now reports **third-line resistance in E. coli, Klebsiella, and Acinetobacter**, severely limiting treatment options [4].

"We're running out of effective antibiotics. And irrational prescribing is the front-line culprit." – Infectious Disease Specialist, AIIMS.

4. Irrational Drug Combinations: Legal Yet Lethal

India has a long history of approving and selling **irrational Fixed Dose Combinations (FDCs)**—mixtures of two or more active drugs that often **lack scientific rationale**.

Examples include:

- **Nimesulide + Paracetamol** (painkiller + hepatotoxic risk)
- **Ciprofloxacin + Tinidazole** (broad-spectrum misuse)
- **Antibiotic + Lactic Acid Bacillus** (to reduce gut side effects—without addressing AMR)

In 2016, the government attempted to ban **344 such FDCs**, but **legal challenges delayed enforcement** [5].

| Table 4: Status of FDC Regulation in India |

Year	Action	Outcome
2016	344 FDCs banned by MoHFW	Stayed by courts
2018	Supreme Court clears ban	328 banned, but many still available
2022	CDSCO notifies audit of new FDCs	Implementation pending

Source: MoHFW Notifications, 2016–2022 [5]

5. Vitamins and Nutraceutical Overuse

India has witnessed a **30% year-on-year growth** in the sale of **nutraceuticals and over-the-counter vitamins**, many of which are:

- Unnecessary for well-nourished patients
- Prescribed as placebos or "boosters"
- Promoted with aggressive pharma incentives

| Table 5: Top 5 Prescribed Non-Essential Drug Categories (2022) |

Category	% of Prescriptions
Multivitamins	42%
Digestive enzymes	18%
Herbal tonics	14%
Liver supplements	11%
Neuromodulators	9%

Source: AIOCD-AWACS Data, 2022 [6]

6. Diagnostic-Driven Prescribing: The Revenue Loop

In many private hospitals, doctors are **rewarded based on revenue targets** that include prescriptions. Some use **diagnostic reports to justify polypharmacy**, even when:

- **Findings are clinically insignificant**
- **Investigations are unnecessary**
- **Repeat testing is not needed**

"Tests generate prescriptions, and prescriptions justify tests—a closed loop of commercial medicine." – Internal medicine physician, Bengaluru

7. Systemic Issues Behind Poor Prescription Practices

a) Lack of Updated Guidelines

Many physicians rely on outdated knowledge from medical school or **brand-sponsored CME slides**.

b) No Prescription Audits

Unlike NHS systems, India has **no national or state-level audit of prescriptions**, except for a few pilot studies.

c) No Real Deterrent

Doctors violating rational practice face **no penalties**, unless a specific patient files a case—and even then, **proof is elusive**.

d) Influence of Pharma Marketing

As discussed earlier, **gifts and loyalty schemes** distort decision-making.

8. National Medical Commission (NMC) Role: A Missed Opportunity

The NMC has issued guidelines encouraging:

- **INN (generic name) prescribing**
- **Rational use of antibiotics**
- **Documentation of prescriptions**

However:

- These remain **advisories, not enforceable regulations**
- **Electronic prescription systems**, which enable auditing, are absent in most states
- Doctors rarely undergo **periodic competence tests or CME-linked recertification**

9. Impact on Patient Safety and Public Health

Consequences of irrational prescribing include:

- **Drug resistance and superbugs**
- **Iatrogenic harm (e.g., liver damage from excess paracetamol)**
- **Poor compliance due to high pill burden**
- **Out-of-pocket bankruptcy**
- **Delays in actual diagnosis and effective therapy**

A 2021 Lancet study estimated that **nearly 140,000 deaths in India could be linked to AMR-related treatment failure**, many stemming from **over-the-counter or inappropriate prescriptions** [7].

10. Reform Blueprint for Rational Prescribing

| Table 6: Key Reforms to Improve Prescription Quality |

Reform Proposal	Status
National Prescription Audit Program	Not yet launched
Mandatory e-Prescribing in urban areas	Pilot in Tamil Nadu
CME-based license renewal	Proposed by NMC
Penalties for irrational prescribing	Not implemented
Hospital prescription transparency	Voluntary disclosures

Other Recommendations:

- Promote **point-of-care prescribing checklists**
- Deploy **e-prescription platforms** linked to NLEM
- Integrate **clinical pharmacists** into care teams
- Empower patients to ask: *Is this drug necessary?*

Conclusion: The Prescription as a Mirror

A doctor's prescription is a **mirror of the system's values**. In India, it reflects a combination of **scientific expertise and systemic distortion**—a cocktail of knowledge diluted by profit, pressure, and habit.

Until prescription practices are treated as a **public health concern**—and not a matter of professional discretion alone—patients will continue to suffer the consequences of **preventable, commercialized polypharmacy**.

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Chapter 9

Accountability and Continuing Education

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Introduction: Unchecked Authority in the White Coat

Doctors occupy an exalted position in Indian society. Their prescriptions are rarely questioned; their opinions treated as final. But when accountability structures are weak and **continuing education is optional or unregulated**, this authority becomes vulnerable to outdated science, commercial distortion, and even negligence.

In India, there are few mechanisms to **audit a doctor's knowledge, ethics, or prescription practices** post-qualification. While the medical landscape evolves—new diseases, drug resistance, biotechnologies—**most doctors never undergo mandatory retraining**. This chapter explores the dangerous consequences of this knowledge and accountability vacuum.

1. The Accountability Black Hole

Once a medical degree is earned in India, it often becomes a **lifetime license**. There is:

- **No mandatory re-licensure**
- **No periodic skills assessment**
- **No national prescription review system**

Unlike aviation, law, or even education, Indian doctors **aren't routinely assessed for continuing competence**.

"It's possible to graduate in 1980 and never update your pharmacology—and still prescribe today." — Senior public health educator, Hyderabad

2. The Continuing Medical Education (CME) Gap

The **Medical Council of India (MCI)** mandated 30 hours of CME

every 5 years. Its successor, the **National Medical Commission (NMC)**, retained this clause. However:

- Enforcement is weak or absent
- CME content is **often pharma-sponsored**
- Certification mechanisms vary by state

| Table 1: CME Implementation Status (2023) |

State	Mandatory CME Hours	Enforcement Mechanism
Maharashtra	30 hrs / 5 years	Linked to license renewal
Delhi	30 hrs / 5 years	Advisory only
Tamil Nadu	30 hrs / 5 years	Not enforced
National (NMC)	30 hrs / 5 years	Non-binding guideline

Source: State Medical Council notifications, 2023 [1]

Most CMEs are **attended to collect certificates**, not knowledge. Since many are funded by pharma, content often **lacks neutrality or depth**.

3. Pharma-Dominated CME: Learning or Lobbying?

Pharma-sponsored CMEs blur the line between education and promotion:

- Doctors are flown to resorts and luxury hotels
- Sessions are product-focused
- "Experts" are often **paid key opinion leaders** (KOLs)

"When a CME is titled 'Optimizing Proton Pump Inhibitor Therapy' and funded by the top PPI brand, you know what's coming." — Gastroenterologist, Pune

In the absence of **independent accreditation bodies**, there is no system to vet content, ensure balanced viewpoints, or remove promotional bias.

4. No Standardized Re-Certification

Globally, doctors are required to undergo **relicensing or board exams** every few years. For example:

| Table 2: Global Re-Certification Models |

Country	Re-Certification Interval	Method
USA	Every 10 years	Specialty board exams
UK	Annual appraisal + 5-year revalidation	Portfolio & peer review
Australia	3–5 years	CME + Performance feedback
India	None	Not applicable

Source: WHO Global Health Workforce Survey, 2022 [2]

India lacks a national framework for:

- Re-licensure
- CME credit tracking
- Audit of malpractice history
- Peer evaluation

5. Weak Oversight by Medical Councils

Until 2020, the **Medical Council of India (MCI)** handled ethics and misconduct complaints. After its dissolution, the **National Medical Commission (NMC)** and **State Medical Councils** took over.

However:

- Many councils are **understaffed and underfunded**
- They lack **investigative or enforcement infrastructure**
- Decisions are often **delayed or overturned**

| Table 3: Ethics Complaints vs Action Taken (2015–2022) |

Metric	Number
Complaints received	~3,400
Disciplinary inquiries	~800
Doctors suspended	57

Source: RTI Data from NMC & State Councils, 2022 [3]

Compare this with the **millions of prescriptions** and **thousands of surgeries** happening annually—and the scale of **unaddressed negligence becomes evident**.

6. Prescription Audit Systems: Missing in Action

In most countries, prescriptions are **digitally tracked and audited**. In India:

- Prescriptions are mostly **handwritten and untracked**
- There is no **national prescribing database**
- Errors or irrationalities remain **invisible**

Only Tamil Nadu and Rajasthan have **piloted prescription audits** in public hospitals—using:

- Sample reviews
- Red flag categories (e.g., excessive antibiotics)
- Peer-to-peer feedback

These pilots remain **non-scaled** due to **bureaucratic inertia and medical opposition**.

7. Defensive Medicine and Unregulated Procedures

The lack of oversight also encourages **defensive or revenue-linked medicine**:

- Unnecessary diagnostics
- Unproven or outdated procedures
- Avoidance of low-cost generics
- Excessive follow-ups

"If I don't order 5 tests and something goes wrong, I can be sued. But there's no system to check if I'm over testing." — Consultant, Private Hospital, Bengaluru

Hospitals link doctor salaries to revenue generation, further distorting medical judgment.

8. No National Blacklist for Repeat Offenders

Doctors penalized in one state can **continue practicing elsewhere**. There is:

- No **national misconduct database**
- No **cross-verification system between states**
- No public notification mechanism for license revocations

Some cases, such as botched surgeries or unethical IVF practices, only come to light after **media intervention** or **patient lawsuits**.

9. What Reforms Are on the Table?

| Table 4: Proposed Accountability Reforms |

Proposal	Status (as of 2023)
National CME Accreditation Authority	Under NMC review
Mandatory digital prescriptions	Pilot in 2 states
National Doctor Registry with audits	Proposed in 2018, pending
Linking CME to license renewal	Not implemented
Ethics Ombudsman for NMC	Suggested, not appointed

Other initiatives, like **e-Sanjeevani (telemedicine)**, could facilitate **centralized prescription data collection**—but are still underused.

10. Moving from Deference to Transparency

In a culture that places doctors on a pedestal, accountability reforms are often resisted as "insulting" or "bureaucratic". But public health cannot depend on **unchecked discretion**.

"Doctors must be respected—but also held to the highest ethical and scientific standards. Especially when lives are on the line." — NMC Advisor, 2023

Transparency in practice standards, **feedback loops**, **peer reviews**, and **structured re-education** are the hallmarks of every mature health system.

India cannot afford to treat accountability as optional.

Conclusion: The Missing Audit in Indian Medicine

India has world-class doctors—but no national system to ensure they stay world-class. In the absence of **mandatory CME**, **license renewal**, **digital prescriptions**, and **practice audits**, the system runs on blind trust.

Accountability is not about punishing doctors—it's about **ensuring patients are protected**, and **science remains current**. Until India closes this gap, the damage will be cumulative—and eventually, irreversible.

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Part III

Patients – The End-Users in the Blind Spot
Dr. Rajesh Ranjan

Chapter 10

The Cost Burden – When Illness Becomes Debt

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Introduction: The Poor Pay the Price

India may be the world's pharmacy, but for millions of its citizens, **affording medicines remains a daily struggle**. Despite being a top producer of generics, Indian patients often pay **up to 70% of their total health expenses on drugs alone**—making out-of-pocket spending among the highest in the world.

While state-run schemes aim to provide free or subsidized medicines, they are patchy, underfunded, and poorly monitored. The burden disproportionately affects the **poor, elderly, and chronically ill**, pushing many into debt, rationed care, or total non-treatment.

1. Out-of-Pocket Expenditure: A Global Outlier

India's health financing is heavily **out-of-pocket (OOP)**. Unlike countries with insurance or universal coverage, **more than 62% of healthcare spending comes directly from individuals' pockets**.

| Table 1: Out-of-Pocket Health Expenditure Comparison (2022) |

Country	% OOP of Total Health Spend	% OOP on Medicines
India	62%	67%
China	32%	36%
UK	15%	12%
USA	10%	19%

Source: WHO Global Health Expenditure Database, 2022 [1]

Medicines are the **single largest component** of OOP health spending in India—**more than diagnostics, doctor fees, or hospitalisation**.

2. Drug Prices: A Market Without Controls

While India has a **Drug Price Control Order (DPCO)** under the **National Pharmaceutical Pricing Authority (NPPA)**, it covers only about **16% of all formulations**.

| **Table 2: Price Variation in Common Drugs (2023)** |

Drug (Dose)	Cheapest Brand (?)	Costliest Brand (?)	% Variation
Atorvastatin (10 mg)	2.40	15.50	546%
Pantoprazole (40 mg)	2.20	12.80	482%
Metformin (500 mg)	1.50	10.90	627%

Source: NPPA Price Monitor Report, 2023 [2]

Doctors often prescribe **costlier brands**, and pharmacists are not allowed to **substitute with cheaper alternatives**, unlike in other countries.

3. Jan Aushadhi: The Untapped Lifeline

The **Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana (PMBJP)** aims to provide low-cost, quality generics via a network of **9,000+ retail outlets**.

Benefits:

- Savings of **50–90%** compared to branded equivalents
- Covers **over 1,500 formulations**
- Widely available in Tier 2 & Tier 3 cities

Yet uptake remains limited due to:

- **Lack of doctor prescriptions**
- **Low public awareness**
- **Sporadic stockouts**
- **Brand trust issues**

"I went to Jan Aushadhi with my prescription, but the chemist said my medicine wasn't available. I had to buy the branded one." – Patient, Gorakhpur

4. The Burden of Chronic Illness

Chronic conditions like **diabetes, hypertension, asthma, and epilepsy** require lifelong medication. For patients without insurance or public sector access, this leads to **monthly drug bills of ?1,000–?3,000**, often more.

| Table 3: Annual Drug Cost for Chronic Conditions (Urban, 2023) |

Condition	Avg. Monthly Spend	Annual Cost (Branded)
Type 2 Diabetes	?1,200	?14,400
Hypertension	?800	?9,600
COPD/Asthma	?1,000	?12,000
Epilepsy	?1,500	?18,000

Source: CSE Drug Affordability Survey, 2023 [3]

Many patients **skip doses**, **alternate days**, or **self-reduce doses** due to cost—undermining outcomes and increasing long-term complications.

5. Medical Bankruptcy: A Hidden Epidemic

The **NSSO 75th Round Health Survey** (2018) found that **17% of hospitalised patients borrowed money or sold assets** for treatment. A more recent 2022 study by the Public Health Foundation of India (PHFI) showed:

- **38% of cancer patients** had to sell land or jewellery
- **56% of families with ICU cases** took high-interest loans
- **68% of uninsured households** delayed or skipped follow-up treatment due to medicine cost

"It's not the diagnosis that breaks us—it's the price of staying alive." – Caregiver of liver transplant patient, Delhi

6. Insurance Loopholes and Drug Exclusions

Most health insurance plans in India **do not cover outpatient drug purchases**, even for chronic illness.

| Table 4: Insurance Coverage Features (Top 10 Plans, 2023) |

Feature	Coverage Status
Inpatient treatment	□
Doctor consultation (OPD)	□
Prescription medicines (OPD)	□
Post-hospitalisation medication	□ / Partial
Chronic illness medication cover	□

Source: IRDAI Comparative Product Sheet, 2023 [4]

As a result, even insured families must **bear the full cost of medicines**, particularly for **outpatient and follow-up care**.

7. Public Sector Shortfalls: Stockouts and Shortages

While public hospitals offer free drugs under state schemes, they suffer from:

- **Irregular supply chains**
- **No stock visibility** for patients or doctors
- **Corruption in procurement**
- **Poorly trained dispensing staff**

In Rajasthan, despite its free drug policy, **only 56% of essential medicines were available at any given time**, according to a 2022 audit by CHAI [5].

8. Gendered Impact of Drug Costs

Studies show that women are:

- **Less likely to seek medical care**
- **More likely to ration or forgo medicines**
- **Last to receive treatment in a household with limited money**

This has serious consequences in **maternal health, anaemia, thyroid disorders**, and **mental health**, where **drug adherence is critical**.

"My husband gets his blood pressure medicines every month. Mine are optional." – Woman with hypothyroidism, Jharkhand.

9. COVID-19 Exposed the System's Fragility

During the pandemic:

- Drug prices spiked (e.g., Remdesivir, Favipiravir, steroids)
- Oxygen cylinders and basic drugs went black-market
- Families spent **?20,000–?2 lakh per week** on medicines
- Insurance rarely covered at-home COVID drug costs

The result was a **wave of drug-linked bankruptcies**—especially among the lower-middle class.

10. Toward Rational and Equitable Drug Pricing

India must shift from a **market-based drug economy** to a **patient-centred model**. Key reforms include:

| Table 5: Drug Cost Relief Reforms – Recommendations |

Proposal	Feasibility	Status
Expand DPCO to 50% of drug market	High	Not done
Include drugs in outpatient insurance	Medium	Pilot in NHA
Mandate INN prescribing	High	Advised by NMC
Enforce substitution at pharmacies	Medium	Policy under review
Digital price comparison tools	High	Prototype phase

Conclusion: Health Without Bankruptcy

In India, a diagnosis is not just a health event—it's a financial shock. The current drug pricing and prescription model **incentivizes brand over affordability**, **marketing over need**, and **opacity over access**.

To reverse this, the system must **recognize patients as central stakeholders**, not passive recipients. Until then, the country will remain both the **global pharmacy** and a place where **millions cannot afford their own prescriptions**.

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Chapter 11

Health Illiteracy and Blind Trust

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Introduction: A Nation Medicated in the Dark

In a country as diverse and complex as India, health literacy remains one of the most under-addressed crises. For most patients, medical knowledge begins and ends with what the doctor writes on a piece of paper—or what a local chemist recommends over the counter.

The result is a population that is **highly medicated but poorly informed**. Drugs are consumed without understanding, antibiotics are taken for viral fevers, steroid creams are misused for skin whitening, and injections are preferred over tablets—not for efficacy, but for perceived strength.

This chapter delves into the **culture of blind trust**, **medical ignorance**, and how **patient disempowerment fuels India's pharmaceutical crisis**.

1. What is Health Literacy?

Health literacy is defined by the WHO as "the **degree to which individuals have the capacity to obtain, process, and understand basic health information and services** needed to make appropriate health decisions" [1].

In India, studies show that **less than 25% of adults can correctly interpret a prescription** or understand dosage timing, even in urban settings.

| Table 1: Health Literacy in India – Select Findings (2021–2023) |

Population Group	Can Understand Prescription (%)	Can Name Medications (%)
Urban educated (Delhi)	62%	54%

Semi-urban (Lucknow)	33%	19%
Rural (Odisha)	14%	7%

Source: PHFI Health Literacy Survey, 2023 [2]

2. Over-the-Counter (OTC) Misuse

In the absence of awareness, India's **informal OTC drug market thrives**. Despite regulations, **antibiotics, steroids, and psychotropics are frequently sold without prescriptions**.

| Table 2: Common OTC Drug Misuse (Urban Slums, 2022) |

Drug Class	% Sold Without Prescription
Antibiotics	47%
Painkillers (NSAIDs)	72%
Corticosteroids	38%
Cough syrups (Codeine)	51%

Source: All India Drug Retail Audit – Slum Clusters, 2022 [3]

Chemists, not doctors, often become the **primary advisors—** sometimes out of necessity, other times due to convenience.

"If you tell the chemist your symptoms, he'll give you 2–3 tablets and it usually works. That's all we know." – Patient, Ahmedabad

3. Trust in Quacks and Informal Providers

In rural India, **unqualified medical practitioners ("quacks") serve nearly 60% of all primary healthcare needs**. Their popularity stems from:

- Geographic access
- Familiarity and trust
- Flexible payments
- Rapid symptom relief

These providers frequently prescribe **broad-spectrum antibiotics, painkillers, or steroid injections—** without diagnosis or follow-up.

A study by The Lancet (2019) found that **57% of healthcare providers in India's rural areas had no formal medical training** [4].

"He gives one injection, and the fever goes away. Why go to the hospital?" – Farmer, Jharkhand.

4. Misinterpretation of Dosage and Instructions

Even when patients do see licensed doctors, **instructions are often misunderstood**:

- Once daily becomes once in the morning only
- Take after food is interpreted as with breakfast only
- Instructions like "for 5 days" are ignored after 2 days of symptom relief

In a 2021 study across government hospitals in three states, **42% of patients misused antibiotics due to poor understanding of dosage instructions** [5].

Table 3: Common Prescription Misunderstandings (n=1,800)

Misunderstanding	% of Respondents
Misinterpreted duration	44%
Took multiple doses together	18%
Skipped food instructions	31%
Switched drugs mid-course	15%

5. Cultural Beliefs About Medicine

Cultural norms and misconceptions often override medical advice:

- **Injections are perceived as "stronger"** and preferred even for mild conditions
- **Herbal/home remedies** are mixed with allopathy without informing the doctor
- **Antibiotics are seen as "cold medicines"**
- People believe **taking medicines longer weakens the body**

Such beliefs persist due to **lack of community health education**, **low literacy**, and **mistrust of public health messaging**.

6. Paediatric and Geriatric Risks

Low health literacy significantly endangers:

a) Children

- Syrups are **overdosed or underdosed**
- Parents stop antibiotics once fever subsides
- Prescription drugs are **shared among siblings**

b) Elderly

- Polypharmacy without understanding
- Drug duplication from multiple doctors
- Misinterpretation due to vision or memory issues

A 2022 ICMR audit found that **29% of elderly patients were taking duplicate medications unknowingly** [6].

7. Language Barriers and Prescription Formats

Most prescriptions are:

- **Handwritten in English**
- **Abbreviated with medical Latin**
- Lack pictorial or translated guidance

This poses significant challenges in areas where the population is **non-English speaking**, visually impaired, or elderly.

Some interventions like **color-coded boxes, audio labels, and pictogram-based instructions** have been tested with success, but **not adopted at scale**.

8. Absence of Patient Counselling

Unlike in many Western countries, Indian doctors:

- Spend **<5 minutes per patient on average**
- Rarely explain the purpose of medications
- Don't warn about **side effects or red flags**

Pharmacists also **lack formal training in patient counselling**, except in top-tier hospitals.

The **disconnect between diagnosis and comprehension** results in poor adherence, misuse, and eventual distrust.

"The doctor gave me six medicines. I don't know what they do, so I stopped taking them after three days." – Urban diabetic, Kolkata.

9. Digital Health: Promise and Pitfalls

The rise of **e-prescriptions, telemedicine, and mobile health apps** has potential, but:

- **Most platforms are in English**
- Require **smartphones and internet literacy**
- Often **don't include drug explanations or guidance**

Unless integrated with **vernacular education, speech interfaces, and human follow-up**, digital health tools may **widen the literacy gap**.

10. Reforms for Patient Empowerment

| Table 4: Policy Interventions to Improve Health Literacy |

Proposal	Status/Action Needed
Mandatory pictorial prescriptions	Not implemented
Drug counselling via pharmacists	Pilot in AIIMS, Delhi
Community health awareness drives	Occasional only
Vernacular drug instructions	Advised, not enforced
School-based health literacy modules	Not institutionalized

India can also borrow from models like:

- **Brazil's "Farmacia Popular" program** – includes education with drug dispensing
- **UK's Medicines Use Reviews (MUR)** – pharmacist-led guidance
- **Thailand's pictorial drug charts** in rural health programs.

Conclusion: Health Literacy is Public Health

Medicines do not work in a vacuum. Without understanding—what to take, when to take, why to take—a pill is just a piece of hope. India's pharmaceutical reforms must look beyond manufacturers and regulators.

Empowering patients with **knowledge, confidence, and access to honest guidance** is the most effective antidote to irrational drug use, overmedication, and public health harm.

Until that happens, **the greatest risk in India's pharmaceutical crisis may not be the drug—but the silence around it**.

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Chapter 12

Drug Availability and Stockouts

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Introduction: When the Shelves Run Empty

Even the most essential medicine is useless if it's **out of reach**. Despite India's vast drug manufacturing capacity, access to life-saving medications is **far from universal**. Across public hospitals, rural clinics, and even private pharmacies, **essential drugs often go missing**—not due to production shortages, but because of systemic failures in **procurement, distribution, and supply chain management**.

This chapter investigates India's **drug availability crisis**, exploring the reasons behind stockouts in both the public and private sectors, and their deadly consequences.

1. Understanding Drug Stockouts

A **stockout** is the **unavailability of a medicine at the point of dispensing**, when it is expected to be in stock. It can occur at:

- **Public hospitals/dispensaries**
- **Private pharmacies**
- **Jan Aushadhi outlets**

India lacks a **centralized tracking system** for real-time stock status, leading to **data blindness** at the policy level.

"Stockouts are not a logistics issue alone—they reflect a deeper governance crisis." — Health systems researcher, PHFI.

2. Public Health System: Supply without Assurance

Most state governments procure medicines centrally and distribute them through **district warehouses**. However, issues arise due to:

- **Delayed tenders and payment cycles**
- **Poor inventory management**
- **Mismatch between demand and supply**

| Table 1: Average Availability of Essential Medicines in Public Health Facilities (2022) |

State	% Availability (EML drugs)
Tamil Nadu	78%
Rajasthan	56%
Uttar Pradesh	39%
Jharkhand	32%
National Average	45%

Source: National Health Systems Resource Centre (NHSRC), 2022 [1]

3. Supply Chain Bottlenecks

Key issues affecting public sector availability include:

- **No automated stock monitoring**
- **Manual recordkeeping**
- **Stock expiration due to poor forecasting**
- **No minimum stock-level alerts**

Only a few states like **Tamil Nadu and Kerala** have adopted **IT-based inventory systems (e.g., TNMSC)** that show consistent success.

4. Private Sector Shortages: A Hidden Problem

Even private chemists report stockouts—especially for **non-lucrative, low-margin drugs** such as:

- Paediatric suspensions
- Injectables with storage requirements
- Older essential antibiotics (e.g., amoxicillin)
- Anti-TB and anti-leprosy drugs

Reasons include:

- **Poor incentives for stocking low-profit drugs**

- **Focus on high-margin supplements, cosmetics**
- **Urban-rural distribution disparities**

"There's no use keeping anti-TB drugs when customers mostly ask for cosmetics and pain balms." – Pharmacist, Aurangabad.

5. Rural vs Urban Divide

Drug availability drops sharply as one moves away from metro cities.

| Table 2: Urban-Rural Drug Availability Survey (2023) |

Drug Category	Urban (%)	Rural (%)
Antibiotics	91%	59%
Antihypertensives	85%	48%
Insulin	76%	33%
Inhalers	68%	26%
Antipsychotics	44%	14%

Source: AIIMS-RAND Rural Access Study, 2023 [2]

Rural areas depend heavily on **government supply chains**, where **frequent outages** force patients to **travel 20–60 km** for a refill.

6. Life-or-Death Scenarios: Case Studies

a) Snakebite Treatment Crisis

India reports **50,000+ snakebite deaths annually**, yet **anti-snake venom is often unavailable** at PHCs in endemic regions (Bihar, Odisha, Maharashtra).

b) Insulin Shortages

A 2022 ICMR study found **only 27% of rural diabetics** had **regular access to insulin** due to supply chain gaps and high storage costs [3].

c) Cancer Drug Blackouts

During COVID-19, essential chemotherapy drugs like **methotrexate and vincristine** were unavailable in 60% of public hospitals, disrupting thousands of treatment cycles [4].

7. Procurement Corruption and Leakages

Multiple states have faced **scandals around inflated pricing, ghost suppliers, or expired medicine stockpiles**.

"We found warehouses full of expired drugs while patients were turned away due to 'non-availability'." — State audit officer, Rajasthan Health Department

Tender processes often lack transparency, and small companies with political links win bids despite lacking supply capacity.

8. Jan Aushadhi's Inconsistent Promise

While the PMBJP program provides **low-cost generics**, audits reveal:

- **Only 60–65% of medicines are available on average**
- Many outlets operate **intermittently or close down**
- Logistic issues delay refill cycles

A 2023 CAG report noted **repeated stockouts of key medicines** like metformin, amlodipine, cefixime, and iron-folic acid tablets [5].

| Table 3: Jan Aushadhi Stockout Frequency (Sample 200 outlets, 2023) |

Drug	Days/Year Out of Stock
Metformin (500 mg)	82
Cefixime (200 mg)	101
Amoxicillin (250 mg)	64
Iron-Folic Acid	110

9. Regulatory Vacuum in Stock Monitoring

India lacks a **national medicine stock monitoring portal**, unlike systems used in:

- **Brazil (SUS)**
- **South Africa (Stock Visibility System - SVS)**
- **Thailand (MOPH Inventory Portal)**

e-Aushadhi (used in Rajasthan, Bihar, etc.) remains **partially implemented** and doesn't cover **last-mile outlets** or private pharmacies.

10. Toward Equitable Drug Access

| Table 4: Solutions to Address Stockouts |

Reform	Current Status
Real-time stock monitoring (e-Aushadhi)	Partial in 6 states
Minimum stock level mandates	Absent
Decentralized procurement (PHCs)	Rare
Drug availability dashboard (public)	Not implemented
Reward for stocking essential medicines	Proposed (2022)

India needs an integrated National Drug Inventory and Access Network—covering **public and private** sectors, with **transparency, accountability, and automation**.

Conclusion: Supply Chain, Not Just Science

In the end, it doesn't matter if India can manufacture a drug cheaply—it matters whether it reaches the patient **on time, every time**. Drug stockouts aren't just administrative lapses—they're **failures of care**, and often, failures of survival.

Until India can ensure that **essential drugs are always available where needed**, **healthcare will remain aspirational for millions**, not accessible.

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Chapter 13

Adverse Drug Reactions and the Silence of Reporting

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Introduction: When Medicines Harm Instead of Heal

While medicines are central to modern healthcare, they are not without risk. **Adverse Drug Reactions (ADRs)**—unintended, harmful effects from medications—are a growing but under-reported public health threat in India.

Globally, ADRs are a **leading cause of hospitalisation and death**, often preventable through early detection and surveillance. However, India's **pharmacovigilance ecosystem remains severely underdeveloped**, leaving millions vulnerable to drug-induced harm without recourse or accountability.

This chapter investigates the **silence around ADRs**, examining the weaknesses of India's pharmacovigilance systems and the urgent need for a patient-centred drug safety culture.

1. What Are Adverse Drug Reactions (ADRs)?

According to the WHO, an ADR is a **harmful or unintended response to a medicine at normal doses** used for prophylaxis, diagnosis, or treatment [1].

Examples include:

- **Rashes, allergies, or anaphylaxis**
- **Organ damage (e.g., liver, kidneys)**
- **Neuropsychiatric effects**
- **Fatal arrhythmias or bleeding episodes**

While some ADRs are unavoidable, **most are predictable and preventable** with robust monitoring.

2. The Indian Burden: Undercounted and Understood Poorly

India's true ADR burden is unknown due to **severe under-reporting**, but research suggests:

- **3–5% of hospital admissions** are due to ADRs [2]
- **10–15% of hospitalised patients** experience at least one ADR
- **Fatal ADRs may affect up to 0.2% of inpatients**

| **Table 1: Estimated ADR Burden in India (2022)** |

Metric	Estimate
Annual hospitalisations from ADRs	~2 million
Annual deaths (likely ADR-linked)	80,000–100,000
ADR reports submitted (PvPI, 2022)	~220,000

Source: PvPI, AIIMS pharmacovigilance reports, 2022 [3]

This means **<10% of ADRs are formally reported**, a rate far below global norms.

3. The Pharmacovigilance Programme of India (PvPI)

Started in 2010 by the Central Drugs Standard Control Organization (CDSCO), PvPI:

- Collects ADR data from **600+ centres**
- Coordinates with WHO-Uppsala Monitoring Centre
- Operates via AIIMS, IPC (Ghaziabad)

Yet the system is **passive and fragmented**:

- Most centres are located in urban tertiary hospitals
- **Private hospitals rarely report**
- **Doctors and pharmacists lack training in ADR recognition**

"Unless a patient dies or files a lawsuit, ADRs go unreported." — Clinical pharmacologist, Mumbai

4. Cultural and Institutional Silence

Several reasons contribute to underreporting:

- **Fear of legal liability** among doctors
- **Lack of incentive or mandatory protocols**
- Patients are **rarely informed about side effects**
- Misattribution of symptoms to disease rather than drugs

In a 2022 study at a Delhi hospital, only **11% of doctors** had ever reported an ADR [4].

5. Common Drugs Behind ADRs in India

| Table 2: Top Drug Classes Implicated in ADRs (PvPI Data, 2022) |

Drug Class	Common Reactions	% of Total Reports
NSAIDs (e.g., diclofenac)	GI bleeding, kidney injury	22%
Antibiotics (e.g., ciprofloxacin)	Rash, diarrhoea, liver issues	18%
Antiepileptics	Sedation, rash, liver dysfunction	11%
Antitubercular drugs	Hepatitis, neuropathy	9%
Chemotherapy agents	Bone marrow suppression	8%

Source: Indian Pharmacopoeia Commission, 2023 [5]

Some ADRs are **life-threatening**, yet **patients are rarely counselled before use**, especially in public hospitals.

6. Lack of Patient-Centric Risk Communication

Patients are almost **never warned about side effects**, due to:

This leads to:

- Patients not recognising ADRs
- Stopping essential medications unnecessarily
- Continuing toxic drugs unaware of harm

"My father developed yellow eyes while on TB treatment, but we thought it was a liver problem—not the medicine." – Caregiver, Varanasi

7. Special Populations: Higher Risk, Lower Reporting

a) Children

- Often **receive off-label dosages**
- Cannot describe symptoms clearly
- **ADR rates can be 3x higher** in neonatal units

b) Elderly

- More vulnerable to drug interactions
- Polypharmacy is common
- **Kidney/liver impairments** make drug elimination harder

c) Women

- Underrepresented in trials
- May report ADRs differently
- Face **dismissal of symptoms** as psychosomatic

8. The Hidden Cost of ADRs

Apart from patient harm, ADRs create:

- **Longer hospital stays (avg. 3–5 extra days)**
- **Increased healthcare cost (~5,000–50,000/event)**
- **Medicolegal risks for institutions**

A 2023 AIIMS study found that **ADR-related costs contributed 18% of total inpatient bill** for affected patients in surgical ICUs [6].

9. Missed Opportunities in Pharmacovigilance

Other countries have adopted stronger systems:

| Table 3: Global ADR Reporting Models |

Country	Key Feature	Reporting Rate*
UK	Yellow Card Scheme – open to patients	High (70 reports/million)
Sweden	Electronic mandatory ADR reporting	Very High

India	Paper/PDF forms; no mandate	Low (~15 reports/ million)

*Reporting rate: Reports per million population/year

In India:

- Patients **can** report via the PvPI website or app, but awareness is near zero
- There are **no financial or professional incentives** for healthcare professionals to report
- Private hospitals often **withhold ADR reports** to avoid scrutiny.

10. Solutions for Safer Medicine Use

| Table 4: Strengthening Pharmacovigilance – Policy Needs |

Recommendation	Status
Mandatory ADR reporting for hospitals	Proposed (2020)
Patient-friendly digital reporting portal	Exists, underused
Training for clinicians on ADR detection	Sparse
Public awareness campaigns	Absent
Real-time ADR data dashboards	Not implemented

India must treat pharmacovigilance as **a critical safety net**, not an academic exercise. This includes:

- Creating **legal frameworks for mandatory reporting**
- Incentivising healthcare providers
- Building **patient-facing communication tools** in local languages
- Including pharmacovigilance modules in **MBBS and pharmacy education**

Conclusion: Safety is Not Optional

When a drug harms instead of heals, silence can be fatal. India's ADR crisis isn't just about biology—it's about a system that doesn't listen, doesn't track, and doesn't learn.

No drug is 100% safe—but the public has a right to be informed, protected, and heard. Until pharmacovigilance becomes embedded in practice and policy, **India's pharmaceutical power will remain incomplete and unsafe.**

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Part IV

Chemists – Gatekeepers or Middlemen?
Dr. Pulkit Khanna

Chapter 14

Unlicensed Stores and Unethical Dispensing

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Introduction: The Last Link—or the Weakest One?

In India's pharmaceutical ecosystem, chemists form the **last mile of drug access**—but also one of the least regulated. While pharmacies are expected to dispense medicines against valid prescriptions, operate with trained pharmacists, and maintain strict inventory controls, the ground reality is far murkier.

A growing network of **unlicensed outlets**, often operating without trained personnel, has led to rampant misuse, substandard storage, and sales without prescriptions. In rural India, these stores often **replace doctors**, blurring the lines between care and commerce.

1. How Widespread Are Unlicensed Pharmacies?

According to a 2023 report by the Drug Controller General of India (DCGI), **approximately 15–20% of all drug retail outlets operate without valid licenses**—particularly in Tier 3 towns and rural areas [1].

| Table 1: Estimated Unlicensed Pharmacy Prevalence by Region (2023) |

Region	Estimated Unlicensed (%)
Urban Metros	<5%
Tier 2 Cities	12–18%
Rural Districts	22–35%
Tribal Areas	40%+

These stores often operate under the radar of State Drug Control

Authorities, selling **both over-the-counter and Schedule H drugs** (prescription-only) without regulation.

2. Lack of Qualified Pharmacists

The **Drugs and Cosmetics Act, 1940**, mandates that medicines be dispensed by or under the supervision of a **registered pharmacist**. Yet, studies show:

- In **62% of rural pharmacies**, no pharmacist is physically present during operating hours [2]
- Many licenses are obtained by pharmacists who then "rent" their registration to owners

A 2022 field survey by the National Pharmacy Council found:

| Table 2: Pharmacy Staffing Compliance (n = 1,200 outlets) |

Compliance Metric	% Compliance
Full-time licensed pharmacist	38%
Pharmacist only on paper	44%
No pharmacist at all	18%

"The pharmacist is supposed to be here, but you'll mostly find the owner's son at the counter." — Interview, drug outlet, Madhya Pradesh.

3. Prescription-Free Sales: The Norm, Not Exception

In most parts of India, Schedule H, H1, and even X drugs (controlled substances) are **sold without prescriptions**.

Common examples include:

- **Antibiotics (e.g., azithromycin, amoxicillin)**
- **Steroids (e.g., prednisolone, dexamethasone)**
- **Psychotropics (e.g., alprazolam, tramadol)**
- **Codeine-based syrups**

Table 3: Drug Sales Without Prescription – Field Audit (2023)

Drug Class	% Sold Without Valid Prescription
Antibiotics	78%

Corticosteroids	61%
Sedatives	44%
Painkillers (NSAIDs)	86%
Cough Syrups (Codeine)	57%

Source: All India Pharmacists' Forum Study, 2023 [3]

4. Financial Drivers Behind Unethical Dispensing

Pharmacies are incentivised to push:

- **High-margin brands** over cheaper generics
- **Unnecessary combinations and tonics**
- **Short-expiry products to clear inventory**

Margins for branded drugs can be **3–4x higher** than generics. For example:

| Table 4: Chemist Margin Comparison – Branded vs Generic (2023) |

Product Type	Average Margin (%)
Branded multivitamin	38%
Branded antibiotic	32%
Jan Aushadhi generic	14%
OTC herbal supplement	52%

This creates a **perverse incentive to upsell**, often at the expense of rational treatment.

5. Regulatory Oversight Gaps

State drug controllers are **grossly understaffed**. A 2022 Parliamentary Standing Committee report found:

- **1 inspector per 1000+ outlets**, against WHO norm of 1:200
- Only 12 states had **computerised inspection logs**

- Inspections are often **delayed, arbitrary, or compromised**

In addition:

- No national blacklist of repeat offenders
- Weak coordination between CDSCO and state FDAs
- Penalties for violation are minimal (often limited to fines)

6. Urban vs Rural Ethics Divide

While cities have more visible regulation, rural chemists operate with **almost no monitoring**.

- Sell expired or repackaged drugs
- Store medicines in non-airconditioned rooms
- Substitute drugs without informing patients
- Recommend medicines based on symptoms (acting as quacks)

"We keep what sells. If villagers ask for a fever tablet, I give them a strip. No need for prescriptions here." — Chemist, Chhattisgarh

7. The Role of Chain Pharmacies and Franchises

Large chains (e.g., Apollo, MedPlus, NetMeds) claim to follow ethical practices. Benefits include:

- Trained pharmacists
- Barcode-based tracking
- Prescription upload verification

However, franchisee models often **replicate the same market distortions**: push branded products, cross-sell supplements, and avoid promoting generics due to lower profits.

8. Licensing Loopholes and Rent-a-License Scams

Pharmacy licenses are often:

- **Obtained under borrowed pharmacist credentials**
- **Sold or leased illegally**
- **Issued without premises verification**

In some cases, pharmacists are listed on **10+ store licenses**—a clear violation of the law.

"He gets ?10,000/month for his degree. Doesn't step foot in the shop." – Pharmacy owner, Bihar

9. Proposed Reforms: Compliance with Accountability

| Table 5: Regulatory Reforms for Ethical Dispensing |

Recommendation	Status
Digital inspection tracking system	Partial
Real-time pharmacy license database (central)	Not implemented
Aadhaar-linked pharmacist attendance	Piloted in 3 states
Barcode tracking of prescriptions	Not mandatory
Graded penalties for violations	Weak

10. Towards Ethical Retail: The Need for Pharmacist-Centric Reform

India's retail drug sector needs to **professionalise its human layer**. Just as doctors are regulated under NMC and lawyers under Bar Councils, pharmacists too must be empowered and monitored:

- Create a **Pharmacy Regulatory Authority**
- **Enforce single-license, single-location pharmacist rules**
- Provide **continuing education and ethics training**
- Implement **mandatory video-linked dispensing audits** for Schedule X drugs

Only when pharmacists are **accountable, qualified, and valued**, will the retail chain move from commercial survival to ethical service.

Conclusion: From Seller to Care Provider

Chemists are more than just drug sellers—they are often the **only accessible health interface for millions of Indians**. Treating them as vendors, not professionals, has led to a crisis of safety, trust, and ethics.

Cleaning up the unlicensed, profit-driven mess at the retail level is not just regulatory housekeeping—it is a **health justice imperative**.

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Chapter 15

Selling Without Prescription – A Grey Market of Medicines

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Introduction: Medicine Over the Counter—Without the Rules

India's pharmacies operate in a paradox: while thousands of medicines are legally categorized as prescription-only, **it is widely possible to purchase them over the counter without any medical consultation**. This unregulated access creates a thriving grey market—one where Schedule H, H1, and even Schedule X drugs are casually dispensed, turning retail counters into **pseudo-diagnostic booths**.

This chapter explores the **depth and dangers of non-prescription drug sales**, unpacking the public health risks, regulatory failures, and moral hazard it fosters within India's retail pharma landscape.

1. Schedule H and Beyond: What the Law Says

Under the **Drugs and Cosmetics Rules, 1945**, several drug categories are restricted:

- **Schedule H:** Prescription-only drugs (e.g., antibiotics, antihypertensives)
- **Schedule H1:** Additional surveillance; pharmacists must maintain a register (e.g., fluoroquinolones, opioids)
- **Schedule X:** Narcotics and psychotropics (e.g., morphine, barbiturates)

Legal Requirement:
To be sold only on the presentation of a **valid, signed prescription**
Pharmacist must maintain **sale records** for H1/X drugs

Yet, field studies show that **more than 60% of Schedule H drugs are dispensed without prescriptions** [1].

2. Drivers of the Grey Market

a) Patient Demand

- Convenience: "Why go to a doctor for a fever?"
- Cost-saving: Consultation is more expensive than the pill
- Reuse of old prescriptions or expired slips

b) Chemist Incentives

- Increased sales
- Pushing high-margin brands
- No penalty for violation (low enforcement)

c) Systemic Failure

- Absence of electronic prescription verification
- Weak inspection frameworks
- Collusion in some districts between inspectors and pharmacies

3. Real-World Snapshot: What Happens at the Counter

"You describe your problem, the chemist hands you medicine. Sometimes even injects it." — Rural patient, Haryana

Common Drugs Sold Without Prescription (2022 Study):

| Table 1: Drug Type vs % Non-Prescription Sales (Urban India) |

Drug Category	% Sold OTC Without Prescription
Antibiotics (azithromycin)	74%
Steroids (prednisolone)	58%
Benzodiazepines (alprazolam)	41%
Antifungals (fluconazole)	64%
Antidiabetics (metformin)	35%

Source: AIIMS-Pharmacovigilance Study, 2022 [2]

4. The Public Health Consequences

a) Antimicrobial Resistance (AMR)

OTC sales of antibiotics for viral fevers, coughs, and minor aches have **accelerated India's AMR burden**, now among the **highest globally**.

"One in three cases of pneumonia in Indian ICUs is now resistant to first-line drugs." – ICMR AMR Report, 2022 [3]

b) Steroid Abuse

Long-term misuse of corticosteroids (for pain, skin whitening, asthma) has led to:

- Immunosuppression
- Bone loss
- Adrenal failure

c) Benzodiazepine Dependence

Sedatives like **alprazolam and clonazepam** are sold freely. Prolonged use without supervision leads to:

- Tolerance and addiction
- Withdrawal seizures
- Depression and memory impairment

5. The Economics of Rule Violation

| Table 2: Incentive Analysis for Chemist to Sell Without Prescription |

Parameter	Estimate
Cost of fine (if caught)	?3,000–?5,000
Extra monthly profit (per drug class)	?15,000–?40,000
Risk of license cancellation	Very Low
Likelihood of inspection	Once in 2–5 years

The **low risk–high reward** structure makes unethical OTC sales a calculated choice, not an accident.

6. Schedule H1 Registers: A Dead Letter

Introduced in 2014, Schedule H1 mandates:

- Maintaining a register of sales
- Name, address of patient
- Prescribing doctor's contact

Ground Reality:

- Registers are often blank or falsified
- Recycled prescriptions are reused
- Pharmacists claim patients "don't cooperate"

In a 2023 audit of 300 chemists in Maharashtra, only **14% maintained correct H1 registers** [4].

7. Policy Gaps and Weak Enforcement

a) Digital Prescription Authentication

No e-prescription tracking system exists that links doctor issuance to chemist verification.

b) No Mandatory CCTV or Barcode Scans

Unlike some countries, pharmacies are not required to record sales via **track-and-trace barcoding**.

c) Undertrained Drug Inspectors

Most are burdened with **inspections, prosecutions, and admin work**, with **no performance metrics** tied to illegal OTC sales.

d) Legal Grey Zones

Many states allow "provisional" drug licenses, sometimes for **up to 1 year without scrutiny**.

8. Public Attitudes: Medicine as Convenience, Not Caution

Indians often trust their chemist more than doctors—especially for recurring ailments.

"We take the same cough syrup and painkiller every time. Why waste money on another visit?" — Patient, Jaipur

This mindset perpetuates the grey market, reinforced by:

- Past success with self-medication
- High out-of-pocket healthcare costs
- Cultural acceptance of "quick fixes"

9. Technology and Reform Opportunities

| Table 3: Technological Interventions for Safer Dispensing |

Technology	Status in India
ePrescription + QR validation	Pilot (Kerala)
Aadhaar-linked patient profiles	Proposed (2021)
Real-time drug sale reporting	Used in private chains
Prescription tracking dashboard	Not implemented

A centralised eRx system (like Estonia's or Sweden's) could **link doctor prescription to chemist sale**, closing the loop.

10. A Path Forward: Policy and Cultural Change

| Table 4: Recommended Actions to Curb Non-Prescription Sales |

Action	Feasibility
Enforce CCTV + electronic registers	High
Penalise repeated OTC violations	Medium
Reward ethical compliance	High
Mass awareness on self-medication risks	Medium
Ban license "renting" and proxies	High

Incentivising ethical retail behaviour, rather than just punishing unethical ones, may offer a **sustainable route forward**.

Conclusion: The Cost of Convenience

In India's pharmacy landscape, the **ease of buying medicine without prescriptions** comes at a steep cost: resistance, addiction, toxicity, and lost trust.

The longer this grey market flourishes unchecked, the more fragile our drug safety system becomes. Real reform must go beyond lawbooks—it requires cultural shift, technological integration, and ethical business practices.

Until then, **a simple visit to a chemist may continue to be more dangerous than it seems.**

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Chapter 16

Online Pharmacies – Disruption or Danger?

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Introduction: The Rise of e-Pharmacies in India

In the last decade, India's pharmaceutical retail landscape has undergone a quiet revolution: **online pharmacies**—or e-pharmacies—have emerged as a new, disruptive force. Platforms like **PharmEasy, 1mg (now Tata 1mg), NetMeds, and Apollo 24|7** have turned medicine procurement into a mobile app transaction.

Offering **discounts, home delivery, subscription models, and teleconsultations**, they promise convenience, affordability, and access—especially for chronic patients. However, this shift has brought its own **risks, loopholes, and regulatory chaos**, with grave implications for patient safety, privacy, and prescription control.

1. The Growth of India's Online Pharmacy Sector

| Table 1: Online Pharmacy Market Metrics (2023) |

Metric	Estimate
Market size	?25,000 crore (US$3B)
CAGR (2020–2025)	~21%
Registered platforms (2023)	110+
Orders per day (top 5 players)	~5 million
Repeat subscription rate	68% (chronic patients)

Source: FICCI eHealth Report, 2023; RedSeer Analytics [1]

e-Pharmacies grew rapidly post-COVID-19, as lockdowns forced patients to **shift online** for medication and consultation.

2. The Value Proposition

Key benefits cited by users:

- **Deep discounts** (10–70%)
- **Doorstep delivery**, often same-day
- **Auto-refill for chronic medication**
- Access to **e-consults, lab services**
- Upload-and-order system avoids pharmacy visits

For those in remote towns, **e-pharmacies offer access where physical chemists are few or absent**.

3. But at What Cost? Regulatory Concerns

India lacks a **comprehensive legal framework** for online pharmacies.

The Drugs and Cosmetics Act (1940) was written in an era of bricks-and-mortar stores. The **proposed e-Pharmacy Rules (Draft 2018)** remain **unnotified**, creating a vacuum where:

- Platforms function in **legal limbo**
- State FDAs have **no uniform guidelines**
- Court cases have **challenged legality** without resolving jurisdiction [2]

4. Common Violations and Grey Areas

| Table 2: Key Compliance Concerns with e-Pharmacies |

Issue	Observed Practice
Sale of Schedule H drugs	Frequently without valid prescriptions
Prescription reuse	Allowed without revalidation
Data privacy breaches	User profiles shared with insurers/ advertisers
Cold chain storage	Often unverified
Identity verification	Rarely enforced

A 2022 Delhi High Court filing accused several platforms of selling **prescription drugs like tramadol and pregabalin without verification** [3].

5. Quality and Counterfeit Risks

With sourcing spread across **third-party warehouses**, there's growing concern about:

- **Expired drugs**
- **Unregulated substitutions**
- Storage violations (e.g., insulin shipped unrefrigerated)
- Risk of **fake listings or lookalike drugs**

"The packaging looked legit, but my blood sugar spiked. Later, I learned the drug was a substandard duplicate." – Patient, Hyderabad

Offline pharmacists allege that some online platforms **procure from unlicensed vendors** to sustain deep discounting.

6. Discounts vs Ethics: The Pricing Problem

Online players offer **unsustainable discounts**—sometimes selling at **below procurement cost**—due to:

- Venture capital subsidies
- Bulk centralised purchasing
- Bypassing traditional distributor margins

This creates:

- **Unfair competition** against licensed offline pharmacies
- Pressure to push **branded** over **essential generic medications**
- Incentives for **over-ordering** and **stockpiling by patients**

7. Lack of Human Oversight

Unlike physical stores, online pharmacies **lack in-person pharmacist counselling**, leading to:

- **Automated substitution of brands**
- Misunderstanding drug schedules
- No explanation of side effects, dose titration, or contraindications

This is particularly risky for:

- **Elderly or tech-illiterate patients**
- Users of **narrow-therapeutic-index drugs (e.g., warfarin, lithium)**
- Polypharmacy patients

8. Teleconsultation: New Opportunity or Conflict of Interest?

Many e-pharmacies now **bundle doctor consultations** into their platform:

- "eRx" generated in-app → fed into their own pharmacy backend
- Pushes branded or own-label drugs
- **No checks on consultation quality**
- Conflict of interest: **Prescriber and seller are the same entity**

"I saw a doctor online who prescribed 5 drugs in 3 minutes—and all were available only on that app." – User, Bengaluru

9. The Way Forward: Regulating Smart, Not Blind

| Table 3: Policy Needs for Online Pharmacy Regulation |

Reform Area	Proposed Action
National e-Pharmacy Law	Notify and implement e-Pharmacy Rules
Central License & Compliance	Single-window licensing by CDSCO
eRx Tracking	Mandatory linking of doctor prescription and dispensation logs
Cold Chain Audit Trail	GPS-enabled storage compliance logs
Prescription Upload Validation	Aadhaar/OTP-enabled prescription checks

10. Learning from Global Models

| Table 4: Global Online Pharmacy Regulation Snapshot |

Country	Key Features
USA (FDA)	NABP Verified Internet Pharmacy Practice Sites (VIPPS)
UK (MHRA)	Mandatory pharmacist approval + GPhC registration
Canada	Requires physician verification + cold chain proof
India	Draft rules pending; compliance voluntary

India can adopt a **tiered regulation model** that:

- Allows innovation in chronic care management
- Protects patient safety via **traceability and accountability**
- Encourages transparency in discounts, sourcing, and substitutions

Conclusion: Balancing Access with Accountability

Online pharmacies have undeniably made drug access more democratic—but without **checks and balances**, they risk turning medicine into a **transaction without care**.

India must act fast to craft an **e-pharmacy law that marries innovation with regulation**, before this growing sector does more harm than good.

Without clarity, what began as a digital solution may quickly become a **regulatory blind spot**, with **millions of lives at stake**.

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Chapter 17

The Challenge of Generic Substitution – Margin Wars and Confusion at the Counter

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Introduction: Same Drug, Different Price – But Who Decides?

Generic medicines are chemically identical to branded drugs and are supposed to be the backbone of affordable healthcare. In theory, they should be widely available, affordable, and easy to prescribe and dispense. In practice, however, **generic substitution in India is deeply flawed**.

Patients are often unaware of alternatives, doctors resist prescribing them, and chemists—motivated by margins—frequently substitute not with generics, but with **higher-profit brands**. The result is a confusing, chaotic market where **the promise of low-cost medicine remains largely unrealised**.

1. What Are Generics—and Why They Matter in India

A **generic drug** is a medication that contains the same active ingredient(s), dosage form, and efficacy as a branded counterpart—but at a fraction of the price.

| Table 1: Branded vs Generic Cost Comparison – Common Drugs (2023) |

Drug Name (Generic)	Branded Price (?)	Generic Price (?)	Price Difference (%)
Atorvastatin 10mg	?84 (Lipitor)	?12 (Jan Aushadhi)	-86%
Metformin 500mg	?56 (Gluformin)	?8 (generic)	-86%

Pantoprazole 40mg	?62 (Pantocid)	?9 (generic)	-85%
Telmisartan 40mg	?78 (Telma)	?13 (generic)	-83%

Source: NPPA Pricing Portal, Jan Aushadhi Dashboard, 2023 [1]

Despite their affordability, generics make up only **~30% of private market prescriptions** in India [2].

2. Why Generic Substitution Fails at the Chemist Counter

a) Lack of Prescription Clarity

Most doctors write **branded prescriptions**, which chemists are hesitant to substitute without legal protection.

b) Margin Motivation

Pharmacists earn more from selling branded drugs.

| Table 2: Chemist Margin Comparison – Branded vs Generic |

Drug Type	Average Margin (%)
Branded (MNC)	25–35%
Generic (open market)	10–15%
Jan Aushadhi generics	<10%

"Why would I sell a ?9 drug when I can make triple the money selling a ?60 one?" — Chemist, Pune

c) No Legal Framework for Substitution

India lacks **clear substitution laws** akin to those in the UK or Australia.

- Chemists cannot legally substitute unless prescription is **explicitly written as generic**
- Fear of medico-legal issues discourages substitution even if patient demands a cheaper version

3. The Jan Aushadhi Dilemma

Launched in 2008, the **Pradhan Mantri Jan Aushadhi Yojana (PMJAY)** aimed to:

- Promote generic drug use
- Create over **9,000 Jan Aushadhi Kendras (JAKs)**
- Offer **up to 90% cheaper alternatives**

Challenges:

- Many doctors still do **not prescribe generics**
- Availability at JAKs is inconsistent
- Some drugs are reported to be **inferior in packaging or perception**, leading to patient mistrust [3]

| Table 3: Jan Aushadhi Generic Use Rate (2022 Survey) |

Patient Location	PMJAY Drug Use (%)
Urban – Metro	12%
Urban – Tier 2	18%
Rural	9%
Overall	13.2%

4. Patient Confusion and Mistrust

- Many patients believe **"branded = better"**
- Similar sounding names cause confusion (e.g., Telma vs. Telmedin)
- Chemists don't often explain the equivalence
- Misinformation by company reps or clinics discourages switching

"My doctor warned me not to use Jan Aushadhi drugs. He said they're of lower quality." — Patient, Jaipur

5. Doctors vs Chemists: A Turf War

- Doctors resist generic substitution, citing **bioavailability concerns**
- Chemists see substitution as **a right to choose among equals**
- Medical associations argue that chemist substitutions **undermine prescriptions and patient safety**

This creates **a grey zone**, with patients caught in the middle.

6. Legal and Policy Gaps

India lacks clear substitution laws seen in the West.

| Table 4: Global Generic Substitution Laws |

Country	Substitution Rights
USA	Mandatory substitution unless prohibited by doctor
UK	Allowed unless brand medically necessary
India	No substitution without explicit permission

The National Medical Commission (NMC) issued a 2022 directive requiring generic prescriptions—but **compliance remains poor** and **enforcement is absent**.

7. Branded Generics: The Great Indian Confusion

India's market is full of **"branded generics"**—generic drugs sold under brand names with marketing. These:

- Occupy **>90% of the private drug market**
- Cost more than open generics but less than innovator brands
- Offer **no therapeutic advantage**, only higher margins

"There are 60 versions of amlodipine in the market—all generics, but all branded differently." – Drug distributor, Delhi.

8. Proposed Reforms for Rational Generic Substitution

| Table 5: Reform Ideas and Status |

Reform Proposal	Implementation Status
Mandate generic prescribing in public hospitals	Partial, unmonitored
Legalise pharmacist substitution of Schedule H drugs	Not implemented
ePrescription systems with auto-substitution option	Pilot in Kerala

Mandatory pharmacist counselling for substitutions	Not enforced
Uniform branding code to avoid sound-alike names	Not in place

9. Can Generic Trust Be Rebuilt?

For generic substitution to become viable:

- **Pharmacists must be trained and empowered**
- **Doctors must be held accountable** for irrational brand loyalty
- **Patients must be educated** on safety and equivalence
- A national generic substitution law must protect **patient rights and pharmacist decisions**

Conclusion: Making Affordability Real

Generics are not just a cost-saving mechanism—they are the **foundation of healthcare equity**. But without reforms, they remain **an underutilized promise**, locked behind **profit-driven dispensing, brand manipulation, and policy vacuum**.

If India wants to make medicine accessible for all, it must **break the brand barrier**, empower ethical pharmacists, and build a culture of **trust in generics**.

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Part 5

Reforms and the Road Ahead
Dr. Pulkit Khanna

Chapter 18

The Policy Vacuum – Fragmented Governance in India's Pharma Sector

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Introduction: A Sector Without a Compass

Despite being one of the largest producers of medicines in the world, India **does not have a unified, comprehensive national pharmaceutical policy** that governs every link in its pharma chain—from manufacturing and pricing to prescribing, distribution, and consumer safety.

Instead, a patchwork of laws, rules, circulars, and outdated Acts—many predating the liberalization era—continue to guide a **$50+ billion industry**. This **policy vacuum** creates contradictions, jurisdictional overlaps, and enforcement gaps.

1. India's Pharmaceutical Governance Landscape – Who Regulates What?

| Table 1: Key Regulatory Bodies in Indian Pharma |

Authority	Primary Role
CDSCO (under MoHFW)	Drug approvals, clinical trials, import/export
State FDAs	Licensing and inspections of pharmacies, wholesalers
NPPA	Drug pricing under DPCO
MCI/NMC	Regulates doctors and prescription behaviour
Pharmacy Council of India	Regulates pharmacy education and practice

BIS, MoCI, DCGI	Quality and labelling standards

The problem: **No single apex authority** coordinates their actions, and most bodies function in **silos**.

2. Legacy Laws in a Modern Industry

The key Acts governing pharma include:

- **Drugs and Cosmetics Act, 1940 –** Defines drug manufacturing and sale
- **DPCO, 2013 –** Enforces price control
- **Pharmacy Act, 1948 –** Regulates pharmacist education
- **NMC Act, 2019 –** Governs medical practice
- **Essential Commodities Act, 1955 –** Covers drug shortages

But these laws:

- **Lack provisions for e-pharmacies, biologics, AI-based trials**
- Have **outdated penalties** (e.g., ?5,000 fine for substandard drugs)

Offer **no clarity** on tech-led innovations like telemedicine-linked prescriptions

3. Jurisdictional Conflicts – Central vs State Tug-of-War

The division of roles between the **Central Drugs Standard Control Organization (CDSCO)** and **state drug controllers** creates massive ambiguity.

| Table 2: Division of Regulatory Responsibilities |

Function	Authority	Issue
New drug approval	CDSCO	Centralised
Retail license inspections	State FDAs	Fragmented, inconsistent
Pharmacovigilance audits	CDSCO + PvPI	Weak coordination
DPCO implementation	NPPA + States	Poor monitoring

Result: **Same drug may face different rules across states**, and violations go unchecked due to blame-shifting.

4. No National Pharma Policy Since 2002

The **last full-fledged National Pharmaceutical Policy (NPP)** was drafted in 2002 and later revised in **draft form in 2017**, but never implemented.

Key areas lacking national direction:

- Rational drug use
- Incentivizing innovation
- Generic substitution laws
- Ethics in promotion and marketing
- Regulation of online pharmacies
- Uniform inspection standards across states

"Pharma is India's sunrise sector. Yet we are navigating it without a national roadmap." – Former DCGI official

5. Lack of Data-Driven Governance

India's drug system is plagued by a **lack of digital infrastructure and real-time analytics**.

- No central database of pharmacies, prescribers, and drugs sold
- No real-time pharmacovigilance integration
- No analytics to track antibiotic overuse or steroid abuse trends

| Table 3: Digital Infrastructure Gaps |

Critical System Needed	Status (2023)
National Pharmacy Registry	Absent
eRx and prescription audit platform	Pilot in Kerala only
Real-time pharmacovigilance dashboard	Incomplete
Integrated supply chain tracking	Absent

6. Fragmentation in Policy Implementation

Even when policies are designed at the Centre, **states interpret and implement them differently**, leading to:

- Delayed drug approvals in some regions
- Uneven price control enforcement
- Arbitrary inspection frequency and penalties
- Lack of harmonisation in pharmacist licensing

This **regulatory heterogeneity** undermines national efforts to ensure consistent drug quality, access, and affordability.

7. No Unified Body for Ethical Oversight

Pharma promotion in India is governed by the **Uniform Code for Pharmaceutical Marketing Practices (UCPMP)**—but it is **voluntary**, not binding.

- No punitive powers
- No transparency on promotional spending
- Doctors continue to receive gifts, trips, devices—untracked

"Without a pharma ethics watchdog, marketing budgets decide prescriptions." – Health activist, Mumbai

8. Missed Opportunities: What Other Countries Got Right

Table 4: Comparison of National Pharma Policy Coordination

Country	Key Feature
USA	FDA centralises all approvals and enforcement
UK	NICE evaluates drug cost-effectiveness nationally
South Korea	Centralised drug audit, online prescription log
India	Fragmented across ministries and states

India lacks **a central authority equivalent to the US FDA**, which coordinates inspections, clinical trials, recalls, and ADR reports.

9. Political Apathy and Pharma Lobbying

The pharma sector enjoys **political patronage** and strong lobbying power, making it difficult to push for strong regulation.

- Regulatory bodies are often **underfunded and understaffed**
- Top bureaucrats have **conflicts of interest** through revolving-door employment
- Whistleblower protections are weak, discouraging reporting of malpractices

10. Towards a Unified, Accountable Framework

India urgently needs a **National Pharmaceutical Commission**—an apex, autonomous body that:

- Integrates CDSCO, NPPA, PvPI, and digital health data
- Audits drug safety, marketing practices, and supply chains
- Coordinates across ministries (Health, Commerce, Chemicals)
- Drives evidence-based policy updates every 5 years

Conclusion: A Sector in Search of Leadership

For a country known as the **"pharmacy of the world"**, India's domestic pharma governance remains **deeply outdated, decentralised, and dangerously permissive**.

Without an integrated pharmaceutical policy that aligns economic growth with patient safety, the system will continue to reward volume over value, and profit over ethics.

It's time India treated medicines not just as commodities, but as **public goods requiring national stewardship**.

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Chapter 19

Strengthening the Regulators – CDSCO, NPPA, and State FDAs

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Introduction: Regulators Under Pressure

India's pharmaceutical regulatory ecosystem is manned by key bodies like the **Central Drugs Standard Control Organization (CDSCO)**, the **National Pharmaceutical Pricing Authority (NPPA)**, and various **State Food and Drug Administrations (FDAs)**. But each of them operates under extreme constraints—legal, logistical, and political.

This chapter dissects the **institutional weaknesses** that prevent these bodies from acting decisively and suggests practical ways to equip them for **21st-century oversight**.

1. The CDSCO: Central but Constrained

The CDSCO is India's apex drug regulator, akin to the US FDA. It is tasked with:

- Approving new drugs and clinical trials
- Regulating imports/exports
- Coordinating pharmacovigilance
- Framing national drug policy rules

Yet, it suffers from:

- **Chronic understaffing**: Less than 2,000 employees for a $50+ billion industry
- **Paper-based processes**: Many approvals and renewals are still offline
- **Political interference**: Key decisions delayed or bypassed

• **No real-time surveillance system** for ADRs or illegal marketing

"It's a national body running on state-level resources." — Former Drug Inspector, CDSCO

2. NPPA: The Price Policeman Without a Stick

The NPPA was created to monitor and control drug prices under the **Drug Price Control Order (DPCO)**. It:

- Publishes ceiling prices for essential drugs
- Fixes prices of medical devices (e.g., stents, knee implants)
- Tracks market price manipulation

However:

- **Price control covers <20% of market drugs**
- Companies evade controls via **product rebranding or dosage changes**
- NPPA lacks **penalty powers** beyond derecognition

| Table 1: NPPA Penalties vs Market Violation (2022) |

Year	Overcharging Cases Detected	Recovery Amount Ordered (?Cr)	Actual Recovered (%)
2022–23	203	?1,158	14.6%
2021–22	177	?988	16.3%

Source: NPPA Annual Report 2023 [1]

3. State FDAs: Overworked and Unequal

Each Indian state has its own FDA or Drug Control Department. Their responsibilities:

- Issue and renew licenses for retailers/wholesalers
- Conduct inspections
- Enforce prescription-only laws
- Act on substandard or spurious drug reports

Major Problems:

- **Wide disparities** between states (e.g., Tamil Nadu vs Bihar)
- **One drug inspector per 1,200 outlets** (WHO recommends 1:200)
- **No uniform IT platform or tracking system**
- **High turnover and low morale**

"We inspect 80–100 outlets a month. It's a checkbox exercise now." — Drug Inspector, Maharashtra

4. Weak Inter-Agency Coordination

The CDSCO, NPPA, and State FDAs often work **in isolation**, leading to:

- Conflicting databases
- Delayed responses to recalls
- Redundant paperwork for manufacturers
- No shared intelligence on bad actors

| Table 2: Key Coordination Failures Identified |

Incident	Impact
2022 cough syrup deaths (Gambia)	Slow recall response; inter-state communication gaps
Repeat violations by known companies	No unified blacklist shared between regulators
Duplicate licensing (state vs central)	Regulatory grey zones exploited by pharma firms

5. Pharmacovigilance: Still a Weak Link

The **Pharmacovigilance Programme of India (PvPI)** is responsible for detecting and managing Adverse Drug Reactions (ADRs). But:

- Reporting is **voluntary**, and under 1% of ADRs are captured
- There's **little integration** with hospitals or chemists
- PvPI data is rarely used for regulatory action

| Table 3: ADR Reporting vs Estimated Cases (2022) |

Metric	Number
Estimated serious ADRs (India)	~5 million/year
ADR reports received by PvPI	130,000
% Captured	~2.6%

Source: PvPI Data, 2022 [2]

6. Digital Infrastructure: Still Primitive

India's drug regulators continue to operate with **largely manual and state-fragmented systems**.

| Table 4: Critical Digital Gaps in Indian Drug Regulation |

Area	Status (2023)
Real-time prescription tracking	Absent
Central drug quality database	Incomplete
Electronic licensing portal	Not fully implemented
Retail sales traceability	Not mandated

CDSCO's **Sugam portal** has faced criticism for frequent downtime and poor user interface.

7. Staffing and Resource Deficit

| Table 5: Staffing Comparison – India vs Other Nations |

Country	Drug Regulatory Staff per 10,000 population
USA (FDA)	4.2
UK (MHRA)	3.1
India (CDSCO + FDAs)	0.6

The **gap is not just quantitative**, but also **qualitative**—few drug inspectors are trained in:

- Biologics
- Medical device safety

- AI-based diagnostic tools
- Clinical trial ethics

8. Lack of Transparency and Accountability

- No **annual public audit** of CDSCO or NPPA
- Whistleblower reports are **not protected or rewarded**
- No **pharma company grading system** (like ESG for corporates)
- **FOI requests often denied** citing commercial confidentiality

This opacity fosters **regulatory capture**, where large companies influence decision-making through lobbying.

9. Blueprint for Strengthening Drug Regulators

| Table 6: Recommended Reforms |

Reform Area	Specific Steps
Staffing	Hire 2,000+ new regulators nationwide
Digital traceability	Mandatory barcode-to-patient logs
PvPI reform	Make ADR reporting mandatory in hospitals
Licensing reform	National pharmacy and drug license registry
Inter-agency council	Monthly CDSCO–NPPA–State FDA dashboard updates
Pharma ethics audit	Independent pharma compliance rating agency

10. Funding the Reform

Currently, India's drug regulation is funded via:

- Central budget allocations
- Licensing fees
- Inspection charges

To improve independence and scalability, India should explore:

- **User fees for new drug approvals (like US FDA PDUFA)**
- **Regulatory surcharge on pharma profits**
- **Public-private innovation grants** tied to compliance

Conclusion: A Watchdog Must Be Able to Bark—and Bite

Regulators are not mere bureaucracies—they are **guardians of public health**. But without resources, power, and political support, even the best laws are toothless.

For India's pharma future to be ethical, safe, and globally respected, **its regulatory backbone must be reengineered, resourced, and revitalised**.

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Chapter 20

Transparency, Technology, and the Way Forward

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Introduction: Beyond Diagnosis – Towards a Cure

After exploring India's pharmaceutical crisis from manufacturing to marketing, from prescription to dispensing, it is clear that **piecemeal reforms will not be enough**. The challenge demands **a systemic overhaul** rooted in **transparency, technology, ethics, and empowerment**.

This final chapter outlines a **realistic yet bold roadmap** to reshape the Indian pharma ecosystem—restoring credibility, improving access, and rebuilding trust.

1. Strengthening Transparency Across the Chain

Transparency is the antidote to opacity, corruption, and conflict of interest. The sector must embrace it at all levels:

| Table 1: Transparency Measures Needed |

Area	Reform Recommendation
Drug Approvals	Publish all meeting minutes & decision rationales
Pharma Marketing	Mandatory public disclosure of doctor payments
Pricing	Real-time access to DPCO-covered drug MRP database
Recalls and Bans	Public alerts dashboard, mandatory notifications

Clinical Trials	Real-time registry updates, post-trial reports

"If people don't know who influences what they consume, they can't make informed decisions." — Health activist, Delhi

2. Embracing Technology – The Digital Pivot

India's scale requires digital solutions. A tech-first approach can address inspection backlogs, pricing inconsistencies, fake drugs, and irrational prescriptions.

a) Barcode-Based Drug Tracking (Track & Trace)

- All drugs to carry a **GS1-standard barcode**
- Scannable from manufacturer to patient
- Enables **real-time recall, expiry, and batch tracking**

b) e-Prescription Integration

- Link **doctors, chemists, and patient Aadhaar**
- Prevents prescription fraud and drug misuse
- Enables **prescription audits** and **rational use analytics**

c) AI for Pharmacovigilance

- Natural language processing to detect ADR patterns from EMRs, social media, and hospital logs
- Flag unsafe drugs or irrational prescribing clusters

| Table 2: Priority Digital Interventions |

System	Status	Urgency
eRx National Platform	Pilot (Kerala)	High
Barcode Track & Trace	Missing	High
Hospital-linked PvPI AI	Incomplete	Medium
Chemist Digital Licensing	State-level	Medium

3. Empowering Patients: From Recipients to Participants

Public health cannot improve unless patients are informed and engaged.

| Table 3: Patient-Centric Reforms |

Reform Area	Action Needed
Prescription Literacy	Simple, illustrated medicine guides
Adverse Reaction Reporting	Toll-free & SMS-based systems (PvPI 2.0)
Pricing Awareness	Mandatory display of generics and MRP on apps/stores
Drug Labelling	Clear, multilingual, colour-coded warnings

India must build a **citizen-pharma compact** that respects patient autonomy and rights.

4. Redefining Ethics in Pharma

The **voluntary UCPMP code** has failed to prevent gifts, foreign junkets, and high-margin inducements.

It must be replaced with a **statutory code**, enforced by an independent regulator.

| Table 4: Ethical Reform Actions |

Stakeholder	Mandate
Pharma Companies	Declare marketing spend, gifts, CME payments
Doctors	Declare affiliations, abide by e-prescription norms
Chemists	Cannot substitute without reason/ documentation

Penalties must include:
- Suspension of license
- Blacklisting in procurement
- Naming and shaming via public database

5. Incentivising Innovation Over Imitation

India must evolve from being a **reverse-engineering hub** to a **true innovation powerhouse**.

Key Steps:

- **Patent reforms**: Fast-track approval of Indian-origin innovations
- **R&D tax credits**: Tie to outcomes (IP filing, clinical results)
- **Public-private incubators**: Biotech and orphan drug accelerators
- **Innovation fund**: Grants for diseases neglected by private sector

"We can't lead the world with 1.5% R&D investment." — Pharma policy expert, Hyderabad

6. Redefining Regulation – From Punishment to Prevention

Regulators must become **risk-based, transparent, and tech-enabled**.

| Table 5: Regulatory Shift – Old vs New |

Dimension	Old Model	New Model
Approach	Reactive, punishment-driven	Proactive, preventive
Information Flow	Paper-based, siloed	Digital, interoperable
Inspection	Periodic, manual	Real-time, AI-prioritised
Accountability	Opaque, centralised	Public dashboards, audit trails

India's **next-generation regulator** must be autonomous, data-driven, and publicly accountable.

7. Creating a National Drug Policy 2.0

India urgently needs a modern, integrated **National Pharmaceutical Policy**, with five pillars:

1. **Access** – Universal availability of essential medicines
2. **Affordability** – Fair, regulated pricing across brands
3. **Quality** – Eliminate substandard, irrational drugs
4. **Ethics** – Stop perverse incentives in prescribing & dispensing
5. **Innovation** – Create an ecosystem for original drug discovery

Such a policy must align with the **National Health Policy (2017)** and be reviewed every **5 years** with public feedback.

8. What Success Could Look Like – A Vision for 2030

| Table 6: Vision 2030 Goals for Indian Pharma |

Indicator	Target by 2030
% Drugs sold with eRx	>75%
ADR reporting rate (per lakh pop)	10x increase
Share of generics in private market	>60%
Patient trust rating (survey index)	80%+ trust in generics and chemists
Pharma innovation rank (global)	Top 10 globally

Achieving this will require **political courage, regulatory independence, and citizen pressure**.

Conclusion: The Prescription for Reform

India's pharmaceutical crisis is not a failure of production capacity—it is a failure of **governance, ethics, and transparency**.

But the crisis is also an opportunity: to become not just the "pharmacy of the world," but **a model for responsible, patient-first healthcare**.

This transformation demands we treat medicines not as mere commodities, but as **public goods tied to the right to life**.

The road ahead will be hard—but the roadmap is clear.

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