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# Biologics and Biosimilars: Current Perspective with reference to India

**Sagar Sahu[1], Sonam Sahu[2], Gunjan Kalyani[1]***

[1] Columbia Institute of Pharmacy, Near Vidhan Sabha,
Village – Tekari, Raipur - 493111, Chhattisgarh, India
[2] Mother Teresa College of Nursing, Near Power Grid,
Village Chorha, Kumhari - 490042, Durg, Chhattisgarh, India

**Corresponding Author's Email**: kalyani.gunjan@yahoo.in

**ABSTRACT:**

For decades, India has maintained its status as the "pharmacy of the world" through the mass production of affordable small-molecule generics. However, a global epidemiological shift toward complex chronic diseases—including cancer, autoimmune disorders, and diabetes—has necessitated a transition toward biopharmaceuticals. With the "patent cliff" of major reference biologics reaching a peak in 2026, the Indian pharmaceutical industry is at a critical juncture, moving from chemical synthesis to high-value biological manufacturing. This paper focusses on the multi-faceted "shift" in the Indian landscape, focusing on the launch of the Biopharma SHAKTI (2026–27) initiative, the integration of Non-Animal Methodologies (NAMs) in drug safety, and the regulatory alignment of the Central Drugs Standard Control Organization (CDSCO) with global standards (EMA/FDA). A review of the Union Budget 2026-27, the National Biopharma Mission, and the 2025 Revised Guidelines on Similar Biologics was conducted. The analysis evaluates the impact of the ₹10,000 crore government outlay and the establishment of a national network of 1,000+ accredited clinical trial sites on the domestic biosimilar ecosystem. The shift toward biologics and biosimilars is essential for India's healthcare sustainability and global competitiveness. By leveraging its skilled workforce and new "science-based" regulatory pathways, India is successfully transitioning from a generic-led model to a global biopharma innovation hub. This evolution not only ensures affordable access to life-saving therapies for India's growing NCD burden but also positions the nation to capture 5% of the global biopharmaceutical market share by 2030.

**KEYWORDS:**

Biosimilars, Biopharma SHAKTI, India 2026, Regulatory Reform, Healthcare Sustainability, Monoclonal Antibodies.

**INTRODUCTION :**

A biologic or biological product is a preparation manufactured from living things, such as humans, animals, yeast, or bacteria, such as a medication or a vaccine. Proteins (and/or their constituent amino acids), carbohydrates (like sugars), nucleic acids (like DNA), or mixtures of these make up biologics. Tissues or cells used in transplants can also be considered biologics. A biosimilar, also known as a follow-on biologic, is a medicinal medication produced by a pharmaceutical or biotechnology business that is comparable to the brand-name biologic but not structurally identical. The innovator or reference product is another term for the brand-name product.

Biologics are complex medicines produced from living organisms, such as bacteria, yeast, or mammalian cells. Because they are derived from living sources, they are much larger and more structurally complex than "small-molecule" chemical drugs.

- Examples: Vaccines, insulin, monoclonal antibodies (used in cancer and autoimmune therapy), and gene therapies.
- Structure: If a traditional drug is like a simple bicycle, a biologic is like a commercial jet engine.
- Sensitivity: They are highly sensitive to heat and light and are usually administered via injection or infusion rather than a pill.

Biosimilars are biologic pharmaceuticals that closely resemble the reference product, a biologic that has already received FDA approval. In terms of safety, purity, and potency, biosimilars do not differ from their reference drugs in a way that is clinically significant. The goal of biosimilar development is to raise therapy choices and lower healthcare expenses by offering less expensive substitutes for current biologics. In order to guarantee that biosimilars fulfil strict requirements for safety and effectiveness, the approval procedure entails a thorough assessment. In comparison to patients taking the original biologics, manufacturers must prove that patients utilizing biosimilars do not encounter any new or worsening side effects. This comprehensive analysis guarantees that biosimilars carry the same risks and offer the same therapeutic advantages as the original biologic.

A biosimilar is a biologic medicine that is developed to be highly similar to an already approved biologic (the "reference" or "original" product).

- Not a "Generic": In the world of chemical drugs, a generic is an exact copy. Because biologics come from living cells, it is impossible to make an "exact" copy. Instead, manufacturers ensure the biosimilar is highly similar in structure and function.

- Clinical Performance: A biosimilar must demonstrate that there are no clinically meaningful differences in terms of safety, purity, and potency compared to the original biologic.
- Purpose: The primary goal of biosimilars is to provide more affordable access to life-saving treatments once the original drug's patent expires.

**2. Why are they important in 2026?**

As we move further into 2026, the global healthcare focus is shifting toward precision medicine. Biologics allow doctors to target specific proteins in the body responsible for diseases like rheumatoid arthritis, Crohn's disease, and various cancers.

By introducing biosimilars into the market, healthcare systems (especially in India) can significantly lower the cost of these advanced therapies, making them accessible to millions more patients who previously found them cost-prohibitive.

**Biologics and biosimilars: India needs the swing**

The shift toward biologics and biosimilars represents a critical evolution in India's healthcare landscape. While India has long been the "pharmacy of the world" for small-molecule generics, the rising burden of chronic diseases—such as cancer, diabetes, and rheumatoid arthritis—requires a transition toward complex large-molecule therapies.

In 2026, this shift is no longer just a medical preference but an economic and strategic necessity for India.

**The Landscape: Biologics vs. Biosimilars**

Biologics are large, complex molecules derived from living organisms (e.g., monoclonal antibodies, vaccines). Unlike generics, which are identical chemical copies, biosimilars are "highly similar" versions of an original biologic, with no clinically meaningful differences in safety or potency.

**3. Why India Needs the Shift?**

**Economic Accessibility & Patient Reach**

Biologic treatments are notoriously expensive. A shift to biosimilars can reduce treatment costs by 25% to 30% in key areas like oncology and autoimmune disorders.

- Cost-Effectiveness: Studies indicate that the incremental cost-effectiveness ratio (ICER) for biosimilar cancer treatments in India falls well below the threshold for favorable cost-effectiveness.
- Market Growth: The Indian biosimilar market is projected to reach approximately $4 billion by 2034, growing at a CAGR of 16.5%.

**Strategic Policy Support (Biopharma SHAKTI)**

The Union Budget 2026–27 introduced the Biopharma SHAKTI initiative, a ₹10,000 crore outlay over five years. This program is designed to:

- Strengthen the end-to-end ecosystem for domestic biologic production.
- Reduce import dependence on high-value biopharmaceutical products.
- Position India to capture 5% of the global biopharmaceutical market.

**Regulatory Maturation**

The Drug Controller General of India (DCGI) recently unveiled new evaluation guidelines (September 2025) to align Indian standards with global benchmarks.

- Rigorous Testing: New mandates require comprehensive data on immunogenicity and comparative efficacy.
- Post-Marketing Surveillance**:** Stricter ongoing monitoring ensures long-term safety, building trust among physicians who were previously hesitant to "switch" patients from originators to biosimilars.

**Barriers to the Shift**

Despite the momentum, several hurdles remain:

- **The "Rebate Wall":** Commercial barriers and vertical integration in pharmaceutical distribution can sometimes prioritize expensive branded biologics over lower-cost alternatives.
- **The Nocebo Effect:** A psychological barrier where patients perceive "cheaper" drugs as less effective, leading to reported side effects driven by anxiety rather than pharmacology.
- **Manufacturing Complexity:** Unlike generics, biologics require specialized facilities and highly skilled labor, making the "barrier to entry" significantly higher for smaller firms.

**4. Key Therapeutic Drivers in India (2025-2026)**

| Drug Class | Primary Indications | Market Impact |
|---|---|---|
| Monoclonal Antibodies (mAbs) | Oncology, Rheumatoid Arthritis | Largest revenue share (over 50%) |
| Insulin & Analogues | Diabetes Mellitus | Fastest growing segment due to high domestic prevalence |
| Growth Factors | Hematologic disorders | Essential for affordable supportive care in cancer |

**5. Current Status**

As of right now, Europe was the first in the world to develop the legal framework for biological product approval. The European Medicines Agency (EMA) authorized Omnitrope, a recombinant human growth, as the first biosimilar in Europe in 2006.The US followed suit much later, approving filgrastim sndz, a biosimilar to filgrastim (granulocyte CSF), in 2015. The USFDA had previously approved filgrastim in 1991. However, the FDA has now authorized several biosimilars to treat cancer and other diseases. Pegfilgratism-JMDB, which lowers the risk of infection after myelosuppressive chemotherapy, was the most recent to be approved in June 2018.

These days, biopharmaceutical companies have created a number of biosimilars that are utilized worldwide for a variety of conditions, from cancer and connective tissue illnesses to diabetes, ophthalmology, and respiratory disorders. Compared to other nations, India has a vibrant biosimilar ecosystem, and as a result, Indian pharmaceutical companies have become the world leaders in the biosimilar business. Much earlier than the US and Europe, India approved its first biosimilar. Despite the lack of precise guidelines for the research and marketing of biosimilars in India at the time, the first biosimilar for hepatitis B was licensed and put on the market there in 2000.

Since then, a number of biosimilars have been created and sold in India by different biopharmaceutical firms. The USFDA recently approved the commercialization of a novel biologic developed by an Indian biopharmaceutical company. Trastuzumab, the active ingredient of Herceptin, was the first biologic to receive approval from FDA, which is applied to some cases of stomach and breast cancer. Additionally, this was the first comparable biologics produced by an Indian business and approved for sale in the US.

**CONCLUSION:**

For India to sustain its healthcare goals, the transition from a "Generics Hub" to a "Biopharma Hub" is essential. By leveraging the Production Linked Incentive (PLI) schemes and the new BioE3 Policy, India is setting the stage to provide not just affordable medicine, but the next generation of life-saving, high-tech therapies for its population.

**CONFLICT OF INTEREST:**

This paper is based on a conceptual review of published literature and does not involve direct funding or collaboration with commercial biotechnology entities. The author declares no financial or personal conflicts of interest related to the subject matter discussed.

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