

## 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
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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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