

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Instead, a patchwork of laws, rules, circulars, and outdated Acts – many predating the liberalization era – continue to guide a **\$50+ billion industry**.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

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- Have **outdated penalties** (e.g., ₹5,000 fine for substandard drugs)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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