Biologicals And Biosimilars: A Paradigm Shift In Indian Pharmaceutical Healthcare

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Abstract

India has long been recognized as the "Pharmacy of the World" due to its established leadership in affordable generic medicines. However, the rising prevalence of non-communicable diseases such as cancer, diabetes, autoimmune disorders, and chronic inflammatory conditions has created an urgent need for advanced targeted therapies. Biologics and biosimilars are emerging as transformative therapeutic options that significantly improve disease management and patient outcomes. With strong policy support through initiatives such as the Biopharma SHAKTI scheme and the Production Linked Incentive (PLI) programme, India is strategically positioned to transition from a generic-driven pharmaceutical model to a global biologics and biosimilars hub. This review discusses the current clinical need, economic opportunities, regulatory framework, implementation challenges, and future prospects of this strategic shift in the Indian context.

Keywords: Pharmaceutical Industry; Healthcare Innovation; Non-communicable diseases

1. Introduction

India is widely regarded as the global "Pharmacy of the World", commanding a prominent position in the supply of affordable, high-quality generic medicines. Over the past decade, the Indian biotechnology industry has undergone a transformational evolution, expanding from approximately Rs. 85,650 crore (US$10 billion) in 2015 to Rs. 8,69,348 crore (US$101.5 billion) in 2024, encompassing over 800 companies and recording the second-highest number of United States Food and Drug Administration (USFDA)-approved manufacturing plants

globally. India has emerged as a frontrunner in the biosimilars space, boasting over 135 approved biosimilars in its domestic portfolio (1). More than 40 biosimilars are currently in the clinical development stage in India, a figure comparable to those in development within the European Economic Area (EEA) and significantly higher than those in active development in the United States (2).

The escalating burden of chronic and Non Communicable Diseases (NCDs) including cancer, type 2 diabetes mellitus, rheumatoid arthritis, and cardiovascular diseases has intensified the demand for biologic-based targeted therapies. Conventional small-molecule drugs are often inadequate for managing such conditions, making biologics an indispensable component of modern precision medicine (3). Biosimilars, which are highly similar versions of approved reference biologics, offer clinically comparable efficacy and safety at substantially reduced costs, thereby democratising access to advanced therapies (4).

2. Biologics and Biosimilars: Definition and Distinction

Biologics are complex, large-molecule medicines derived from living biological sources such as cells, proteins, or nucleic acids. They include monoclonal antibodies, recombinant proteins, hormones, vaccines, and gene therapies. Their molecular complexity and sensitivity to manufacturing conditions distinguish them fundamentally from conventional small-molecule drugs.

A biosimilar is defined as a biological medicinal product that is demonstrated to be highly similar to an already approved reference biologic (the originator), with no clinically meaningful differences in terms of safety, purity, and potency (5). Biosimilars are developed after the expiry of the originator's patent protection and typically enter the market at 20 - 30% lower prices than the reference product, thereby improving treatment affordability and accessibility (6, 7).

	Biosimilar	Generic
Source	Living organisms	Chemical synthesis
Size	Large molecule	Small molecule
Structure	Complex, heterogeneous	Well defined
Manufacturing process	Difficult	Relatively simple
Stability	Unstable, sensitive to external conditions	Stable
Immunogenicity	Immunogenic	Mostly non-immunogenic
Bio-equivalence with reference product	No	Yes
Interchangeable with Reference product	No	Yes
Cost	High	Low

Figure 1. Key differences between Biosimilars and Generics

3. Rising Need for Biologics in India

Cancer, diabetes, and autoimmune diseases require targeted therapies that conventional medications cannot adequately provide. Monoclonal antibodies, for example, have significantly improved outcomes in oncology and autoimmune disease management by selectively targeting specific disease pathways (3). India is simultaneously grappling with increasing rates of rheumatoid arthritis, inflammatory bowel disease, chronic kidney disease, and cardiovascular conditions, all of which necessitate long-term biologic-based treatment regimens.

The Indian biosimilars market was valued at approximately Rs. 437 crore (US$51 million) in 2024 and is projected to grow at a compound annual growth rate (CAGR) of 14.2%, reaching an estimated Rs. 1,649 crore (US$192.5 million) by 2034 (8). This growth reflects not only expanding domestic demand but also India's growing export footprint in regulated markets, including the European Union, United Kingdom, and United States.

4. Role of Biosimilars in Affordable Healthcare

One of the most significant barriers to biologic therapy adoption in India is cost. A substantial proportion of healthcare expenditure in India is borne out-of-pocket by patients, rendering expensive originator biologics financially inaccessible for a large segment of the population (9). The availability of affordable biosimilars directly enhances the following critical dimensions of healthcare:

- Treatment adherence: Reduced financial burden encourages patients to maintain long-term therapy.
- Accessibility: Biosimilars extend the reach of advanced therapies to lower- and middle-income populations.
- Disease management: Timely initiation and sustained use of biologic therapy improves clinical outcomes in chronic diseases.
- Long-term therapeutic outcomes: Consistent access reduces disease progression and hospitalisation rates.

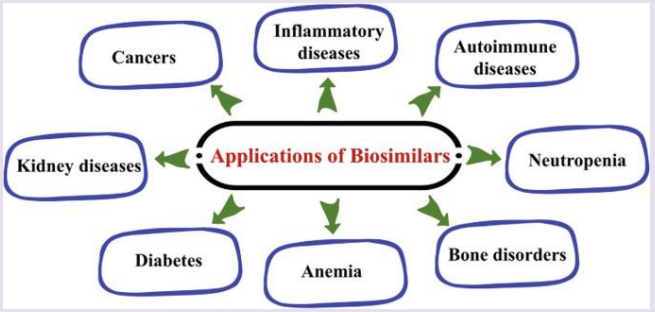

Figure 2. Therapeutic uses of Biosimilars

Table 1 List of FDA approved Biosimilar Products

S.No.	Biosimilar Name	Approved date
1.	Ontruzant (Trastuzumab-dttb)	January 2019
2.	Trazimera (Trastuzumab-qyyp)	March 2019
3.	Eticovo (Etanercept-ykro)	April 2019
4.	Kanjinti (Trastuzumab-anns)	June 2019
5.	Zirabev (Bevacizumab-bvzr)	June 2019
6.	Ruxience (Rituximab-pvvr)	July 2019
7.	Hadlima (Adalimumab-bwwd)	July 2019
8.	Ziextenzo (Pegfilgrastim-bmez)	November 2019
9.	Abrilada (Adalimumab-afzb)	November 2019
10.	Avsola (Infliximab-axxq)	December 2019
11.	Nyvepria (Pegfilgrastim-apgf)	June 2020
12.	Hulio (Adalimumab-fkjp)	July 2020
13.	Riabni (Rituximab-arrx)	December 2020
14.	Source Plasma (prepared by plasmapheresis)	June 2021
15.	StrataGraft (Allogeneic cultured keratinocytes and dermal fibroblasts in murine collagen-dsat)	June 2021
16.	Prevnar 20 (Pneumococcal 20-valent Conjugate Vaccine)	June 2021
17.	Ryplazim (Plasminogen, Human-tvmh)	June 2021
18.	Abecma (Idecabtagene vicleucel)	March 2021
19.	Breyanzi (Lisocabtagene maraleucel)	February 2021

5. Government Policy Support and Regulatory Framework

5.1 Biopharma SHAKTI Initiative

India's transition toward biologics and biosimilars has received significant impetus from the Biopharma SHAKTI initiative, announced in the Union Budget 2026–27 (10). The scheme provides an allocation of ₹10,000 crore over five years.

5.2 Production Linked Incentive (PLI) Scheme

The PLI scheme for pharmaceuticals provides targeted financial incentives for the domestic manufacture of key starting materials, active pharmaceutical ingredients, and complex biologics, reducing import dependence and encouraging capital investment in biopharmaceutical infrastructure (11).

5.3 BIRAC and Startup Ecosystem

The Biotechnology Industry Research Assistance Council (BIRAC), a not-for-profit entity established under the Department of Biotechnology (DBT), provides structured funding support through several schemes, including: the Biotechnology Ignition Grant (BIG), Sustainable Entrepreneurship and Enterprise Development (SEED), Launching Entrepreneurial Driven Affordable Products (LEAP), Intensifying the Impact of Industrial Innovation (i4), and Promoting Academic Research Conversion to Enterprise (PACE) (12).

As of June 2024, the Department for Promotion of Industry and Internal Trade (DPIIT) had recognised 1,40,803 startups, of which 2,127 were in the pharmaceutical sector (13).

5.4 Regulatory Alignment

The Central Drugs Standard Control Organisation (CDSCO) has progressively aligned its biosimilar regulatory guidelines with international standards established by the US FDA, the European Medicines Agency (EMA), and the Medicines and Healthcare products Regulatory Agency (MHRA) (14). This harmonisation facilitates simultaneous regulatory submissions and approvals in multiple markets, strengthening India's position as a preferred global biosimilar supplier.

6. Economic and Industrial Opportunities

The global biosimilars market is undergoing rapid expansion, driven primarily by the impending patent expiry of blockbuster reference biologics. Between 2025 and 2032, over 39 high-value biologic patents are projected to expire, presenting a substantial opportunity for biosimilar manufacturers worldwide (15, 16).

Indian pharmaceutical companies including Biocon, Sun Pharma, Zydus Cadila, Reliance Life Sciences, Lupin, Intas Biologicals, and Wockhardt have made significant inroads into regulated global markets. Biocon, in particular, has received biosimilar approvals from the US FDA, European Medicines Agency (EMA), and regulatory bodies in Australia and Japan, including the landmark USFDA approval for Yesafili (Aflibercept biosimilar) for ophthalmic indications.

7. Challenges in Implementation

Despite the considerable opportunities, India's transition to a biologics-centric pharmaceutical model is accompanied by complex challenges that require systematic resolution.

7.1 Manufacturing Complexity

Unlike small-molecule drugs, biologics are produced from living cell systems and are inherently sensitive to manufacturing conditions. Minor variations in culture media, temperature, pH, or downstream processing can substantially alter the product's structural characteristics and biological activity (17).

7.2 Regulatory and Pharmacovigilance Requirements

Biosimilars require extensive analytical characterisation, comparative non-clinical studies, and clinical evaluation against a reference product to demonstrate biosimilarity. Safety concerns may emerge beyond the clinical study period, particularly with regard to immunogenicity, long-term adverse effects, off-label use, and drug interactions (18). Robust post-marketing surveillance (pharmacovigilance) systems and clear product naming

conventions to ensure traceability and interchangeability are essential components of a mature regulatory framework (19).

7.3 Cold Chain and Logistics Infrastructure

Biologics are thermolabile and require continuous temperature-controlled storage and transportation throughout the supply chain. Strengthening India's cold-chain logistics infrastructure particularly in tier-2 and tier-3 cities and rural areas is essential to ensure product integrity and patient safety (20).

7.4 Patent Litigation

Biosimilar producers globally encounter significant patent-related barriers, including evergreening strategies, secondary patent filings, and litigation initiated by originator companies. These challenges delay market entry, reduce profitability, and deter investment in new biosimilar development programmes.

8. Academic and Research Implications

The expansion of India's biologics sector necessitates a fundamental realignment of academic curricula in pharmacy, biotechnology, and life sciences programmes. Future professionals must be equipped with competencies in:

- Molecular biology and recombinant DNA technology
- Immunology and immunogenicity assessment
- Bioprocess engineering and fermentation technology
- Biosimilar regulation and global regulatory affairs
- Clinical pharmacology and pharmacovigilance (21)

9. Future Prospects

Indian manufacturers are increasingly establishing world-class biomanufacturing facilities and building value-added CDMO capabilities, positioning India as a preferred destination for global biopharmaceutical outsourcing. The continued expiry of high-value biologic patents through 2032 further consolidates the opportunity for Indian biosimilar companies to penetrate both regulated and semi-regulated markets.

10. Conclusion

India's trajectory in the biopharmaceutical sector reflects a compelling convergence of clinical necessity, economic opportunity, policy intent, and industrial capacity. The strategic shift toward biologics and biosimilars is not merely a market evolution, it is a public health imperative. With a robust domestic approval pipeline, government-backed innovation schemes, a cost-competitive manufacturing ecosystem, and a growing cadre of skilled

biopharmaceutical professionals, India is uniquely equipped to lead the global biosimilars landscape.

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