Chapter 3

The Broken Chain of R&D

Dr. Rajni Kuman Rai
AssistantProfessor, Dept. of Pharmacology GS Medical College, Hapur, Uttar Pradesh

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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