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India Pharma 2026: The Volume-to-Value Shift in the 'Pharmacy of the World'

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WHY IN NEWS

The **9th edition of India Pharma 2026** was inaugurated at Federation House, FICCI, New Delhi on **April 13-14, 2026** by Union Minister **Jagat Prakash (J.P.) Nadda** (Chemicals & Fertilizers) and Minister of State **Anupriya Patel**. The theme — ***"Discover in India: Leapfrogging Life-Sciences Innovation"*** — signals a strategic shift from India's "volume-driven generics" identity to **value-led, IP-anchored pharmaceutical innovation**.

INDIA'S PHARMA SECTOR AT A GLANCE (2026)

METRIC	VALUE (2024-25 / 2025-26 EST.)
Total domestic pharma market size	**~$55 billion**
Exports	**~$27 billion** (FY 2024-25)
Share of global generic supply (by volume)	**~20%** (largest single-country source)
Share of world's vaccine supply (by volume)	**~60%**
Ranking	3rd by volume (after USA, China); **11th by value** globally
Number of FDA-approved facilities	**>650** (highest outside USA)
R&D spend as % of revenue	**~7-8%** (vs global Big Pharma at 15-18%)

Why the volume-vs-value gap matters: India produces roughly one in every five generic pills consumed globally, but captures only about 3% of the global pharma industry's value — because generics are low-margin commodities while innovator drugs (biologics, new molecular entities) command 10-30x pricing.

THE STRATEGIC SHIFT — FROM "PHARMACY" TO "DISCOVERY"

The Policy Framing

India Pharma 2026's theme — "Discover in India" — echoes the government's larger "Make in India" brand, now applied specifically to pharmaceutical R&D and intellectual property creation. The four identified shifts:

1. **Generics → Biosimilars + Complex Generics:** Biosimilars (follow-on biologics of off-patent biologic drugs like Humira, Herceptin) and complex generics (inhalers, injectables, ophthalmics) are 3-5x more profitable than small-molecule generics
2. **Contract Manufacturing → CRDMO (Contract Research, Development & Manufacturing Organisation):** Moving beyond "make it" to "design and make it" — capturing more of the value chain
3. **Small molecules → Biologics:** mAbs (monoclonal antibodies), cell and gene therapies, mRNA platforms — all high-margin, IP-intensive
4. **Domestic + Export → Global IP Origination:** Patents filed in India that get transferred globally, rather than licensing-in from Western innovators

Government Schemes Supporting the Shift

SCHEME	OUTLAY	PURPOSE
PLI for Pharmaceuticals (2021)	₹15,000 crore	Incentives for manufacturing niche complex generics + drug intermediaries
PLI for Bulk Drugs / APIs (2020)	₹6,940 crore	Reduce import dependence on Chinese APIs (from ~70% to target 30% by 2030)
Promotion of Bulk Drug Parks (2020)	₹3,000 crore	3 parks in Gujarat, Himachal Pradesh, Andhra Pradesh
PRIP — Promotion of Research & Innovation in Pharma MedTech (2023)	₹5,000 crore	Support R&D in biosimilars, precision medicine, regenerative medicine
Strengthening of Pharmaceuticals Industry (SPI, 2022)	₹500 crore	Common facility centres for MSME pharma

THE API (ACTIVE PHARMACEUTICAL INGREDIENT) PARADOX

India is the world's largest supplier of **finished formulations** but **imports roughly 70% of its APIs** — the active chemical compounds that are the raw materials for drugs. Of those, approximately **68% come from China**.

Why India's API Self-Sufficiency Collapsed

- **1991-2000:** India was largely self-sufficient in API production
- **Post-2000:** Chinese APIs flooded markets at 30-40% price discounts due to massive government subsidies, cheap energy, and environmental externalities
- **Indian API manufacturers shuttered** — ~70% of small API units closed between 2000-2015
- **Result:** India — the "Pharmacy of the World" — depends on China for its pharmacy's raw materials

COVID-19 Wake-Up Call

During COVID-19 (2020), China's temporary export restrictions on paracetamol APIs caused global shortages and price spikes. This triggered:

- **PLI scheme for KSMs (Key Starting Materials) & APIs** — ₹6,940 crore
- **Bulk Drug Parks** — to create clusters for backward integration
- Target: **50% API self-reliance by 2030**

BIOSIMILARS — INDIA'S HIGH-VALUE OPPORTUNITY

Biosimilars are follow-on versions of biologic drugs (monoclonal antibodies, insulin, EPO, G-CSF) once the original's patent expires. Unlike small-molecule generics (simple chemical copies), biosimilars require new clinical trials because living cell-produced proteins cannot be replicated identically.

India's Biosimilar Leadership

- India was the **first country to approve a biosimilar globally** — Reliance Life Sciences' ReliGrast (filgrastim biosimilar) in 2007
- Indian firms (Biocon, Dr Reddy's, Intas, Zydus, Lupin) lead the global biosimilar market by volume
- Indian biosimilars offer **50-70% price reductions** versus originator biologics

Biosimilar Regulatory Pathway (India)

- **CDSCO (Central Drugs Standard Control Organisation)** approves biosimilars under 2016 guidelines
- **DBT (Department of Biotechnology)** co-regulates when live organisms are involved
- Reference Biologic must be approved in India or a regulated market (US/EU/Japan)

Global Biosimilar Market

- Projected **$100+ billion by 2030** (from ~$35 billion in 2025)
- Major patent expiries (2026-2030): Humira (already), Stelara, Keytruda — each a $10-20 billion/year opportunity

- India's share: Currently ~**25-30% by volume** globally; government target to capture **40%+ by 2030**

THE INNOVATION ECOSYSTEM GAPS

Where India Lags

DIMENSION	INDIA	USA	CHINA
NME (New Molecular Entity) approvals/year	1-2	40-60	5-10
Pharma R&D spend (USD)	~$2 billion	~$80 billion	~$20 billion
Phase III trial cost (indicative)	$10-50 million	$50-200 million	$20-80 million
Patent filings (pharma, ~2024)	~1,500	~15,000	~10,000
Biotech IPOs (past 5 years)	<10	~500	~200

Structural Reasons for the Gap

1. **R&D funding gap** — Indian pharma spends 7-8% on R&D; global innovators spend 15-18%. Reinvestment rates are structurally lower due to lower margins
2. **Risk capital shortage** — Indian biotech VC ecosystem is ~15-20% the size of China's, <5% of USA's
3. **Regulatory friction** — CDSCO-to-USFDA/EMA process harmonisation gaps slow multi-market trials
4. **Talent gap** — Senior PhD-MD clinician-scientists (critical for translational research) still largely emigrate
5. **IP uncertainty** — India's **Section 3(d) of the Patents Act, 1970** (disallowing ever-greening) creates periodic friction with originator firms — though this is also a public-health strength

SECTION 3(D) — INDIA'S COMPULSORY INNOVATION FILTER

Section 3(d) of the Patents Act, 1970 (inserted via the 2005 amendment) is central to India's pharma landscape. It states that the "mere discovery of a new form of a known substance" is not patentable unless it shows enhanced efficacy.

The Novartis Case (2013)

Novartis AG v. Union of India — Supreme Court upheld Section 3(d) when Novartis tried to patent a new crystalline form of its cancer drug Gleevec (imatinib). The ruling's impact:

- **Positive:** Prevents "ever-greening" — extending patents through minor molecular modifications; keeps generics affordable
- **Negative:** Big Pharma has cited Section 3(d) as a disincentive for Indian R&D; some argue it affects inbound biotech investment

The India Pharma 2026 dialogue acknowledged this tension: encouraging innovation while preserving affordability.

GLOBAL CONTEXT — THE PHARMA CHESSBOARD

The "China+1" Opportunity

Post-COVID and amid US-China tensions, global pharma supply chains are diversifying away from pure China dependence. India is the natural beneficiary because:

- Large English-speaking STEM workforce
- Democratic governance (lower supply-chain political risk)
- Existing USFDA-approved manufacturing base

However, Vietnam, Indonesia, and increasingly Malaysia are competing for the same diversification dollars.

The US-India Pharma Relationship

- USA is India's **largest pharma export destination** (~$9 billion, FY 2024-25)
- India supplies **~40% of all generic drugs** consumed in the USA
- US pharma imports from India save American consumers an estimated **$200+ billion annually**
- Tensions: USTR Special 301 Report periodically flags India's IP regime; some Big Pharma lobbies for weaker Section 3(d)

UPSC RELEVANCE

PAPER	ANGLE
GS2 — IR	India-US pharma trade; global supply chain diversification; USTR Special 301
GS3 — Economy	PLI schemes; CRDMO; biosimilar market; API self-sufficiency; trade deficit
GS3 — S&T	Drug discovery pipeline; biologics; mRNA platforms; CDSCO regulation
GS4 — Ethics	Patent vs public health tension; Section 3(d); affordable medicines vs innovation incentives
Prelims	India Pharma 2026 — 9th edition; Min: **J.P. Nadda + Anupriya Patel**; venue: FICCI New Delhi; India share of global generics: ~20%; FDA-approved sites: >650; PLI for Pharma: ₹15,000 cr; Section 3(d) — Novartis case (2013); Patents Act 1970
Interview	"Has India's generics model reached structural limits? What policy would push innovation without sacrificing affordability?"

Edition: **9th** · *Dates: April 13-14, 2026* · *Venue:* **Federation House, FICCI, New Delhi** · *Theme:* **"Discover in India: Leapfrogging Life-Sciences Innovation"** · *Inaugurated by* **J.P. Nadda** *(Chem & Fert.) +* **Anupriya Patel** · *Organised by: Dept of Pharmaceuticals + FICCI.*

Domestic market: **~$55 billion** · *Exports:* **~$27 billion (FY 2024-25)** · *Global generics share (volume):* **~20%** · *Global vaccine share (volume):* **~60%** · *USFDA-approved sites:* **>650** · **3rd by volume**, *11th by value globally.*

PLI Pharma (2021): ₹15,000 cr · **PLI Bulk Drugs (2020): ₹6,940 cr** · **PRIP (2023): ₹5,000 cr** · *Bulk Drug Parks: 3 (Gujarat, HP, AP)* · *API import dependence:* **~70%**; *from China:* **~68%**.

CDSCO *under Drugs & Cosmetics Act 1940* · **Section 3(d) Patents Act 1970** *(anti-ever-greening)* · **Novartis v. UoI (2013)** — *SC upheld 3(d)* · *GS3: Economy + S&T; GS2: IR.*

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