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**EDITORIAL ANALYSIS**

# Biopharma SHAKTI – Can India Bridge the Biologics Gap and Become the Next Pharmacy Frontier?

 **ECONOMIC TIMES**

25 March 2026

**SUBJECTS COVERED****SCIENCE & TECH****ECONOMY****GS PAPERS****GS3****CURATED & WRITTEN BY****Bharat Choudhary**

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

 The Economic Times

25 March 2026

GS3
ET

The Economic Times

MAINS RELEVANCE:

GS Paper 3


## INTERVIEW ANGLE

*"India supplies 20% of global generics but only 3.2% of biosimilars. What structural bottlenecks prevent India from replicating its generics success in the biologics space?"*

## WHY IN NEWS

The Union Budget 2026-27 allocated Rs 10,000 crore for Biopharma SHAKTI (Strategy for Healthcare Advancement through Knowledge, Technology, and Innovation), aiming to transform India from the “Pharmacy of the World” for generics into a global biologics and biosimilars manufacturing hub.

## The Editorial Argument

The Economic Times argues that Biopharma SHAKTI correctly identifies the next frontier for India’s pharmaceutical industry — but success depends on overcoming structural bottlenecks in regulatory speed, research infrastructure, and clinical trial capacity that have kept India at just 3.2% of the global biosimilars market.

### The Generics-Biologics Paradox

| PARAMETER            | GENERICS                 | BIOLOGICS  |
|----------------------|--------------------------|--|
| Molecule type        | Small chemical molecules | Large complex proteins from living cells                     |
| Replication          | Exact copy possible      | Only “similar” versions (biosimilars)                        |
| Manufacturing        | Chemical synthesis       | Cell culture, fermentation — requires specialised facilities |
| Regulatory pathway   | ANDA (abbreviated)       | Full analytical + clinical studies needed                    |
| India’s global share | ~20%                     | ~3.2%  |
| Market size (global) | ~\$400 billion           | ~\$500 billion (growing to \$800B by 2030)                   |

India dominates generics because the pathway is well-established: reverse-engineer the chemical formula, prove bioequivalence, manufacture at scale. Biologics are fundamentally different — they require **living cell cultures, cold chain logistics, and extensive clinical validation.**

### What SHAKTI Proposes

| COMPONENT            | DETAIL                                 |
|----------------------|--|
| NIPERs               | 3 new + 7 upgraded                     |
| Clinical trial sites | 1,000+ accredited                      |
| CDSCO strengthening  | Dedicated scientific review cadre      |
| Non-animal testing   | Shift to 3Rs (Replace, Reduce, Refine) |
| Budget               | Rs 10,000 crore                        |

### The Bottlenecks

- 1 Regulatory speed:** India’s CDSCO takes 12-18 months for biosimilar approval vs 10 months at the US FDA
- 2 Research talent:** India produces abundant pharma graduates but few with biomanufacturing expertise
- 3 Cold chain:** Biologics require -20°C to -80°C storage; India’s cold chain infrastructure is inadequate outside metros
- 4 Clinical trial capacity:** India conducts only ~3% of global clinical trials despite having 17% of the world’s population
- 5 IP barriers:** Many originator biologics are still under patent protection in key markets

## Indian Biosimilar Leaders

| COMPANY    | KEY BIOSIMILAR                                |
|------------|---|
| Biocon     | Trastuzumab (breast cancer), Insulin Glargine |
| Dr Reddy's | Rituximab (blood cancer)                      |
| Cipla      | Adalimumab (autoimmune)                       |
| Zydus      | Pegfilgrastim (neutropenia)                   |

These companies have achieved US FDA and EMA approvals for biosimilars, proving India can compete — but at a scale far below potential.

## Global Context

The biologics revolution is reshaping healthcare:

- **Cancer immunotherapy** (checkpoint inhibitors) — \$50+ billion market
- **GLP-1 agonists** (semaglutide for diabetes and obesity) — \$40+ billion market
- **Gene therapies** — emerging, with treatments costing \$2-3 million per patient
- **mRNA vaccines** — proven during COVID, now expanding to cancer and rare diseases

India's cost advantage — manufacturing at 30-40% lower cost than Western competitors — is a massive opportunity if the regulatory and infrastructure gaps are closed.

### 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; S&T policy for economic growth

## ★ FACTS CORNER — KNOWLEDGE PEDIA

### BIOPHARMA SHAKTI:

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

Budget: Rs 10,000 crore

NIPERs: 3 new + 7 upgraded (total 10)

Clinical trial sites: 1,000+

Non-animal testing: 3Rs principle

### INDIA PHARMA INDUSTRY:

Global rank: 3rd by volume

Generics: 20% of global supply

Vaccines: 60% of global supply

Biosimilar share: 3.2% globally

Domestic biosimilars: 95+ approved

Industry size: ~\$50 billion

Exports: ~\$28 billion/year

### GLOBAL BIOLOGICS MARKET:

2025: ~\$500 billion

2030 (projected): ~\$800 billion

Growth rate: 8-10% annually

Top companies: Roche, AbbVie, Amgen, J&J

### OTHER RELEVANT FACTS:

India's clinical trial share: ~3% of global

CDSCO approval time: 12-18 months

US FDA approval: ~10 months

NIPERs: 7 currently (est. under NIPER Act 1998)

Indian Pharmacopoeia Commission: sets drug quality standards

Sources: [Economic Times](#), [Business Standard](#)



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