## Chapter 2

## Quality Control or Chaos?

**Dr. Amit Singhal**
Professor and Head, Dept. of Pharmacology Santosh Medical College, Ghaziabad

### 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.

**References**


1. WHO. Substandard and falsified medical products: Fact sheet. Geneva: World Health Organization; 2023.
2. CDSCO. Annual Report 2021–22. Ministry of Health and Family Welfare, Govt. of India.
3. WHO. Medical Product Alert No.6/2022 and No.1/2023: Maiden and Marion Pharma. Geneva; 2023.
4. WHO Drug Alerts Database. WHO Pharmaceuticals Newsletter, 2015–2023.
5. USFDA. Compliance Reports and Warning Letters: India. 2015–2023.
6. Africa CDC. Statement on Indian pharmaceutical imports. Africa Union; 2023.
7. Pharmexcil. Status Report on Indian Pharma Manufacturing. 2022.
8. Drugs Technical Advisory Board. Recommendations on Small and Medium Pharma Enterprises. 2018.

9. Parliament of India. 59th Standing Committee on Health: CDSCO Oversight Report. 2021.

10. CDSCO. iVEDA Platform Brochure. Ministry of Health and Family Welfare; 2022.

11. Sharma DC. Indian cough syrup deaths: a history of diethylene glycol poisonings. Lancet. 2023;401(10379):1159.

12. Ministry of Health & Family Welfare. National Drug Regulatory Authority Bill. 2020 (unpassed).