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**.

References

1. National Pharmaceutical Pricing Authority. Annual Performance Report 2022–23. NPPA; 2023.

2. Indian Pharmacopoeia Commission. PvPI National Report. IPC; 2022.

Ministry of Health and Family Welfare. Drug Regulatory Capacity Review. MoHFW; 2022.