



UPSC &amp; STATE PCS CURRENT AFFAIRS · UJIYARI.COM

**DAILY CURRENT AFFAIRS**

# Biopharma SHAKTI – India's Rs 10,000 Crore Push to Become Global Biologics Hub

25 March 2026

SUBJECTS COVERED

SCIENCE &amp; TECH

ECONOMY

CURATED &amp; WRITTEN BY

**Bharat Choudhary**

UPSC Educator &amp; Content Creator •

[linkedin.com/in/epicbharat](https://www.linkedin.com/in/epicbharat)

Free UPSC &amp; State PCS Resources

[ujiyari.com](http://ujiyari.com)

# Biopharma SHAKTI — India's Rs 10,000 Crore Push to Become Global Biologics Hub

25 March 2026 · 3 min read

## ▼ On this Page

- **What Are Biologics and Biosimilars?**
- Key Components of Biopharma SHAKTI
- India's Pharma Industry — Current Standing
- Why Biologics Matter
- NIPERs — National Institutes of Pharmaceutical Education and Research
- CDSCO — Regulatory Body

## 🔪 WHY IN NEWS

The Union Budget 2026-27 announced the Biopharma SHAKTI (Strategy for Healthcare Advancement through Knowledge, Technology, and Innovation) initiative with a Rs 10,000 crore allocation to position India as a global biomanufacturing hub for biologics and biosimilars.

## What Are Biologics and Biosimilars?

**Biologics** are complex medicines derived from living cells — they include monoclonal antibodies, vaccines, gene therapies, and cell therapies. Unlike chemical drugs (generics), biologics cannot be exactly replicated because they are produced by living organisms.

**Biosimilars** are “similar” versions of approved biologic medicines, comparable in quality, safety, and efficacy. They are to biologics what generics are to chemical drugs — but with far greater complexity in manufacturing and regulatory approval.

## Key Components of Biopharma SHAKTI

### Educational Infrastructure

- **3 new NIPERs** (National Institutes of Pharmaceutical Education and Research)
- **7 existing NIPERs upgraded** with biopharmaceutical research facilities
- Focus on training workforce in biologics R&D, manufacturing, and regulatory science

### Clinical Trial Ecosystem

- Network of **1,000+ accredited India Clinical Trial sites**
- Standardised protocols aligned with ICH-GCP (International Council for Harmonisation – Good Clinical Practice) guidelines
- Faster recruitment for multi-site trials

### Regulatory Strengthening

- **CDSCO** to be strengthened with a **dedicated scientific review cadre**
- Target: match global approval timeframes (currently India takes 12-18 months vs US FDA's 10 months)
- Shift toward **non-animal testing models** (3Rs principle: Replace, Reduce, Refine)

## India's Pharma Industry – Current Standing

PARAMETER	DATA
Global pharma production rank	3rd by volume
Generic medicines share	~20% of global supply
Vaccine supply share	~60% of global supply
Domestic biosimilars approved	95+
Global biosimilar market share	~3.2% (2025)
Industry size	~\$50 billion (2025)
Pharma exports FY2025	~\$28 billion

Despite being the “Pharmacy of the World” in generics and vaccines, India’s share in the **\$500+ billion global biologics market** remains under 4%.

### Why Biologics Matter

Biologics are critical for treating:

- **Cancer** – monoclonal antibodies (trastuzumab, rituximab, pembrolizumab)
- **Diabetes** – insulin analogs
- **Autoimmune diseases** – adalimumab, infliximab
- **Rare diseases** – gene therapies, enzyme replacement therapies

The global biologics market is expected to reach **\$800+ billion by 2030**, growing at 8-10% annually. India’s cost advantage in manufacturing could make biosimilars 30-40% cheaper than originator biologics.

## NIPERs — National Institutes of Pharmaceutical Education and Research

NIPERs are institutes of national importance established under the **NIPER Act, 1998**. Currently, there are **7 NIPERs** across India:

NIPER	LOCATION
NIPER-1	S.A.S. Nagar (Mohali), Punjab
NIPER-2	Hyderabad, Telangana
NIPER-3	Ahmedabad, Gujarat
NIPER-4	Hajipur, Bihar
NIPER-5	Kolkata, West Bengal
NIPER-6	Guwahati, Assam
NIPER-7	Raebareli, Uttar Pradesh

With Biopharma SHAKTI, **3 new NIPERs** will be established (locations to be announced), and all existing 7 will be upgraded.

## CDSCO — Regulatory Body

The **Central Drugs Standard Control Organisation** functions under the **Drugs and Cosmetics Act, 1940**. It is headed by the **Drugs Controller General of India (DCGI)**. CDSCO regulates:

- New drug approvals
- Clinical trial permissions
- Import licences for drugs
- Blood bank regulation

### UPSC RELEVANCE

NIPER Act 1998, CDSCO, DCGI, Drugs and Cosmetics Act 1940, biologics vs biosimilars, 3Rs principle

India's pharmaceutical industry; Make in India for healthcare; science and technology policy

“India is the pharmacy of the world for generics but not for biologics. What structural changes does Biopharma SHAKTI address?”

## ★ FACTS CORNER — KNOWLEDGEPEDIA

### BIOPHARMA SHAKTI:

Full form: Strategy for Healthcare Advancement through Knowledge, Technology, and Innovation

Budget allocation: Rs 10,000 crore

New NIPERs: 3; existing upgrades: 7

Clinical trial sites: 1,000+ accredited

Non-animal testing: 3Rs principle (Replace, Reduce, Refine)

### INDIA'S PHARMA SECTOR:

Global rank: 3rd by volume

Generic medicines: ~20% of global supply

Vaccines: ~60% of global supply

Biosimilar market share: ~3.2% globally

Approved domestic biosimilars: 95+

Industry size: ~\$50 billion

Exports: ~\$28 billion/year

### REGULATORY FRAMEWORK:

CDSCO: under Drugs and Cosmetics Act, 1940

DCGI: Drugs Controller General of India

NIPERs: 7 existing (NIPER Act, 1998) + 3 new

Indian Pharmacopoeia Commission (IPC): sets quality standards

### OTHER RELEVANT FACTS:

Global biologics market: \$500+ billion (2025), expected \$800+ billion by 2030

Top biologics companies: Roche, AbbVie, Johnson & Johnson, Amgen

Indian biosimilar leaders: Biocon, Dr Reddy's, Cipla, Zydus

PM-ABHIM (Ayushman Bharat Health Infrastructure Mission): Rs 64,180 crore for health infra

Sources: [Business Standard](#), [Insights on India](#), [Inc42](#)

## RELATED EDITORIALS

---

### ECONOMIC TIMES

**Biopharma SHAKTI — Can India Bridge the Biologics Gap and Become the Next Pharmacy Frontier?**

25 Mar

### BUSINESS STANDARD

**Semaglutide Goes Generic — Can India's Drug Oversight Keep Up with the Weight-Loss Revolution?**

25 Mar

### THE HINDU

**The Judicial Push for Environmental CSR — From Charity to Constitutional Duty**

25 Mar

### BUSINESS STANDARD

**India at 5.9% — The Oil Shock Exposes Structural Fragility in India's Growth Model**

25 Mar

---

CURATED & WRITTEN BY

# Bharat Choudhary

UPSC Educator & Content Creator

 [linkedin.com/in/epicbharat](https://www.linkedin.com/in/epicbharat)

 [Read Full Article on Ujyari](#) →

<https://ujyari.com/daily/2026/03/25/biopharma-shakti-biologics-hub/>

---

Free UPSC & State PCS Current Affairs · [ujyari.com](https://ujyari.com)