Biologics And Biosimilars In India: Strengthening India's Healthcare System

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Abstract:

Biologics and biosimilars are increasingly transforming India's healthcare landscape by improving applications to advanced therapies. Biologics including monoclonal antibodies, vaccines, recombinant proteins and hormones, have revolutionized the treatment of chronic and life-threatening diseases such as cancer, diabetes and autoimmune disorders. However, their high cost limits its use in the larger sector of population. Biosimilars have highly similar and more affordable versions of biologics and viable solutions to cost challenges.

India has emerged as a major role player in the global biosimilar market due to its strong pharmaceutical manufacturing capabilities, skilled workers and supportive regulatory environment. The adaptation of biosimilars can significantly reduce healthcare cost and enhance treatment accessibility. There are some challenges while adaptation of biosimilars in treatments, like limited awareness among healthcare providers and efficacy assurance. Addressing these issues through policy reforms, education and a stringent pharmacovigilance system is essential. Strengthening the integration of biologics and biosimilars into India's healthcare system will not only improve patient outcomes but also position the country as a global leader in affordable biopharmaceutical innovation.

Keywords: Biosimilars, Biologics, Healthcare System.

1. Introduction

Traditional drugs are synthesized through synthetic procedures, whereas biologics are extracted from biological sources. With the increase in chronic diseases like cancer, rheumatoid arthritis, diabetes mellitus, these biologics become a necessity. However, the high cost of therapy makes it difficult for the population to use biosimilars in treatment (1). Biosimilars are nothing but a very similar product to the biologics, excluding minor differences in clinically inactive compounds. Also, it is of extreme importance for the biosimilar to have no clinical difference in terms of safety, purity and effectiveness to the biologics (2). The global pharmaceutical landscape is also undergoing a seismic shift so it is important that we keep up to the revolution from small molecule drugs that can be easily synthesized and replicated as generics to biologics that are complex containing over 25,000 atoms and provide a cost-effective alternative to high-priced therapies (3).

2. Biologics

Biologics are medications that are composed of DNA/RNA, polypeptide, sugars or complex combinations of these substances. They may consist of living entities such as tissues and cells. As they are sourced from living cells, the manufacturing process is highly delicate, and even minute changes in temperature and light can alter the final product. Various examples of biologics along with its therapeutic uses are mentioned in table 1.

Table 1. Examples of biologics and their therapeutic uses

Category	**Therapeutic Uses**	**References**
Monoclonal Antibody (mAb)	Rheumatoid arthritis, Various cancers	(4, 5)
Recombinant Protein	Diabetes mellitus	(6, 7)
Fusion Protein	Plaque psoriasis, Pulmonary arterial hypertension	(8)
mRNA Vaccine	COVID-19 prevention	(9)
Cell Therapy (CAR-T)	Certain types of Leukaemia/ Lymphoma	(10)

2.1. Biosimilars

Biosimilars use a biologic product that is already approved as a reference and is developed very identical to it. Unlike conventional medications that are chemical look-alike copies, biologics are engineered to match very finely with the reference product's functionality and structure so that there is no clinical difference between both. Biosimilars are also made after the patent of a biologic expires and manufacturers come up with similar products to the costly one. All the biosimilars with their genetic names and therapeutic uses are mentioned in table 2.

Table 2. Biosimilars with their generic names and therapeutic uses (4,5,6)

Generic names	**Therapeutic uses**
Trastuzumab	HER2- positive breast cancer
Bevacizumab	Colorectal, lung and renal cancers
Basalog, Glaritus, Glarvia	Type 1 & Type 2 Diabetes
Adalimumab	Rheumatoid Arthritis
Erythropoietin	Anaemia in kidney disease

2.2. Global landscape of biosimilars

Even though biosimilars do not compromise quality and its clinical properties it still complicates things when made independently by different countries. Therefore, there is a need for global harmonization, which will directly streamline the manufacturing protocols and will improve the drug development lifecycle (11). Also, recent literature on biosimilars highlights different targets such as Antibody-Drug Conjugates (ADCs) and antibodies, positioning 2026 as the second wave for biosimilars (12). Also, a major 2026 trend was observed in the US for private labelled biosimilars that are launched by Pharmacy Benefit Managers (PBMs). They include blockbuster drugs such as Cordavis by CVS health to capture the net prices (13).

2.2.1 Market growth and trends in US & EU

On 1st January 2026 under the Inflation Reduction Act the first Maximum Fair Prices (MFP) was approved in the US. The government negotiated the prices for the brand Stelar, which is now directly competing with the new biosimilars creating the "Stelara Paradox" and also reducing the profit margin for biosimilar makers (14). On October 29th 2025 the USFDA officially removed the need for switching studies to achieve interchangeable status which directly allow the pharmacists to substitute biosimilars at the counter without any need for a physician's intervention, which significantly fast-tracks the market penetration (15).

Now switching to the European Union who hold 50% of the market shares for the biosimilars. The EMA (European Medicine Agency) formally endorsed its paper on Clinical approach that is tailored on 2026 March. This historic decision enables researchers to rely on advanced analytical and Pharmacokinetic (PK) data in the place of extensive Phase 3 comparative efficacy studies (CES) for most biosimilars (16). This change will cut the costs of biosimilar development by $20M-$40M per product allowing niche manufacturers to enter the biosimilar market.

2.2.2. The 2026 Patent cliff and opportunities

Instead of focusing on basic equivalency, manufacturers are now targeting Bio-betters biologics that are purposefully altered to be superior to the original example: through longer half-lives or subcutaneous administration. Shown below are some of the opportunities that can be targeted in the year 2026 in table 3. Including molecule brand name, its therapeutic area and brand names.

Table 3. Molecules with their brand names, therapeutic area and opportunity status

Molecule (Brand)	Therapeutic area	Opportunity Status 2026	Reference
Ustekinumab (Stelara)	Immunology	Its $12 billion+ market share is being rapidly eroded by many biosimilars.	(17, 18, 19, 20)
Aflibercept (Eylea)	Ophthalmology	The "patent thicket" lawsuit has been resolved, enabling the mass introduction of biosimilars for macular degeneration.	(21)
Trastuzumab Emtansine (Kadcyla)	Oncology (ADC)	One of the first important ADC biosimilar candidates with notable action in 2026	(22, 23)
Daratumumab (Darzalex)	Oncology	With its principal patent expiration approaching, 2026 is a crucial year for developers to prepare.	(24)
Pembrolizumab (Keytruda)	Oncology	The year of "At-Risk" launch preparations for the world's best-selling medication is 2026, although the entire cliff is closer to 2028.	(25, 26)

2.3. The Indian Pharmaceutical Scenario

2.3.1. India’s position

India supplies 62% of the world's vaccines and produces 46% of its follow-on biologics. Despite supply chain difficulties, Indian businesses like Bharat Biotech and Serum Institute of India increased production during COVID-19 to sell reasonably priced drugs to more than 133 countries (27,28). With their biosimilar insulin that is named glargine, which was the first biosimilar that could interchange insulin authorized by the FDA of the US, Biocon-Viatris made history (29). The Hepatitis B vaccine was the first recombinant biologics approved in India in 2000. Through clinical testing, Indian has proven biosimilar equivalency. In phase 3 research including 202 patients in 19 Indian centres, Lupin's ranibizumab demonstrated therapeutic equivalency to Lucentis® with good safety and immunogenicity profiles (30). Prominent Indian biosimilar businesses include well-known firms like Biocon and Dr. Reddy's as well as up-and-coming firms like Enzene Biosciences Ltd., all of which promote greater market access and competition (28). India continues to encounter difficulties despite its leadership, such as complicated regulations, a lack of local production capacity for some goods, a lack of market knowledge, and ambiguous interchangeability regulations (31).

2.3.2. Key Indian Companies involved

In 2025-2026 some of these companies have been driving the global reputation for India in large molecules mentioned in figure 1, which includes;

i) Biocon Biologics: Launched Yesintek and Yesafili, also preparing for the launch of Denosumab that focuses on Oncology, Immunology, Diabetes

ii) Dr. Reddy’s: First to submit BLA for an interchangeable Abatacept biosimilar to the US FDA and launched Semaglutide focused on Autoimmune, Metabolic.

iii) Lupin: Received European Commission approval for Ranibizumab (Feb 2026); US FDA approval for Armlupeg (Pegfilgrastim). Focusing on Ophthalmology, Respiratory systems.

iv) Intas (Accord): Partnered with Bio-Thera for Golimumab rights in India (March 2026). Already has 15+ biosimilars in the market which focus on oncology and rheumatology.

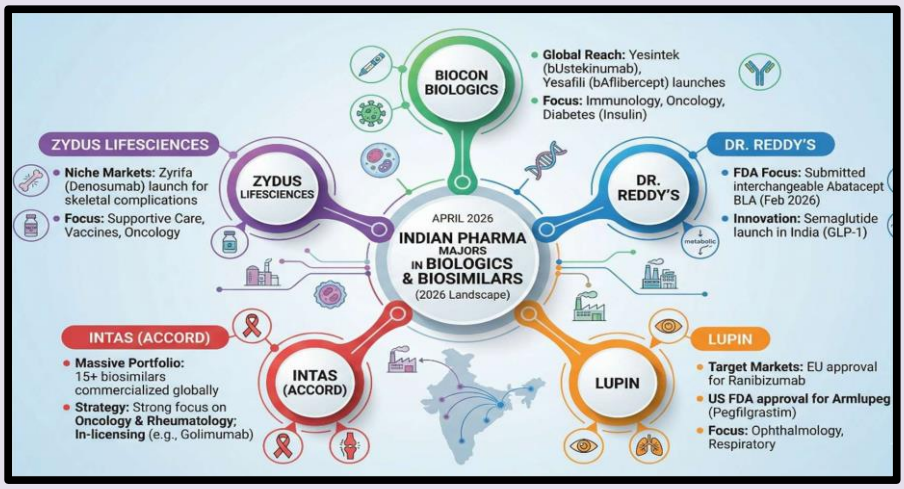

Figure 1. Diagram showing different Indian companies contributing to biosimilars.

2.4. Regulatory framework in India

In India, biologics and biosimilars are subject to strict legal and scientific regulations as "drugs." They need different regulatory mechanisms than small-molecule medications because of their complexity (derived from biological systems). Figure 2 explains Indian regulatory framework for biologics.

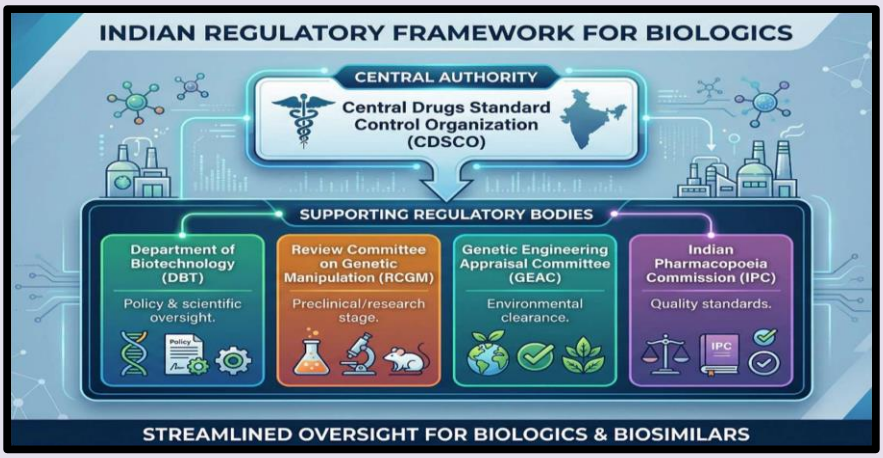

Figure 2. Regulatory bodies for biosimilars and biologics.

2.4.1. CDSCO & DTB guidelines for biologics and biosimilars

i) Reference Product Selection: An Indian license is required for the reference biologic. It must have been sold in an ICH (International Council for Harmonization) nation for at least four years if it is not licensed in India (32).

ii) Stability data: To guarantee that the biological activity stays consistent throughout the course of the shelf life, thorough stability tests across a range of temperature and humidity conditions are necessary.

iii) Manufacturing quality: Schedule M-III of the Drugs and Cosmetics Rules must be followed by facilities. The production facilities for drug substances and drug products must be audited by CDSCO inspectors.

iv) Genetic construction: According to DBT requirements, the host cell line, the vector system, and the recombinant organism's genetic stability must all be well documented.

v) In vitro compatibility: The DBT currently strongly supports in vitro bioassays (cell-based assays) to show that the biosimilar binds to the same receptors and elicits the same biological reactions as the original, as opposed to conventional "LD50" animal testing.

vi) Environmental Safety: Prior to large-scale production, approval from the GEAC (under the Ministry of Environment) is necessary if the manufacturing incorporates "Living Modified Organisms" (LMOs).

2.4.2. Approval Pathway for biosimilars in India

To guarantee comparability with the note biologic in terms of safety, purity and effectiveness, biosimilars are developed by a methodical and rigorous scientific procedure. Choosing an appropriate reference biologic, the innovator product that has already received approval based on a comprehensive regulatory dossier is the first step. All comparison studies use this reference product as the standard. It must be authorized in India or in a member nation of the International Council for Harmonization (ICH), and the biosimilar should be similar in terms of the dosage form, potency, and the course of administration (33).

The final product's quality and clinical performance are largely determined by the manufacturing process. Biologics' structure and function can be affected by even little modifications since they are extremely sensitive to manufacturing circumstances. To ensure quality consistency throughout the development, it would be essential to agree with ICH requirements (Q5A, Q5B and Q5D). To understand the analytical variability, one would have to thoroughly learn about the manufacturing and formulation characteristics of the source product.

Quality evaluation is an important aspect of biosimilar development and requires in depth understanding of comparability. Comparing structural and functional characteristics using approved ways in line with ICH recommendations and guidelines is the main goal of analytical characterisation. Its product characterization involves physiochemical properties, biological and purity, including strength and immunological properties. Also, since any slight modifications could cause reduced efficacy or enhanced immunogenicity, quality comparability studies ensure manufacturing with purifying and formulation processes which do not compromise the structural integrity.

Examples of animal toxicology study include those on repeat dose toxicity, reproductive toxicity, mutagenicity and many more and part of preclinical assessment include those that are cancer causing which is carcinogenicity. However, if there is enough safety information from previously authorized products, these standards could be lowered or removed. Phased clinical development is used to verify human biosimilarity. Phase I studies concentrate on pharmacokinetics, safety, toxicity, and hypersensitivity evaluations. While Phase III verifies

effectiveness, safety, and immunogenicity in larger groups, Phase II entails additional assessment of safety and dose-response relationships. After approval, phase IV investigations are carried out to track long-term safety. Good Laboratory Practice (GLP) guidelines must be followed in any research, especially when it comes to in vivo toxicological evaluations.

Because there is little clinical evidence available before approval, post-marketing surveillance is essential. Periodic safety update report (PSUR) must be presented every 6 months for the first binary years and yearly from the next two, as part of an extensive pharmacovigilance plan. Regulatory authorities must be notified of adverse medication reactions as soon as possible. Post-marketing (Phase IV) studies, which often involve more than 200 patients, collect additional safety and immunogenicity data. The outcomes are contrasted with the reference biologic's historical data.

Also, for a minimum of five years following marketing consent, manufacturers must properly record and archive all quality, preclinical, and clinical data. For data storage and sample preservation, including vital items like biological samples and the standard operating procedures (SOP) must be defined. An entirety of evidence methodology is often appreciated in the biosimilar development process, guaranteeing that the finished product is comparable to the reference biologic while preserving patient safety and therapeutic effectiveness.

2.5. Challenges in Adoption

Institutional and technological constraints that manufacturing businesses must overcome, together with regulatory concerns about safety, efficacy, and adherence to international standards, are the main impediments to the adoption of biosimilars in India (34).

The implementation of biosimilars continues to see several legal, financial and perception driven issues across the world although they can enhance access and affordability. The absence of appropriate reference biologic items in various countries is one of the key hindrances to the implementation of timelines and comparability studies which are typically posed by regulations. Antiappeasement of regulatory resources and knowledge is also faced in many areas which results in a lack of uniformity or balance in the evaluation standards and a slow approval system. The fear of the quality of certain biosimilars and non-innovator products gradually undermines the confidence of regulators and healthcare professionals. Due to the ambiguities on interchangeability and substitution policies and the naming requirements, the physicians are hesitant in prescribing biosimilars (35).

Economically, the probable price benefit over the original biologic is significantly diminished by the research costs that are high and tend to be between 100 to 300 million dollars, which is an average price to pay. The chief reasons for this financial burden are complicated regulatory regulations and extremely long procedures of clinical validation. The delivery channel barriers may also be an obstacle to market access including the influence of the middleman, like pharmacy benefit managers. Another major challenge that prevents the adoption of biosimilars in clinical practice is the long-held belief among medics and patients that biosimilars would be less safe or effective and that this position is typically supported by original organizations (36).

To bring the acceptance of biosimilars it's important to educate the stakeholders and also to strategize the economic policies and the regulatory policies. The problems that are faced by rejection of study can be solved by changing the regulatory procedures by international harmonization with models that are long-lasting. This ensures the regulatory confidence and permits foreign-approved reference biologics to be imported which can as well help in the construction and provide objective measuring standards. In addition, the cost of the research can also be cut since it is possible to target more sophisticated methods of analysis rather than being forced to conduct extended clinical trials without the efficacy and the safety.

Building trust among people and individuals who are health care providers is also important. This makes a demand on targeted education campaigns and awareness campaigns to eliminate the myths on the efficacy and the safety. Also, real life evidence will be helpful in monitoring the safety. Considering all of this, acceptance of more biosimilars and biologics will require a balanced mixture of regulatory leniency as well as cost minimization and spreading the awareness.

3. Conclusion

Biosimilars offer an opportunity to increase the availability and affordability of the biologic therapies especially in a country such as India where the demand of health services is always increasing. But even though we have a robust regulatory framework that is led by CDSCO and DBT creating a solid baseline, there still remains issues of market entry and high costs for expansion and complex regulatory framework and lack of awareness continue to serve as a barrier to achieve their full potential. The focus of these issues must be facilitated to show increased utilisation by stakeholder education and procedures that are developed, and coordination of regulations. In the long term the procedures of biosimilars are getting more efficient and sustaining due the continuous scientific advancements which allows enhancing

the level of analysis and reducing the duration of clinical trials. For the achievement of the full potential of biosimilars, the industry including the healthcare sector and the regulators must all collaborate. India can start itself as a worldwide leader in biosimilar innovation and guarantee that its people may have a fair access to life saving medicines by overcoming all of these current issues.

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