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APTI Women's Forum Newsletter

Biologics and Biosimilars: India needs the shift

EDITOR'S NOTE

Prof. Vandana B. Patravale
The Chief Editor,
Apti Women's Forum Newsletter

Dear Readers,

This edition of our newsletter is dedicated to exploring one of the most transformative and rapidly advancing areas in modern therapeutics; Biologics and biosimilars in India. These innovative therapies are redefining the landscape of disease management, offering targeted, effective, and increasingly accessible treatment options for a wide range of conditions.

Our theme for January-April 2026 APTI women's newsletter is "**Biologics and Biosimilars in India: Strengthening India's Healthcare System",** which brings together a collection ranging from scientific foundations and emerging technologies to regulatory considerations, clinical applications, and real-world challenges. The contributions highlight key aspects such as the development and approval pathways of biosimilars, regulatory scrutiny, challenges in ensuring quality and equivalence and the opportunities they present in improving healthcare affordability and accessibility in India. Through diverse perspectives, this issue aims to provide a comprehensive understanding of how biologics and biosimilars are shaping the future of Indian healthcare, fostering innovation while addressing critical public health needs.

The editorial board is confident that you will find this exploration of biologics and biosimilars as insightful and enriching as our previous APTI Women Forum newsletters. We express our heartfelt gratitude to all contributing authors for their excellent scholarly work and for presenting complex concepts with clarity and depth. I extend my sincere appreciation to the entire editorial team for their dedication; from conceptualizing the theme to meticulously reviewing articles from contributors across the country. Special thanks to Dr. Shubhini Saraf, Dr. Vanaja Kenchappa, Dr. Preeti Suresh, Dr. Rakhi Khabiya, and Dr. Jubie Selvaraj for their valuable editorial inputs. I also thank Dr. Clara Fernandes for thoughtfully curating the puzzles featured in this issue.

Lastly, I wish to express my gratitude to the VBP research group¸ especially Alice John, Kasish Jain and Rama Yamkammardi for their constant support in bringing this newsletter to fruition.

APTI Women's Forum
Editorial Board

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

Asvitha Basker[1,2], Snehal Chakorkar[1,2*]

[1]Department of Pharmacology, Dr. D. Y. Patil Dnyan Prasad University, School of Pharmacy and Research, Pimpri, Pune.

[2]Department of Pharmacology, Dr. D. Y. Patil Unitech Society's, Dr. D. Y. Patil Institute of Pharmaceutical Sciences and Research, Pimpri, Pune

Email: snehalchakorkar@gmail.com

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.

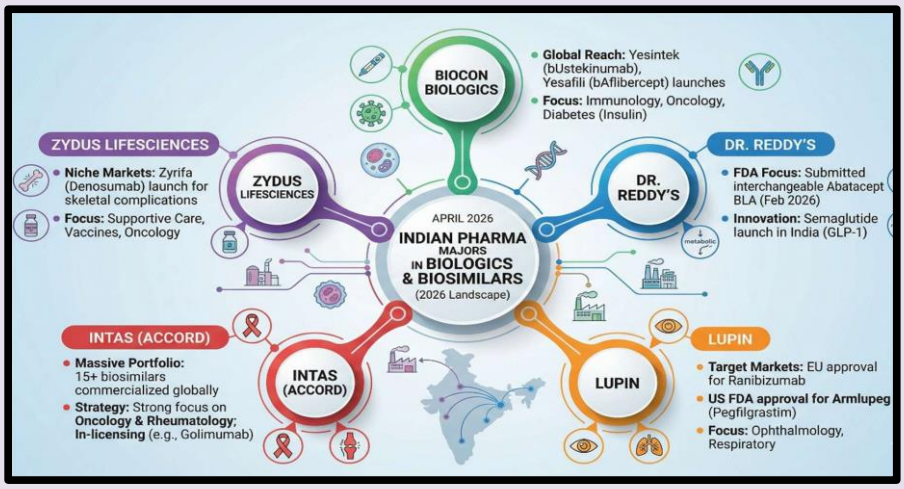

Figure 1. Diagram showing different Indian companies contributing to biosimilars.

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.

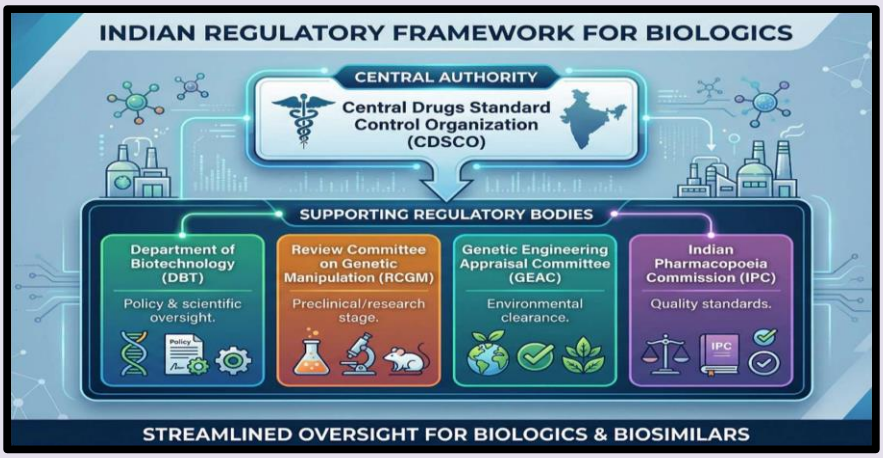

Figure 2. Regulatory bodies for biosimilars and biologics.

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.

4. References

1. Chen BK, Yang YT, Bennett CL. Why biologics and biosimilars remain so expensive: despite two wins for biosimilars, the Supreme Court's recent rulings do not solve fundamental barriers to competition. Drugs. 2018;78(17):1777–81. doi:10.1007/s40265-018-1009-0
2. De Mora F. Biosimilars: a value proposition. BioDrugs. 2019;33(4):353–6. doi:10.1007/s40259-019-00360-7
3. Gomollón F. Biosimilars: are they bioequivalent? Dig Dis. 2014;32(Suppl 1):82–7. doi:10.1159/000367833
4. Conran CA, Moreland LW. A review of biosimilars for rheumatoid arthritis. Curr Opin Pharmacol. 2022;64:102234. doi:10.1016/j.coph.2022.102234
5. Ternant D, Bejan-Angoulvant T, Passot C, et al. Clinical pharmacokinetics and pharmacodynamics of monoclonal antibodies approved to treat rheumatoid arthritis. Clin Pharmacokinet. 2015;54:1107–23. doi:10.1007/s40262-015-0296-9
6. Kundnani NR, Lolescu B, Dinu AR, Berceanu-Vaduva DM, Dumitrescu P, Tamaș TP, Sharma A, Popa MD. Biotechnology revolution shaping the future of diabetes management. Biomolecules. 2024;14(12):1563. doi:10.3390/biom14121563
7. Bhoria S, Yadav J, Yadav H, et al. Current advances and future prospects in production of recombinant insulin and other proteins to treat diabetes mellitus. Biotechnol Lett. 2022;44:643–69. doi:10.1007/s10529-022-03247-w
8. Langley RG, Gupta A, Cherman AM, Inniss KA. Biologic therapeutics in the treatment of psoriasis. Part 1: review. J Cutan Med Surg. 2007;11:122–9
9. Simonetti O, Rizzetto G, Molinelli E, Diotallevi F, Radi G, Cirioni O, D'Errico MM, Offidani A. Safety and efficacy of vaccines during COVID-19 pandemic in patients treated with biological drugs in a dermatological setting. Healthcare. 2021;9(4):401. doi:10.3390/healthcare9040401
10. Mantripragada KC, Reagan JL, Quesenberry PJ, Fast LD. Advances in cellular therapy for the treatment of leukemia. Discov Med. 2014;17(91):15–24.
11. Car E, Barbier L, Huys I, Simoens S, Vulto AG. Evolving global regulatory landscape for approval of biosimilars: current challenges and opportunities for convergence. Expert Opin Biol Ther. 2025;25(6):649–68. doi:10.1080/14712598.2025.2507832
12. Aggarwal D, Yang J, Salam MA, Sengupta S, Al-Amin MY, Mustafa S, Khan MA, Huang X, Pawar JS. Antibody-drug conjugates: the paradigm shifts in targeted cancer therapy. Front Immunol. 2023;14:1203073. doi:10.3389/fimmu.2023.1203073
13. DrugPatentWatch. The biosimilar paradox: 2026 market report on systemic challenges, policy collisions, and the future of biologic competition. 2026 Jan 22. Available from: https://www.drugpatentwatch.com
14. Beinfeld MT, Ghule P, LaMountain F, Wong W, Ko S, Chambers JD. The unintended consequences of the inflation reduction act on biosimilar market incentives and Medicare savings. Health Aff Sch. 2025;3(11):qxaf222. doi:10.1093/haschl/qxaf222
15. US Food and Drug Administration. FDA moves to accelerate biosimilar development and lower drug costs. Available from: https://www.fda.gov
16. European Medicines Agency. Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 23–26 March 2026. Available from: https://www.ema.europa.eu
17. Chow V, Mytych DT, Das S, Franklin J. Pharmacokinetic similarity of ABP 654, an ustekinumab biosimilar candidate: results from a randomized, double-blind study in healthy subjects. Clin Pharmacol Drug Dev. 2023;12:863–73. doi:10.1002/cpdd.1301
18. Cantin G, Liu Q, Shah B, et al. Analytical and functional similarity of the biosimilar candidate ABP 654 to ustekinumab reference product. Drugs R D. 2023;23:421–38. doi:10.1007/s40268-023-00441-7
19. Blauvelt A, Papp K, Trivedi M, Barragan C, Chow V, Mytych DT, Yamauchi P, Crowley J, Franklin J. Efficacy and safety of the ustekinumab biosimilar ABP 654 in patients with moderate-to-severe plaque psoriasis: a randomized double-blinded active-controlled comparative clinical study over 52 weeks. Br J Dermatol. 2025;192(5):826–36. doi:10.1093/bjd/ljae402
20. Humphreys S. Understanding interchangeable biosimilars at the federal and state levels. Am J Manag Care. 2023;29(Spec No 7):SP545–8. doi:10.37765/ajmc.2023.89419

21. Dodeller F, Alliger P, Heyn J, Urosevic D, Allmannsberger L, Wersig C, Silva R. Development of biosimilar aflibercept SDZ-AFL. Curr Ther Res. 2025;103:100812. doi:10.1016/j.curtheres.2025.100812
22. Nixon NA, Hannouf MB, Verma S. The evolution of biosimilars in oncology, with a focus on trastuzumab. Curr Oncol. 2018;25 (Suppl 1):171–9. doi:10.3747/co.25.3942
23. Chen L, Wang L, Shion H, Yu C, Yu YQ, Zhu L, et al. In-depth structural characterization of Kadcyla® (ado-trastuzumab emtansine) and its biosimilar candidate. mAbs. 2016;8(7):1210–23. doi:10.1080/19420862.2016.1204502
24. Rugo H, Linton K, Cervi P. A clinician's guide to biosimilars in oncology. Cancer Treat Rev. 2016;46:73–9
25. Stüber J, Uhland K, Reiter A, et al. Comparative analytical evaluation of the proposed biosimilar FYB206 and its reference medicinal product Keytruda®. Drugs R D. 2024;24:447–64. doi:10.1007/s40268-024-00485-3
26. Poole RM. Pembrolizumab: first global approval. Drugs. 2014;74:1973–81. doi:10.1007/s40265-014-0314-5
27. Panda S, Singh PK, Mishra S, Mitra S, Pattnaik P, Adhikary SD, Mohapatra RK. Indian biosimilars and vaccines at crossroads—replicating the success of pharmagenerics. Vaccines. 2023;11(1):110. doi:10.3390/vaccines11010110
28. The global landscape of manufacturers of follow-on biologics: an overview of five major biosimilar markets and 15 countries. BioDrugs. 2013;27(2):235–45. doi:10.1007/s40259-022-00568-0
29. Joshi SR, Mittra S, Raj P, Suvarna VR, Athalye SN. Biosimilars and interchangeable biosimilars: facts every prescriber, payor, and patient should know. Expert Opin Biol Ther. 2023;23(8):693–704. doi:10.1080/14712598.2022.2112664
30. Singh R, Chauhan R, Saxena A, Shah A, Mondal L, Bakhle D, Shah C, Shah A, Deoghare S, Krishnan N, Godse N. A prospective, randomized, parallel group, double blind, multicenter study to compare the efficacy, safety and immunogenicity of Lupin's ranibizumab with Lucentis® in patients with neovascular age-related macular degeneration. Indian J Ophthalmol. 2022;70(8):3008–14. doi:10.4103/ijo.IJO_2118_21
31. Amthaniwala BK, Rathod JA. Comparative insights into biosimilar development in the UAE and India: opportunities, challenges, and global trends. Indian J Pharm Pharmacol. 2026;12(4):194–205. doi:10.18231/j.ijpp.14082.1767693473
32. Hammoodi R, Khalaf M. The current status of regulation of biosimilars in India, the United States of America, and Europe. J Soc Sci Humanit. 2025;7(4):112–17. doi:10.53469/jssh.2025.7(04).19
33. Regulatory requirements for biosimilars in India: a comprehensive review. Int J Biol Pharm Allied Sci. 2024;13(12). doi:10.31032/ijbpas/2024/13.12.8355
34. Singh P, Desai PN, Dutta V. Rising biosimilars in the Indian biopharmaceutical industry: emerging challenges and way forward. Technol Anal Strateg Manag. 2021;35(9):1145–60. doi:10.1080/09537325.2021.1994139
35. Kang HN, Thorpe R, Knezevic I, Casas Levano M, Chilufya MB, Chirachanakul P, Chua HM, Dalili D, Foo F, Gao K, et al. Regulatory challenges with biosimilars: an update from 20 countries. Ann N Y Acad Sci. 2021;1491:42–59. doi:10.1111/nyas.14522
36. Niazi SK. Biosimilars adoption: recognizing and removing the roadblocks. Clinicoecon Outcomes Res. 2023;15:281–94. doi:10.2147/CEOR.S404175

Biologicals And Biosimilars: A Paradigm Shift In Indian Pharmaceutical Healthcare

T. Shri Vijaya Kirubha[1]*, S. Shrinithi[2]

[1]Department of Pharmacognosy, Mother Teresa College of Pharmacy,

Illuppur, Pudukkottai - 622 102, Tamil Nadu, India

[2]Swamy Vivekanandha College of Pharmacy, Tiruchengode - 637 205, Tamil Nadu.

Email: tsvkirubha@gmail.com

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.

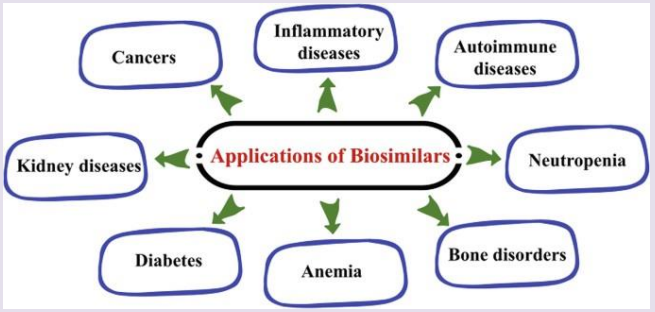

Figure 2. Therapeutic uses of Biosimilars

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.

11. References

1. Aspen Institute. India's biosimilar advantage: Regulatory pipeline and market leadership, New Delhi: Aspen Institute India; 2023 [cited 2024 Nov 15]. Available from: https://www.aspeninstitute.in

2. European Medicines Agency. Biosimilar medicines: Overview of the European regulatory pathway, Amsterdam: EMA; 2023 [cited 2024 Dec 10]. Available from: https://www.ema.europa.eu

3. Scott AM, Wolchok JD, Old LJ. Antibody therapy of cancer. Nat Rev Cancer. 2012;12(4):278–87. doi:10.1038/nrc3236

4. World Health Organization. Biological medicines and biosimilars: Ensuring access, safety and quality, Geneva: WHO; 2022 [cited 2024 Oct 20]. Available from: https://www.who.int

5. US Food and Drug Administration. Scientific considerations in demonstrating biosimilarity to a reference product: Guidance for industry, Silver Spring (MD): FDA; 2015 [cited 2024 Sep 18]. Available from: https://www.fda.gov

6. Dranitsaris G, Amir E, Dorward K. Biosimilars of biological drug therapies: Regulatory, clinical and commercial considerations. Drugs. 2011;71(12):1527–36. doi:10.2165/11593730-000000000-00000

7. Krishnan A, Nair VN. Biosimilars in India: Market landscape, regulatory framework and physician perspectives. Indian J Pharmacol. 2021;53(2):112–20. doi:10.4103/ijp.IJP_738_20

8. Expert Market Research. India biosimilars market report 2024–2034 [Internet]. Dubai: Expert Market Research; 2024 [cited 2024 Nov 28]. Available from: https://www.expertmarketresearch.com

9. Berman P, Ahuja R, Bhandari L. The impoverishing effect of healthcare payments in India: New methodology and findings. Econ Polit Wkly. 2010;45(16):65–71.

10. Government of India, Ministry of Finance. Union Budget 2026–27: Biopharma SHAKTI Initiative, New Delhi: Ministry of Finance; 2026 [cited 2026 Feb 5]. Available from: https://www.indiabudget.gov.in

11. Government of India, Department of Pharmaceuticals. Production Linked Incentive (PLI) scheme for pharmaceuticals: Guidelines and eligibility [Internet]. New Delhi: DoP; 2021 [cited 2024 Aug 12]. Available from: https://pharmaceuticals.gov.in

12. Biotechnology Industry Research Assistance Council (BIRAC). Funding schemes and programmes, New Delhi: BIRAC; 2024 [cited 2024 Oct 5]. Available from: https://www.birac.nic.in

13. Department for Promotion of Industry and Internal Trade (DPIIT). Startup India: Dashboard and statistics, New Delhi: DPIIT; 2024 [cited 2024 Jul 31]. Available from: https://www.startupindia.gov.in

14. Central Drugs Standard Control Organisation. Guidelines on similar biologics: Regulatory requirements for marketing authorisation in India, New Delhi: CDSCO; 2016 [cited 2024 Sep 14]. Available from: https://cdsco.gov.in

15. Evaluate Pharma. World preview 2023–2028: Patent expiry landscape and biosimilar pipeline, London: Evaluate; 2023 [cited 2024 Dec 1]. Available from: https://www.evaluate.com

16. McKinsey & Company. The next wave in the biosimilars industry: Implications for India's pharmaceutical workforce, New York: McKinsey; 2022 [cited 2024 Nov 10]. Available from: https://www.mckinsey.com

17. Schiestl M, Stangler T, Torella C, Cepeljnik T, Toll H, Gruber R. Acceptable changes in quality attributes of glycosylated biopharmaceuticals. Nat Biotechnol. 2011;29(4):310–2. doi:10.1038/nbt.1839

18. Strand V, Goncalves J, Isaacs JD. Immunogenicity of biologic agents in rheumatology: An educational review. Arthritis Res Ther. 2020;22(1):226. doi:10.1186/s13075-020-02317-6

19. Davio K. Naming, traceability, and interchangeability of biosimilars: Evolving global standards. BioPharma Asia. 2021;10(3):44–9.

20. Prashant P, Singh AK. Cold chain logistics in pharmaceutical distribution: Challenges and innovations in India. J Pharm Innov. 2022;17(2):451–60. doi:10.1007/s12247-021-09521-0

21. Pharmacy Council of India. Revised B.Pharm and M.Pharm curriculum framework incorporating biotechnology and biosimilar sciences, New Delhi: PCI; 2023 [cited 2024 Sep 22]. Available from: https://www.pci.nic.in

Nanocarrier Based Drug Delivery Of Biologics: Enabling The Rise Of Biosimilars In India



Akshay R. Yadav*, Dr. Shubhangi A. Patil, Dr. Niranjan D. Chivate

Department of Pharmaceutical Chemistry, KCT's Krishna College of Pharmacy, Karad, Maharashtra, India-415539

Email: akshayyadav24197@gmail.com

Abstract

Biologics are redefining modern therapies but the clinical efficacy is hampered by bioavailability, stability and delivery issues. Nanocarrier based drug delivery presently shows new opportunities to optimize targeted drug delivery, immunogenicity and pharmacokinetics. In India, for enhancing treatment outcomes and to improve accessibility with clinical efficacy, researchers are integrating nanotechnology and biosimilars emerging transformative approaches. Advances in polymeric and inorganic and lipid based nanocarrier systems have remarkably improved the delivery of biologics by addressing challenges such as low bioavailability, targeted delivery and poor stability limitations. These advancements are making a strategic shift from conventional towards the high value biopharmaceutical. Further, they support cost-effective therapies options, promote innovation and strengthen India's competitiveness in the global pharmaceutical sector.

Keywords: Nanocarriers, Biosimilars, Biologics, Drug delivery, Indian Pharmaceutical Industry.

1. Introduction

The development of a novel drug delivery system for targeted distribution of biologics and increasing stability to enhance therapeutic outcomes results in paradigm shift in India's biosimilar sector (1). But there are some restrictions to their rapid approval by some regulatory agencies to launch in the market (2). This barrier is hampering market expansion

and limiting availability of inexpensive biosimilar choices for large patient populations (3). In drug delivery systems for selection of proper formulation are critical in disease like inflammatory bowel disease (IBD). So, Nanocarrier drug delivery is also not easy to remove legislative barriers to improve accessibility (4).

1.1 Overview of Biologics and Biosimilars

Biologics are specialized biological products prepared by using advancing technologies and transformed in a way for the health care system to receive therapy for autoimmune disease and different types of cancers (5). Copies of these biologics are referred to as biosimilars that entered the market for offering more affordable options for costly biologic drugs (6). To make sure biosimilars efficacy, safety and regulatory agencies such as FDA created approval rules with procedures that are difficult to understand (7). As the market impact of biosimilar is advantageous, by reducing cost and increasing patient access for effective therapy (8,9).

1.2 Need for Advanced Drug Delivery in India

In India, nanocarrier drug delivery is used to know a variety of health care concerns including a lack of access to effective medicines. Drug delivery facilitates the site specific drug release by improving bioavailability and reducing systemic side effects with increasing patient compliance. Advance technological breakthroughs may address the current health care situation (10).

2. Challenges in Delivery of Biologics

There are multiple challenges faced by delivery of biologics in formulation to remain stable. Key limitations in delivery of biologics include achieving highly selective targeting strategies without causing unintended damage to healthy cells along with navigating complex regulatory frameworks (11). Noncompliance by patients may also impact biologics effectiveness because educating patients related to important steps for treatment remains tough and the problem related with biologics (12).

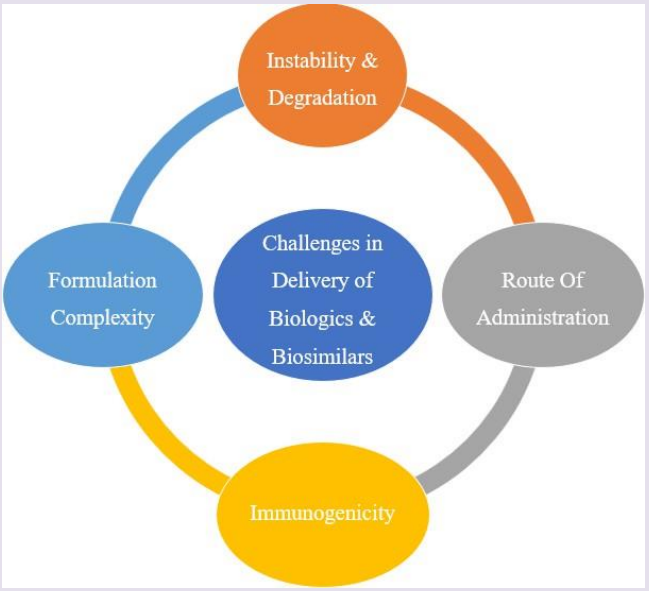

Figure 1. Different challenges in drug delivery

2.1 Stability and Degradation Issues

The delivery of biologics in India faces challenges associated with degradation and stability. Most biologics are very sensitive to environmental conditions requiring strict temperature control throughout the supply chain. To maintain the cold chain from the point of manufacturing to final administration to patients makes it difficult due to increased risk of temperature control at multiple stages. Regulatory complexities related to importation and approval of biologics are limiting patient accessibility. Overcoming these challenges is important to ensure equitable and improved access to advanced healthcare in the Indian population (13).

2.2 Poor Bioavailability and Targeting Limitations

In disease conditions the targeting of biologics and biosimilars with bioavailability continues to be a significant challenge (14). Rheumatoid arthritis and Inflammatory diseases require prompt treatment but due to bioavailability of currently available biologics is often insufficient to achieve optimal therapeutic level. Additionally, issues associated with infliximab along with challenges in targeting strategies can adversely affect both safety and effectiveness of biologic therapies (15).

Table 1. Comparative disadvantage of Bioavailability, distribution and targeting efficiency

Aspect	Biologics	Biosimilars	Key Limitation
Bioavailability	Low oral bioavailability due to large molecular size and enzymatic degradation	Similar limitations as reference biologics (protein instability and degradation)	Requires parenteral administration (IV/SC) (16)
Permeability & Distribution	Poor membrane permeability and limited tissue penetration	Comparable distribution challenges due to structural similarity	Inefficient delivery to intracellular or specific tissue targets (16)
Targeting Efficiency	Limited site-specific targeting; relies on passive distribution or antibody binding	Emerging targeting strategies but still under development	Need for advanced delivery systems (nanocarriers, active targeting) (17)

3. Development of Biologics and biosimilars by Nanocarrier based drug delivery strategies

Nanocarriers may be used for targeting and distributing biologics and biosimilars for improving their safety and efficacy (18).

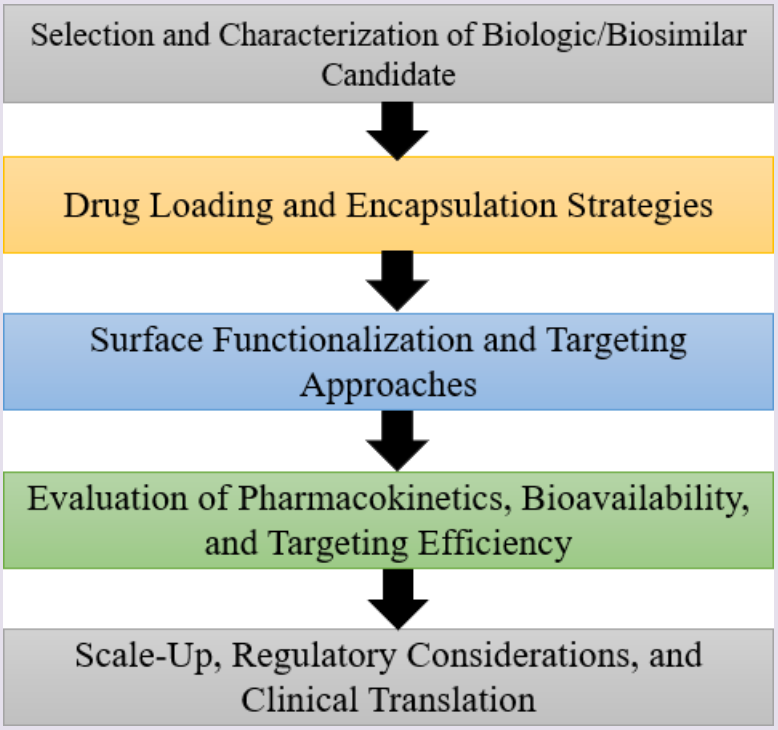

Figure 2. Integrated Strategy for Nanocarrier-Based Enhancement of Biologic and Biosimilar Therapeutics

Nanocarriers may help to lower the side effects and enhance therapeutic effectiveness. They are more feasible to target oral delivery of the biologics orally by overcoming challenges related with absorption and stability (19,20).

3.1 Nanocarrier Systems for Enhanced Delivery of Biologics

Nanocarrier and intracellular delivery of biologic drugs like peptides, proteins and monoclonal antibodies has shown interest in the field of drug delivery (21,22). Many attempts have been made to overcome challenges like biosafety and instability concerns to achieve oral administration of drugs (23,24).

3.2 Recent Advances and Case Studies in Nanocarrier enabled Biosimilars

Recent advances in nanocarrier delivery have enhanced targeted delivery of drugs used for enhancing the safety & efficacy in biosimilars. As they are changing clinical practice with patient expectations in a number of therapeutics disciplines, this article explains how nanocarriers enhance targeted drug delivery for disease sites. Nano emulsions are the best examples of nanocarriers to enhance delivery of drugs to the disease sites and show potential in treatment of diseases such as IBD. As biosimilars show new outcomes in treatment of

illness linked to abnormal immune response, testing, production and regulatory issues need to be resolved. The different approaches have been researched and present obstacles and potential paths for applications of nano based drug delivery for treatment of IBD. Personalized medicine in which treatments are made for specific illnesses and made possible by smart nanocarriers may enhance the focus of the delivery of medicine to disease areas and rapid evolution of biologics and biosimilars in clinical practices and patient expectations (25).

4. Indian Scenario and Opportunities

India's market for biologics and biosimilar offers tremendous development potential. The demand for reasonable biologic substitutes for expanding healthcare demands a nation with an enormous population. The biopharmaceutical areas are also facing a number of difficulties and remain competitive to endure over the long run, and this area urgently needs to paradigm (26,27). Regulatory environment of nation are becoming easily favourable for the biosimilar approval with large number of approvals have occurred recently and India might potentially adopt some techniques to develop biosimilars to keep an eye on global landscape, As technology continues to advance the Indian market may expand rapidly (28,29)

Table 2. Indian Scenario and opportunities for biosimilars drugs

Aspect	**Current Scenario in India**	**Opportunities**	**Challenges**	**Key Insight**
Market Landscape	Rapidly expanding biosimilars market with strong domestic companies	Entry into global regulated markets	Pricing pressure and competition	India is emerging as a global biosimilars (29)
Regulatory Framework	CDSCO and DBT guidelines support biosimilar approval	Scope for regulatory harmonization	Complex approval pathways	Strengthened regulations will improve trust (30)
Manufacturing & R&D	Cost-effective biologics production infrastructure	Investment in innovation and advanced delivery systems	High R&D costs and technical complexity	Strong potential for global manufacturing leadership (31)

Therapeutic & Export Potential	High demand in oncology, diabetes, autoimmune diseases	Expanding exports to US, EU, emerging markets	Stringent international compliance requirements	Enhances global access to affordable biologics (32)

4.1 Growth of Biosimilars Market in India

Regulatory framework for quicker biosimilar certification supported by India quickly by expanding biosimilars market. Other elements driving the market expansion are the cost-effectiveness for biosimilars comparatively to innovative biologic drugs (33). The pharmaceutical industry with the competitive environment has shown more innovation and cost cutting measures for producing high quality biosimilars (34).

4.2 Nanotechnology in Enhancing Accessibility

Biologics and biosimilars are better prepared and delivered in healthcare areas for advancement in nanotechnology. Biosimilars are delivered and targeted by using small nanocarriers, which also offer defense against degradation of the environment. Nanotechnology simplifies the formulation and development while supporting regulatory pathways and enabling design innovation based nanocarrier systems for targeted drug delivery systems across different disease conditions (35,36).

5. Regulatory and Technological Challenges and future directions

In India regulatory frameworks for biologics and biosimilars face major challenges they need to be addressed including heterogeneity in present inadequate bioinformatics resources and biosimilar approval procedure and lack of standards with respect to biosimilar references and weak scientific approach for characterization with frequently antiquated manufacturing technologies. Market access and their growth felicitated by improving technology and regulatory frameworks (37).

6. Conclusion

Nanocarrier based drug delivery gives revolutionary solutions to different problems related with biologics and biosimilars and these systems increase therapeutic efficacy while lowering the side effects by enhancing bioavailability and targeted drug delivery and stability. The

integration can strengthen the biopharmaceutical industry in India and enable the production of affordable biosimilars. To fully realize the potential and positioning India as a global leader in the cutting edge in drug delivery technologies with respect to encouraging frameworks, sustained innovation and scalable manufacturing techniques would be essential.

7. References

1. Rishishwar S, Asokan N. Innovations in drug delivery systems for biologics: enhancing stability and targeted delivery for next-generation therapeutics. Chin. J. Appl. Physiol. 2025;41:e20250001.
2. Panda S, Singh PK, Mishra S, Mitra S, Pattnaik P, Adhikary SD, Mohapatra RK. Indian biosimilars and vaccines at crossroads–replicating the success of pharmacogenetics. Vaccines. 2023;11(1):110.
3. Farswan AS, Joshi S, Sanwal R, Dhsamana A. Biopharmaceuticals: A Review of Biopolymeric Drugs and Accessibility Challenges in India. Journal of Polymer & Composites. 2024;12(5): 32-28
4. Aljabri A, Soliman GM, Ramadan YN, Medhat MA, Hetta HF. Biosimilars versus biological therapy in inflammatory bowel disease: Challenges and targeting strategies using drug delivery systems. Clinical and Experimental Medicine. 2025;25(1):107.
5. Naser-Tavakolian A, Heard JR, Ahdoot M. Biologics. In: Translational Urology. Amsterdam: Academic Press; 2025. p. 355–360..
6. Mascarenhas-Melo F, Diaz M, Gonçalves MB, Vieira P, Bell V, Viana S, Nunes S, Paiva-Santos AC, Veiga F. An overview of biosimilars development, quality, regulatory issues, and management in healthcare. Pharmaceuticals. 2024;17(2):235.
7. Cosenza ME. Biologics. In: An overview of FDA regulated products. Amsterdam: Academic Press; 2025. p. 111–132.
8. Hariprasad SM, Gale RP, Weng CY, Rezk MF, Tadayoni R. An introduction to biosimilars for the treatment of retinal diseases: a narrative review. Ophthalmology and Therapy. 2022;11(3):118-129.
9. Klein K, Gencoglu M, Heisterberg J, Acha V, Stolk P. The Global Landscape of Manufacturers of Follow-on Biologics: An Overview of Five Major Biosimilar Markets and 15 Countries: K. Klein et al. BioDrugs. 2023;37(2):235-45.
10. Dua K, Mehta M, Pinto TD, Pont LG, Williams KA, Rathbone M, editors. Advanced drug delivery systems in the management of cancer. Academic Press; 2021. p. 355–360..
11. Yu YB, Briggs KT, Taraban MB, Brinson RG, Marino JP. Grand Challenges in Pharmaceutical Research Series: Ridding the Cold Chain for Biologics: Yu et al. Pharmaceutical Research. 2021;38(1):3-7.
    Sarkis M, Bernardi A, Shah N, Papathanasiou MM. Emerging challenges and opportunities in pharmaceutical manufacturing and distribution. Processes. 2021;9(3):457.
12. Sarvepalli S, Pasika SR, Verma V, Thumma A, Bolla S, Nukala PK, Butreddy A, Bolla PK. A review on the stability challenges of advanced biologic therapeutics. Pharmaceutics. 2025;17(5):550.
13. Akram MS, Pery N, Butler L, Shafiq MI, Batool N, Rehman MF, Grahame-Dunn LG, Yetisen AK. Challenges for biosimilars: focus on rheumatoid arthritis. Critical reviews in biotechnology. 2021;41(1):121-53.
14. Cheshomi M, Shobeiri N, Tajani AS, Khameneh B. Strategic approaches for overcoming peptide and protein drug limitations. The Protein Journal. 2026;45(1):8-21.
15. Mitragotri S, Burke PA, Langer R. Overcoming the challenges in administering biopharmaceuticals: formulation and delivery strategies. Nat Rev Drug Discov. 2014;13(9):655–672.
16. Aljabri A, Soliman GM, Ramadan YN, Medhat MA, Hetta HF. Biosimilars versus biological therapy in inflammatory bowel disease: challenges and targeting strategies using drug delivery systems. Clin Exp Med. 2025;25(1):107.
17. Cao Y, Rewatkar P, Wang R, Hasnain SZ, Popat A, Kumeria T. Nanocarriers for oral delivery of biologics: small carriers for big payloads. Trends in pharmacological sciences. 2021;42(11):957-72.
18. Mühlberg E, Burtscher M, Umstätter F, Fricker G, Mier W, Uhl P. Trends in liposomal nanocarrier strategies for the oral delivery of biologics. Nanomedicine. 2021;16(20):1813-32.
19. Dirisala A, Li J, Gonzalez-Carter D, Wang Z. Delivery systems in biologics-based therapeutics. Frontiers in Bioengineering and Biotechnology. 2023;11:1274210.
20. Zhu YF, He MQ, Lin CS, Ma WH, Ai Y, Wang J, Liang Q. Multifunctional nanocarrier drug delivery systems: from diverse design to precise biomedical applications. Advanced Healthcare Materials. 2026;15(2):e02178.
21. Hassan A, Zameer MD, Khan M, Hassan T, Umair M, Iqbal MN, Ahi MJ, Gul P, Ahmed N. Smart nanocarriers for biosimilars: a new frontier in targeted drug delivery. J Drug Deliv Sci Technol. 2026 Feb;116:107955.
22. Kalaw San Pascual JC, Kangsamaksin T. Biologics, Biosimilars, and Biobetters: Therapeutic Innovations Reshaping Modern Medicine. Advanced Biology. 2025;9(12):e00326.
23. Singh P, Desai PN, Dutta V. Rising biosimilars in the Indian biopharmaceutical industry: emerging challenges and way forward. Technology Analysis & Strategic Management. 2023;35(9):1145-60.

24. Rathod JA, Amthaniwala BK. Comparative insights into biosimilar development in the UAE and India: Opportunities, challenges, and global trends. Indian Journal of Pharmacy and Pharmacology. 2025;12(4):194–205
25. Sinha S, Raphael R. Developing Biosimilars: Challenges and Opportunities. Pharmaceut Med. 2025;39(5):341-352
26. Heise T, DeVries JH. Biosimilar insulins: Narrative review of the regulatory framework and registration studies. Diabetes Obes Metab. 2025;27 Suppl 5(Suppl 5):16-23.
27. Evan Kuilenburg ABP, Hollak CEM, Travella A, Jacobs M, Gentilini LD, Leen R, der Vlugt KMMG, Stet FSB, Goorden SMI, van der Veen S, Criscuolo M, Papouchado M. Development of a Biosimilar of Agalsidase Beta for the Treatment of Fabry Disease: Preclinical Evaluation. Drugs R D. 2023;23(2):141-153.
28. Ascef BO, Almeida MO, Medeiros-Ribeiro AC, Oliveira de Andrade DC, Oliveira Junior HA, de Soárez PC. Therapeutic Equivalence of Biosimilar and Reference Biologic Drugs in Rheumatoid Arthritis: A Systematic Review and Meta-analysis. JAMA Netw Open. 2023;6(5):e2315872.
29. Gandhi S, Patankar D, Kashiramka S, Rathore AS. The economics of translating a biosimilar from lab to market in India. Annals of the New York Academy of Sciences. 2024;1541(1):219-29.
30. BS AK, PM H. A Review on Emerging Trends in Biologic Drugs and Biosimilars. Plant Biotechnology Persa. 2025;7(3):58-67
31. Nikitina V, Laurini GS, Montanaro N, Motola D. Comparative Safety Profiles of Biosimilars vs. Originators Used in Rheumatology: A Pharmacovigilance Analysis of the EudraVigilance Database. J Clin Med. 2025;14(5):1644.
32. Bas TG. Innovative formulation strategies for biosimilars: trends focused on buffer-free systems, safety, regulatory alignment, and intellectual property challenges. Pharmaceuticals. 2025;18(6):908.
33. Rizwan A, Dubey K, Malhotra V, Bhatnagar S. Biosimilars: Bridging the Gap in Biologics, Access, and Affordability. Journal of Pharmaceutical and BioTech Industry. 2026;3(1):2.
34. Kaur S, Yadav S, Sahu V, Sharma N, Shukla VK. Biosimilar regulations: Current framework and future prospects. Current Drug Safety. 2025 May 23.
35. Singh P, Desai PN, Dutta V. Rising biosimilars in the Indian biopharmaceutical industry: emerging challenges and way forward. Technol Anal Strateg Manag. 2021;35(1):1-17
36. Wei K, Kou Y, Kan H, He W, Li J, Guo X. Biosimilars: navigating the regulatory maze across two worlds. Trends Biotechnol. 2023;41(7):847-850.
37. Joshi D, Khursheed R, Gupta S, Wadhwa D, Singh TG, Sharma S, Porwal S, Gauniyal S, Vishwas S, Goyal S, Gupta G, Eri RD, Williams KA, Dua K, Singh SK. Biosimilars in Oncology: Latest Trends and Regulatory Status. Pharmaceutics. 2022 ;14(12):2721.

India As A Global Biosimilar's Hub: Economic Impact, Make-In-India Potential, And Emerging Challenges

Venumadhuri R*

Department of Pharmacology, Creative Educational Society's College of Pharmacy, Affiliated to Jawaharlal Nehru Technological University Anantapur, Andhra Pradesh INDIA.

Email: rageerveumadhuri@gmail.com

ABSTRACT

The treatment of chronic and sometimes fatal illnesses has been completely transformed by biologics, especially in the areas of cancer, autoimmune diseases, and metabolic disorders. However, in underdeveloped nations like India, its exorbitant cost severely restricts accessibility. Biosimilars, which are biological products that closely resemble authorized reference biologics, provide an affordable substitute without sacrificing quality, safety, or efficacy. India is becoming a global centre for biosimilars thanks to its extensive pharmaceutical manufacturing base and knowledge of generics. This paper examines the financial effects of biosimilars on India's healthcare system, assesses how the "Make in India" campaign has strengthened domestic production, and identifies important market, scientific, and regulatory issues. Increased patient access, significant cost reductions, and better healthcare sustainability are all facilitated by biosimilars. However, issues such low physician acceptance, regulatory heterogeneity, and immunogenicity continue to exist. To reach India's full potential as a worldwide leader in biosimilars, strategic investments in research, regulatory harmonization, and awareness campaigns are necessary.

Keywords

Biosimilars, Biologics, India, Pharmacoeconomics, Make in India, Regulatory Framework, Healthcare Access

1. Introduction

Biologics are sophisticated medicinal compounds made from live organisms through cutting-edge biotechnological techniques including recombinant DNA technology. Treatment outcomes for conditions like cancer, rheumatoid arthritis, diabetes, and inflammatory illnesses have greatly improved because of these drugs. Biologics are linked to high production costs despite their clinical benefits because of their intricate manufacturing procedures, strict quality standards, and lengthy clinical testing (1-7). Biosimilars are

described as biologic medicines that show a high degree of similarity to a reference biologic that has already been approved, with no clinically significant changes in terms of potency, safety, or purity (2). Because biological systems are inherently variable, biosimilars, in contrast to small-molecule generics, require thorough comparability studies, including analytical, preclinical, and clinical evaluations (6).

India has long been a world leader in generic pharmaceuticals, providing reasonably priced medications all across the world. Due to rising disease rates, the need for affordable treatments, and the patent expirations of major biologics, the Indian pharmaceutical industry has recently diversified into biosimilars. This shift offers India a strategic chance to improve access to healthcare and bolster its standing in the international biopharmaceutical industry (10).

2. Biosimilars' Economic Effect On India's Healthcare System

The financial impact of biologic treatments is substantial, particularly in countries like India where out-of-pocket expenses make up a substantial amount of healthcare funding. Biosimilars provide a viable solution because they provide comparable therapeutic effects at significantly lower costs. According to research, biosimilars can reduce treatment costs by around 20–70% (1,5).

The introduction of biosimilars has enhanced market competition, leading to price reductions for both originator biologics and biosimilars. This competitive environment has made advanced medications more widely available and reasonably priced (3). Additionally, because biosimilars reduce costs, healthcare organizations are able to reallocate resources toward other critical healthcare services, increasing overall system efficiency. Biosimilars are crucial for expanding access to care for chronic illnesses including cancer and autoimmune disorders from the perspective of public health. Improved patient adherence to treatment regimens brought about by increasing affordability leads to better clinical outcomes and cheaper long-term healthcare costs (4). Furthermore, including biosimilars into government-funded healthcare programs like Ayushman Bharat may significantly reduce the financial burden on patients and the healthcare system.

3. Biologics Made In India: Strategic And Industrial Consequences

In many areas, including biotechnology and pharmaceuticals, the "Make in India" program has been instrumental in promoting domestic production. With regard to biologics and biosimilars, this approach has improved India's standing in the global pharmaceutical supply chain, encouraged domestic manufacturing, and reduced dependency on imports. India's competitive advantages include a highly skilled labour force, an affordable manufacturing infrastructure, and a plethora of experience in large-scale pharmaceutical manufacturing. Indian companies are now able to successfully produce and sell biosimilars thanks to these factors. Prominent pharmaceutical companies like Dr. Reddy's Laboratories, Biocon, and Intas Pharmaceuticals have successfully entered foreign markets, demonstrating India's ability to compete on a global scale (13–15).

India continues to struggle with developing new biologics despite these benefits. Compared to other nations, the country invests relatively little in R&D, which limits its ability to

compete in high-end biologics innovation. To close this gap, more funding, state-of-the-art research facilities, and enhanced collaboration between business, government, and academic institutions are all required (10).

4. Approval Processes And Regulatory Framework

Biosimilar regulatory approval in India is supervised by the Central Drugs Standard Control Organization (CDSCO) and the Department of Biotechnology (DBT). The methodical approach of the regulatory framework emphasizes the "totality of evidence," which comprises analytical characterization, preclinical research, and clinical evaluation (6).

India modified its 2012 biosimilar guidelines in 2016 to comply with international standards, including those established by the World Health Organization and the European Medicines Agency (8,9). Prior to approval, these regulations ensure that biosimilars meet stringent requirements for quality, safety, and efficacy.

An important aspect of the regulatory process is post-marketing monitoring, which monitors the long-term safety and immunogenicity of biosimilars. This is especially important because of the complexity of biologics and the potential for immunological responses. Ongoing regulatory reforms and conformity to international standards are essential for the international acceptance of Indian biosimilars.

5. India As A Global Center For Biosimilars

India is now a major hub for biosimilars due to its robust manufacturing capabilities, economic advantages, and growing biotechnology expertise. The patent expiration of a number of well-known biologics has created significant potential for the development of biosimilars, particularly in developing nations where cost is a significant issue (3).

Due to expanding export opportunities, supportive government policies, and growing healthcare demand, the Indian biosimilars market is expected to grow rapidly in the future years (4). Indian companies are aggressively approaching regulated markets like the US and Europe through strategic alliances and adherence to international regulatory requirements.

Furthermore, India is positioned as a preferred supplier for global markets because of its ability to produce premium biosimilars at lower costs. This improves access to affordable biologic medicines, which advances global healthcare while also boosting India's economic growth.

6. New Obstacles To The Adoption Of Biosimilars

6.1 Scientific Difficulties

It is inherently challenging to create biosimilars since biological systems are so different. Small changes to manufacturing processes can lead to variations in the structure, stability, and biological activity of proteins. Strict quality control protocols and advanced analytical techniques are required to ensure consistency and quality (11).

Immunogenicity remains a major concern since biosimilars' safety and efficacy may be affected by immune reactions. In order to mitigate these risks, comprehensive clinical assessment and continuous observation are essential.

6.2 Regulatory Obstacles

Although India has made significant progress in building a robust regulatory framework, differences in national legislation make it challenging to penetrate other markets. Harmonization with international regulatory standards is crucial to minimizing effort duplication and promoting global acceptance (3).

6.3 Perception and Market Difficulties

The adoption of biosimilars by physicians and patients remains a significant challenge. Concerns regarding efficacy, safety, and interchangeability regularly impact prescription decisions. Raising awareness through education and empirical facts is necessary to foster trust in biosimilars.

7. Prospects For The Future

India must take a comprehensive strategy that combines innovation, regulatory tightening, and market development if it is to reach its full potential as a worldwide hub for biosimilars. Among the top priorities are:

- Raising funding for biotechnology research and development.
- Enhancing mechanism for pharmacovigilance.
- Encouraging global cooperation.
- Improving the harmonization of regulations.
- Promoting education and public awareness

It is anticipated that improvements in bioprocessing and analytical technology would enhance the effectiveness and calibre of biosimilar development (6). India can become a global leader in biopharmaceutical innovation and move from being a manufacturer of biosimilars with consistent efforts.

8. Conclusion

Biosimilars provide a revolutionary chance to boost the pharmaceutical sector and increase healthcare accessibility and cost in India. India is positioned as a potential worldwide leader in biosimilars thanks to the economic advantages and the strategic push from the "Make in India" drive. Sustainable expansion, however, requires addressing market, regulatory, and scientific issues. India can effectively become a global powerhouse for biosimilars and support fair healthcare globally through innovation, policy support, and strategic investment.

9. References

1. Gunnam S, Reddy PK, Kumar V. Economic benefits of biosimilars in emerging healthcare systems. *J Pharm Innov Res.* 2025;12(2):101–109.
2. Garai P, Singh A, Das S. Biosimilars: a comprehensive review of development and regulatory perspectives. *J Pharm Res Int.* 2024;36(5):45–58.
3. Rizwan A, Khan M, Ali S. Biosimilars and global affordability: challenges and opportunities. *J Pharm Biotechnol Ind*. 2026;3(1):12–21.
4. Al Meslamani AZ. Economic implications of biosimilars adoption in healthcare systems. *Expert Opin Biol Ther*. 2024;24(3):233–245.
5. Virani S, Patel R, Mehta D. Cost-effectiveness analysis of biosimilars in oncology. *Indian J Pharmacol*. 2024;56(2):85–92.

6. Monga A, Sharma K, Gupta P. Regulatory landscape of biosimilars: global and Indian perspectives. *AAPS PharmSciTech*. 2025;26(1):45.
7. Shanmugarajan D, Kumar R. Overview of biosimilars and their clinical applications. *Int J Basic Clin Pharmacol*. 2024;13(4):567–574.
8. World Health Organization. Guidelines on evaluation of similar biotherapeutic products (SBPs). Geneva: World Health Organization; 2022.
9. European Medicines Agency. Biosimilar medicines: overview. Amsterdam: European Medicines Agency; 2023.
10. Panda S, Mishra S, Kumar A. Indian biosimilars industry: current status and future prospects. *Vaccines (Basel)*. 2023;11(2):245.
11. Rathore AS, Kumar D, Kateja N. Manufacturing challenges and analytical considerations for biosimilars. *Biotechnol Prog*. 2021;37(3):e3124.
12. Niazi SK. Biosimilars in emerging markets: regulatory and economic considerations. *Biologics*. 2023;17:45–60.
13. Biocon Ltd. Annual report 2024. Bengaluru: Biocon Ltd; 2024.
14. Dr Reddy's Laboratories Ltd. Annual report 2024. Hyderabad: Dr Reddy's Laboratories Ltd; 2024.
15. Intas Pharmaceuticals Ltd. Global report 2024. Ahmedabad: Intas Pharmaceuticals Ltd; 2024.

Biologics And Biosimilars: Bridging Innovation And Affordability In India

Devid Verma, Arun Kumar*, Kuldeep Singh, Shom Prakash Kushwaha, Mehtab Alam

Department of Pharmaceutical Chemistry, Faculty of Pharmacy, Integral University, Kursi Road, Lucknow-226026, Uttar Pradesh, India.

E-mail: arun.mpharm@gmail.com

Abstract

Biologics have revolutionized the treatment of serious medical conditions, such as cancer and autoimmune diseases, which kill people prematurely and make them sick for a long time. In India, the high cost of advanced synthetic drugs has limited their uses, making it inaccessible to millions of people living in the country. Biosimilars may be a potential solution to this problem. Essentially, these are authorized medications that closely resemble biologics and show no clinically significant differences. India is frequently referred to as the pharmacy of the world. India, as the pharmacy of the world, is in a good situation to increase the uptake and development of biosimilars with a view to enhancing patient access and making the health system more resilient. In India, the biosimilars and biologics sector has gained unprecedented traction recently. The papers have elaborated on scientific merit, therapeutic significance, regulatory environment, commercial potential and cost. Biosimilars are difficult to develop due

to manufacturing complexity, a lack of regulatory harmonisation, physician confidence, pharmacovigilance, and public awareness. According to the article, a change in strategy regarding biosimilars can permit innovating for cheaper medicines and make future medicines affordable to the Indian people. Through strengthening focuses of research, policy, industry, and education, India can be established as a global leader in biosimilars and a model for equitable health care delivery.

Keywords: Biologics; Biosimilars; Healthcare affordability; India; Regulatory pathway; Patient access

1. Introduction

In complex disease, the practice of modern medicine has moved away from addressing symptoms/clinical judgement towards guiding therapy focused on a specific pathway to achieve a measurable improved outcome. In the transition towards precision-based healthcare, one of the big enablers and advances is biopharmaceuticals, which are specialized medicines obtained from living systems. These have revolutionized the treatment of cancers, autoimmune disorders, diabetes, and rare disorders where traditional medicines have failed (1).

The steep cost of biologics is still a barrier. The creation, manufacturing, and distribution of biologics are increasingly complicated, costing more than small molecule drugs by many orders of magnitude. In many nations, including India, where most healthcare expenses are paid directly by the patient, treatment costs of modern times are not feasible for many patients. Medical innovation must be effective, affordable, and equitable (2).

Biosimilars serve as a solution. The biosimilars are analogous to approved biologics, which must have comparability in quality, safety, and efficacy with the reference product. Biosimilars improve accessibility to lifesaving therapies, and do not compromise quality; they increase cost-effectiveness and range of use (3).

2. Understanding Biologics: A New Frontier in Therapy

Biologics are complex medicines made in living cells, like bacteria, yeast, or mammalian cells, whereas traditional drugs are chemically synthesized and structurally simpler than biologics. Monoclonal antibodies, recombinant proteins, hormones, enzymes, and vaccines fall in this category (4). They are excellent at targeting disease pathways. The targeted treatment techniques and immunotherapy have made a revolution in cancer therapies. In addition, patients with rheumatoid arthritis, psoriasis, and inflammatory bowel disease have also hugely

benefited from them. Lastly, recombinant insulin has brought about a fundamental change (5). They have also widened treatment opportunities for rare and genetic disorders, resulting in better disease control, greater quality of life, and more hope for patients (6).

3. Biosimilars: Expanding the Reach of Innovation

Biosimilars are a cost-effective alternative to the high-priced biologic therapy. They are very similar to licensed reference biologics with no clinically meaningful differences in safety, purity, or efficacy (7). Unlike generic drugs, which are exact chemical replicas of small-molecule medicines, biosimilars cannot be identical because biologics are large and complex molecules made in living cells. Instead, they are developed through extensive analytical, preclinical, and clinical comparisons to establish similarity (8). Evidence that small differences are irrelevant to clinical performance is demanded by regulatory agencies. The existence of biosimilars enhances market rivalry and enhances access to innovation. Besides providing similar therapeutic benefits at lower cost, it reduces the long-term treatment burden on health budgets especially in resource-constrained settings (7). The comparison of the biologics and biosimilars is summarised in Table 1.

Table 1. Comparative overview of biologics and biosimilars in terms of development, regulation, cost, and clinical application

Parameter	Biologics	Biosimilars
Definition	Original complex biological medicines derived from living systems	Highly similar versions of already approved biologic medicines
Reference Status	Innovator or reference product	Compared against a reference biologic for similarity
Nature of Product	Large, complex molecules produced in living cells	Similar large, complex molecules produced through biological processes
Development Pathway	Full discovery, preclinical, and clinical development required	Comparative analytical, preclinical, and clinical studies required
Time for Development	Usually longer	Comparatively shorter than original biologics
Cost of Development	Very high	Lower than biologics, but higher than generic drugs

Cost to Patient	Generally expensive	Relatively more affordable
Regulatory Requirement	Complete dossier for quality, safety, and efficacy	Demonstration of high similarity in quality, safety, and efficacy
Clinical Performance	Established through original trials	No clinically meaningful difference from reference product
Market Impact	Introduces innovation in therapy	Expands access through cost reduction and competition

4. Why India Needs the Shift

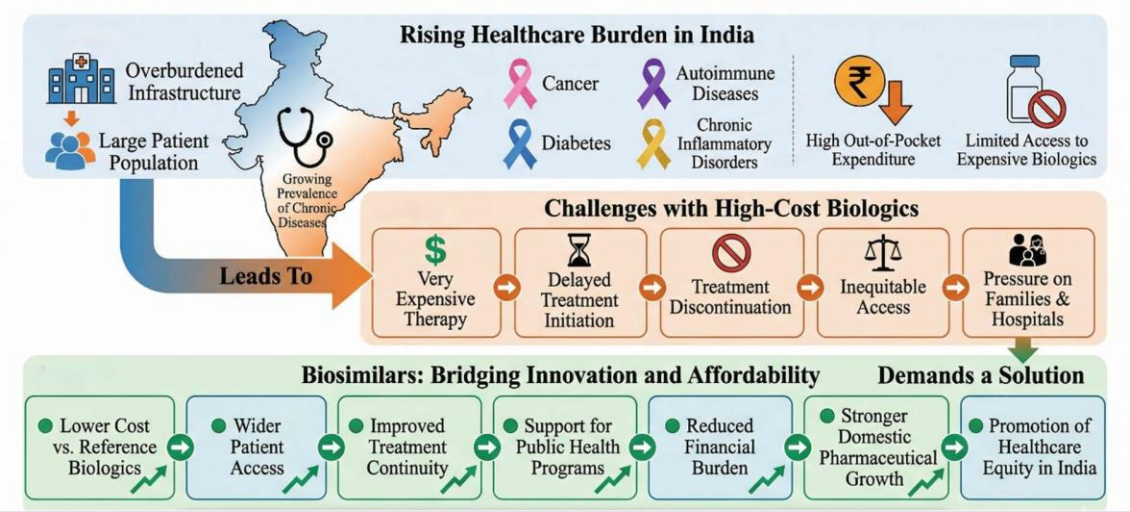

Figure 1. Why India needs the shift to Biosimilars

India has a pressing need for biologics and biosimilars, as chronic diseases such as cancer, diabetes and autoimmune disorders are on the rise in India, while access to advanced therapy is constrained by cost, as illustrated in Figure 1 (9). As healthcare costs are largely out of pocket, this has led to the postponing, discontinuation or never commencing of treatment with biologics and, in turn, enabled disease progression and complications as well as repeat hospitalisation (10). According to table 2, biosimilar availability not only improves access but also alleviates our public health care budgets from Tenders/Competitive Negotiation. The budget impact analysis assesses cost savings realized over the first three years following biosimilar market entry in Germany. India has a chance to seize this opportunity as it is already globally significant in vaccines, generics and pharmaceuticals (9).

Table 2. Major opportunities and challenges associated with the adoption of biosimilars in India

Aspect	Opportunities in India	Challenges in India
Patient Access	Can improve access to advanced therapies for larger populations	Limited awareness among patients may affect acceptance
Affordability	Can reduce treatment cost compared with reference biologics	Price reduction may still not be sufficient for all patients
Healthcare System	May reduce financial burden on hospitals and public health programs	Uneven healthcare infrastructure can limit wider use
Pharmaceutical Industry	Supports domestic manufacturing and global market growth	High investment needed for development and quality assurance
Scientific Capability	India has skilled workforce and strong biotech potential	Need for further strengthening of R&D and advanced technology platforms
Regulatory Growth	Scope for stronger alignment with global standards	Regulatory clarity and harmonization still need improvement
Physician Acceptance	Increasing clinical experience can build confidence	Concerns about interchangeability and long-term outcomes may persist
Pharmacovigilance	Opportunity to build robust post-marketing surveillance systems	Adverse event reporting and traceability systems need strengthening
Public Health Impact	Can promote equitable access to lifesaving therapies	Adoption may remain slow without policy and educational support
Global Positioning	India can emerge as a global biosimilar leader	Must maintain consistent quality and international compliance

5. India’s Strengths in the Biosimilar Landscape

Today India is strongly placed to emerge as an important player in the biosimilars sector. India has the world's 3rd largest pharmaceutical industry, with extensive manufacturing capacity, scientific skill, and low-cost production methods. For years, Indian entities have been trusted partners in the large-scale production of medicines and vaccines. They are specially trained in dealing with complex biologics and other forms of biotechnology (11). It is expanding because of pharmacists, biotechnologists, researchers, regulatory professionals, etc. An increase in domestic demand from improved diagnosis and access to specialist services only adds to the potential opportunity. The biosimilars industry can help make essential medicines affordable, increase exports, improve self-reliance, and strengthen India’s global biopharmaceutical sector (7).

6. Regulatory Framework: Building Trust Through Science

In order for biogenerics to be successful, a strong regulatory framework will be necessary, as biologics are somewhat complex products and sensitive in nature. India regulates biosimilars through the CDSCO and DBT, which ensures that any product approved meets proper quality, safety, and efficacy (12). Approval can be obtained without any clinical studies showing similarity to a reference biologic as long as evidence is provided through analytical and nonclinical and possibly clinical studies. The procedure protects patients and instills confidence in the prescriber, pharmacist, and healthcare institution. India’s guidelines on biosimilars are becoming better but require further improvement through a guidance document that is based broadly on global scientific standards with special reference to interchangeability. A robust pharmacovigilance program and traceability will further strengthen the guidelines. A transparent regulatory system, based on evidence, enables investment in industry and sustainable growth of the biosimilar sector, all of which aid public health (13).

7. Economic and Healthcare Benefits

The utilization of biosimilarity in cancer, diabetes, and autoimmune states is not a new phenomenon of biological therapy. A generic medicine is not an identical copy of an existing medicine, but it is similar to the branded medicine in terms of quality, safety, and efficiency. The EMA and the Government of India began strict criteria and guidelines to review and approve biosimilar medicines. Furthermore, their economic and clinical benefits are remarkable. The complications could be minimised and the long-term result maximised. Biosimilars help healthcare organizations save limited funds and give access to innovative

treatments for a greater number of patients. They can help cancer survival, improve disability in autoimmune diseases, and improve quality of life. More ample utilization may enable the delivery of equitable and sustainable healthcare (14).

8. Barriers to Adoption

Although promising, numerous barriers exist for biosimilars. The development of a drug requires high technology, strict control of manufacture, and high investment. Hence, entry into the market is limited. Concerns about switching, interchangeability, long-term outcomes, and more among clinicians are also slowing adoption, especially in stable patients. Patients can be sceptical because a lower cost can infer lower quality. It is necessary to have good pharmacovigilance. India needs better traceability, adverse event reporting, and real-world evidence generation to strengthen confidence in biosimilars (15).

9. Future Perspective

Achieving the full potential of biosimilars in India will require a collaborative investment strategy in research, manufacturing, and analytical capacity with active participation through public-private partnerships. In addition, education is essential for improving understanding between clinicians, pharmacists, nurses, and patients. The pharmacists have a unique opportunity to promote rational prescribing, educate the patient, monitor adherence, and engage in pharmacovigilance as intermediaries in the transfer of scientific evidence into clinical care (16).

10. Conclusion

The therapeutic area has been revolutionised with the advent of biologics. They ensure precision, efficiency, and success in handling complex ailments. If a drug or treatment isn’t used by enough patients, it doesn't reach its full value. The availability of biosimilars can enhance the accessibility of modern therapeutics in India, where there is a huge need for better modern therapies and affordability is a limiting factor.

Biosimilars not only offer promising business prospects but also hold significant advantages for public health. It demonstrates a firm commitment to what modern medicine ought always to be, which is not a service for those who can afford the most advanced care, but for those who need it most. India possesses the scientific knowledge, manufacturing capabilities, and enhanced ambition in healthcare to lead this change effectively. By implementing effective containment measures, continuous education, an industry with commitment, and cooperation

of the health sector, biologics and biosimilars together may help usher a future wherein innovation does not become a privilege of few but a promise of many.

11. References

1. Pascual J, Kangsamaksin T. Biologics, Biosimilars, and Biobetters: Therapeutic Innovations Reshaping Modern Medicine. Advanced Biology. 2025 Nov;9(12). doi:10.1002/adbi.202500326 PubMed PMID: 41243801.

2. Pettifor JM, Saloojee H. Unequal access: the prohibitive costs of new drugs in low- and middle-income countries. Nature Reviews Nephrology. 2025 Mar;21(5):281–2. doi:10.1038/s41581-025-00948-z PubMed PMID: 40087511.

3. Webster C, George K, Woollett GR. Comparability of Biologics: Global Principles, Evidentiary Consistency and Unrealized Reliance. BioDrugs. 2021 Jun. doi:10.1007/s40259-021-00488-5 PubMed PMID: 34143406.

4. Haltaufderhyde K, Roberts B, Khan S, Terry F, Boyle CM, McAllister M, et al. Immunoinformatic Risk Assessment of Host Cell Proteins During Process Development for Biologic Therapeutics. The AAPS Journal [Internet]. Springer Science+Business Media; 2023. Available from: https://doi.org/10.1208/s12248-023-00852-z doi:10.1208/s12248-023-00852-z PubMed PMID: 37697150.

5. Jain A, Bishnoi M, Prajapati SK, Acharya S, Kapre S, Singhvi G, et al. Targeting rheumatoid arthritis: a molecular perspective on biologic therapies and clinical progress. Journal of Biological Engineering. 2025 Jul;19(1):67–67. doi:10.1186/s13036-025-00534-8 PubMed PMID: 40707975.

6. Thombre K, Gupta KR, Masne TP, Umekar M. Recombinant Proteins: Evolution to their Therapeutic Potential. Protein and Peptide Letters. 2025 Aug;32(8):557–74. doi:10.2174/0109298665387985250710041016 PubMed PMID: 40760755.

7. Vhanale* D. Biosimilars: Opportunities, Challenges, and the Future of Affordable Biologics. Open MIND. 2026 Jan. doi:10.5281/zenodo.18440620

8. Nori LP, Ravi P. Comparability Pathway for the Approval of Similar Biologics with Respect to Reference Biologics in Europe and Brazil. Indian Journal of Pharmaceutical Education and Research. 2020 May;54. doi:10.5530/ijper.54.2s.58

9. Panda S, Singh PK, Mishra S, Mitra S, Pattnaik P, Adhikary SD, et al. Indian Biosimilars and Vaccines at Crossroads–Replicating the Success of Pharmagenerics. Vaccines. 2023 Jan;11(1):110–110. doi:10.3390/vaccines11010110 PubMed PMID: 36679955.

10. Prinja S, Dixit J, Gupta N, Dhankhar A, Kataki AC, Roy P, et al. financial toxicity of cancer treatment in India: towards closing the cancer care gap. Frontiers in Public Health. 2023 Jun; 11:1065737–1065737. doi:10.3389/fpubh.2023.1065737 PubMed PMID: 37404274.

11. Uppal A, Chakrabarti R, Chirmule N, Rathore AS, Atouf F. Biopharmaceutical Industry Capability Building in India: Report from a Symposium. Journal of Pharmaceutical Innovation. 2021 Nov;17(4):1555–62. doi:10.1007/s12247-021-09596-9 PubMed PMID: 34849178.

12. Panda A, Sahoo BM, Brahma CK, Samal HB. Regulatory Evolution of Biologics in India: Innovation Gaps and Strategic Imperatives for Global Leadership. Current Drug Discovery Technologies. 2026 Mar;23. doi:10.2174/0115701638413104251112080107 PubMed PMID: 41830583.

13. Alnaqbi KA, Bellanger A, Brill A, Castañeda-Hernández G, Estela AC, Sánchez OD, et al. An international comparative analysis and roadmap to sustainable biosimilar markets. Frontiers in Pharmacology. 2023 Aug;14. doi:10.3389/fphar.2023.1188368 PubMed PMID: 37693908.

14. Rasekh M, Arshad MS, Ahmad Z. Advances in Drug Delivery Integrated with Regenerative Medicine: Innovations, Challenges, and Future Frontiers. Pharmaceutics. 2025 Apr;17(4):456–456. doi:10.3390/pharmaceutics17040456 PubMed PMID: 40284451.

15. Paul P, Kapur R, Mittra S, Shah N, Rao GK, Erick ME, et al. Increasing adoption of quality-assured biosimilars to address access challenges in low- and middle-income countries. Generics and Biosimilars Initiative Journal. 2024 Aug;13(2):40–54. doi:10.5639/gabij.2024.1302.008

16. Thorakkattil SA, Parakkal SA, Salim KTM, Arain S, Krishnan G, Madathil H, et al. Improving patient safety and access to healthcare: The role of pharmacist-managed clinics in optimizing therapeutic outcomes. Exploratory Research in Clinical and Social Pharmacy. 2024 Oct; 16:100527–100527. doi: 10.1016/j.rcsop.2024.100527 PubMed PMID: 39469652.

Biologics Vs Biosimilars: Addressing Affordability And Access In Indian Healthcare


P. S. Bhandare[1]*, P. A. Patil[2]

[1]Department of Pharmacology, KCT's Krishna College of Pharmacy Malkapur, Karad, India.

[2]Department of Pharmaceutics, KCT's Krishna College of Pharmacy Malkapur, Karad, India.

Email: pooja14511@gmail.com

Abstract

Biologics have revolutionised treatment of cancer, diabetes, rheumatoid arthritis, and other chronic diseases by offering targeted and effective therapies. However, their high-cost limits access, particularly in developing countries like India where out-of-pocket healthcare expenses are significant. Biosimilars, which are highly similar versions of approved biologics, provide a safe, effective, and more affordable alternative, often at 30-70% lower prices. India has made early progress with over 100 approved similar biologics and updated regulatory guidelines, yet challenges in manufacturing complexity, regulatory enforcement, pharmacovigilance, and stakeholder confidence persist. This review examines the science of biologics and biosimilars, India's regulatory framework, market status, key challenges, opportunities, and recommendations. A full shift towards quality assured biosimilars is essential to improve patient access, reduce financial burden, strengthen India's biopharmaceutical industry, and position the country as a global hub for affordable biologics. Robust regulation, investment in infrastructure, education, and real-world evidence generation will be critical for success.

Keywords: Biosimilars, Regulatory guidelines, Biotechnology

1. Introduction

Biologics are large, complex therapeutic proteins or other molecules produced using living cells. They include monoclonal antibodies, insulin, erythropoietin, and growth factors used to treat serious conditions such as cancer, autoimmune disorders, and diabetes. These medicines have transformed patient outcomes but come at a steep price, often running into lakhs of

rupees per year of treatment. In India, where most healthcare costs are borne directly by patients, many families cannot afford originator biologics (4).

Biosimilars are not identical copies like small-molecule generics but are highly similar to the reference (originator) biologic in structure, function, safety, and efficacy. They undergo rigorous comparability exercises to demonstrate no clinically meaningful differences. When patents on original biologics expire, biosimilars enter the market at significantly lower costs, expanding access without compromising quality. India, already a global leader in generic medicines, has an opportunity to replicate this success in the biosimilar space. With a large patient population suffering from chronic diseases and growing patent expiries worldwide, the shift to biosimilars is not just desirable but necessary for public health and economic growth.

2. What Are Biologics and Biosimilars?

Biologics are produced through biotechnology processes involving genetically engineered cells. Their complex structure, including post-translational modifications like glycosylation, makes them sensitive to manufacturing changes. Even minor variations can influence immunogenicity or potency (5).

Biosimilars must prove "high similarity" through a stepwise approach: extensive analytical characterisation, non-clinical studies, pharmacokinetic/ pharmacodynamic (PK/PD) equivalence, and, where needed, comparative clinical trials. Regulatory agencies use the "totality of evidence" to approve them. Unlike generics, biosimilars cannot be automatically substituted in all jurisdictions due to potential subtle differences (7).

Table 1. Comparison of Generics vs Biosimilars

	Generics	**Biosimilars**
Origin	Chemical & therapeutic equivalents of chemical drugs	Copies of existing biological medicinal products or protein drugs.
Structure	Smaller, less complex, one dimensional (1D)	Large & complicated (100-1000x), three dimensional (3D)
Molecular weight	Low	High
Stability	More stable	Sensitive to change in physical conditions
Route	Oral	Injection/inhalational
Manufacturing procedure	Less complex	Complex, lengthy & expensive (requires different cell lines)

Registration procedure	Simple, Abbreviated New Drug Application (ANDA)	Complicated (EMA/FDA)

The key differences in manufacturing, similarity, and substitution requirements are represented in Figure 1. This flowchart shows the stepwise comparability exercise, starting from quality attributes through clinical studies, with possible re-optimisation loops.

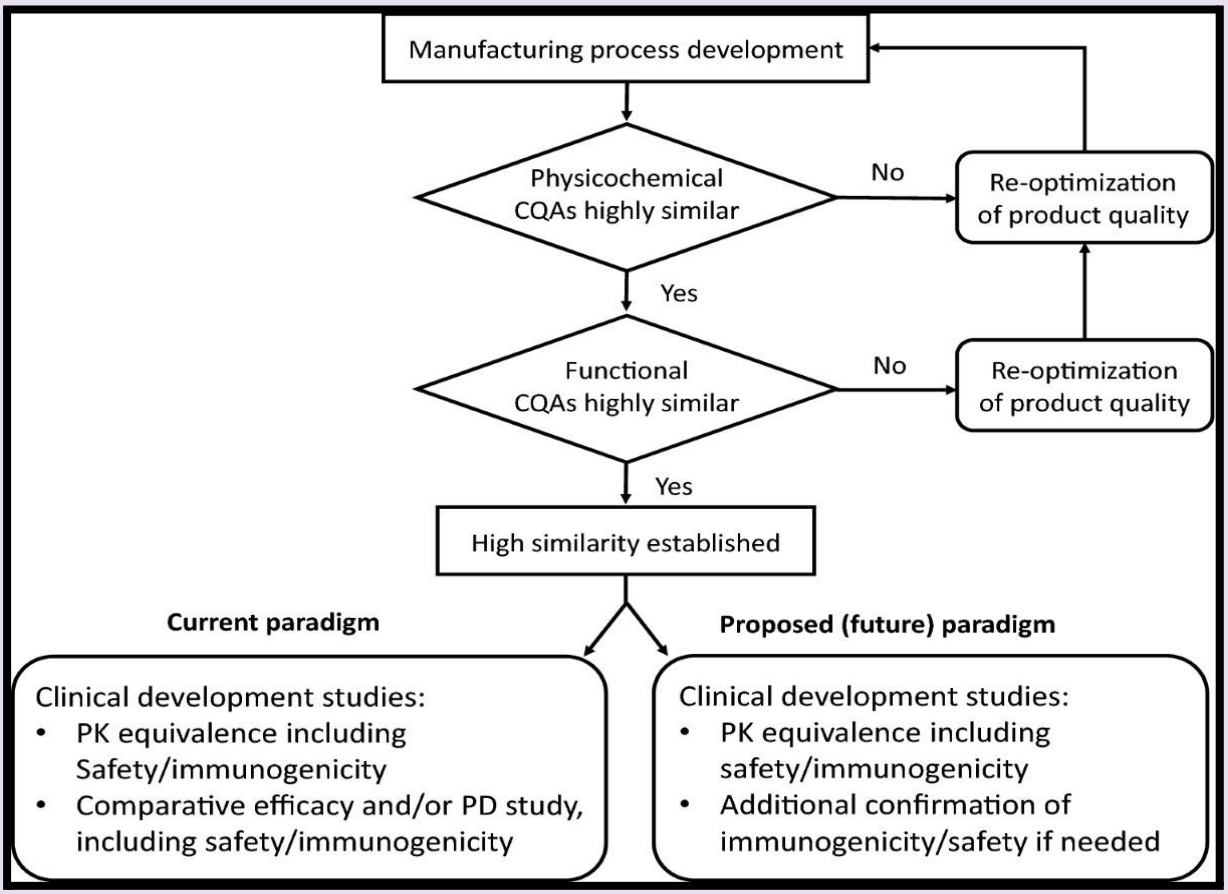

Figure 1. Biosimilar Development and Approval Process

3. Global and Indian Regulatory Framework

The European Medicines Agency (EMA) pioneered biosimilar regulation in 2006, followed by the US FDA in 2015. Both emphasise analytical similarity as the foundation, supported by clinical data when uncertainty remains. The World Health Organization (WHO) guidelines help countries establish pathways (8).

India introduced Guidelines on Similar Biologics in 2016 version as the primary approved framework, with a draft revision released on May 06, 2025. The 2025 draft provides forward looking insights but is not yet enforceable, still pending finalization through the Central Drugs Standard Control Organization (CDSCO) and Department of Biotechnology (DBT). The process includes quality studies, non-clinical tests, PK/PD studies, optional efficacy

trials, and a mandatory Phase IV post-marketing study (at least 200 patients within two years). While progressive, the guidelines remain advisory rather than statutory in some aspects (1,2,9).

4. Current Status of Biosimilars in India

India approved its first biosimilar (hepatitis B vaccine) in 2000 and now has over 100 similar biologics covering insulin glargine, filgrastim, adalimumab, bevacizumab, trastuzumab, and others. Companies such as Biocon, Dr Reddy's, Intas, and Zydus have gained recognition, with some products receiving approvals in regulated markets (1).

The domestic biosimilar market was valued at approximately USD 0.8-1.3 billion in recent years and is projected to reach USD 3.6–5.9 billion by 2030–2033, with a CAGR of 16-21%. Exports are also rising, with the potential to reach USD 4.2 billion by 2030 (10, 11).

Table 2. Selected Biosimilars Approved in India

Product	Active Substance	Main Indications	Name of the Company	Year of launch
Glaritus	Insulin glargine	Diabetes mellitus	Wockhardt	2009
Basalog			Biocon	2014
Grafeel	Filgrastim	Neutropenia	Dr Reddy's Laboratories	2012
Razumab	Ranibizumab	Age-related macular degeneration	Intas Pharmaceuticals	2015
Adfar	Adalimumab	Rheumatoid arthritis	Biocon	2017
Krabeva	Bevacizumab	Various cancers	Biocon	2018
RLS-Nivolumab	Nivolumab	Cancer (trials going on)	Reliance Life Sciences	2026

5. Why India Urgently Needs the Shift

India faces a growing burden of non-communicable diseases. Cancer incidence is rising rapidly, over 100 million people live with diabetes, and autoimmune conditions are common. Originator biologics remain unaffordable for most, straining government schemes like Ayushman Bharat. Biosimilars can reduce treatment costs substantially while maintaining therapeutic outcomes, leading to better adherence, fewer complications, and improved quality

of life. The shift also supports industrial growth, job creation in biotechnology, and India's ambition to become a global biopharma hub (9).

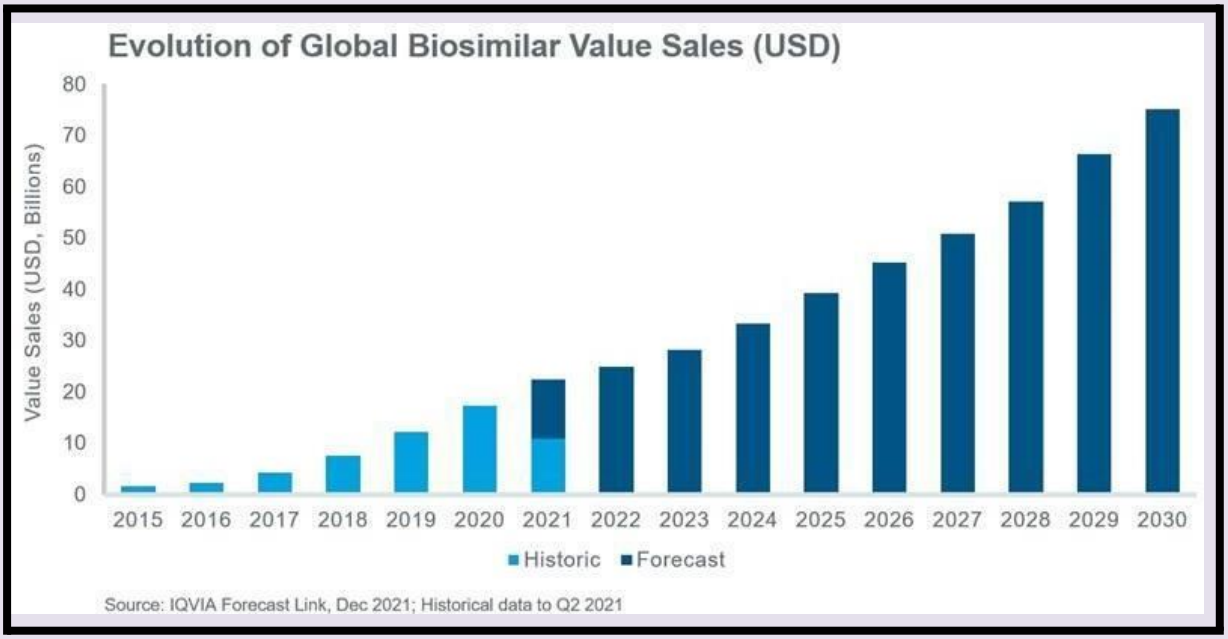

Figure 2. Global Biosimilar Market Growth

6. Regulatory Challenges on the Path Forward

Despite progress, regulatory and implementation hurdles slow India's transition to world-class biosimilars that impede growth and market penetration. The Central Drug Standard Control Organisation (CDSCO) guidelines issued in 2012 for similar biologics are updated periodically, there are gaps in robust post marketing surveillance for immunogenicity and long-term safety, variability in manufacturing processes and frequent scrutiny, all of which increase the costs and delay affordability benefits. Furthermore, limited harmonization with international standards from bodies like FDA or EMA restricts export potential and global competitiveness, despite India's robust production infrastructure.

7. Manufacturing and Analytical Complexity

Biosimilars require advanced analytical tools (mass spectrometry, bioassays) to demonstrate similarity in critical quality attributes. Small process variations can affect glycosylation or aggregation, potentially influencing safety. Many Indian facilities face challenges in infrastructure and skilled manpower. Past regulatory observations from international agencies highlight the need for stronger process validation and data integrity (2, 11).

8. Ambiguity in Guidelines and Enforcement

The 2016 guidelines are not fully legally binding, leading to interpretive differences. Historical approvals of some "intended copies" with limited comparability data have raised

concerns. Issues include inconsistent requirements for local clinical trials, lack of a clear interchangeability policy (unlike the US FDA designation), and coordination challenges between CDSCO and DBT. Court cases and patent disputes further delay market entry (1, 2, 9).

9. Post-Marketing Surveillance and Pharmacovigilance

Rare immunogenicity or potency issues may emerge only after widespread use. India mandates Phase IV studies, yet the Pharmacovigilance Programme of India (PvPI) faces under-reporting, limited traceability (no unique naming or batch tracking specific to biosimilars), and challenges in distinguishing products. Long-term real-world data from Indian patients remain limited for many molecules (3).

10. Physician, Patient, and Stakeholders Confidence

Many clinicians prefer originators due to limited local long-term evidence or fear of nocebo effects. Surveys indicate knowledge gaps about biosimilar development. Patients worry about switching therapies. Without strong education and robust real-world evidence, adoption lags despite cost advantages (4, 5).

11. Global Market Access Barriers

Entering stringent markets (US, EU) requires additional studies to meet higher standards, increasing costs and timelines. Differences in expectations for reference products, clinical data, and pharmacovigilance create duplication of effort (2).

Table 3. Key Regulatory Differences – India vs Major Agencies

Aspect	**India (CDSCO/DBT 2016)**	**EMA / FDA**
Guideline Status	Advisory guidelines	Legally binding
Reference Product	From well-regulated markets allowed	Primarily from own jurisdiction
Clinical Efficacy Trial	Often waivable	Required unless low residual uncertainty
Interchangeability	Not formally defined	Specific pathway (US) with switching data
Post-Marketing Study	Mandatory Phase IV (≥200 patients)	Risk management plan + enhanced surveillance
Pharmacovigilance	Evolving, traceability challenges	Highly structured with identifiers

12. Opportunities and Recommendations

India possesses low-cost manufacturing, a skilled workforce, and a large domestic market. Key recommendations include:

- Making core regulatory requirements legally enforceable while keeping a science-based, risk-proportionate approach.
- Investing in national centres for advanced analytics and immunogenicity testing.
- Strengthening PvPI with biosimilar-specific traceability and mandatory real-world evidence generation.
- Launching nationwide education campaigns for healthcare professionals and patients.
- Promoting public-private partnerships and incentives (e.g., PLI scheme) for next-generation biosimilars and biobetters.
- Pursuing greater harmonisation with EMA, FDA, and WHO for smoother global approvals.

These steps can transform challenges into strengths, enabling India to supply affordable, high-quality biosimilars domestically and internationally. (8)

13. Conclusion

Biologics have transformed modern medicine, yet their cost restricts access for millions in India. Biosimilars offer a proven pathway to affordability and wider reach. India has laid a strong foundation with early approvals, guideline updates, and an emerging industry. However, addressing regulatory ambiguities, strengthening manufacturing and pharmacovigilance capabilities, and building stakeholder trust are essential for a complete and successful shift. With concerted efforts from regulators, industry, clinicians, and policymakers, India can not only meet its healthcare needs but also emerge as a global leader in biosimilar innovation and supply. The time for this shift is now improving lives, reducing economic burden, and securing a competitive edge in biotechnology.

14. References

1. Kang HN, Knezevic I, Casas M, et al. Regulatory challenges with biosimilars: an update from 20 countries. BioDrugs. 2021;35(1):13-31. doi:10.1007/s40259-020-00456-7
2. Rahalkar H, et al. Challenges faced by the biopharmaceutical industry in the development and approval of biosimilars in BRICS-TM countries. Ther Innov Regul Sci. 2021;55(6):1195-1205. doi:10.1007/s40290-021-00395-8
3. Singh A, et al. Postmarketing safety of biosimilars: current status, challenges, and opportunities in the spontaneous reporting system. Ther Innov Regul Sci. 2020;54(2):482-492. doi:10.1177/2168479019872144
4. Joshi D, et al. Biosimilars in oncology: latest trends and regulatory status. Indian J Med Paediatr Oncol. 2022;43(6):456-462. doi:10.1055/s-0042-1759680
5. Monga A, et al. Biosimilars: a critical review of development, regulatory issues, and clinical use. Pharmaceuticals (Basel). 2025;18(1):45. doi:10.3390/ph18010045 (example recent synthesis)
6. Kang HN, et al. The regulatory landscape of biosimilars: WHO efforts and progress made from 2009 to 2019. Biologicals. 2020; 65:1-9. doi:10.1016/j.biologicals.2020.02.003

7. Rahalkar H, et al. Biosimilar development and review process in the BRICS-TM countries. Ther Innov Regul Sci. 2022;56(3):491-500. doi:10.1007/s40290-021-00420.
8. Morin S, et al. Expanding access to biotherapeutics in low-income and middle-income countries through public health non-exclusive voluntary intellectual property licensing. Lancet Glob Health. 2023;11(2):e234-e242. doi:10.1016/S2214-109X (22)00460-0
9. Rathore AS, et al. The global landscape on interchangeability of biosimilars. Expert Opin Biol Ther. 2022;22(1):1-10. doi:10.1080/14712598.2021.1948530
10. Ditani AS, et al. Biosimilars accessible in the market for the treatment of cancer. J Oncol Pharm Pract. 2021;27(8):1893-1902. doi:10.1177/10781552211020828
11. Uppal A, et al. Biopharmaceutical industry capability building in India. J Pharm Innov. 2022;17(3):789-801. doi:10.1007/s12247-021-09596-9
12. Priyarega S, et al. An overview of biosimilars for cancer, diabetes mellitus, and rheumatoid arthritis. J Appl Pharm Sci. 2022;12(8):045-056. doi:10.7324/JAPS.2022.120805
13. Rizwan A, et al. Biosimilars: bridging the gap in biologics, access, and affordability. J Pharm Bioinnov. 2026;3(1):2. (recent open-access synthesis)

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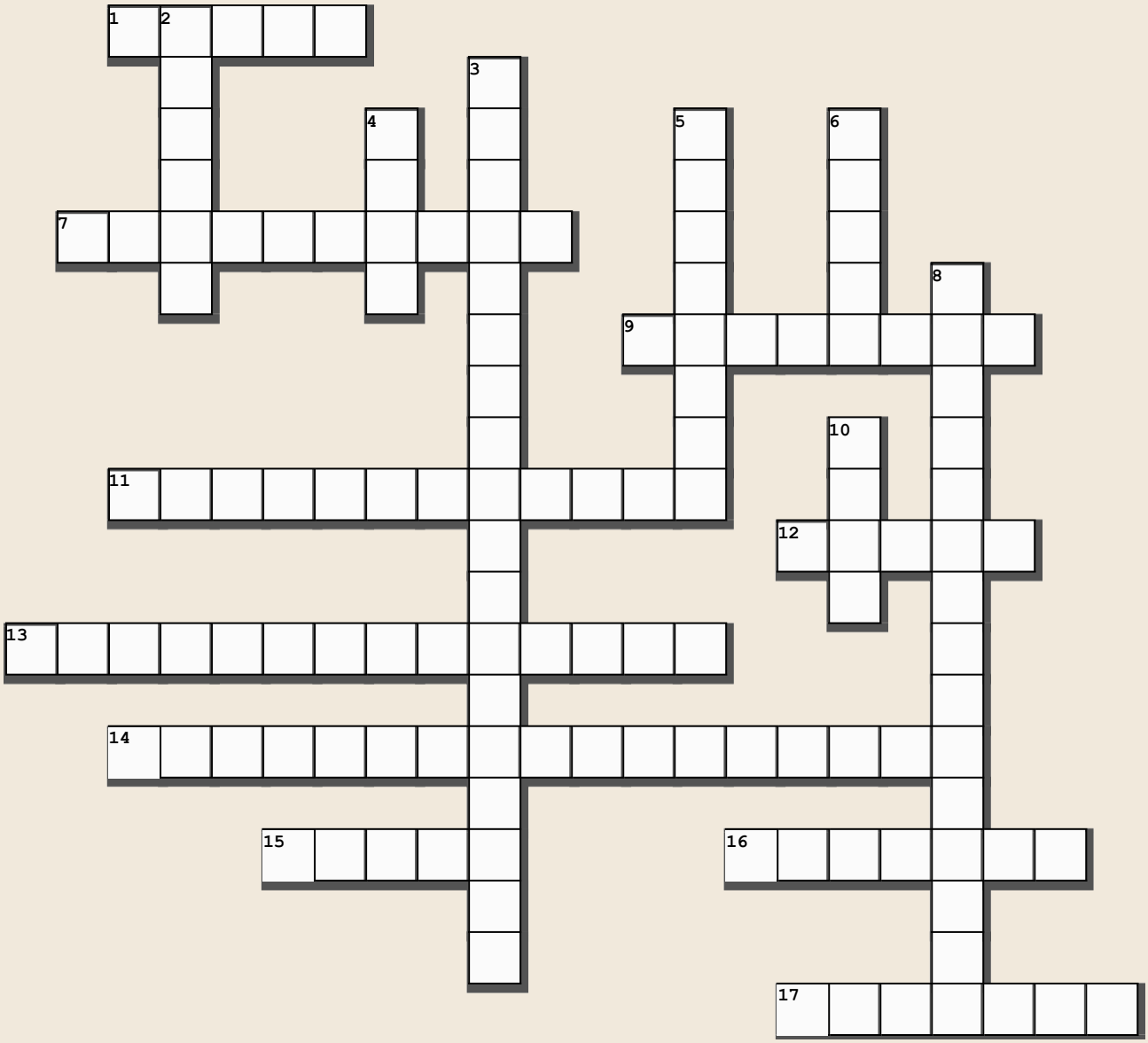

Created using the Crossword Maker on TheTeachersCorner.net

Across

1. Generic semaglutide launched by Dr. Reddy's Laboratories
7. Large-scale cell-based system used for producing biologics
9. Complex protein drugs produced from living cells
11. Indian Biotech Cluster Renowned as a vaccine hub
12. Organization funding biotech startups in India
13. Technique enabling high-yield protein production via gene insertion
14. Indian CDMOs Specializing in ADCs
15. Regulatory authority approving biologics in India
16. Industrial parks supporting biotech manufacturing
17. India's first rituximab biosimilar

Down

2. Indian company known for insulin biosimilars
3. Fastest-growing class dominating biosimilars by type
4. Antibody-drug conjugates abbreviation
5. Structural level crucial for biologic function
6. Outsourcing model where India supports global biologics manufacturing
8. Government scheme to support biologics and biosimilars
10. Promotion of Research and Innovation in Pharma-MedTech Scheme (abbreviation)

Transforming India's Biopharmaceutical Landscape: The Expanding Role Of Biosimilars In Cost-Effective Healthcare



Pranjal Yadav, Sandip Zine, Akshata Pahelkar*

Department of Pharmaceutical Analysis, SVKM's Dr. Bhanuben Nanavati College of Pharmacy (Autonomous), Vile Parle, Maharashtra, India.

Email: akshata.pahelkar@bncp.ac.in

Abstract

The development of biological treatments has changed the treatment modality for chronic diseases and diseases that could be life-threatening, but the issue is the exorbitant cost, making them inaccessible, especially in underdeveloped and developing countries. Biosimilars present an effective solution that is equally safe, effective, and of equal quality compared to biologics, hence offering affordable healthcare. This article examines the movement from biologicals to biosimilars, highlighting the science behind them, their regulation, and validation. The article also notes the growing bioeconomy in India, involvement of local pharmaceutical companies, and initiatives by the Indian government to encourage the development of biosimilars and advances in drug delivery systems.

Keywords: Bioeconomy; Biosimilars; India's pharmaceutical industry

1. Introduction

Biologics are approved drug products that are manufactured using living organisms or components thereof, like cells, tissues, or microorganisms. They usually comprise large, complex biomolecules like proteins or nucleic acids and are manufactured using biotechnology techniques or cell culture methods, which greatly affect their properties due to their highly process-sensitive nature. Estimates indicate that the price of some high-molecular-weight biologics is set to become even more unaffordable in developing countries between 2030 and 2040 (1). Biosimilars, on the other hand, are drugs of biological origin that closely resemble a pre-existing drug referred to as the reference product and have no significant qualitative and quantitative (safety, purity/quality, or efficacy) differences compared to the reference product. Due to the inherent variability of the biological system, biosimilars are not exactly identical to reference products, like generics. Therefore, a comprehensive evaluation of the product is needed, taking into account analytical, non-clinical, and clinical assessments to determine the similarities (2). The introduction of biosimilars provides an economical option, allowing significant price cuts and encouraging

competition, thereby reducing medical expenses. This has been proven by experience in Australia (3) as well as other international studies. Further budget analyses indicate that biosimilars, such as adalimumab and tocilizumab, can save €187 million annually in major European countries, thereby expanding patient access to these treatments (4).

2. Indian Market Dynamics and Growth Trajectory

2.1 Growth of bioeconomy

The bio-economy of India has shown substantial growth, accounting for around 4.25% of its Gross Domestic Product (GDP) at present. In the past ten years, there have been significant gains made in this industry, as shown in Figure 1. This is made possible through infrastructure development via funding from organizations such as the Biotechnology Industry Research Assistance Council (BIRAC), which offers financial support to fund capital expenditure and operational expenditure needs to develop a comprehensive end-to-end biopharmaceutical research lab (5, 6).

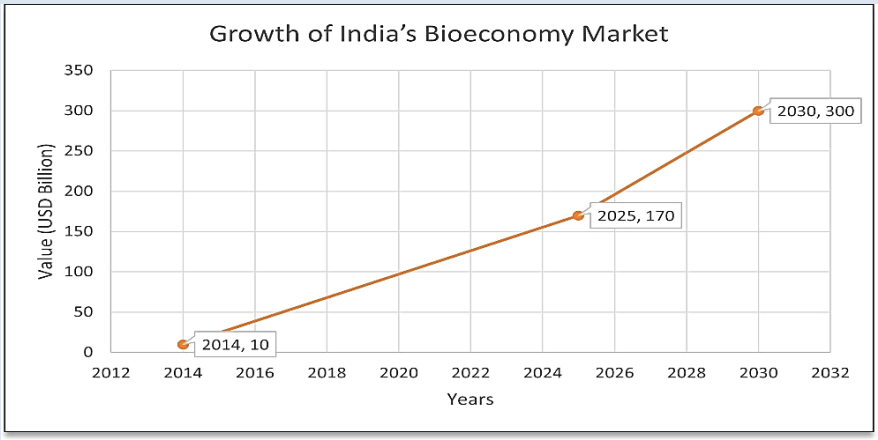

Figure 1. Growth trend of India's bioeconomy market from 2014 to 2030. By 2030, India's bioeconomy market is expected to hit $300 billion (5).

2.2 Role of Indian pharma companies

Indian pharmaceutical companies are currently gaining more prominence globally, not only by securing more drug approvals (more than 100) but also by succeeding in entering markets that have stringent regulations (7). For instance, the Biocon-Mylan alliance secured United States Food and Drug Administration (USFDA) approval of their biosimilars Ogivri (trastuzumab), Fulphila (pegfilgrastim), and Semglee (insulin glargine) in the United States(US) (7).

2.3 Global position of India

India is among the top countries globally for the pharmaceutical sector owing to its robust production capacity, cost-effectiveness, and high-quality standards. India enjoys a considerable stake in global pharmaceutical regulations through production in developed economies such as the US and Europe. India's participation in the global pharmaceutical industry can be summed up in three categories: generics, vaccines, and US prescriptions (8), as shown in Figure 2.

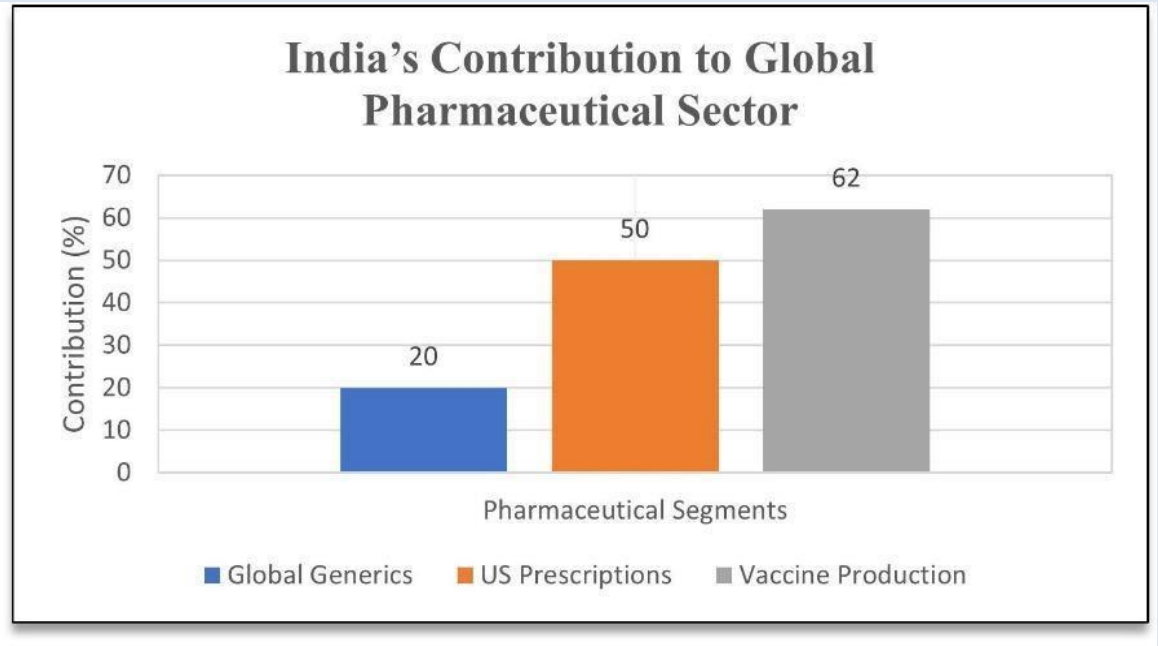

Figure 2. Comparative illustration of India's performance in various sectors of the global pharmaceutical industry.

3. Economic & Healthcare Impact

Biosimilar drugs have led to reductions in drug prices of 20% to 70% in sectors like oncology and rheumatology, making these medicines more accessible. This enables funding for new drug research while offsetting the high costs of biologics despite their relatively low utilization (9).

4. Clinical Evidence & Regulatory Aspects of biosimilars

Despite the considerable economic value associated with reduced costs and improved availability of biosimilars, biosimilars require strong clinical evidence and rigorous regulatory evaluation to ensure safety, efficacy, and quality.

4.1 Comparable safety & efficacy

Backtracking the study of 38 biosimilar developments revealed similar efficacies for all products, thus validating the existing developmental methods, while in 95% of the cases, the clinical efficacy studies did not add any extra value apart from analytical and pharmacokinetic information. The observations indicate that clinical studies are less sensitive in comparison to physicochemical, functional, and pharmacokinetic assessments in picking up minute variations (10).

4.2 Role of regulatory bodies

Regulatory bodies are key stakeholders in ensuring biosimilar safety, efficacy, and quality. The roles of major regulatory agencies in biosimilar evaluation are outlined in Table 2 (11).

Table 1. Role of Major Regulatory Agencies in Biosimilar Evaluation

Regulatory Agency	Role
Food and Drug Administration (FDA)	Biosimilars are regulated using the "Totality of the evidence" approach, a unique three-tier statistical evaluation to rank critical quality attributes based on their impact on biological activity.
European Medicines Agency (EMA)	Analyzes products that consist of a particular variant of an active substance that has been authorized within the European Economic Area (EEA).
World Health Organization (WHO)	Provides global guidance to standardize the evaluation of biosimilars and promote international harmonization of regulations

4.3 Totality-of-evidence approach

This represents a step-wise approach that considers analytical, clinical, and non-clinical data. Aims to resolve any ambiguities that may exist concerning the similarities between the product and any other analytical uncertainties to guarantee human safety. It includes the evaluation of primary sequences, protein structure, glycosylation profile, and biological activities (12).

5. Technological Developments in Biologics and Their Impact on Biosimilars

Innovations in biologics have revolutionized the treatment methods due to improvements in drug delivery systems and molecular engineering techniques. Examples of such advances include liposomal nanoparticles, hydrogels, exosomes, and viral vectors, which can increase the stability, marketability, and efficacy of biologics.

Another result of such technological progress has been the development of "bio-betters," i.e., improved versions of biologics intended to produce better therapeutic results than those offered by the original drugs. Even though these innovations were developed with new biologics and "bio-betters" in mind, they can also be used to improve biosimilar drugs.

5.1 Liposomes and Lipid Nanoparticles (LNPs)

Liposomes are spherical vesicles with a phospholipid bilayer used to deliver hydrophilic and hydrophobic drugs. The application includes oncology, antibody, gene, and small interfering ribonucleic acid (siRNA) delivery. Characterized by size, polydispersity, zeta potential, efficiency of encapsulation, stability and release profile. Manufacturing challenges include scalability, batch consistency, aggregation, cost, and immune responses; advanced processes and material modifications are being developed (13).

5.2 Hydrogels and Nano-Particle-loaded Hydrogels

Hydrogels are hydrated polymer matrices with adjustable pore sizes, swelling, and degradation, enabling controlled delivery of proteins, cells, or nanoparticles through ocular, dermal, and parenteral routes, evaluated based on Porosity, swelling behaviour, degradation speed, and mechanical stability. Nanogel formulations require measuring particle size,

loading, and release profiles. Used for localized, sustained delivery of proteins, cells, and nanoparticles in medicines, oncology, ocular, and dermal indications. Main challenges are release control, shelf life, immunogenicity, need for a more standardised and quality-by-design approach (14).

5.3 Exosomes & exosome–liposome hybrids

Exosomes are natural nanovesicles with lipid bilayers that transport proteins, nucleic acids, and lipids between cells. This system is typically evaluated based on parameters such as size (NTA-Nanoparticle Tracking Analysis/ DLS-Dynamic Light Scattering), morphology (electron microscopy), surface markers, cargo loading, stability, and biodistribution. Used for Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) plasmid delivery to hard-to-transfect cells (e.g., mesenchymal stem cells); systemic RNA/protein delivery. Challenges include low/variable loading, stability issues (−80°C storage), rapid clearance, scalability, and regulatory hurdles (15).

5.4 Lentivirus-derived nanoparticles (LVNPs)

The LVNP system mimics viral delivery without replication; its characterization involves p24 particle quantification, electron microscopy (EM), ribonucleoprotein content analysis, and on/off-target editing via Next-Generation Sequencing (NGS). These systems have demonstrated utility in *in vitro* CRISPR editing, base/prime editing, and *in vivo* eye gene targeting and have the potential for donor-free precise editing. Challenges include manufacturing complexity, safety and regulatory classification concerns vs. classical lentiviral vectors, and scalability limitations (16).

6. Government Initiatives (India)

India has implemented several initiatives to strengthen the biosimilar sector, which are summarized in Table 3.

Table 2. Government initiatives supporting biosimilar development in India

Scheme	Year	Application Scope	Funding	Ref.
Biopharma SHAKTI	2026	Building capacity & enabling innovations	₹10,000 crore (5-year allocation).	(17)
BioE3 Policy	2024	Economy, Environment, and Employment. leveraging common infrastructure, such as bio-foundries. Supports India's net-zero goals.	Strategic policy framework with infrastructure support and innovation incentives	(18)
National Biopharma Mission (NBM)	2017	local development of innovative products related to vaccines (like Human Papillomavirus, Dengue), biologics, and advanced diagnostics.	₹1,500 crore (World Bank-supported program).	(19)

7. Manufacturing, Quality Considerations and Challenges in Biosimilars

In the absence of cell line and process information of the originator's biologic, companies are forced to perform lengthy reverse engineering and process development. With respect to the downstream process, the maintenance of critical quality attributes (CQAs) involves rigorous control over all steps of purification, from the protein step up to viral inactivation, to prevent aggregate formation due to immunogenicity (20). Immune response continues to be an important issue. It is necessary to carefully evaluate and benchmark the incidence of anti-drug antibodies (ADAs) and neutralizing antibodies (NAbs) against that of the reference biologic (21). Patent thicketing and Intellectual Property (IP) lawsuits remain a prominent challenge, leading to a delay in introducing inexpensive biosimilars into the market by an estimated one-and-a-half to two years (9). Pricing strategies and competition complicate matters further. Biosimilars often reduce costs by 20–70%. However, intellectual property issues could impede market entry by 12–18 months (9).

8. Case Studies / Real-World Evidence

The Ontario, Canada, case study is an example of the effect that a policy of compulsory use of approved biosimilars on patients can have, resulting in cost savings and optimal resource utilization. The fast adoption of the scheme made it possible for 96.5% adoption of biosimilars to be realized in a short period of time, hence enabling cost savings of above $65 million in the span of just 15 months, with more anticipated economic savings expected to total approximately $96 million in the second year (22). The case study for Aflibercept biosimilars involves a Randomized Controlled Trial (RCT) Phase 3 wherein the biosimilar products showed safety, efficacy, and immunogenicity comparable with the reference products in the treatment of nAMD(Neovascular (wet) age-Related Macular Degeneration)
(23). The real-world adoption has demonstrated significant cost savings and improved access

9. Conclusion

The use of biosimilars leads to cost reduction, as biosimilars provide 20-70% savings compared to expensive biologics. This leads to savings that can be used for the benefit of patients and allows for a wider reach of treatments. Also, their use allows for improvement in the capacity of healthcare systems due to the ability to invest in new innovations and diversification of manufacturing. The effectiveness of their usage, though, depends on the management of increased health care utilization due to switching programs. India has taken an impressive position in the field of biosimilars and bioeconomy. With an existing bioeconomy worth $195.3 billion that aims to reach up to $300 billion by 2030, India proves its strong position in the area.

10. References

1. Rathore AS, Gardner PJ, Chhabra H, Raman R. Global outlook on affordability of biotherapeutic drugs. Ann N Y Acad Sci. 2024 Jul;1537(1):168–78.
2. Mascarenhas-Melo F, Diaz M, Gonçalves MBS, Vieira P, Bell V, Viana S, et al. An Overview of Biosimilars—Development, Quality, Regulatory Issues, and Management in Healthcare. Pharmaceuticals. 2024 Feb 11;17(2):235.
3. Hillen JB, Stanford T, Ward M, Duszynski K, Tong X, Li SX, et al. Medicines Policy in Action: The Impact on Volume and Cost of Biologic Medicines After Biosimilar Introduction. Value Health Reg Issues. 2025 Nov;50:101173.
4. Clarke K, Ainslie-Garcia M, Ferko N, Shastri K. Modelling the opportunity for cost-savings or patient access with biosimilar adalimumab and tocilizumab: a European perspective. J Med Econ. 2024 Dec 31;27(1):952–62.

5. Lalitha N. India's Bioeconomy: A Pathway to Sustainable Growth through Biotechnology. Int J Sci Res IJSR. 2025 Jun 2;1922–6.
6. A Global Bioeconomy Powerhouse [Internet]. Government of India, Press Information Bureau. Available from: https://www.pib.gov.in/PressNoteDetails.aspx?ModuleId=3&NoteId=155153&id=155153&reg=3&lang=2
7. Emergence of India as a Global Manufacturing Hub for Biosimilars [Internet]. Available from: https://www.biopharminternational.com/view/emergence-of-india-as-a-global-manufacturing-hub-for-biosimilars?
8. Panda S, Singh PK, Mishra S, Mitra S, Pattnaik P, Adhikary SD, et al. Indian Biosimilars and Vaccines at Crossroads–Replicating the Success of Pharmagenerics. Vaccines. 2023 Jan 2;11(1):110.
9. Sailaja Gunnam, Kaunain Fathema, Nijhawan M, R Surya Anusha Venna, Aleti R. A Review on Economic Benefits and Impact of Biosimilars on Healthcare System: Review Article. J Pharma Insights Res. 2025 Aug 5;3(4):181–90.
10. Schiestl M, Ranganna G, Watson K, Jung B, Roth K, Capsius B, et al. The Path Towards a Tailored Clinical Biosimilar Development. BioDrugs. 2020 Jun;34(3):297–306.
11. Kurki P, Kang HN, Ekman N, Knezevic I, Weise M, Wolff-Holz E. Regulatory Evaluation of Biosimilars: Refinement of Principles Based on the Scientific Evidence and Clinical Experience. BioDrugs. 2022 May;36(3):359–71.
12. McClellan JE, Ómarsdóttir S, Roy N, Berger V, Michel C, Berti F. The totality of evidence approach in the development of AVT02 (adalimumab), a biosimilar to Humira. Ther Adv Chronic Dis. 2024 Jan;15:20406223231223286.
13. Wu J, Zhang Y, Wu Z, Townsend J, Crooks I, Watt B, et al. Characterization of lipid nanoparticles using macro mass photometry: Insights into size and mass. Anal Chim Acta. 2025 May;1351:343944.
14. Stevanović M, Jović M, Filipović N, Lukač S, Tomić N, Popović Maneski L, et al. Multifunctional Nanomaterial-Integrated Hydrogels for Sustained Drug Delivery: From Synthesis and Characterization to Biomedical Application. Gels. 2025 Nov 5;11(11):892.
15. Mehryab F, Rabbani S, Shahhosseini S, Shekari F, Fatahi Y, Baharvand H, et al. Exosomes as a next-generation drug delivery system: An update on drug loading approaches, characterization, and clinical application challenges. Acta Biomater. 2020 Sep;113:42–62.
16. Haldrup J, Andersen S, Labial ARL, Wolff JH, Frandsen FP, Skov TW, et al. Engineered lentivirus-derived nanoparticles (LVNPs) for delivery of CRISPR/Cas ribonucleoprotein complexes supporting base editing, prime editing and *in vivo* gene modification. Nucleic Acids Res. 2023 Oct 13;51(18):10059–74.
17. Department of Biotechnology. Biopharma SHAKTI Scheme. Available from: https://dbtindia.gov.in
18. BioE3 Policy (Biotechnology for Economy, Environment and Employment). Available from: https://dbtindia.gov.in Akshata Palhekar, Transforming
19. Biotechnology Industry Research Assistance Council. National Biopharma Mission (Innovate in India i3). Available from: https://birac.nic.in/national_biopharma_mission.php
20. Ratih R, Asmari M, Abdel-Megied AM, Elbarbry F, El Deeb S. Biosimilars: Review of regulatory, manufacturing, analytical aspects and beyond. Microchem J. 2021 Jun;165:106143.
21. Kurki P, Barry S, Bourges I, Tsantili P, Wolff-Holz E. Safety, Immunogenicity and Interchangeability of Biosimilar Monoclonal Antibodies and Fusion Proteins: A Regulatory Perspective. Drugs. 2021 Nov;81(16):1881–96.
22. Iacono A, Ho MKH, Yang J, Campbell T, Wynne W, Shearer D, et al. Measuring the Impact of the Substitution of Innovator Biologics With Biosimilars on Uptake and Costs Among Ontario Public Drug Benefit Recipients. Clin Pharmacol Ther. 2026 Jan 27;cpt.70214.
23. Balser S, Capsius B, Hole R, Papp A, Preissinger N, Rozenknop A, et al. Randomised, double-masked trial to compare the efficacy, safety and immunogenicity of the biosimilar aflibercept FYB203 with reference aflibercept in patients with neovascular age-related macular degeneration. BMJ Open Ophthalmol. 2026 Jan;11(1):e002398.

Biologics And Biosimilars In India: The Imperative Shift With Insights From Ivf Treatments

Itishree Mohanty*

Kanak Manjari Institute of Pharmaceutical Sciences, Rourkela

Email: itushree9a@gmail.com

Abstract

India's pharmaceutical industry is undergoing a strategic transition from small-molecule generics to complex biologics and biosimilars. This shift is driven by rising disease burdens, patent expiries, and the need for affordable advanced therapies. The pharmaceutical landscape is shifting toward biologics, with biosimilars offering cost-effective alternatives. India, traditionally strong in generics, is now transitioning into biologics to address rising healthcare costs and complex diseases. The global pharmaceutical industry is shifting from small-molecule drugs to biologics, with biosimilars emerging as cost-effective alternatives. India, historically dominant in generics, is now transitioning into biologics and biosimilars to address rising healthcare costs and complex disease burdens. This paper explores the necessity of this shift, focusing on In Vitro Fertilization (IVF) as a case study. IVF treatments rely heavily on biologics such as recombinant follicle-stimulating hormone (rFSH), which significantly increase treatment costs. Evidence suggests that biosimilars offer comparable efficacy and safety while improving affordability, making them crucial for expanding access in India.

Keywords: Biologics, Biosimilars, India, IVF, Fertility Treatment, Pharmaceutical Industry, Healthcare Access etc.

1. Introduction

Biologics represent a new frontier in medicine, offering targeted therapies for chronic and life-threatening conditions. Biosimilars, as cost-effective alternatives, play a crucial role in expanding access. India, known globally for its generics industry, is now positioning itself to become a major player in biologics. The shift is particularly relevant in high-cost treatment areas like IVF, where biologic drugs are essential but often unaffordable for a large segment of the population. Biologics are large, complex molecules derived from living organisms and represent a major advancement in modern medicine. However, their high-cost limits accessibility, particularly in developing

countries like India. Biosimilars, highly similar versions of approved biologics, offer a pathway to reduce costs and improve access.

India's pharmaceutical sector is uniquely positioned to lead this transition due to its strong manufacturing base and experience in generics. The IVF sector provides a compelling example of how biosimilars can transform access to specialized healthcare. As we know, biologics are complex, life-saving drugs derived from living systems, widely used in treating chronic diseases and infertility. However, their high-cost limits access in developing countries like India. Whereas biosimilars provide a solution by offering similar therapeutic outcomes at lower costs. India's transition toward biologics is both a healthcare necessity and an economic opportunity.

2. Biologics and Biosimilars: Conceptual Framework

2.1 Biologics

Biologics are complex molecules produced using living systems. Biologics are produced through biotechnology and include hormones, monoclonal antibodies, and recombinant proteins. These therapies are inherently complex and exhibit variability due to their biological origin. In IVF, biologics such as recombinant follicle-stimulating hormone (rFSH) are used to stimulate ovarian function (2).

2.2 Biosimilars

Biosimilars are highly similar versions of approved biologics with no clinically meaningful differences in safety or efficacy. They offer:

- Lower cost
- Comparable therapeutic outcomes
- Increased patient access

Biosimilars are not exact copies but are "highly similar" to reference biologics, requiring rigorous comparability studies to demonstrate equivalent safety and efficacy. They play a critical role in improving affordability and access to advanced therapies globally (3).

Table1. Examples of Marketed biosimilars in the IVFsector

Sl No.	Biosimilar Name	Reference Product	Molecule (API)	Indication in IVF	Manufacturer	Approved Region
01.	Ovaleap	Golan-f	Recombinant Human FSH (Follitropin alfa)	Controlled Ovarian stimulation	Teva Pharma B.V./Theramax	Europe
02.	Zyfoll	Golan-f	Recombinant Human FSH	Infertility treatment	Zydus Life Sciences	India
03.	Folisurge	Golan-f	Recombinant Human FSH	Ovarian stimulation	Intas Pharmaceuticals	India

04.	Folitime	Golan-f	Recombinant Human FSH	Controlled Ovarian stimulation	Intas Pharmaceuticals	India
05.	Bemfola	Golan-f	Recombinant Human FSH (Follitropin alfa)	Ovarian follicle development	Gedeon Richter PLC/Finox Biotech	Europe Australia
06.	Primapur	Golan-f	Recombinant Human FSH	Ovarian stimulation	IVFarma	Russia

3. The Need for a Shift in India

3.1 Growing Healthcare Demand

India is experiencing increasing rates of chronic diseases and infertility. Lifestyle changes, delayed parenthood, and environmental factors have contributed to growing demand for assisted reproductive technologies. IVF demand is rising rapidly, but treatment costs remain a barrier (4).

3.2 Economic Opportunity

Indian pharmaceutical companies such as Biocon and Dr. Reddy's Laboratories are investing in biosimilars to tap into global markets while addressing domestic needs.

The biologics market is expanding rapidly, and biosimilars are becoming essential for sustainable healthcare systems. India's entry into this segment allows:

- Global market penetration
- Domestic cost reduction
- Technological advancement
- Patent expirations creating entry points
- India's manufacturing advantage

3.3 Patent Expirations

Many biologics used in reproductive medicine are losing patent protection, enabling biosimilar entry and price competition.

4.1 Role of Biologics in IVF

IVF treatment relies heavily on biologics, including:

- Recombinant FSH (ovarian stimulation)
- Human chorionic gonadotropin (hCG)
- Luteinizing hormone (LH)

These drugs stimulate ovarian follicle growth and are essential for IVF success. FSH is particularly critical, as it stimulates ovarian follicle development and directly influences IVF success rates.

4.2 Emergence of Biosimilars in IVF

Recent years have seen the development of biosimilars of rFSH (e.g., follitropin alfa biosimilars). These drugs:

- Are structurally and functionally similar to originators
- Follow the same dosage and administration protocols
- Require stringent regulatory approval

Studies confirm that biosimilar rFSH demonstrates comparable efficacy and safety to original biologics.

4.3 Cost and Accessibility Impact

Biologics constitute a major portion of IVF costs. Biosimilars can:

- Reduce drug expenditure significantly
- Increase treatment accessibility
- Expand IVF adoption beyond high-income groups

4.4 Clinical Considerations

Clinical and real-world studies indicate the following:

- Biosimilars must demonstrate equivalence in ovarian response and pregnancy rates
- Physician confidence is essential for adoption
- Regulatory oversight ensures safety and quality

A large proportion of IVF practitioners report no significant difference in outcomes between biosimilars and originators, though awareness and confidence are still evolving (3).

4.5 Cost Barrier in India

An IVF cycle in India can cost ₹1.5-2.5 lakh or more, with medications contributing up to 40-60% of the total expense. Imported biologics further increase costs. Globally, cost pressures have driven the adoption of biosimilar FSH due to patent expirations and affordability concerns (3).

5. Challenges in India's Biologics Transition

5.1 Regulatory Framework

Biosimilars require extensive clinical trials and comparability data, making approval more complex than generics. Approval processes governed by the Central Drugs Standard Control Organization require continuous strengthening to match global standards.

5.2 Manufacturing Complexity

Biologics production involves:

- Advanced biotechnology infrastructure
- Skilled workforce
- Stringent quality control

5.3 High Investment Requirements

Development timelines are long and capital-intensive compared to generics. Developing biosimilars requires significant capital, long timelines, and clinical validation.

5.4 Adoption Barriers

- Limited awareness among clinicians
- Concerns regarding interchangeability
- Need for real-world evidence

6. Policy and Strategic Recommendations

6.1 Strengthening Regulatory Frameworks

India should align with global standards to ensure faster approvals and international acceptance.

6.2 Investment in Infrastructure

Provide incentives for biologics research and infrastructure. Example:

- Biotech parks
- Skilled workforce development
- Advanced manufacturing facilities

6.3 Promote public-private partnerships

Collaboration between academia and industry can accelerate innovation.

6.4 Enhancing Awareness

Educational initiatives for doctors and patients will increase biosimilar adoption. Educate clinicians about biosimilar efficacy and safety.

6.5 Expanding Insurance Coverage

Including IVF and biologic therapies in insurance schemes can improve accessibility.

7. Conclusion

India's shift toward biologics and biosimilars is both necessary and strategic. The IVF case highlights the transformative potential of biosimilars in reducing costs and expanding access to advanced treatments. With appropriate regulatory support, investment, and awareness, India can emerge as a global leader in biosimilars while addressing critical domestic healthcare challenges (5). The IVF example demonstrates how biologics dominate high-cost therapeutic areas and how

biosimilars can democratize access. India’s transition is not merely industrial but socio-economic, directly affecting healthcare equity.

8. References

1. Bergandi L, et al. Human recombinant FSH and its biosimilars: clinical efficacy, safety, and cost-effectiveness in IVF. Pharmaceuticals. 2020;13(7).
2. Rizwan A, et al. Biosimilars: bridging the gap in biologics, access, and affordability. J. Pharm. BioTech Ind. 2026, 3(1), 2; https://doi.org/10.3390/jpbi3010002
3. Sanagoudar S, et al. Efficacy and safety of biosimilar rFSH versus originator in IVF. Cureus. 2025.
4. Youssef M, et al. Biosimilar follitropin alpha in IVF: a systematic review, Human Reproduction, Volume 37, Issue Supplement_1, July 2022, https://doi.org/10.1093/humrep/deac104.012
5. Bergandi L, et al. Clinical efficacy of biosimilar rFSH in IVF. Pharmaceuticals. 2020;13(7).

Unlocking Alzheimer's: Biologics To Biosimilars- India's Healing Horizon



Bheemachari, Firdos Sultana , RaziyaBegum*

Aruna College of Pharmacy. Behind Ashwini Ayurvedic Hospital, Maraluru Ring Road, Tumakuru. Karnataka-572105

Email: emraan2002@gmail.com

Abstract

To address the growing need for complex medications, India must strategically shift toward biologics and biosimilars, utilizing its manufacturing capabilities in the face of a worldwide patent cliff. For conditions such as Alzheimer's, where biologics such as anti-amyloid antibodies show promising results, this shift promotes easy access. Bharat explores therapeutic potential through integrated therapeutics, encompassing traditional bioactives such as flavonoids like quercetin and curcumin, alongside biosimilars like donanemab, which have the ability to directly affect pathogenic events such as dysregulated gene expression, tau hyperphosphorylation, and amyloid formation. Moreover, since AD is a heterozygous disorder, biologics can provide a pathway to disease-modifying therapies that can be tailored to the genetic and molecular profile of a patient. This presents India (Bharat) as a pioneer in fusing traditional knowledge with cutting-edge biotechnology for comprehensive and cost-effective management of Alzheimer's disease.

Keywords: Alzheimer’s, Bioactive, Biosimilar, Donanemab

1. Introduction

India is now among the most vibrant biosimilar centres of the globe, and its biosimilar ecosystem is advanced and rapidly expanding. The 146 biosimilars (recombinant medicinal products) approved by India by December 2025 included insulins, growth factors, peptide hormones, fusion proteins, and monoclonal antibodies. India began developing and regulatory approving recombinant medicines much earlier than other growing economies with the first approvals being first reported as early as 2000. However, throughout the first ten years, biosimilar activity was still restricted to relatively basic recombinant proteins such as insulin, follicle-stimulating hormone, erythropoietin, and granulocyte colony-stimulating factors.

Following 2018, the approvals of biosimilars have risen dramatically. The significant increase in the number of approvals between 2020 and 2024 was driven by multiple approvals of monoclonal antibody biosimilars in immunology and oncology and an increase in the number of approvals of insulin analogs and peptide hormones. The peptide- and protein-based biosimilars constitute the basic layer of the ecosystem in India biosimilars and have been able to secure about 74 approvals within this time. The biggest and quickest growing segment since 2013 is antibody and fusion protein-based biosimilars, which have about 72 approvals as of December 2025.

The common type of dementia is Alzheimer disease (AD), a multifactorial neurodegenerative CNS disease prevalent in the elderly population. With over 300 million elderly people in a silver tsunami by 2026, India is projected to have over 5 million cases of Alzheimer's (third in the world) and 10 million cases in 2030 (1). On the molecular scale, AD is defined by oxidative stress that causes deposition of neurofibrillary tangles (2, 3). β-amyloid plaques and mitochondrial dysfunction (4), neuroinflammation (5), loss of synapses (6), and eventually, massive neuronal degeneration, especially in the hippocampus and cerebral cortex. Thus, it may be possible to prevent the appearance of these aggregates by using natural antioxidants or ROS scavengers (7). The recent advancements of fluid and imaging biomarkers in the prediction of AD even during preclinical stages have been significantly improved, including computerized cognitive tests and plasma phosphorylated tau (pTau217). The changes in the Apolipoprotein E (ApoE) gene, especially the ApoE4 allele, have been significantly linked to an increased likelihood of AD and a younger onset (8). Likewise, anti-aggregating/AB-degrading molecules might be useful in preventing AD. Otherwise, conventional anti-Alzheimer medications like AChEl and NMDA receptor antagonists (9) improve memory and attention deficits but only superficially help to prevent or reverse disease progression. Over the past years, biologic therapies, including monoclonal antibodies, vaccines, antisense oligonucleotides (ASOs), and gene therapies, have become a significant part of promising disease-modifying approaches.

2. Current situation of Alzheimer's disease in India

India is a country with a growing burden of Alzheimer's disease, with the highest number of patients in the world and a potential 80 lakh cases of dementia by 2030. Due to the rising aging population and unmet needs, the market size of the Alzheimer's therapeutics market will grow by a compound annual growth rate (CAGR) of 28% between the 2022 value of USD 41.3 million and USD 297.4 million by 2030. Most of the existing therapies consist of symptomatic small molecule drugs, but only a limited number of disease modification options exist, which are expensive (10).

2.1. New Biologics for Alzheimer's and Access in India

Disease-modifying biologics, such as lecanemab (Eisai/Biogen) and donanemab (Eli Lilly), which are monoclonal antibodies that target amyloid plaques, are a breakthrough. Donanemab was approved globally and in India in late 2025, with a scheduled launch in 2026. These reduce cognitive deterioration, but most Indians cannot afford them without affordability measures because they cost thousands of dollars per dose (11).

2.2. The Biologics and Biosimilars Ecosystem in India

The country is currently growing through BioPharma SHAKTI (a ₹10,000 crore project from the 2026 Union Budget) and 2025 draft guidelines that are in accordance with FDA/EMA for quicker approvals and non-animal testing. The biosimilars market is expected to increase at a 21% CAGR from USD 184 million in 2026 to USD 1.02 billion by 2035, driven by manufacturing strengths and patent expirations. By 2025, more than 200 novel biologics are expected to be developed (12).

2.3. Why India Needs This Alzheimer's Shift

Biosimilars could reduce costs by 30–40% through local manufacturing, legislative support (such as clinical trial waivers), and export agreements such as the 2026 India-US trade agreement. Originator biologics, such as donanemab, are expensive and unavailable on a large scale. This is consistent with the Indian pharmaceutical industry's shift from generics to high-value biologics and biosimilars, tackling Alzheimer's epidemics with precision treatments, biomarkers, and monoclonal antibody research and development. Regulations and hefty development expenses are obstacles, yet programs like SHAKTI establish India as a worldwide center (13).

2.4. Mechanistic approach of biologics and biosimilars in Alzheimer’s

Curcumin is a pharmacologically safe natural product, which suppresses the expression of Egr-1 protein and Egr-1 DNA-binding activity in THP-1 monocytic cells induced by Ab. Previous studies have shown that curcumin inhibits tissue factor gene expression in endothelial cells by affecting the transcription factors Egr-1, AP-1 and NF-kB. was effective in blocking amyloid peptide-induced cytochemokine expression, indicating that a low dose of curcumin may be effective in preventing amyloid peptide-induced neuroinflammation in Alzheimer’s disease (14, 15).

Previous studies have implied that long-term (12-month) oral preventive quercetin administration significantly reduces amyloidosis and tends to reduce tauopathy in the amygdala and hippocampal regions. These reductions had a positive impact on the 3xTg-AD mice's cognitive functional recovery without changing their emotional abilities (16). Quercetin crosses the blood-brain barrier, lowers ROS levels through Nrf2 activation, and modifies microglia (M1 to M2 shift).

Meta-analyses from 2024-2026 highlight promising cognitive benefits of natural compounds like curcumin and flavonoids in mild Alzheimer's disease (AD), while India-led nano-curcumin research addresses bioavailability hurdles for better progression control (Cognitive Improvement Meta-Analyses) (15–30%) (17). Curcumin inhibits BACE1 (Aβ synthesis) and AChE (cholinergic boost). Aβ/tau sites have binding affinities of -7 to -9 kcal/mol according to in silico docking.

Using measures such as the MMSE (Mini-Mental State Exam) and Alzheimer's Disease Assessment Scale-Cognitive (ADAS-Cog), recent systematic reviews (2024–26) pooled RCTs on natural extracts/compounds (≥6 weeks), demonstrating 15–30% improvements in mild AD/MCI.

Conventional curcumin bioavailability is low (~1%, fast metabolism); however, brain transport is made possible by nanoformulations (liposomes, SLNs, and micelles) that increase it 12–20 times (or 700–2000% with piperine/nano adjuvants). AIIMS/NIMHANS research: ICMR-funded Indian studies from 2023 to 2026 examine nano-curcumin, which results in a 20% slower development of mild AD (Morris Water Maze/MMSE metrics); it also restores Akt/CaMKII-α signaling and reduces hippocampal apoptosis by 40–50% in STZ models (brain insulin resistance). One study found that simple curcumin reduced plaque by 20% compared to 20x plasma levels (15).

The top drug authority in India has approved donanemab, one of the two groundbreaking treatments praised worldwide for exhibiting encouraging outcomes in the treatment of Alzheimer's disease, and its manufacturer, Eli Lilly and Company, is getting ready to introduce it in a few months

For patients with mild cognitive impairment (MCI) and those in the mild dementia stage of early symptomatic Alzheimer's disease, the most prevalent type of dementia, medication is administered as monthly injections that target amyloid.

Given the poor results of previous pharmacological treatments for Alzheimer's disease, the introduction of lecanemab and donanemab has sparked global interest. However, researchers and medical professionals have cautioned that these medications have limitations. Monoclonal antibodies are produced in laboratories. They are used to treat a variety of illnesses, and they are created to bind to particular targets in the body. Donanemab is the second monoclonal antibody licensed in several nations to treat Alzheimer's, a neurodegenerative disease that frequently advances quickly, after lecanemab by Eisai and Biogen.

According to the findings of clinical trials, they may have adverse effects, such as bleeding and swelling of the brain, which can be fatal. Additionally, according to Lilly, donanemab may cause severe side effects, including infusion-related responses and amyloid-related imaging abnormalities (ARIA). There are currently no disease-modifying medications such as donanemab available in the market. To produce safety and efficacy data for India, a local Phase IV study or post-marketing surveillance would be carried out.

3. Conclusion

India can provide scalable disease-modifying medicines, reducing the AD epidemic while exporting innovation, turning burden into a healing horizon by creating donanemab biosimilars and producing nano-bioactives.

4. References

1. https://www.grandviewresearch.com/horizon/outlook/alzheimers-therapeutics-market/india. Accessed on 15.04.2026
2. Gulisano W, Maugeri D, Baltrons MA, Fà M, Amato A, Palmeri A, et al. Role of amyloid-β and tau proteins in Alzheimer's disease: confuting the amyloid cascade. J Alzheimers Dis. 2018;64:S611–S631. doi:10.3233/JAD-179935.
3. Zhang H, Wei W, Zhao M, Ma L, Jiang X, Pei H, et al. Interaction between Aβ and tau in the pathogenesis of Alzheimer's disease. Int J Biol Sci. 2021;17:2181–2192. doi:10.7150/ijbs.57078.
4. Ashleigh T, Swerdlow RH, Beal MF. The role of mitochondrial dysfunction in Alzheimer's disease pathogenesis. Alzheimers Dement. 2023;19:333–342. doi:10.1002/alz.12683.
5. Zhang W, Xiao D, Mao Q, Xia H. Role of neuroinflammation in neurodegeneration development. Signal Transduct Target Ther. 2023;8:267. doi:10.1038/s41392-023-01486-5.

6. Subramanian J, Savage JC, Tremblay M. Synaptic loss in Alzheimer's disease: mechanistic insights provided by two-photon in vivo imaging of transgenic mouse models. Front Cell Neurosci. 2020;14:592607. doi:10.3389/fncel.2020.592607.
7. Moya-Alvarado G, Gershoni-Emek N, Perlson E, Bronfman FC. Neurodegeneration and Alzheimer's disease (AD): what can proteomics tell us about the Alzheimer's brain? Mol Cell Proteomics. 2016;15:409–425. doi:10.1074/mcp.R115.053330.
8. Maruszak A, Silajdžić E, Lee H, Murphy T, Liu B, Shi L, et al. Predicting progression to Alzheimer's disease with human hippocampal progenitors exposed to serum. Brain. 2023;146:2045–2058. doi:10.1093/brain/awac472.
9. Liu J, Chang L, Song Y, Li H, Wu Y. The role of NMDA receptors in Alzheimer's disease. Front Neurosci. 2019;13:43. doi:10.3389/fnins.2019.00043.
10. Grand View Research. Alzheimer's therapeutics market in India [Internet]. Available from: https://www.grandviewresearch.com/horizon/outlook/alzheimers-therapeutics-market/india
11. Gupta R. The role of blood-based biomarkers in managing the epidemic of Alzheimer's disease in India. Future Health. 2026 Jan 8.
12. Current Affairs AI. Biopharma Shakti to transform biologics and non-animal models [Internet]. Available from: https://currentaffairsai.com/daily-current-affairs/biopharma-shakti-transform-biologics-non-animal-models-article4117
13. Pallium India. The promise of biosimilars in India [Internet]. 2025 Jul. Available from: https://palliumindia.org/2025/07/the-promise-of-biosimilars-in-india
14. Pendurthi UR, Rao LV. Suppression of transcription factor Egr-1 by curcumin. Thromb Res. 2004;97:179–189.
15. Moosavi M, Soukhaklari R, Bagheri-Mohammadi S, Firouzan B, Javadpour P, Ghasemi R. Nanocurcumin prevents memory impairment, hippocampal apoptosis, Akt and CaMKII-α signaling disruption in the central STZ model of Alzheimer's disease in rat. Behav Brain Res. 2024;471:115129. doi:10.1016/j.bbr.2024.115129.
16. Paula PC, Angelica Maria SG, Luis CH, Gloria Patricia CG. Preventive effect of quercetin in a triple transgenic Alzheimer's disease mice model. Molecules. 2019;24(12):2287. doi:10.3390/molecules24122287.
17. Hoang LN, Lee H, Lee SJ. Improving cognitive impairment through chronic consumption of natural compounds/extracts: a systematic review and meta-analysis of randomized controlled trials. Front Aging Neurosci. 2025;16:1531278. doi:10.3389/fnagi.2024.1531278.

Next-Generation Therapeutics In India: Bridging Innovation And Accessibility Through Biosimilars In The Precision Medicine Era

Lathamani Lakshmanan*, Snehal Dasharath Pawar, Dhanasekar Jayakumar, Sudhamani Thangavel, Selvakumar muruganandham, Nandhakumaran Subramanian

Department of Pharmaceutics, Vivekanandha Pharmacy College, Sankari, Salem, Tamil Nadu - 637 303 (Affiliated to The Tamil Nadu DR MGR Medical University, Chennai)

Email: lathamanilakshmanan@gmail.com

Abstract

Biosimilars are an important milestone in the health care industry, particularly in the era of precision medicine, as they offer cost-effective alternatives to the complex and expensive originator biologics. Biologics are medications with active ingredients that are derived from biological molecules (such as proteins), and therefore, due to its high target. specificity and biological compatibility. Biologics have had a major impact on the treatment of many diseases such as cancer, autoimmune diseases and genetic disorders. However, their high development and manufacturing costs tends to limit the access to these drugs, and can easily cost tens of thousands of dollars per patient per year. Biosimilars, which are developed to be similar in quality, safety and effectiveness

to reference biologic. India, in particular, has been positioned to be a giant in the global market of biosimilar products by leveraging its own strong pharmaceutical industry to enhance access to healthcare services with these technologies. This overview will explore the intricate biosimilar landscape in India, its regulatory and market aspects, as well as the role of biosimilars in innovation and accessibility in the era of precision medicine.

Keywords: Biosimilars, Precision medicine, Next-generation therapeutics

1. Introduction

Biologics, also known as biopharmaceutical products, have a history of clinical application, dating back more than 30 years, and offer considerable therapeutic advantages to degenerative and critical metabolic disorders (1). These advanced therapies accounted for nearly one-quarter of global drug spending in 2015, a fraction expected to grow further, especially for conditions like cancer, diabetes, and immune disorders (2). Biologics are successful due to their ability to be complex in terms of structure, which allows high levels of target specificity and biological compatibility (3). However, the high cost associated with their development, manufacturing, and procurement limits patient access, particularly in developing nations (4). Biosimilars have proven to be an important solution to these accessibility problems. They are biologic drugs, which are very similar to reference biologics, providing low-cost substitutes when the patents of originator drugs are out of date (5, 6, 7). The concept of precision medicine, which tailors medical treatment to individual patient characteristics, is increasingly integrating these advanced biological therapies. Such integration is especially required in India, where there is a large disparity in the provision of medical services and inequality in the spread of health benefits (8). This review aims to comprehensively analyze the role of biosimilars in bridging innovation and accessibility in India within the precision medicine era.

2. Biologics vs Biosimilars

Biologics are complex biological products derived from living organisms, including hormones, vaccines, monoclonal antibodies, and antibody-drug conjugates (8, 9). They differ in size, structure, and sensitivity to manufacturing conditions compared to chemically synthesized small-molecule drugs, which have a large molecular size, complexity, and sensitivity to their production processes (Figure 1) (9, 10). Such complexity implies that even minor changes in the manufacturing conditions can cause changes in the pattern of glycosylation, folding, and other post-translational

modifications of the final product, which may affect their immunogenicity, efficacy, and safety (4, 10).

Biosimilars are biological products highly resembling a prior approved reference biologic and have no clinically meaningful differences in regard to quality features, biological activity, safety, or efficacy (5, 11, 12). They are not the same as their reference products but are similar but not the same (9). This is their essential difference with generic drugs, which are the same chemical copies of small-molecule drugs and which normally only need bioequivalence studies to be approved (7, 10). The biosimilar approval routes necessitate deep analytical characterization, *in-vitro*, functional assessments, and comparative clinical testing to show biosimilarity, alternatively known as a totality of evidence strategy (Table 1) (5, 6).

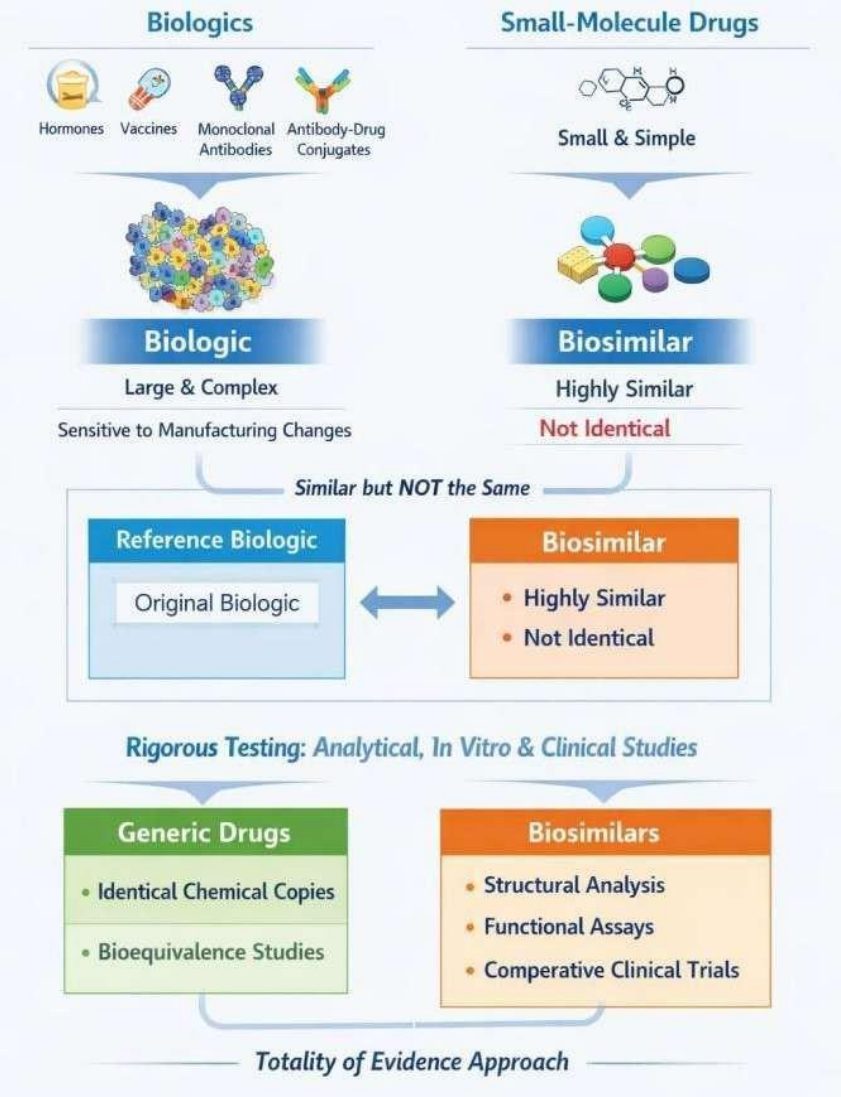

Figure 1. Biologics Vs Small molecule drug

Table 1. Comparative overview of generics, biosimilars, and reference biologics (3, 4)

S. No.	Feature	Generics (Small Molecule)	Biosimilars (Biologic)	Reference Biologics
1	Nature	Chemically synthesized, simple structure	Biologically derived, complex structure	Biologically derived, complex structure
2	Similarity	Identical copy to originator	Highly similar, but not identical	Original, innovator product
3	Manufacturing	Straightforward chemical synthesis	Complex biological processes	Complex biological processes
4	Approval pathway	Bioequivalence studies	Totality of evidence (analytical, functional, clinical)	Full clinical development (novel drug approval)
5	Cost	Significantly lower than originator	Lower than reference biologic, higher than generics	Very high due to R&D and manufacturing
6	Interchangeability	Generally interchangeable with originator	Interchangeability requires specific regulatory designation	Nil

3. Precision Medicine and Next-Generation Therapeutics

Precision medicine is proposed to tailor medical therapy according to the individual differences in genes, environment, and lifestyle (6). Biologics are central to this paradigm because they are very specific in their mechanism of action, which makes it possible to conduct a targeted therapy that engages specific disease pathways or cell targets (3). Indicatively, monoclonal antibodies may be engineered to block certain growth factor receptors in cancer or quench inflammatory cytokines in autoimmune diseases, resulting in better and less toxic therapies against certain patient groups (Figure 2) (6, 9).

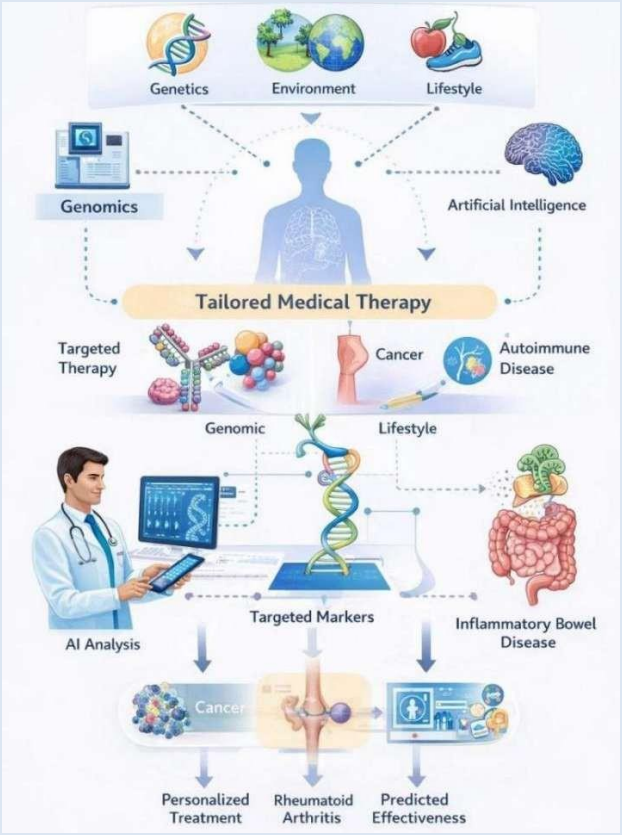

Figure 2. Precision Medicine & Next Generation Therapeutics

The convergence of genomics and artificial intelligence (AI) is also contributing to the accuracy of the approach to precision medicine further (13). Genomic information can also be used to determine genetic markers of susceptibility to disease, disease progression, and response to particular biologics which can be used by clinicians to decide the most appropriate treatment to be used on a particular patient (14). Artificial intelligence algorithms have the potential to process large volumes of patient data, such as genetic data, clinical outcomes, and imaging data, and extract patterns, predicting the effectiveness of treatment and thus personalizing therapy (13). This is especially important in treating chronic and complex conditions, including different types of cancer, rheumatoid arthritis, and inflammatory bowel diseases, in which patient responses to traditional therapies may be highly variable (6, 15).

4. Indian Biosimilar Landscape

India has established itself as a leader in the biosimilar industry, showing impressive growth in its development, production, and distribution of these complex biologics (12, 16). The pharmaceutical industry of India, which is already a large producer of generic drugs and vaccines around the world, has used their strong manufacturing capacities to

play a major role in the biosimilar market (16). India has the unique distinction of having the biggest number of approved biosimilars globally (12). Major Indian corporations, including Biocon and Dr. Reddy's Laboratories, have led this growth, making investments in process innovation to strengthen their competitiveness (17). An example is Biocon, which has managed to commercially produce biosimilar trastuzumab, which has greatly enhanced access to treatment by the patients of HER2+ breast cancer in India (18). Likewise, in 2015, India became the first country in the world to license a ranibizumab biosimilar, Razumab (Intas Pharmaceuticals Limited), long before the expiration of the patent on the innovator product in key Western markets
(29). It has proactively caused an influx of new drug filings and biosimilar ranibizumab approval in India in particular, to the point that the country already has the highest number of approved ranibizumab biosimilars in the country (29). Three of these market trends show that there is a robust domestic potential in the development and production of biosimilars in India with an aim of overcoming the high cost and accessibility challenges related to the use of the originator biologics, thus contributing to the growth of healthcare accessibility in India (Figure 3) (8, 12).

Figure 3. Indian Biosimilar Landscape

5. Regulatory Framework

A regulatory control on biosimilars exists in India that is largely controlled by the Department of and Central Drugs Standard Control Organization (CDSCO) (20, 21). All these organizations have worked together to create an extensive regulatory framework that incorporates the guidelines on similar biologics, which were introduced on August 15, 2012 (20). According to such guidelines, manufacturers must demonstrate similarity to an approved reference biologic in India or one licensed and marketed for at least four years in a regulated market (20). The approval process in India relies on rigorous test requirements such as the analytical characterization, functional assays, non-clinical studies, and comparative clinical trials to establish biosimilarity in terms of quality, safety, and efficacy (21). A comparative study of the regulatory system of India and those of the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) shows some similarities and differences. Each of the three regulatory bodies uses a totality of evidence approach and would need extensive data packages to prove the existence of biosimilarity (11, 22). There are, however, some major differences. The regulatory environment in India has some of the most restrictive provisions like compulsory local trials, which may be a major impediment to market entry (22). Also, interchangeability guidelines and pricing controls differ as compared to the US FDA and EMA (24). Although the international trend is to harmonize regulation to enable the development and approval process of biosimilars, especially in vaccines and immunotherapeutics, existing differences among countries pose problems to developers (Figure 4) (23).

Figure 4. Regulatory framework for Biosimilars

6. Biosimilar Adoption challenges

Although the benefits are markedly evident, the mass adoption of biosimilars is associated with a number of serious challenges. One of the major concerns is regulatory challenges. The international market entry and acceptance of biosimilars is complicated by divergent approval pathways and different needs of various countries (23). For instance, India's requirement for mandatory local clinical trials can add to the time and cost of development (22). The other significant impediment is the complexity of manufacturing. Biologics and biosimilars are big, complex molecular structures generated in biological systems, which complicates their production processes and renders them complex and delicate to manufacture (4, 17). This involves highly skilled biotechnological applications, high-quality control, and intense investment, which adds to the long development cycles and high expenses (17, 24). Developing a biosimilar in India, for example, can demand an investment of approximately 65-70 million USD and nearly a decade from inception to post-market studies (24).

Biological products have immunogenicity issues that are imperative. Biologics consisting of proteins are capable of eliciting an immune response and lead to the production of anti-drug antibodies (ADAs) (4). These ADAs can reduce the effectiveness of medications, slow the rate of clearance, or cause adverse events (4). Evidence that a biosimilar has no clinically significant differences in immunogenicity from its reference product is a difficult but a critical part of the approval process (Figure 5) (4).

Physician and patient awareness and perceptions also significantly influence adoption rates (25, 26). Concerns regarding the efficacy, safety, and reliability of biosimilar data, even when robust evidence supports their similarity to originator biologics, can limit their acceptance in clinical practice (26, 27). Studies in India show that while clinicians generally agree on the importance of biosimilars for increasing access and reducing costs, concerns about efficacy and safety persist (26). These perceptions need to be addressed through effective educational programs and open communication strategies to promote trust (25). Lastly, stringent pharmacovigilance and post-marketing surveillance are essential to constantly check the safety and effectiveness of biosimilars in real-world conditions in the long term (4).

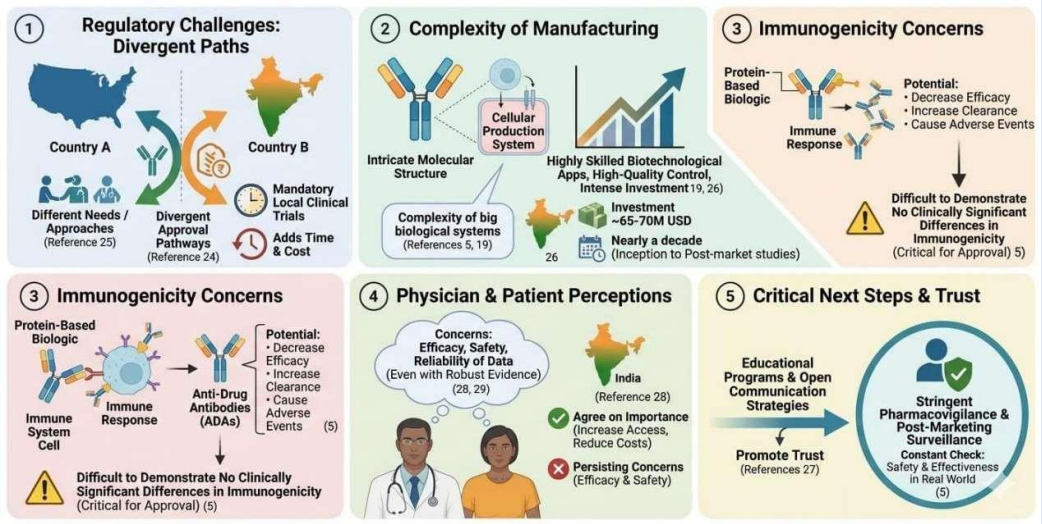

Figure 5. Overcoming Critical Challenges in Biosimilar Adoption

7. Economic and Healthcare Impact

Biosimilars are promising a significant saving opportunity, which is the most important factor to relieve the financial stress on health systems and increase access to more advanced treatment options among patients (6, 29). The prohibitive price of originator biologics has traditionally posed a strong obstacle to care, especially in resource-limited environments (14). Biosimilars create a competitive force in the market and are usually associated with a decline in price (6). These cuts may be less significant (approximately 20 percent to 40 percent) than the 70 percent to 90 percent of big-molecule generics, but the savings that biologics will create will still be enormous owing to their high initial price (29). The enhanced patient access that biosimilars provide can be translated into earlier and more regular treatment of various chronic and life-threatening illnesses, including cancer, diabetes, rheumatoid arthritis, and other immune-related diseases (6, 15, 28). This increased access may result in improved health outcomes, quality of life, and decreased disease progression (6). Biosimilars play a crucial role in India in filling the current disparity in medical services provision and enhancing more equal health provisions to the populace (8). Biosimilars can be crucial in the transition to universal healthcare objectives and in the provision of advanced treatment to a larger portion of the population by making biological therapies more affordable and accessible (12).

8. Future Perspectives

The future of biosimilars is likely to be characterized by sustained innovation and growth, which will be greatly affected by technological advances. Artificial intelligence (AI) is expected to become more significant in different steps of biosimilar

development (13). This involves speeding up research and discovery, streamlining complex manufacturing, and improving clinical trial design by anticipating patient reactions and finding optimal study parameters (13). The combination of AI has the potential to create so-called personalized biosimilars, i.e., biosimilar therapies that are further customized to patient features, thus taking the precision medicine agenda a step further. With its existing manufacturing capabilities and biosimilar market leadership, India is poised to exploit a huge export opportunity (16, 17). India can further the cause of global affordable healthcare solutions by still innovating with the process development and not compromising on the quality of production (17). In order to achieve this potential to the fullest, further policy enhancements are necessary. These involve the simplification of regulatory routes, the creation of a welcoming atmosphere to innovation, and improved market accessibility to biosimilars within the country and abroad (22, 24). The alignment of global regulations is especially important because harmonized standards may lead to a considerable decrement in the cost of development and speed up the global accessibility of these vital medicines (23).

9. Conclusion

Biosimilars play a crucial role in overcoming the barrier between game-changing and expensive biologics and accessibility by patients, particularly in the changing age of precision medicine (3, 6). India has shown to be a global pioneer in this field, with its strong pharmaceutical sector being used to make it a global center in producing and distributing biosimilar products and services (12, 16). Although some still struggle to overcome issues like harmonization of regulations, the complexity of the manufacturing process, stringent testing of immunogenicity, and improving clinician and patient acceptance, the overall financial and healthcare value of biosimilars cannot be denied (23, 24, 26). Biosimilars facilitate patient access to life-altering therapeutic options, better patient outcomes, and lower healthcare access goals by offering cost-effective treatments that help patients and contribute to universal healthcare goals (6, 8, 12). Further development of artificial intelligence and adoption of progressive, proactive policy frameworks will further cement India as a key player in the future of next-generation therapeutics and equitable availability of these essential biological medicines worldwide.

10. References

1. Aggarwal G, Nagpal M, Sharma A, Puri V, Dhingra GA. Upcoming drifts in bio-similars. Curr Rev Clin Exp Pharmacol. 2021;16(1):39–51.https://doi.org/10.2174/1574884715666200507131943
2. Eisenstein M. Bring on the biosimilars. Nature. 2019;569(7755):S2–S3. https://doi.org/10.1038/d41586-019-01401-5
3. Kalaw San Pascual JC, Kangsamaksin T. Biologics, biosimilars, and biobetters: therapeutic innovations reshaping modern medicine. Adv Biol. 2025;9(12).https://doi.org/10.1002/adbi.202500326
4. Kaur S, Yadav S, Sahu V, Sharma N, Shukla VK. Biosimilar regulations: current framework and future prospects. Curr Drug Saf. 2025;20.https://doi.org/10.2174/0115748863360017250509063745
5. Kim H, Alten R, Avedano L, Dignass A, Gomollón F, Greveson K, et al. The future of biosimilars: maximizing benefits across immune-mediated inflammatory diseases. Drugs. 2020;80(2):99–113. https://doi.org/10.1007/s40265-020-01256-5
6. Kajale M, Kakuste S, Raut H, Kakad A, Shaikh MRN. Biosimilars: an emerging therapeutic approach. Int J Pharm Biomed Sci. 2023;3(9). https://doi.org/10.47191/ijpbms/v3-i9-08
7. Singh P, Desai PN, Dutta V. Rising biosimilars in the Indian biopharmaceutical industry: emerging challenges and way forward. Technol Anal Strateg Manag. 2021;35(9):1145–60. https://doi.org/10.1080/09537325.2021.1994139
8. Sinha S, Raphael R. Developing biosimilars: challenges and opportunities. Pharm Med. 2025;39(5):341–52.https://doi.org/10.1007/s40290-025-00578-7
9. Mehra A, Kaur H, Fatima A, Noor A, Gupta K, Shukla A, et al. Biosimilars: novel emerging field of biomedicine. Int J Pharm Sci Nanotechnol. 2021;14(5):5588–93. https://doi.org/10.37285/ijpsn.2021.14.5.2
10. Kute N, Mankar SD, Bhawar SB. Biosimilar and its current perspective – a review. Res J Pharmacol Pharmacodyn. 2022:84–88. https://doi.org/10.52711/2321-5836.2022.00015
11. Hammoodi R, Khalaf M. The current status of regulation of biosimilars in India, the United States of America, and Europe. J Soc Sci Humanit. 2025;7(4):112–17.https://doi.org/10.53469/jssh.2025.7(04).19
12. Varghese D, Karbelkar S. Current state of regulatory oversight of biosimilars in India and its implications on the quality of drugs: a comparative assessment with EU and FDA regulations. J Biotechnol Bioinform Res. 2021:1–7. https://doi.org/10.47363/jbbr/2021(3)140
13. Wu Y, Xi S, Yao Y, Xu F, Tong H, Lu J. Guiding supervised topic modeling for content based tag recommendation. Neurocomputing. 2018;314:479–89. https://doi.org/10.1016/j.neucom.2018.07.011
14. Si C, Yang D, Hashimoto T. Can LLMs generate novel research ideas? A large-scale human study with 100+ NLP researchers. arXiv. 2024. https://doi.org/10.48550/ARXIV.2409.04109
15. Priyarega S, Natarajan R. An overview of biosimilars for cancer, diabetes mellitus, rheumatoid arthritis and other immune-mediated diseases approved between 2016 and 2021. Results Chem. 2022;4:100356.https://doi.org/10.1016/j.rechem.2022.100356
16. Panda S, Singh PK, Mishra S, Mitra S, Pattnaik P, Adhikary SD, et al. Indian biosimilars and vaccines at crossroads–replicating the success of pharmagenerics. Vaccines. 2023;11(1):110.https://doi.org/10.3390/vaccines11010110
17. Rathore A, Shereef F. Innovating manufacturing technology in emerging economies. Nat Biotechnol. 2022;40(12):1714–16.https://doi.org/10.1038/s41587-022-01499-5
18. Ramanjinappa N, Upveja KH, Agarwal J. Shifting trends in the usage of trastuzumab with its biosimilar inception in India. J Clin Oncol. 2023;41(16 Suppl):e13037. https://doi.org/10.1200/jco.2023.41.16_suppl.e13037
19. Sharma A, Kumar N, Parachuri N, Bandello F, Loewenstein A, Kuppermann BD. Biosimilar ranibizumab in India: overview of phase 3 clinical trial designs. Eye. 2024;38(10):1796–98.https://doi.org/10.1038/s41433-024-03001-8

20. Kumar A, Jha A. Biosimilars: present status, challenges and future prospects. 2021. https://doi.org/10.9734/jpri/2024/v36i127639
21. Ashok Kumar P, Nayana GU, Nithin N, Sharath Kumar N, Sharvari B, Yashaswini PR. Regulatory requirements for biosimilars as per CDSCO in India in comparison with Yemen. World J Adv Res Rev. 2024;23(3):2292–303. https://doi.org/10.30574/wjarr.2024.23.3.2830
22. S JG, Ramachandran V. Navigating regulatory complexities in biosimilar approvals and imports for autoimmune disorder management: a comparative analysis of FDA (US), EMA (EU), and CDSCO (India) guidelines. Recent Adv Drug Deliv Formul. 2025;19.https://doi.org/10.2174/0126673878360952250715031025
23. Jarab AS, Abu Heshmeh SR, Al Meslamani AZ. Bridging the gap: the future of biosimilars regulations. Hum Vaccin Immunother. 2024;20(1). https://doi.org/10.1080/21645515.2024.2362450
24. Gandhi S, Patankar D, Kashiramka S, Rathore AS. The economics of translating a biosimilar from lab to market in India. Ann N Y Acad Sci. 2024;1541(1):219–29.https://doi.org/10.1111/nyas.15252
25. Patel PK, King CR, Feldman SR. Inertia in adaptation of healthcare system to biologics and biosimilars. J Assoc Physicians India. 2023. https://doi.org/10.59556/japi.71.0278
26. Ramesh A. Clinicians' perceptions and adoption of oncology biosimilars in India: results from a national survey. Indian J Med Paediatr Oncol. 2025;47(2):150–54. https://doi.org/10.1055/s-0045-1811566
27. Thongpooswan S, Das A, Patil P, Latymer M, Llamado L, Wee J. Physicians' and patients' perception of biosimilars and factors affecting biosimilar prescribing in selected Asian countries: a survey study. Expert Opin Biol Ther. 2024;24(10):1171–82.https://doi.org/10.1080/14712598.2024.2400523
28. Shubow S, Sun Q, Nguyen Phan AL, Hammell DC, Kane M, Lyman GH, et al. Prescriber perspectives on biosimilar adoption and potential role of clinical pharmacology: a workshop summary. Clin Pharmacol Ther. 2022;113(1):37–49.https://doi.org/10.1002/cpt.2765
29. Herndon K, Braithwaite J, Berry B, Bourget K. Biosimilar perceptions among healthcare professionals and commercial medical benefit policy analysis in the United States. BioDrugs. 2021;35(1):103–12. https://doi.org/10.1007/s40259-020-00463-6

WORD SCRAMBLER: Indian Biologics Companies

1. SCOBION GLOCIBOLOSI
2. SANTIT PARACEUMHALSCIT
3. RSD EDYD’S LOTBARAOERSI
4. SUYDZ LCESEIFINESC
5. PINUL LITDEMI
6. DRHATCKWO
7. OERTHE SDRUG
8. ECURME PARACEUMHALSCIT
9. EACNRIEL FIEL CSECSNIE
10. EACNAPEA TECIBOT

Emergence, Applications, And Challenges Of Biosimilars In The Indian Healthcare System


Anjali Bhardwaj, Seema Rohilla*

Geeta Institute of Pharmacy, Geeta University, Naultha-132145, Panipat, Haryana, India

E-mail: seemarohilla4@gmail.com

Abstract

This paper explores the realm of biosimilars and how they are transforming the pharmaceutical sector. Unlike generic pharmaceuticals, biosimilars are biologic therapies that are designed to closely mimic authorized reference biologics. This paper attempts to clarify the development and history of biologics, as well as the advantages and difficulties of biosimilars through a thorough examination. The biologic market is now more competitive because of the emergence of biosimilars, which have improved patient access to necessary therapies and reduced costs. Treatment flexibility provided by interchangeability may increase therapeutic adherence. With the production of several biosimilars, India's biopharmaceutical sector has become a powerful force. India's emphasis on biosimilars is in line with the worldwide trend toward affordable biological medicines, even if issues like standardizing legislation, ensuring quality, and encouraging innovation still exist.

Keywords: Biosimilar, Generic drug, Harmonizing regulations

1. Introduction: A Changing Pharma Identity

India has been one of the biggest suppliers by volume of generics during the last 20 years. Almost twenty percent of the world's generic medicine demand is supplied by Indian businesses, which are still growing. However, the global pharmaceutical sector is shifting toward more sophisticated, focused, and individualized treatments. At the vanguard of this change are biologics, which are sophisticated medications derived from living things. Biologics are the years to come of high-value, high-impact therapy alternatives, ranging from

vaccinations and monoclonal antibodies to cell and gene treatments. India's goal is now to become a worldwide leader in sophisticated biologics discovery, development, and production rather than just a low-cost manufacturing hub (1).

The treatment of several chronic and fatal illnesses, including various malignancies, autoimmune conditions, and metabolic abnormalities in the human body, has been transformed by biological products (2). However, the cost of original biologics is excessively costly, particularly in low- and medium-income countries (LMICs), which has restricted the accessibility to these treatments in nearly all circumstances (3). This need led to the creation of biosimilars. In terms of efficacy, purity, and potency, biosimilars are very identical to an already approved reference biologic; they do not exhibit clinically significant variations from the reference biologic in terms of immunogenicity or effectiveness (4). Because they are neither biologics nor comparable in terms of complexity, biosimilars are not considered generic goods. Furthermore, because they are derived from biological systems, they must be developed through rigorous, step-by-step demonstrations of comparability using conceptual, nonclinical, and clinical methods (5). Due to two considerations, the demand for biosimilars is expanding globally: the off-patent of popular biologics and the growing need for sustainable treatment choices and rising healthcare expenditures (6). Due to the Central Drugs Standard Control Organization's (CDSCO) significant involvement in establishing regulatory procedures, India has become a center for leading biosimilar development (7). This chapter gives a summary of the therapeutic uses of biosimilars in India for a range of illnesses, emphasizing both their clinical advantages and the difficulties in adopting and using them.

2. Background: The History and Development of Biologics

Biologics differ from traditional small-molecule medications in that they are large, complex molecules (typically proteins) made utilizing cutting-edge methods like cell culture systems and recombinant DNA technologies. Cancer, autoimmune illnesses, metabolic disorders, and other chronic and potentially fatal conditions can be treated using biologics. (8). Therefore, the advent of biopharmaceuticals throughout the last quarter of the 20th century marked a paradigm change in pharmacotherapy itself, which has highly targeted and precise modes of action. The creation of monoclonal antibodies and medicinal protein, which make up the majority of current biotherapeutic interventions, was made possible by some of the earlier instances, like recombinant insulin and erythropoietin (9).

2.1. Evolution of Biosimilars

Many prospects for biosimilars emerged when the patent durations for all popular biologics sold as therapeutic proteins or monoclonal antibodies ended (figure 1). It is clear that biosimilars are biologic medicines that have no clinically significant differences from a reference biologic in terms of quality, safety, and effectiveness. Because of the complex manufacturing methods and the variability in these biological systems, these biosimilars cannot be precisely replicated, unlike conventional pharmaceuticals (10). Biosimilars are not the same as the reference biologic, unlike generic medications. Due to the complexity of biologics and the manufacturing process, they exhibit slight differences in structure, post-translational modifications, and impurities compared to the reference biologic.

2.2. Approvals and Achievements:

The first biosimilar, Omnitrope® (somatropin), was approved by the European Medicines Agency (EMA) in 2006. Subsequent approvals were granted in highly regulated areas including the US and Japan (11). India was among the first to approve a biosimilar, a hepatitis B vaccination, in 2000. Since then, the worldwide pipeline has grown significantly, and several other biosimilars for endocrinology, rheumatology, and cancer are already available on the market (12). The function of patent expiration Numerous biosimilars has emerged as a result of the "patent cliff" for biologics including trastuzumab, rituximab, and adalimumab. Patent expiries have increased accessibility and lessened the financial strain on health care systems by opening up markets to less expensive alternatives (13).

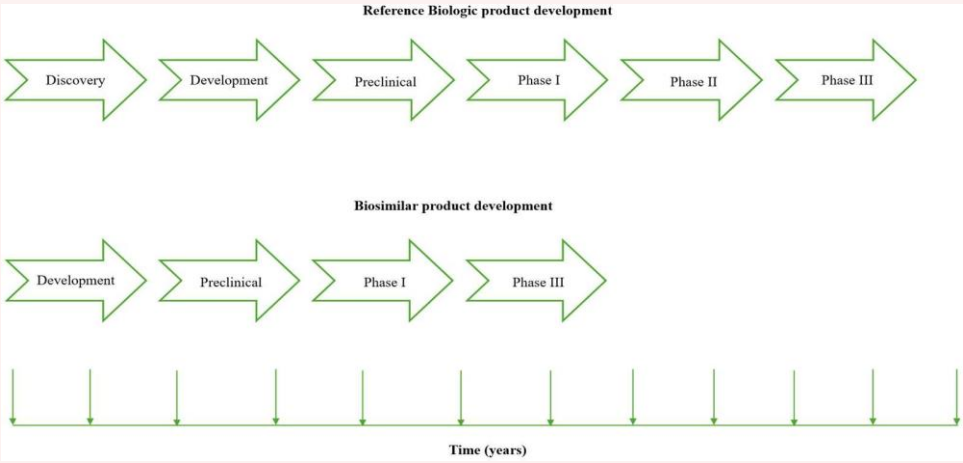

Figure 1. Development phases and the timeline (in years) of reference biologics versus biosimilars.

3. Therapeutic Uses

Due to its robust pharmaceutical manufacturing capabilities, sizable patient population, and emphasis on expanding access to reasonably priced biologic medicines, India has become a major player in the global biosimilars industry. Many chronic and life-threatening illnesses that were previously solely treatable with expensive original biologics now have more treatment choices thanks to biosimilars.

3.1. Biosimilars in Different Domains

The development and growing use of biosimilars has had a major influence on India's therapeutic environment. Despite slight variations in therapeutically inert ingredients, these products have shown equivalent effectiveness, safety, and quality to an authorized reference biologic product. Their use covers a number of important disease domains and offers affordable substitutes for well-established biologic therapies.

3.1.1. Cancer

The National Comprehensive Cancer Network (NCCN) as well as American Society for Clinical Oncology (ASCO) recommend biologics for the treatment of various types of cancer because they improve clinical outcomes, notably overall survival (OS). Biologics are an important part of the modern cancer treatment arsenal. In the US health care system, biologics accounted for almost 55% of all antineoplastic medication spending, according to a 2011 drug spending analysis. Among these biologics are: (14).

- Nearly fifty percent of the top 20 antineoplastic expenses in outpatient clinics were attributed to trastuzumab (Herceptin; Roche). Human epidermal growth factor receptor 2 (HER2) positive breast cancer and metastatic gastric and gastroesophageal junction adenocarcinomas can be treated with **trastuzumab** (16).
- Colorectal, brain, lung, fallopian tube, kidney, and other malignancies can all be treated with **bevacizumab** (17).
- Leukemia and CD20-positive non-Hodgkin lymphoma can be treated with **rituximab** (18).

3.1.2. Rheumatology

The development of biologics has transformed rheumatology treatment and greatly enhanced patient outcomes. Rheumatoid arthritis (RA), ankylosing spondylitis (AS), psoriatic arthritis (PsA), and juvenile inflammatory arthritis are examples of systemic rheumatic illnesses with largely overlapping clinical symptoms of inflammation that are most damaging in and around

joints. The treatments employed for the illnesses also greatly overlap due to the parallels in key clinical characteristics. Methotrexate (MTX), leflunomide, sulfasalazine, and hydroxychloroquine were among the oral disease-modifying antirheumatic medications (DMARDs) that were typically used in earlier treatments. Since 1999, all of the new pharmaceuticals that have been presented have been biologics, which are proteins that have been produced in vitro and refined for subcutaneous or an injection through the IV Biosimilars improve patients' quality of life by providing a long-term solution for the management of chronic inflammatory illnesses (19).

- Antibodies or fusion proteins that inhibit the cytokine tumor necrosis factor alpha (TNFα) also known as anti-TNFα have made up the first class of biologics. As of right now, the United States has approved five such medications: golimumab (Simponi®), certolizumab pegol (Cimzia®), ADA (Humira®), etanercept (Enbrel®), and infliximab (Remicade®).
- Other biologics have targeted other elements of inflammatory pathways, such as B cells (rituximab), interleukin (IL)-1 (anakinra), the IL-6 receptor (tocilizumab), T-cell costimulation (abatacept) or T-cell costimulation and apoptosis (alefacept), and IL-12 and IL-23 (ustekinumab) (20).

3.1.3. Diabetes

Since the 1920s, insulin therapy has been a mainstay in the treatment of diabetes. It has developed from crude mammal extracts to highly pure human insulin produced by contemporary recombinant DNA technology. By enabling customized insulin regimes that replicate natural insulin secretion patterns, this development has greatly enhanced the quality and effectiveness of diabetes therapy. Patients now have access to a range of insulin formulations, such as combination, long-acting, and rapid-acting insulins, which are tailored to each patient's unique metabolic requirements and lifestyle (21). It is anticipated that the development of biosimilar insulins would increase competitiveness in the insulin market, which might reduce costs and improve access for patients who find original biologics too expensive. To guarantee their equivalency to reference products, biosimilars must undergo a thorough clinical examination because of the complicated regulatory environment and regional variations in standards (22).

4. Clinical Advantages of Biosimilars:

- **Treatment Flexibility:** Biosimilars enable smooth transitions between the reference biologic and the biosimilar without the need for intervention or notice to the prescribing physician. Healthcare professionals have additional treatment options thanks to this flexibility, which enables them to select the best therapy for their patients depending on their unique needs, reaction to treatment, and pharmaceutical availability (23).
- **Patient Preferences:** Certain dose forms or administration techniques (such as subcutaneous injection vs intravenous infusion) may be preferred by some patients. Biosimilars might provide different choices, meeting patient preferences and perhaps increasing adherence to therapy.
- **Cost Savings:** The ability of biosimilars to lower treatment costs is one of their most important advantages. Generally speaking, biosimilars are less expensive than the reference biologic, and interchangeability makes the substitution procedure easier, enabling medical professionals to prescribe the less expensive biosimilar without facing extra administrative challenges. Healthcare systems can reduce the cost of biologic medicines by including biosimilars in treatment plans. As a result, funds may be available for use in other facets of patient care along with medical research.
- **Patient Adherence:** Effective management of chronic illnesses depends on better treatment adherence. By enabling patients to regularly get their prescribed medicine even in the event of supply shortages or other problems with the reference biologic, interchangeable biosimilars can assure continuity of treatment. There is less chance of treatment disruptions brought on by things like shortages of goods or changes in insurance coverage when patients may easily transition between the reference biologic and its biosimilar. Better treatment results result from patients being able to continue the treatment without interruptions.
- **Enhanced Market Access and Competition:** The biologics market is more competitive as a result of the availability of biosimilars. Manufacturers may be encouraged to provide competitive prices when more biosimilars become interchangeable with the reference biologic, resulting in additional cost reductions for patients and healthcare systems. Patients' access to biologic treatments may be enhanced by interchangeable biosimilars. More patients can now afford these medicines, which could have been prohibitively expensive with the reference biologic alone, thanks to lower pricing and greater accessibility of biosimilars (24).

5. Role of India in Juggling Innovation and Affordability

As a leader in the pharmaceutical industry, India has a distinct story to tell. Despite being rated tenth in terms of value, its pharmaceutical market commands an excellent third place in terms of volume. These remarkable achievements highlight India's ability to develop innovative, reasonably priced vaccines and biosimilars, highlighting its position as a global competitor. Ultimately, the tale of biosimilars depicts change, creativity, and adaptability. It illustrates how economics, science, and legislation come together to produce a world where sophisticated biopharmaceuticals not only fight illnesses but also overcome obstacles to reach people who need them most (24).

BB (Biocon Biologics Limited), a pioneer with a history of successful approvals in the US, Europe, and other developed and developing countries, has had incredible successes in the field of biosimilars. Eight marketed goods from this prestigious firm have found their way into international markets. Being the first company to receive FDA clearance for an interchangeable biosimilar a feat accomplished with its Insulin Glargine is a significant milestone in its history. Over the course of the last 10 years, biosimilars have emerged as powerful substitutes for the expensive field of biologics (25).

They are strong competitors in the therapy of chronic illnesses, including cancer, diabetes, inflammation, and infections, receiving much-needed attention and creating new opportunities in the field of healthcare.

6. Barriers and Amendments

The inherent characteristics of biologic products provide difficulties. Replication and characterisation are challenging because of their complex and unstable composition, which contrasts with the stability of conventional medications. Even while switch studies have shown that interchangeable biosimilars are equivalent, they might not always be better than other biosimilars. The preference for adaptable biosimilars versus generic biosimilars may be confused by this differential (26).

Even when more reasonably priced biosimilars are available, patient and physician preferences frequently favor certain insulins or delivery methods, leading to resistance to treatment adjustments. Patients and healthcare professionals may get overwhelmed by the abundance of options as the market grows with additional authorized biosimilar insulins. This emphasizes the necessity of thorough education in order to enable a smooth transition. A key factor in the broader use of biosimilar insulins will be educating patients and healthcare professionals about the transition from reference insulin to biosimilar insulin variations.

7. Strengths and Positive Contributing Factors:

Young and ambitious workforce: The existence of a young and driven staff can support industry innovation, research, and development.

Cost competitiveness: The capacity to manufacture vaccines and biosimilars at a lower cost than in other areas can boost competitiveness and possibly result in greater market shares. **High efficacy, low cost, and equivalent safety level:** The healthcare business may be drawn to the industry's emphasis on creating high-quality biosimilars for lower costs with comparable safety levels to original goods (27).

Low-cost, inexpensive biosimilars: In the price-conscious Indian market, inexpensive biosimilars can make drugs more affordable, increasing market penetration and acceptance.

Reduced cycle in synthesis along with regulatory compliance: Biosimilars can be developed and introduced to the market more quickly if they are synthesized and comply with regulations more quickly than innovator molecules.

Government regulatory support: Government regulatory help can guarantee adherence to quality standards and expedite the production of biosimilars.

Government activities: The industry's growth and development can be accelerated by government programs that promote investment and foster trust (28).

8. Conclusion

The development of biosimilars is a testament to the complex interactions between science, policy, and economics in pharmaceutical innovation and regulation. Unlike conventional small-molecule medications, biosimilars have carved out an own route by navigating the challenging seas of clinical equivalency as a break from patent dependency. India plays a significant role in this story, becoming a major player in the global biopharmaceutical market. India has established itself as a global leader in the supply of generic drugs and the demand for vaccines thanks to a mix of innovative firms like Biocon and Dr. Reddy's and more recent entrants like Enzyme Biosciences Ltd. The difficulties in promoting innovation, enhancing quality control, and harmonizing laws highlight how India's biopharma sector is still developing.

Biosimilars provide a powerful option as the world's healthcare system struggles with illnesses and financial obstacles. This revolutionary path, characterized by achievements, difficulties, and continuous innovation, demonstrates the pharmaceutical industry's extraordinary resilience in meeting the constantly changing requirements of patients throughout the globe. Enhanced regulatory frameworks, better education, and a broader use of biosimilars to provide easily accessible, reasonably priced, and efficient healthcare solutions to people who most need them are all promising aspects of the future.

9. References

1. Calleja MA, Albanell J, Aranda E, García-Foncillas J, Feliu A, Rivera F, et al. Budget impact analysis of bevacizumab biosimilars for cancer treatment in adult patients in Spain. European Journal of Hospital Pharmacy. 2023;30(e1): e40. DOI: 10.1136/ejhpharm-2021-002955
2. Wolff-Holz E., Tiitso K., Vleminckx C., Weise M. Evolution of the EU Biosimilar Framework: Past and Future. BioDrugs. 2019; 33:621–634. doi: 10.1007/s40259-019-00377-y.
3. Afzali A., Furtner D., Melsheimer R., Molloy P.J. The Automatic Substitution of Biosimilars: Definitions of Interchangeability are not Interchangeable. Adv. Ther. 2021; 38:2077–2093. doi: 10.1007/s12325-021-01688-9.
4. Isaacs J., Gonçalves J., Strohal R., Castañeda-Hernández G., Azevedo V., Dörner T., McInnes I. The biosimilar approval process: How different is it. Consid. Med. 2017; 1:3–6. doi: 10.1136/conmed-2017-100003.
5. Blandizzi C., Meroni P.L., Lapadula G. Comparing Originator Biologics and Biosimilars: A Review of the Relevant Issues. Clin. Ther.2017;39:1026–1039. doi: 10.1016/j.clinthera.2017.03.014.
6. Mirjalili S.Z., Sabourian R., Sadeghalvad M., Rezaei N. Therapeutic applications of biosimilar monoclonal antibodies: Systematic review of the efficacy, safety, and immunogenicity in autoimmune disorders. Int. Immunopharmacol. 2021; 101:108305. doi: 10.1016/j.intimp.2021.108305.
7. Ramanan S, Grampp G. Drift, evolution, and divergence in biologics and biosimilars manufacturing: Current perspectives. BioDrugs. 2021; 35:1–14. doi:10.1007/s40259-020-00458-2.
8. Halimi V., Daci A., Ancevska Net kovska K., Suturkova L., Babar Z.U., Grozdanova A. Clinical and Regulatory Concerns of Biosimilars: A Review of Literature. Int. J. Environ. Res. Public Health. 2020; 17:5800. doi: 10.3390/ijerph17165800.
9. Declerck P., Danesi R., Petersel D., Jacobs I. The Language of Biosimilars: Clarification, Definitions, and Regulatory Aspects. Drugs. 2017; 77:671–677. doi: 10.1007/s40265-017-0717-1.
10. Mitra S., Murthy G.S. Bioreactor control systems in the biopharmaceutical industry: A critical perspective. Syst. Microbiol. Biomanuf. 2022; 2:91–112. doi: 10.1007/s43393-021-00048-6.
11. Declerck P., Farouk Rezk M. The road from development to approval: Evaluating the body of evidence to confirm biosimilarity. Rheumatology. 2017; 56: iv4–iv13. doi: 10.1093/rheumatology/kex279.
12. Meher BR, Balan S, Mohanty RR, Jena M, Das S. Biosimilars in India; Current Status and Future Perspectives. J Pharm Bioallied Sci. 2019 Jan-Mar;11(1):12-15. doi: 10.4103/jpbs.JPBS_167_18. PMID: 30906134; PMCID: PMC6394151.
13. Ismail S., Abu Esba L.,Khan M., Al-Abdulkari H., Modimagh H., Yousef C. An Institutional Guide for Formulary Decisions of Biosimilars. Hosp. Pharm. 2023; 58:38–48. doi: 10.1177/00185787221138007.
14. Abraham J. Developing oncology biosimilars: An essential approach for the future. Semin Oncol. 2013;40(suppl 1): S5–S24. doi: 10.1053/j.seminoncol.2013.09.015.
15. Zelenetz AD, Ahmed I, Braud EL, et al. NCCN biosimilars white paper: Regulatory, scientific, and patient safety perspectives. J Natl Compr Canc Netw. 2011;9(suppl 4): S1–S22. doi: 10.6004/jnccn.2011.0136.
16. Hanna NH, Schneider BJ, Temin S, et al. Therapy for stage IV non–small-cell lung cancer with driver alterations: ASCO and OH (Ontario Health) guideline update. J Clin Oncol. 2021;39(9):1040–1091**.** doi:10.1200/JCO.20.03570.
17. Patterson JA, et al. Medicare Part D coverage of drugs selected for the drug price negotiation program. JAMA Health Forum. 2024;5(2): e240123. doi:10.1001/jamahealthforum.2024.0123.
18. Smith MR. Rituximab (monoclonal anti-CD20 antibody): mechanisms of action and resistance. Oncogene. 2003; 22:7359–7368. Doi. 10.1038/sj.onc.1206939.
19. Bartelds GM, Krieckaert CLM, Nurmohamed MT, et al. Development of antidrug antibodies against adalimumab and association with disease activity and treatment failure during long-term follow-up. JAMA. 2011;305(14):1460–1468. doi: 10.1001/jama.2011.406.
20. Heinemann L, Davies M, Home P, Forst T, Vilsbøll T, Schnell O. Understanding biosimilar insulins - development, manufacturing, and clinical trials. J Diabetes Sci Technol 2023; 17:1649-61. DOI: 10.1177/19322968221105864
21. Owens DR, Landgraf W, Schmidt A, Bretzel RG, Kuhlmann MK. The emergence of biosimilar insulin preparations--a cause for concern? Diabetes Technol Ther 2012; 14:989-96. DOI: 10.1089/dia.2012.0105
22. Patel A, Bhatt N, Prakash SS, Biswas G, Nagarkar R, Roy B, Samal P, Agrawal N, Meshram S, Kaushal A, Satheesh CT. Rituximab biosimilar for the treatment of diffuse large B-cell lymphoma: a phase 3 randomized study in India. Cancer Chemotherapy and Pharmacology. 2023 Jun;91(6):457-68. DOI: 10.1007/s00280-023-04530-x
23. Bashir NS, Hughes A, Ungar WJ. Infliximab Pricing in International Economic Evaluations in Inflammatory Bowel Disease to Inform Biologic and Biosimilar Access Policies: A Systematic Review. MDM Policy & Practice. 2023 Feb;8(1):23814683231156433. DOI: 10.1177/23814683231156433
24. Car E, Vulto AG, Houdenhoven MV, Huys I, Simoens S. Biosimilar competition in European markets of TNF-alpha inhibitors: a comparative analysis of pricing, market share and utilization trends. Frontiers in Pharmacology. 2023 Apr 21;14: 1151764. doi: 10.3389/fphar.2023.1151764.
25. Zeng X, Jia Y, Chen H, Luo Q, Zhao H, Liang G, Chen W, Li Y. A real-world analysis of survival and cost-effectiveness of sintilimab plus bevacizumab biosimilar regimen in patients with advanced hepatocellular carcinoma. Journal of Cancer Research and Clinical Oncology. 2023 May 16:1-7. DOI: 10.1007/s00432-023-04775-2

26. Patel A, Bhatt N, Prakash SS, Biswas G, Nagarkar R, Roy B, Samal P, Agrawal N, Meshram S, Kaushal A, Satheesh CT. Rituximab biosimilar for the treatment of diffuse large B-cell lymphoma: a phase 3 randomized study in India. Cancer Chemotherapy and Pharmacology. 2023 Jun;91(6):457-68. DOI: 10.1007/s00280-023-04530
27. Bashir NS, Hughes A, Ungar WJ. Infliximab Pricing in International Economic Evaluations in Inflammatory Bowel Disease to Inform Biologic and Biosimilar Access Policies: A Systematic Review. MDM Policy & Practice. 2023 Feb;8(1):23814683231156433. DOI: 10.1177/23814683231156433
28. Yu T, Jin S, Li C, Chambers JD, Hlávka JP. Factors Associated with Biosimilar Exclusions and Step Therapy Restrictions Among US Commercial Health Plans. BioDrugs. 2023 Apr 1:1-0. DOI: 10.1007/s40259-023-00593-7

The Trust Gap: Why Doctors And Patients Still Hesitate To Adopt Biosimilars In India?



Sneha Kahar, Sakshi Sharma, Vaishali Raghuwanshi*

Sri Aurobindo Institute of Pharmacy, Indore, Madhya Pradesh

Email: raghuwanshivaishali435@gmail.com

Abstract

Biosimilars gave a surety to advance access to biological therapies, particularly in countries with low resources such as India. These alternatives show reliability as a cost-effective solution that matches the innocuousness and utility of existing treatments yet remains underused in the medical environment. The main reason for this situation is that a mutual distrust persists among healthcare workers and patients. Doctors prescribe medications differently and patients respond towards treatments because of their concerns regarding immunogenicity, lack of information about biologically similar drugs and limited knowledge of the governing system's function. India is a market for biosimilars, due to its strong manufacturing capabilities and expanding biosimilar portfolio. However, optimal utilization remains a challenge. Clinical studies and real-world evidence show that biosimilars are trustworthy through studies on trastuzumab and other medications. Educational programs, clear regulatory information and better communication methods can address perception-based barriers because they will increase biosimilar acceptance in standard healthcare procedures.

Keywords: Biosimilars, biologics, trastuzumab, cost-effective, oncology

1. Introduction

Biologic therapies establish new treatment methods for multiple long-lasting and deadly diseases because they allow doctors to perform precise molecular treatments. The broad clinical use of this treatment method remains restricted because its high costs make it difficult for the suffering population to get treated. Biosimilars offer a solution to this problem because they provide treatment results that match original products while costing less (1,2).

Biosimilars enable healthcare systems to decrease costs while making modern treatments more accessible to patients. The way subsequent entry biologics (SEBs) are used in medical settings over the world shows different patterns of implementation (3). People do not base their decisions only on economic matters and regulatory requirements because they also respond to social norms and their own beliefs. Evidence shows that doctors who have safety and therapeutic equivalence doubts about treatments choose specific drugs, which leads to different patient outcomes (4).

2. Concept and Scientific Basis of Biosimilars

The complexities of biologics and biosimilars require a deep understanding for their clinical application. The two categories of current medical treatments show essential similarities but their burgeoning processes and structural features and regulatory assessment methods create distinct differences which result in different public opinions about them. The various aspects of biosimilar adoption present distinct challenges which researchers need to understand (5).

2.1. Biologics and Biosimilars: Key Differences

Biologics are sophisticated medicinal substances generated from bio-organismal networks. Their size of molecule is large and has a convoluted make-up, due to which they are produced through hard biotechnological procedures involving organism cells. These agents have immensely enhanced the treatment of chronic and fatal illnesses by working on certain biological pathways (6).

Biosimilars are the biological medicines which are very same as a previously approved original drug. They do not have any medically significant variations in terms of harmlessness, quality or potency. Because of the inherently variable biological systems and manufacturing methods, SEBs cannot be regarded as exact replicas, unlike generic medicines (7).

This fundamental distinction differentiates biologics from the conventional generics, which are chemically produced and identical to their reference analogues. The acceptability of biosimilars in the clinical setting is influenced by their complexity and non-identical character, which may cause misunderstanding among stoicals and professionals of medical service (8).

2.2. Regulatory Framework for Biosimilars in India

The regulation of biologics and biosimilars in India has changed along with the country's efforts to increase availability and affordability of essential medicines. The Central Drugs Standard Control Organization (CDSCO) and the Department of Biotechnology (DBT), collaboratively create recommendations for the licensing of SEBs using a methodical, step-by-step outlook that comprises inquisitive, preclinical and clinical examination. Globally, India holds a strong position in producing biologics, vaccines and recombinant medicines like erythropoietin and insulin. This helps India to lead in the worldly biopharmaceutical sector. There are certain supervisory bodies that watch over the biologics in India like the Review Committee on Genetic Manipulation(RCGM) and the Genetic Engineering Appraisal Committee(GEAC). These groups help us to make sure if the biologics are safe. The administrative framework has been largely adapted from the other nations. The problem is that people do not always understand or adhere to these rules in the right way, making it hard for people to trust biosimilars (9).

3. Current Landscape of Biosimilars in India

India keeps on being a key player in the biosimilar market worldwide. This is because India can manufacture cost-effective biosimilars and its companies are getting better in formulating biopharmaceuticals. Over the past decade, pharmaceutical companies of India have been working very hard to produce and sell SEBs to manage many chronic ailments (10).

Many SEBs have been successfully introduced into Indian trade, which means people can access advanced therapies (11). Prominent examples of these biologically similar drugs and their medical use are given in (Table 1).

Table 1. Selected Biosimilars in India and their Clinical Applications

Biosimilars	**Reference Biologics**	**Indication**	**Impact**
Trastuzumab	Herceptin	HER2+ Breast Cancer	Improved access to targeted therapy
Bevacizumab	Avastin	Colorectal, lung and other cancers	Increased access to anti-angiogenic therapy
Adalimumab	Humira	Rheumatoid arthritis, autoimmune disorders	Expanded treatment availability
Rituximab	MabThera	Non-Hodgkin lymphoma, rheumatoid arthritis	Improved affordability of monoclonal antibody therapy
Filgrastim	Neupogen	Neutropenia(chemotherapy-induced)	Reduced infection risk through cost-effective therapy
Etanercept	Enbrel	Rheumatoid arthritis, psoriasis	Broadened biologic therapy access
Infliximab	Remicade	Crohn's disease, ulcerative colitis, rheumatoid arthritis	Improved management of inflammatory disease
Erythropoietin	Epogen	Anaemia(Chronic kidney disease-associated, Chemotherapy-induced)	Enhanced access to supporting care
Pegfilgastrim	Neulasta	Chemotherapy induced neutropenia	Reduced dosing frequency and improved compliance
Insulin (glargine)	Lantus	Diabetes Mellitus	Enhanced affordability

The SEBs have made treatments cheaper so that a large proportion of the population can be benefitted by this (11). The cost advantage of biosimilars in India can be easily understood by (Figure 1).

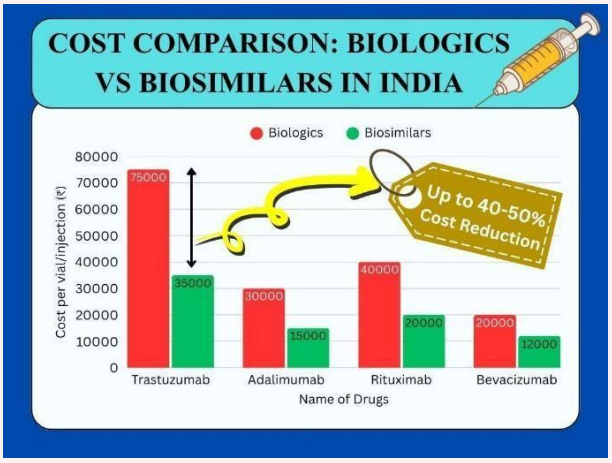

Figure 1. Comparative cost analysis of original medicine and their biosimilars in India

The usage of SEBs in standard clinical practice is still inconsistent despite these developments. This is surprising because India has a growing portfolio and robust production

capabilities. The main issue is integration of biosimilars into medical care systems. It depends upon things like whether stakeholders trust them, doctors prescribing practices and how much people know about biosimilars. The gap between having biosimilars available and using them effectively in hospitals and clinics is quite large. Biosimilars are not being used to their potential in clinical settings. We need to focus on similar biotherapeutic products and their role in the medicinal sector. This can make a difference if used correctly (10,11).

4. Barriers to Biosimilar Adoption

Health workers in India face difficulties when they need to choose follow-on biologics because they lack sufficient understanding and comprehension with regard to these treatments. Medical practitioners still doubt the harmlessness and effectiveness of similar biological medicinal products which serve as affordable substitutes for originator biologics. Health service givers display positive feelings toward SEBs yet they refuse to switch from using biologics until they receive complete clinical evidence about biosimilar use (12).

The trust gap between patients and healthcare providers appears partly because patients themselves create this gap. Many patients show uncertainty about the treatment value of biosimilars because they lack basic knowledge about these treatments. Patients demonstrate different attitudes about treatment costs because most patients think biosimilars provide cost savings while some patients display mixed reactions (13). The multistakeholder factors contributing to trust, access and adoption are given in (Figure 2).

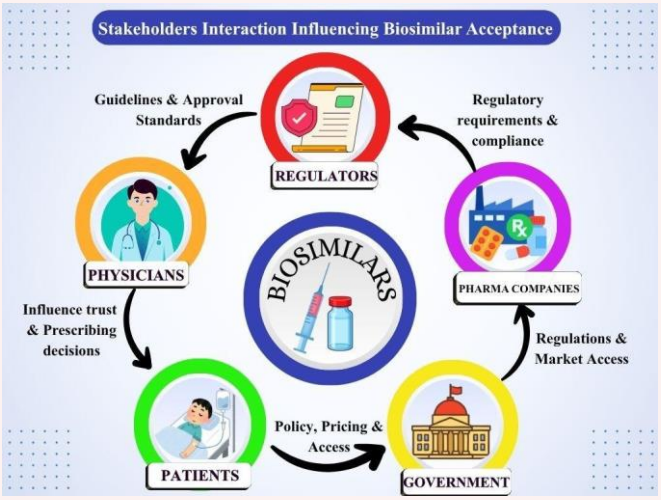

Figure 2. Biosimilar acceptance driven by interactions among key healthcare stakeholders

Pharmacists perform essential functions in managing medication therapy when they go beyond their basic role of dispensing medications. They inform patients about how drugs work when they take them and their safety aspects and situations where they should not use specific medications while also helping doctors and patients to learn about biosimilar usage. This involvement can significantly promote cost-effective and accessible healthcare delivery (14).

4.1. Physician Perspectives and Prescribing Barriers

Physicians avoid prescribing biosimilars because they lack proper knowledge about these medicines and they also base their decisions on negative experiences from using generic medications. Physicians need to understand biosimilar approval processes because their knowledge gap creates difficulties for them. Physicians question whether biosimilars achieve the same safety and efficacy results as originator biologics because these products require less development time and they operate at lower production costs (15).

Healthcare professionals need to decide whether they prefer to use biosimilars instead of biologics which creates delays in SEBs adoption. Current evidence shows that switching between these two treatments creates no changes in safeness or efficiency or immunogenicity (16).

4.2. Patient Awareness and Perception Barriers

The need for increased biosimilar education exists because Indian patients lack sufficient understanding of biosimilars. The practice of adequate professional counselling enables healthcare providers to assist patients in reducing their negative viewpoints concerning SEBs while enhancing their acceptance of these treatments. Some patients mistakenly consider biosimilars identical to biologics while others view them as inferior drugs that cause more adverse reactions (17).

The nocebo effect explains this perception as it shows that people with negative expectations will experience negative effects. Patients believe that SEBs have lower quality and effectiveness because they cost less. The following patient groups show higher chances of having negative perceptions about SEBs: Patients who have symptoms of anxiety disorders show different disease patterns from patients who have all other medical conditions and patients with acute conditions may exhibit higher resistance to treatment switching. The groups involved in this study show common worries about switching from originator biologics to biosimilars (13,18).

5. Real-World and Clinical Evidence of Biosimilars

Trastuzumab remains a standard, first-in-class resurfaced antibody targeting the domain IV of the HER2 receptors. It has notably improved survivorship outcomes in convalescent with cancer in breast. However, within resource-limited settings such as India, it is difficult to get biologics due to their high price. The development of trastuzumab biosimilars has contributed as a cost-effective alternative and increased accessibility to targeted neoplasm therapy.

A systematic review of the use of trastuzumab biosimilars in patients with breast cancer has shown that these drugs have similar effectiveness, safety and immunogenicity profiles to the reference product (19). Real-world comparison trials have revealed that there are no appreciable variations amongst original trastuzumab and its biosimilars in terms of clinical outcomes and protection parameters. Although there is substantial clinical and practical evidence to support their utilization, trastuzumab biosimilars have not been widely adopted (20). The clinician's initial reluctance, mostly because of the worries about long-term well-being and therapeutic equivalency has greatly affected the prescription practices. Still, biosimilars are progressively gaining confidence majorly due to growing clinical experience and gathering empirical data. This helps us to understand how clinical evidence plays a crucial role in bridging the trust gap in biosimilar acceptance (19, 20).

6. Future Outlook of Biosimilars

Biologics will increasingly become the primary remedy for long-standing diseases, for instance, cancer and autoimmune disorders. Expiration of patents for originator medicines will lead to a major transition toward follow-up biologics, which shall make treatments more affordable as well as accessible for suffering people. SEBs furnish a safer and effective treatment option that costs less than standard treatments. The health regime requires improved public knowledge related to these therapeutics together with educational programs and specific training for clinical pharmacists to achieve successful implementation of these treatments. Evidence-based knowledge together with real-world data will help establish trustworthiness. The academic research process will identify biosimilar educational needs, whose policy development will help resolve through strategic educational initiatives (21, 22).

7. Conclusion

Biosimilars are a step forward in ameliorating the availability of biological therapies for the people, especially in countries like India, where a lot of people have chronic diseases. The scientific evidence proves that SEBs are innocuous and effective. Many doctors and patients are still not sure about them, which is just a perception-based barrier. Bridging the trust gap is necessary for maximizing the true potential of SEBs. Strengthening cognizance, enhancing regulatory transparency, and fostering real-world evidence are essential in boosting credence towards similar biological medications. Ultimately, stakeholders' willingness to accept biosimilars will be just as important to their efficient incorporation into clinical practice as their availability.

8. References

1. Crisci E, Nicoletti MM, Pentella C, Cantone A, Ruggiero D, Anatriello A, Scavone C. Switching between originators and biosimilars in dermatology: a systematic review of real-world clinical studies. Biologics. 2023 Apr 27;3(2).
2. Mascarenhas-Melo F, Diaz M, Gonçalves MB, Vieira P, Bell V, Viana S, Nunes S, Paiva-Santos AC, Veiga F. An overview of biosimilars—development, quality, regulatory issues, and management in healthcare. Pharmaceuticals. 2024 Feb 11;17(2):235.
3. Tursi A, Elisei W, Terlizzi AP, Antonino N, Casamassima C, Rizzi FV, Di Pierro F, Di Brino E, De Chiara C, Covino M, Papa A. Impact of biosimilars on the costs of advanced therapies for inflammatory bowel diseases: a population-based study in Italy. Eur J Gastroenterol Hepatol. 2026 Jan;10:97.
4. Chong SC, Rajah R, Chow PL, Tan HC, Chong CM, Khor KY, Lee WP, Tan WY. Perspectives toward biosimilars among oncologists: a Malaysian survey. J Oncol Pharm Pract. 2026 Feb;32(2):189–199.
5. Ngo D, Chen J. A clinical review of biosimilars approved in oncology. Ann Pharmacother. 2021 Mar;55(3):362–377.
6. Naser-Tavakolian A, Heard JR, Ahdoot M. Biologics. In: Eltorai AEM, Arab A, Atala A, Siddiqui MM, editors. Handbook for designing and conducting clinical and translational research. Academic Press; 2025. P. 355–360.
7. Thongpooswan S, Das A, Patil P, Latymer M, Llamado L, Wee J. Physicians' and patients' perception of biosimilars and factors affecting biosimilar prescribing in selected Asian countries: a survey study. Expert Opin Biol Ther. 2024 Oct;24(10):1171–1182.
8. Joshi D, Khursheed R, Gupta S, Wadhwa D, Singh TG, Sharma S, Porwal S, Gauniyal S, Vishwas S, Goyal S, Gupta G. Biosimilars in oncology: latest trends and regulatory status. Pharmaceutics. 2022 Dec 5;14(12):2721.
9. Sasidhar B. Biosimilars and biobetters in India: regulatory framework, scientific challenges, and implementation strategies—a comprehensive review. World J Pharm Sci. 2025 Jul 24.
10. Monga A, Gagan, Jamwal P, Sharma S, Kaur A. Biosimilars: a critical review of development, regulatory landscape, and clinical implications. AAPS PharmSciTech. 2025 Jan 27;26(1):46.
11. Bhargavi S, Kumar BS, Hema PM. A review on emerging trends in biologic drugs and biosimilars. Plant Biotechnol Persa. 2025 Jan;7:58–67.
12. Ramesh A. Clinicians' perceptions and adoption of oncology biosimilars in India: results from a national survey. Indian J Med Paediatr Oncol. 2025 Sep 11.
13. Gibofsky A, Evans C, Strand V. Provider and patient knowledge gaps on biosimilars: insights from surveys. Am J Manag Care. 2022 Nov 1;28(12 Suppl):S227–S233.
14. Jarab AS, Al-Qerem W, Alzoubi KH, Abu Heshmeh SR, Al Hamarneh YN, Alefishat E, Aburuz S. Understanding community pharmacists' knowledge, attitudes, and practices regarding biosimilar drugs: a cross-sectional survey. Int J Clin Pract. 2025;2025(1):2248512.
15. Rupert DJ, Jordan AM, Ziemian MA, Brown RM, Fleming NS, Lefebvre RC. Understanding US physician and pharmacist attitudes toward biosimilar products: a qualitative study. BioDrugs. 2022 Sep;36(5):645–655.
16. Kurki P, Barry S, Bourges I, Tsantili P, Wolff-Holz E. Safety, immunogenicity and interchangeability of biosimilars. Nat Rev Drug Discov. 2021 Aug;20(8):576–592.
17. Vandenplas Y, Barbier L, Simoens S, Van Wilder P, Vulto AG, Huys I. Perceptions about biosimilar medicines among Belgian patients in ambulatory care. Front Pharmacol. 2022 Jan 5;12:789640.
18. Gelissen LMY, Strijbis EMM, van Oosten BW, de Jong BA, Veldkamp AI, Rispens T, Killestein J, van Kempen ZLE. Safety and patient experiences with the natalizumab biosimilar in multiple sclerosis treatment. Mult Scler Relat Disord. 2026 May;109:107147.
19. Triantafyllidi E, Triantafillidis JK. Systematic review on the use of biosimilars of trastuzumab in HER2+ breast cancer. Biomedicines. 2022 Aug 21;10(8):2045.
20. Mamori T, Tanioka M, Takada K, et al. Real-world comparative analysis of trastuzumab originator and biosimilars: safety, efficacy, and cost effectiveness. BioDrugs. 2025 Jan;39:131–142.
21. Jarab AS, Abu Heshmeh SR, Al Meslamani AZ. Bridging the gap: the future of biosimilars regulations. Hum Vaccin Immunother. 2024 Dec 31;20(1):2362450.
22. Kaur S, Yadav S, Sahu V, Sharma N, Shukla VK. Biosimilar regulations: current framework and future prospects. Curr Drug Saf. 2025 May 23

Biosimilar Acceptance In India: Bridging Knowledge Gaps Among Healthcare Professionals


Simran Winerkar, Aparna Palshetkar*

Vivekanand Education Society's College of Pharmacy, Hashu Advani Memorial Complex, Behind Collector Colony, Chembur, Mumbai 400074.

Email: aparna.palshetkar@ves.ac.in

Abstract

Biosimilars have emerged as a cost-effective alternative to biologic therapies, offering substantial potential to improve access to advanced treatments in resource-constrained settings such as India. Despite the country's strong manufacturing capabilities and early adoption of biosimilar development pathways, their clinical uptake remains suboptimal. This review examines the knowledge gaps influencing biosimilar acceptance among Indian healthcare professionals, including physicians, pharmacists, and allied stakeholders. Evidence indicates that limited understanding of biosimilar science, concerns regarding immunogenicity and safety, ambiguity surrounding interchangeability, and inadequate pharmacovigilance systems contribute to hesitancy in prescribing and utilization. Additionally, gaps in regulatory communication and the lack of robust real-world evidence further exacerbate uncertainty. This article synthesizes current literature to identify key barriers and proposes strategic interventions, including targeted educational initiatives, strengthening pharmacovigilance frameworks, enhancing regulatory transparency, and promoting real-world evidence generation. Bridging these knowledge gaps is essential for optimizing biosimilar adoption and ensuring equitable access to biologic therapies in India.

Keywords: Biosimilars, Regulatory, Pharmacovigilance

1. Introduction

Biologic therapies have fundamentally reshaped modern medicine by offering highly targeted and effective treatment options for a wide range of chronic and life-threatening diseases, including cancer, autoimmune disorders, and metabolic conditions. These therapies have improved survival rates, enhanced quality of life, and opened new possibilities for disease management. However, their high cost continues to present a significant barrier, particularly in low- and middle-income countries such as India, where healthcare systems often face

resource constraints and a large proportion of healthcare expenses are paid out-of-pocket by patients (1).

In this context, biosimilars have emerged as a promising alternative. Biosimilars are biological products that are highly similar to an already approved reference biologic, with no clinically meaningful differences in terms of safety, efficacy, and quality. By offering comparable therapeutic outcomes at a lower cost, biosimilars have the potential to improve access to advanced treatments and reduce the financial burden on both patients and healthcare systems.

India has established itself as a global leader in the biosimilar space, supported by a robust pharmaceutical manufacturing sector, cost-efficient production capabilities, and a growing number of approved biosimilar products. Indian companies are not only supplying domestic markets but are also actively participating in global biosimilar development and export (2, 3).

Despite these advancements, a notable disconnection exists between India's strong production capacity and the relatively limited adoption of biosimilars in clinical practice. While biosimilars are available, their uptake among healthcare professionals-particularly physicians and pharmacists-remains inconsistent. This paradox highlights an important issue: the challenge is no longer solely about availability but about acceptance.

Recent studies suggest that this gap is largely driven by cognitive and perceptual factors rather than purely scientific or regulatory limitations (4). Misconceptions about biosimilar safety, limited understanding of their development process, and lack of confidence in their clinical performance significantly influence prescribing decisions. Therefore, addressing these knowledge gaps is essential to ensure that biosimilars fulfil their potential in improving healthcare access and affordability in India.

2. Scientific and Regulatory Context of Biosimilars

Biosimilars differ significantly from conventional generic drugs in both their development and regulatory evaluation. While generic medicines are chemically identical copies of small-molecule drugs, biosimilars are derived from living organisms, making them inherently complex and sensitive to manufacturing processes. Even minor variations in production conditions can influence their structural and functional characteristics (5).

Because of this complexity, biosimilars cannot be considered exact copies of their reference products. Instead, they are evaluated through a rigorous "comparability exercise," which ensures that any differences do not affect clinical performance. This process includes detailed analytical characterization, non-clinical testing, and clinical studies designed to demonstrate similarity in pharmacokinetics, efficacy, and safety.

Globally, regulatory agencies such as the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) have established well-defined pathways for biosimilar approval. These frameworks emphasize the "totality of evidence" approach, ensuring that biosimilars meet strict standards before entering the market (6).

In India, the Central Drugs Standard Control Organization (CDSCO) introduced biosimilar guidelines in 2012, which were subsequently revised to align more closely with international standards (3). These guidelines outline requirements for quality, safety, and efficacy evaluation and have facilitated the growth of India's biosimilar industry.

However, certain gaps remain. Notably, the Indian regulatory framework lacks clear guidance on interchangeability-the ability to substitute a biosimilar for its reference product without additional clinical risk and automatic substitution at the pharmacy level. This ambiguity creates uncertainty among healthcare professionals, who often rely on clear regulatory direction to guide clinical decisions. As a result, even when biosimilars meet rigorous scientific standards, their adoption may be hindered by a lack of clarity in policy and practice.

3. Knowledge Gaps Among Indian Healthcare Professionals

The knowledge gaps among Indian healthcare professionals are shown in figure 1.

3.1 Limited Understanding of Biosimilar Science

One of the most significant barriers to biosimilar adoption is the limited understanding of their scientific principles among healthcare professionals. Concepts such as structural variability, comparability studies, and extrapolation of indications are often not fully understood. In many cases, biosimilars are mistakenly perceived as equivalent to generic drugs. This misunderstanding can lead to unrealistic expectations of identicality or, conversely, unwarranted concerns about variability. Such confusion ultimately affects clinical decision-making and reduces confidence in prescribing biosimilars (4).

3.2 Safety and Immunogenicity Concerns

Safety concerns, particularly related to immunogenicity, remain a major obstacle. Immunogenicity refers to the potential of a biological product to trigger an immune response, which can affect both safety and efficacy. Although extensive clinical studies and post-marketing data have demonstrated that biosimilars have safety profiles comparable to their reference products, many clinicians remain cautious. This caution is often amplified by the lack of long-term safety data from Indian populations, leading to a preference for originator biologics (7).

3.3 Ambiguity in Interchangeability and Switching

The absence of clear guidelines on interchangeability in India contributes significantly to clinician hesitation. Switching a patient from an originator biologic to a biosimilar requires confidence that therapeutic outcomes will remain consistent. In the absence of explicit regulatory support, healthcare professionals may be reluctant to make such decisions, particularly for patients who are stable on existing treatments. This uncertainty slows the integration of biosimilars into routine clinical practice (6).

3.4 Lack of Awareness of Regulatory Rigor

Another important factor is the perception that biosimilars are subject to less stringent regulatory scrutiny than originator biologics. In reality, biosimilars undergo extensive evaluation to ensure their quality, safety, and efficacy. However, this rigorous process is not always well understood by healthcare professionals. As a result, misconceptions about regulatory standards can undermine trust and contribute to resistance (8).

3.5 Pharmacovigilance Knowledge Deficit

Pharmacovigilance is essential for monitoring the safety of biosimilars in real-world settings. In India, however, pharmacovigilance systems face several challenges, including underreporting of adverse events, limited traceability, and insufficient awareness among healthcare providers. These limitations reduce the availability of real-world safety data and further reinforce concerns about biosimilar use (9).

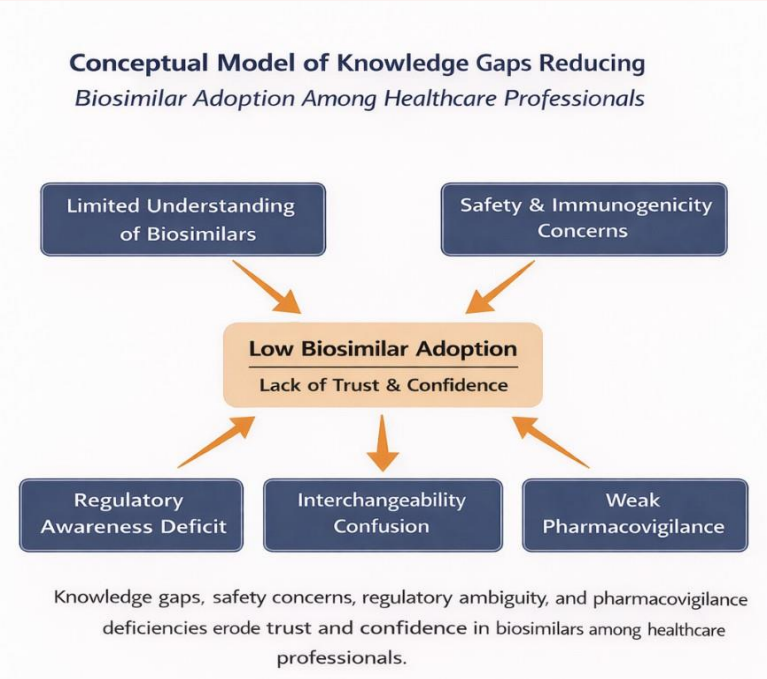

Figure 1: Knowledge Gaps among Indian Healthcare Professionals
*image created from ScholarGPT

4. System-Level Barriers to Knowledge Translation

Beyond individual knowledge gaps, several systemic factors hinder the translation of biosimilar knowledge into clinical practice.

4.1 Educational Limitations

Biosimilars are not comprehensively covered in medical and pharmacy curricula in India. As a result, many healthcare professionals enter clinical practice without a strong foundation in biosimilar science. Additionally, Continuing Medical Education (CME) programs often do not adequately address this topic, leaving limited opportunities for professionals to update their knowledge.

4.2 Ineffective Regulatory Communication

Regulatory guidelines are often presented in highly technical language, making them difficult for clinicians to interpret and apply in practice. This lack of clarity creates a gap between policy and implementation. Simplifying and translating regulatory information into clinician-friendly formats could significantly improve understanding and adoption (6).

4.3 Market and Perception Bias

Prescribing behaviour is often influenced by brand familiarity and marketing strategies. Originator biologics, supported by strong brand recognition, may be preferred over biosimilars even when evidence supports their equivalence. This perception bias can act as a barrier to the wider acceptance of biosimilars (1).

4.4 Lack of Real-World Evidence (RWE)

Real-world evidence plays a critical role in building confidence among healthcare professionals. While global data on biosimilars is substantial, locally generated evidence in India remains limited. The absence of large-scale, India-specific studies makes it difficult for clinicians to assess how biosimilars perform in their own patient populations (2,10).

5. Impact of Knowledge Gaps

The combined effect of these individual and system-level barriers is reflected in the relatively low adoption of biosimilars in India. This has several important implications. First, the continued reliance on expensive originator biologics increases healthcare costs and places a significant financial burden on patients. Second, limited adoption restricts access to life-saving therapies, particularly for economically disadvantaged populations. Furthermore, the underutilization of biosimilars undermines India's strong manufacturing capabilities and limits the potential economic benefits of its pharmaceutical sector. Finally, slow adoption hinders progress toward achieving universal healthcare goals and equitable access to advanced treatments.

6. Strategies to Bridge Knowledge Gaps

6.1 Targeted Educational Interventions

Developing structured educational programs is essential for improving understanding of biosimilars. This includes integrating biosimilar-related content into undergraduate and postgraduate curricula, as well as expanding CME programs. Digital platforms, workshops, and case-based learning approaches can further enhance knowledge and engagement among healthcare professionals.

6.2 Strengthening Pharmacovigilance Systems

Improving pharmacovigilance infrastructure is critical for building trust in biosimilars. This can be achieved through digital reporting systems, enhanced traceability mechanisms, and active surveillance programs. Encouraging healthcare professionals to report adverse events and participate in monitoring systems can strengthen confidence in biosimilar safety (9).

6.3 Enhancing Regulatory Transparency

Clear and accessible regulatory guidance is essential for reducing uncertainty. Defining interchangeability policies and providing practical recommendations for switching can support clinical decision-making. Transparent communication from regulatory authorities can also help build trust among healthcare professionals (6).

6.4 Promoting Real-World Evidence Generation

Encouraging the generation of real-world evidence through multicentre studies, hospital registries, and collaborative research initiatives can provide valuable insights into biosimilar performance in Indian settings. Such evidence can play a crucial role in addressing clinician concerns and supporting adoption. (10).

6.5 Multistakeholder Collaboration

Effective implementation of biosimilars requires collaboration among multiple stakeholders, including government agencies, academic institutions, healthcare providers, and the pharmaceutical industry. Coordinated efforts can help align policies, education, and clinical practice, creating a supportive environment for biosimilar adoption.

7. Global Lessons for India

International experience offers valuable insights for improving biosimilar adoption. The European Union has achieved high uptake through strong regulatory frameworks, clear substitution policies, and extensive physician education. Similarly, the United States has introduced interchangeability designations to guide clinical decision-making and increase confidence among healthcare providers. India can learn from these models while adapting strategies to its unique healthcare system, resource constraints, and patient population (1).

8. Conclusion

Biosimilars represent a significant opportunity to enhance access to advanced therapies and reduce healthcare costs in India. However, their successful integration into clinical practice depends not only on scientific and regulatory advancements but also on the knowledge, perceptions, and confidence of healthcare professionals. Persistent gaps in understanding biosimilar science, safety, and regulatory processes continue to hinder their acceptance. Addressing these challenges requires a comprehensive approach that combines education, regulatory clarity, and evidence generation. By strengthening pharmacovigilance systems, improving communication, and fostering collaboration among stakeholders, India can build trust in biosimilars and encourage their wider adoption. Ultimately, bridging these knowledge gaps is essential for unlocking the full potential of biosimilars and advancing toward a more equitable, accessible, and sustainable healthcare system.

9. References

1. Godman B, Haque M, Leong T, Allocati E, Kumar S, Islam S, et al. The current situation regarding long-acting insulin analogues including biosimilars among African, Asian, European, and South American countries: findings and implications for the future. Front Public Health. 2021;9:671961. Available from: https://www.frontiersin.org/articles/10.3389/fpubh.2021.671961
2. Panda S, Singh PK, Mishra S, Mitra S, Pattnaik P, Adhikary SD, Mohapatra RK. Indian biosimilars and vaccines at crossroads–replicating the success of pharmagenerics. Vaccines (Basel). 2023;11(1):110. doi:10.3390/vaccines11010110
3. Sasidhar B. Biosimilars and biobetters in India: regulatory framework, scientific challenges, and implementation strategies – a comprehensive review. World J Pharm Sci. 2025;13(3). Available from: https://wjpsonline.com/index.php/wjps/article/view/1893

4. Rahalkar H, Sheppard A, Dasgupta C, et al. Current regulatory requirements for biosimilars in six member countries of BRICS-TM: challenges and opportunities. Front Med (Lausanne). 2021;8:726660. doi:10.3389/fmed.2021.726660
5. Ghosh PK. Similar biologics: global opportunities and issues. J Pharm Pharm Sci. 2017;19(4):552–596.
6. Patil N, Ranjan A, Mukherjee D, Panda BK, Narang RK, Singh A. Navigating biosimilar regulatory pathways in emerging markets: insights from BRICS nations. Appl Drug Res Clin Trials Regul Aff. 2024;10:e26673371316219. doi:10.2174/0126673371316219240929170401
7. Sathyan A, Mohanapriya M, Madhanraja R, Indu Vadana KS, Indhuja K, Sumathi P, Varshini G. A comprehensive review of evidence and challenges in switching from originator drugs to biosimilars of monoclonal antibodies: focus on rituximab and trastuzumab. J Drug Deliv Ther. 2025;15(2):149–155.
8. Jarab AS, Abu Heshmeh SR, Al Meslamani AZ. Bridging the gap: the future of biosimilars regulations. Hum Vaccin Immunother. 2024;20(1):2362450. doi:10.1080/21645515.2024.2362450
9. Kaur S, Yadav S, Sahu V, Sharma N, Shukla VK. Biosimilar regulations: current framework and future prospects. Curr Drug Saf. 2025. doi:10.2174/0115748863360017250509063745
10. Rizwan A, Dubey K, Malhotra V, Bhatnagar S. Biosimilars: bridging the gap in biologics, access, and affordability. J Pharm BioTech Ind. 2026;3(1):2. doi:10.3390/jpbi3010002

Regulatory Perspectives And Scientific Insights On Biosimilars In India


Shubhangi J. Patil[1*], Rutuja M.Patil[2]

[1]Dept. Of Pharmaceutics, KCT's Krishna College of Pharmacy, Karad Maharashtra. 415539

[2]Dept. Of Pharmaceutics, KF's Jayawant Institute of Pharmacy, Karad Maharashtra. 415539

Email: patil.shubhangi13@gmail.com

Abstract

Biologics have transferred the management of chronic and life threatening diseases such as cancer, autoimmune disorder and Diabetes. Biosimilars are playing an important role in strengthening India's healthcare system by providing cost-effective biologic therapies and improving patient access. With support from the Central Drugs Standard Control Organization and Department of Biotechnology, India is emerging as a key centre for biosimilar research and production, helping make healthcare more affordable and widely available. This review looks at how biosimilars are changing in India, with a focus on regulatory frameworks, development challenges, market dynamics, and clinical considerations. It brings up important topics like immunogenicity, interchangeability, pharmacovigilance, and how doctors feel about it. The review also looks at how biosimilars affect the economy by making healthcare more affordable and easier to get. Even though a lot of progress has been made, there are still problems like complicated rules, a lack of knowledge, and limited infrastructure. The paper says that biosimilars are at the forefront of changing Indian healthcare and calls for a strategic approach that includes policy changes, more money for biotechnology, and educating all stakeholders. A well-planned shift to biosimilars could make healthcare in India more fair and long-lasting.

Keywords: Biosimilars, Healthcare in India, Biologic drugs, Cost reduction, Chronic illnesses, Regulatory system, CDSC Organization, Industry growth.

1. Introduction

1.1 Biologics and Biosimilars

Biologics are advanced medicines produced using living cells and are commonly used to treat serious conditions such as diabetes, cancer, and autoimmune diseases. Biosimilars are highly comparable versions of these biologic drugs, offering similar safety and therapeutic effects at a lower cost. They play an important role in making these treatments more accessible, particularly in countries like India.

1.2 Importance of Biosimilars Globally and in India

Biosimilars serve as cost-effective substitutes for expensive biologic medicines, helping to lower treatment costs and improve access to therapies for chronic illnesses. In India, pharmaceutical companies like Biocon and Dr. Reddy's Laboratories contribute significantly to the availability of these medicines, supporting improved healthcare access and long-term sustainability (1, 2).

1.3 Burden of Chronic Diseases in India

Chronic diseases such as heart disease, cancer, diabetes, and respiratory conditions are a major health concern in India. As reported by the World Health Organization, they cause around 63% of total deaths, showing their serious impact on public health (3, 4).

1.4 Key Characteristics of Biosimilars

Biosimilars are similar to original biologics with comparable safety and effectiveness. They undergo strict testing and approval, and being more affordable, they help expand access to quality treatments (5, 6).

1.5 Difference Between Biosimilars and Generics

Biosimilars and generics are both designed to provide cost-effective alternatives to original branded medicines. However, they are quite different in terms of how they are made, their molecular structure, and the regulatory standards required for their approval.

Table 1. Difference Between Biosimilars and Generics (7, 8)

Feature	Biosimilars	Generics
Definition	Highly similar versions of approved biologic medicines	Exact copies of small-molecule drugs
Origin	Produced using living organisms such as cells or bacteria	Made through chemical synthesis
Molecular Structure	Large and structurally complex	Small and relatively simple

Feature	Biosimilars	Generics
Identical to reference product	Not identical, but highly similar	Completely identical
Manufacturing Process	Highly complex, based on biotechnology	Simple and well-established chemical methods
Regulatory Requirements	Require extensive analytical, preclinical, and clinical comparability studies	Require only bioequivalence testing
Cost Reduction	Moderate reduction (around 20–40%)	High reduction (up to 80–90%)
Examples	Monoclonal antibodies, insulin products	Paracetamol, ibuprofen

1.6 Central Drugs Standard Control Organization (CDSCO)

The Central Drug Standard Control Organization (CDSCO) functions under the Ministry of Health and Family Welfare of the Government of India and is responsible for regulating drug and pharmaceuticals in the country (9,10).

1.6.1. Key Roles of CDSCO in Biosimilar Regulation

- Market Approval
- Clinical Trial Oversight
- Assessment of Safety and Effectiveness
- Post-Market Monitoring
- Regulatory Compliance

Overall, CDSCO plays a crucial role in confirming that biosimilars are sufficiently similar to their reference biologics before allowing their use in the Indian healthcare system.

1.6.2. Department of Biotechnology (DBT)

The Department of Biotechnology, under the Ministry of Science and Technology, supports biosimilar development in India by providing scientific guidance and promoting research and innovation in the biopharmaceutical sector.

1.6.3. Key Roles of DBT

- Support for Scientific Assessment
- Development of Guidelines
- Technical Advisory Role
- Promotion of Research Capacity

1.6.4. Collaborative Regulatory Mechanism

In India, biosimilars are regulated under a collaborative system between the Central Drug Standard Control Organization (CDSCO) and the department of biotechnology, following the "Guideline on Similar Biologics"

This collaboration ensures:

• Strong scientific evaluation through DBT expertise

• Strict regulatory oversight by CDSCO

• Alignment with global standards set by the World Health Organization and European Medicines Agency

1.6.5. Importance of the Regulatory Framework

- Ensures safety and effectiveness of biosimilar medicines
- Builds confidence among healthcare providers and patients
- Encourages innovation in India's biopharmaceutical sector
- Strengthens India's position in the global biosimilars market (7,8)

2. Guidelines for Similar Biologics (2016, Revised 2019) and Approval Process

The "Guidelines on Similar Biologics" were jointly prepared by the Central Organization Standard Control Organization and the department of biotechnology outline the regulatory route for the development and approval of biosimilars in India. Initially introduced in 2012 and later updated in 2016 and 2019, these guidelines aim to ensure that biosimilars closely match the reference biologic in terms of quality, safety, and therapeutic effectiveness (11,12). The framework is also consistent with international standards, including those

2.1. Analytical Studies

Analytical testing is the first and most important stage in biosimilar development. It involves detailed analysis of physicochemical properties like structure, purity, molecular weight, and glycosylation, along with testing biological activity through specific assays.

2.2. Preclinical Studies

After analytical similarity is confirmed, preclinical studies are performed. These include in vitro experiments to assess biological activity, help evaluate safety, guide dose selection, and reduce risks before clinical trials.

2.3. Clinical Studies

Clinical trials are conducted to confirm similarity in human subjects.

- Usually performed in Phase I and Phase III, depending on regulatory requirements.

- Evaluate pharmacokinetics (PK), pharmacodynamics (PD), safety, efficacy, and immunogenic response.

2.4. Post-Marketing Surveillance (Additional Requirement)

Even after approval, continuous monitoring is essential.

- Involves tracking long-term safety and identifying rare or unexpected adverse reactions.
- Ensures ongoing assessment of the benefit–risk balance after the product is introduced to the market (10).

3. Current Scenario of Biosimilars in India

India has developed into one of the most rapidly expanding and significant markets for biosimilars worldwide.

3.1 Market Size and Growth

The biosimilars market is rapidly growing, driven by demand in cancer, diabetes, and autoimmune treatments. India is also a key exporter, supplying biosimilars to global markets.

3.2 Number of Approved Biosimilars in India

India has around 90-100+ approved biosimilars, making it a global leader. Approvals began in the early 2000s with products like the hepatitis B vaccine and increased significantly after structured guidelines were introduced in 2012 and later updated (13,14, 15).

4. Applications of Biosimilars

Biosimilars are extensively used in multiple therapeutic areas in India and worldwide (16, 17, 18).

Table 2: Applications Of Biosimilars

Sr. No.	Therapeutic Area	Medicine	Indications /Uses	Key Benefits
1.	Oncology	Trastuzumab, Rituximab,	Breast cancer; Blood cancers	Largest application area globally; biosimilars

		Bevacizumab	(lymphoma, leukemia)	reduce cost and improve access to therapy
2.	Autoimmune Disease	Adalimumab, Infliximab, Etanercept	Rheumatoid arthritis; Psoriasis; Crohn's disease	Supports long-term disease management at affordable cost
3.	Diabetes Management	Insulin glargine, Recombinant insulin products	Type 1 diabetes; Type 2 diabetes	Highly significant in India due to large diabetic population

4. Advantages of Biosimilars

Biosimilars offer a range of significant benefits to patients, healthcare systems, and the pharmaceutical industry.

4.1. Cost-effectiveness

Biosimilars offer high-quality treatment at a lower cost than original biologic drugs. Since they do not require full clinical trials like new biologics, their development is faster and less expensive, making treatments more affordable.

4.2. Improved Patient Access

Biosimilars help make advanced treatments more affordable, especially in low- and middle-income countries, allowing more patients to access proper care and reducing healthcare inequalities.

4.3. Reduced Healthcare Burden

Biosimilars help ease the overall burden on healthcare systems by lowering both direct treatment costs and indirect expenses linked to chronic disease management. Direct savings are achieved through reduced drug prices, while indirect benefits include better disease

4.4. Encouragement of Competition

Biosimilars boost market competition, reducing medicine prices and driving innovation. They encourage companies to improve efficiency and develop better therapies, while regulators like the FDA and European Medicines Agency help ensure biologic treatments remain affordable (19,20).

5. Challenges and Limitations

Biosimilars have greatly improved access to biologic medicines and helped lower overall healthcare expenses.

5.1. Manufacturing Complexity

A key limitation of biosimilars is the complexity of biologic drug production. Since biologics are made using living cells, even small changes in production or storage conditions can affect the final product.

5.2. Regulatory Hurdles

The approval process for biosimilars is complex and strict. Manufacturers must show close similarity to the original biologic through detailed testing, including laboratory studies, animal studies, and sometimes clinical trials.

5.3. Lack of Awareness Among Clinicians and Patients

A key challenge with biosimilars is limited awareness and misconceptions among doctors and patients. Concerns about safety and effectiveness make doctors cautious, while patients often mistakenly believe biosimilars are low-quality or simple generics.

5.4. Pharmacovigilance Issues

Pharmacovigilance is essential for biosimilars but faces challenges like traceability. It can be difficult to identify whether a patient received the original biologic or a biosimilar, requiring proper naming and accurate record-keeping.

5.5. Patent and Legal Barriers

Intellectual property rights and legal barriers can delay biosimilar entry into the market. Multiple secondary patents, known as “patent thickets,” protect original biologics and can slow down biosimilar development even after the main patent expires.

6. Future Perspectives of Biosimilars

The future of biosimilars is promising due to rising demand for affordable treatments, increasing chronic diseases, and ongoing improvements in regulations and industry practices.

6.1. Growth Opportunities in India

India is a fast-growing biosimilar market due to high disease burden and demand for affordable treatments. With strong production capacity and support from the CDSCO, the country is emerging as a major global hub for biosimilars.

6.2 Government Initiatives (Make in India)

The Make in India program supports biosimilar growth by encouraging local production and reducing imports, with help from Biotechnology Industry Research Assistance Council and Department of Biotechnology through funding and infrastructure support.

6.3. Export Potential

India has strong biosimilar export potential due to low-cost manufacturing and compliance with standards from the World Health Organization, European Medicines Agency, and FDA, helping expand affordable treatments globally.

6.4. Development of Biobetters

Biobetters are improved versions of existing biologic drugs designed to enhance features like longer action, reduced immune reactions, better effectiveness, and more convenient dosing, unlike biosimilars which are copies of original biologics.

6.5. Role of Technology (AI and Personalized Medicine)

AI improves manufacturing by optimizing cell line selection, predicting protein structures, and ensuring consistent production. It also enhances clinical trials by identifying suitable patients and accurately assessing immune response risks (20, 21).

7. Conclusion

Biosimilars are changing the Indian healthcare system by making life-saving biologic therapies much cheaper and easier to get. India has made it easier for high-quality biosimilars to be developed and approved by setting up a strong regulatory framework through the Central Drugs Standard Control Organization (CDSCO) and providing strategic policy and scientific support through the Department of Biotechnology (DBT).

These improvements have made it easier for more people to get important treatments for chronic and life-threatening conditions like cancer, diabetes, and autoimmune diseases. This has made things less expensive for both patients and the healthcare system. Also, Indian pharmaceutical companies are actively involved in biosimilar innovation and production, which has made the country a stronger player in the global biopharmaceutical market.

In the future, it will be very important to keep investing in research and development, make pharmacovigilance systems stronger, and make sure that regulations are in line with global standards. Another important factor in getting more people to accept biosimilars is making sure that both healthcare professionals and patients know how safe and effective they are.

In conclusion, biosimilars are not only a cheaper option than biologics, but they also have a lot of potential to change the future of healthcare in India by making it more fair, accessible, and long-lasting.

8. References

1. World Health Organization. Guidelines on evaluation of similar biotherapeutic products. Geneva: WHO; 2009.

2. European Medicines Agency. Biosimilars in the EU: information guide. London: EMA; 2020.

3. World Health Organization. Noncommunicable diseases country profile: India. Geneva: WHO; 2022.

4. Indian Council of Medical Research. India: health of the nation's states report. New Delhi: ICMR; 2017.
5. European Medicines Agency. Guideline on similar biological medicinal products. London: EMA; 2014.
6. Central Drugs Standard Control Organization. Guidelines on similar biologics. New Delhi: CDSCO; 2019.
7. Department of Biotechnology. Regulatory guidelines for similar biologics. New Delhi: DBT; 2016.
8. Central Drugs Standard Control Organization. List of approved similar biologics in India. New Delhi: CDSCO; 2023.
9. Indian Council of Medical Research. Cancer and diabetes treatment guidelines. New Delhi: ICMR; 2022.
10. Biocon Ltd, Dr. Reddy's Laboratories Ltd, Zydus Lifesciences Ltd. Company product monographs. India; 2024–2025.
11. Biocon Biologics. Product portfolio data. Bengaluru: Biocon Biologics; 2023–2024.
12. Dr. Reddy's Laboratories. Biosimilar pipeline information. Hyderabad: Dr. Reddy's Laboratories; 2024–2025.
13. Pharma Outlook, 6W Research. India biosimilars market analysis reports. 2020–2025.
14. Biosimilars in India: current status and future perspectives. PMCID/PMC. 2021–2022.
15. European League Against Rheumatism. Position statements on biosimilars. EULAR; 2022.
16. IQVIA Institute. The impact of biosimilars on healthcare systems. IQVIA; 2023.
17. Blackstone EA, Fuhr JP. The economics of biosimilars. Am Health Drug Benefits. 2013;6(8):469–478.
18. U.S. Food and Drug Administration. Biosimilars action plan: 2018–2023 updates. Silver Spring (MD): FDA; 2023.
19. World Health Organization. Guidelines on evaluation of similar biotherapeutic products. Geneva: WHO; 2019.
20. World Health Organization. Guidelines on similar biotherapeutic products and global access strategies. Geneva: WHO; 2019–2023.
21. Central Drugs Standard Control Organization. Guidelines on similar biologics in India: updated framework. New Delhi: CDSCO; 2016.

India's Emergence As A Global Biopharmaceutical Player: Aligning CDSCO Guidelines With International Standards For Health Equity


Kirti Rajput, Kamla Pathak*

Department of Pharmaceutics, Faculty of Pharmacy, Uttar Pradesh University of Medical Sciences, Saifai, Etawah 206130, Uttar Pradesh

Email: kamlapathak5@gmail.com

Abstract

The world of pharmaceuticals is in a state of transformation as biologics - complex drugs derived from living organisms, become increasingly significant for chronic and severe diseases. Despite their transformative impact on patient lives, their exorbitant prices restrict their access. However, a major "patent cliff" from 2022 to 2032, with almost 300 drug patents expiring each year, has set impetus for rapid growth of the biosimilar market. This article explores the changing regulatory landscape of USFDA, EMA, CDSCO and other nations. At the same time, India is gradually escalating the ladder from being a local manufacturer to global player by adopting 2025 guidelines in line with WHO standards, enabling availability of biopharmaceuticals for low- and middle-income nations. This article also discusses the opportunities and challenges in the global uptake of biosimilars. Conclusively, a holistic approach, blending scientific excellence with equity, is needed to ensure access to life-saving drugs for all patients worldwide.

Keywords: Biologics, biosimilars, patent cliff, USFDA, EMA, CDSCO

1. Introduction

Biologics is a rapidly evolving industry in the pharmaceutical sector that utilizes biotechnological methods involving live systems and tissues to produce sophisticated medications. The introduction of biologics around ten years ago revolutionized the way chronic

and potentially fatal diseases like psoriasis, ulcerative colitis, juvenile idiopathic arthritis and rheumatoid arthritis were treated (1, 2). As per FDA, a biosimilar is a biological product significantly similar to an existing FDA-approved reference product (RP), assuring no clinically significant differences (3). Likewise, the EMA (European Medicines Agency) defines a biosimilar as a therapeutic agent potentially similar to another biological therapeutic agent already commercialized in the European Union (4). The description of biosimilar as per CDSCO is a biological product similar in terms of quality, efficacy and safety to a pre-approved Reference Biological product (5). Biologics necessitate advanced production techniques to guarantee uniform product quality, safety, and efficacy throughout their lives (6).

Biosimilars, which are less expensive substitutes, have set foot in the market as original biologics are losing their exclusivity. A biological product designed to closely resemble an already-approved "reference" biologic is called a biosimilar (7, 8). In order to ensure that patients receive the same therapeutic benefit without the need for unnecessary clinical testing, regulatory organizations such as the FDA and EMA increasingly rely on sophisticated analytical technologies to verify that the biosimilar's molecular structure and function match the original.

According to research by Drug Patent Watch, almost 300 drug patents in various categories will expire annually during the patent cliff period of 2022–2032, a list of more than 300 US patents that will expire in 2020–2030. This pattern will persist until 2036. According to an estimate, twenty-four significant blockbuster patents will expire between 2020 and 2030. As a result, megasellers like Humira (adalimumab) will no longer have exclusivity in the US starting in 2023. In 2019, Humira biosimilars were introduced in Europe, which has already caused the brand's scale to deteriorate (9).

As of 2025, the growing frequency of chronic diseases, patent expirations, and the growing need for reasonably priced biologics are all contributing factors to the worldwide biosimilar market's rapid expansion. The market is valued at more than 28 billion USD in 2024 and is expected to increase annually at a robust rate to surpass 120 billion USD by 2033. While Europe, which holds more than half of the global market, continues its stewardship via strong replacement policies, regulatory frameworks, and clinical acceptance, the United States is anticipated to generate significant savings through increased FDA approvals and greater use
(10). The recently approved biosimilars (2024-2026) are listed in Table 1.

Table 1. Currently approved biosimilars in different regulatory authorities (11-13)

Regulatory Authority	Reference product	Approved Biosimilar	Year
USFDA	Eylea®(Aflibercept)	Eydenzelt	2025
	Prolia / Xgeva (Denosumab)	Boncresa /Oziltus, Osvyrti /Jubereq, Enoby / Xtrenbo, Aukelso /Bosaya	
	Lucentis (Ranibizumab))	Nufymco	2025
	Stelara® (Ustekinumab)	Starjemza	
	Actemra® (Tocilizumab)	Tyenne® Avtozma®	
	Perjeta (Pertuzumab)	Poherdy	
	Prolia (Denosumab)	Ponlimsi	2026
	Neupogen (Filgrastim)	Filkri	
Europe	Stelara	Uzpruvo, Fymskina	2024
	Prolia®/Xgeva	Stoboclo, Osenvelt	2025
	Eylea	Eydenzelt	
	ROACTEMRA	Avtozma	
Japan	Stelera	Ustekinumab BS	
	Ranmark	Denosumab Biosimilar	
	Simponi	Golimumab Biosimilar 1	
	Eylea	Aflibercept Biosimilar 2	
	Xolair	Omalizumab BS	2026
	Actemra	Tocilizumab BS	

2. Regulatory Landscape

Biosimilar development is a laborious process that encompasses clinical trials, analytical, functional, and nonclinical evaluations. The selection of an appropriate reference medicine, which must denote similarity in quality, efficacy and safety via a stepwise method, is a critical challenge in this process. In this phase, functional analytical investigations are essential because they evaluate the structural and functional characteristics of biosimilars in comparison to their reference products. Rather than separately proving the biosimilar's safety and efficacy, these studies seek to confirm its similarity. There are still disagreements over things like immunogenicity, interchangeability, and nomenclature even though our understanding of biosimilars has grown. To guarantee that quality, safety, and efficacy criteria are upheld, regulators and developers must work together to maximize the benefits of biosimilars (14). The regulatory guidelines for biosimilars in the US, EU and India will be scrutinized in the preceding text.

2.1 USFDA Regulations

The US biosimilar regulatory journey has progressed from the initial Biologics Price Competition and Innovation Act (BPCIA) under section 351k of the Public Health Service Act (PHSA) of 2009 where the first approval occurred in 2015 with figrastim-sndz Zarxio® (15,16) to a revolutionary "analytical first" approach in 2025. This historic decision officially exempted the default requirement for comparative efficacy and safety clinical trials, as long as residual doubts are resolved by definitive analytical similarity, functional characterization, pharmacokinetic (PK) profiles and immunogenicity data. This shift is reflected in the approval of the first interchangeable biosimilar Wezlana (ustekinumab) to Stelara, and the first applications for monoclonal antibodies without efficacy trials (17,18).

With this totality-of-evidence, risk-based assessment, even interchangeability can be approved without mandatory switching studies if the analytical and PK data are decisive. This led to market explosion in 2015 with 18 biosimilars approved referencing 10 compounds across a wide range of therapeutic areas - such as denosumab, ophthalmology (aflibercept), immunology (tocilizumab) and diabetes (insulin aspart) - driving the number of active development programs in the FDA's Biosimilar Biological Product Development (BPD) program to 135 (18).

2.2 EMA Regulations

In 2004, the EU established the first biosimilar approval system in history, making it a global leader in biosimilar regulation (19). The EMA has constructed a comprehensive regulatory landscape for biosimilars, with three key overarching guidelines that cover the general principles, questions of quality, and the pre-clinical and clinical requirements for biotechnology products (proteins). This core guidance is now evolving towards a more product-specific and clinical-based approach, with recent concept papers focusing on optimising development strategies for efficiency and specificity. To enhance specificity, the EMA has a detailed product-specific list of guidelines for various therapies, including recombinant erythropoietins, granulocyte-colony stimulating factors (G-CSF), low-molecular-weight heparins, somatropin and various insulins.

Additionally, complex biologics, including monoclonal antibodies, follicle-stimulating hormones, and various interferons (alpha and beta), have specific non-clinical and clinical requirements in place to demonstrate their biosimilarity. These rules are complemented with an array of cross-functional guidelines that cover key technical challenges, such as immunogenicity (of therapeutic proteins and monoclonal antibodies), pharmacokinetics, and product comparability for manufacturing changes. These guidelines collectively constitute a

high scientific standard to ensure that biosimilars are equivalent in safety and efficacy to their biological reference therapeutic agents (20, 21).

2.3 CDSCO Regulations

The guidelines for biosimilars (Similar biologics) regulatory requirements for marketing in India were published by CDSCO in 2012 in alliance with the Department of Biotechnology to discourse the regulatory framework for biosimilars in India. The framework was revised in 2016 with focus on the scientific principles involved and the incremental approach to be solicited during the corroboration of similarity between a biosimilar and its reference biological product (22).

Due to their complexity, generally, regulations on clinical trials for biosimilars are far more rigorous in comparison to the generics. Additionally, biosimilars are also monitored for manufacturing, clinical trials and import thereof. These regulations warrant testing of biosimilars in the pre-clinical phase and clinical trials for efficacy and safety (10). However, the Indian regulatory framework has come under scan for being unclear, especially when it comes to implementation. The challenges in Indian context are depicted in Fig. 1. The guidelines on biosimilars are thorough, but they are still only recommendations rather than legally binding regulations, allowing for interpretation and legal conflicts. As a result, neither the government regulatory authority nor the business houses can be held accountable for not following the regulatory guidelines. Furthermore, the current biosimilar regulations should be neatly written, which gives innovators the opportunity to cast doubt on the introduction of new biosimilars (23).

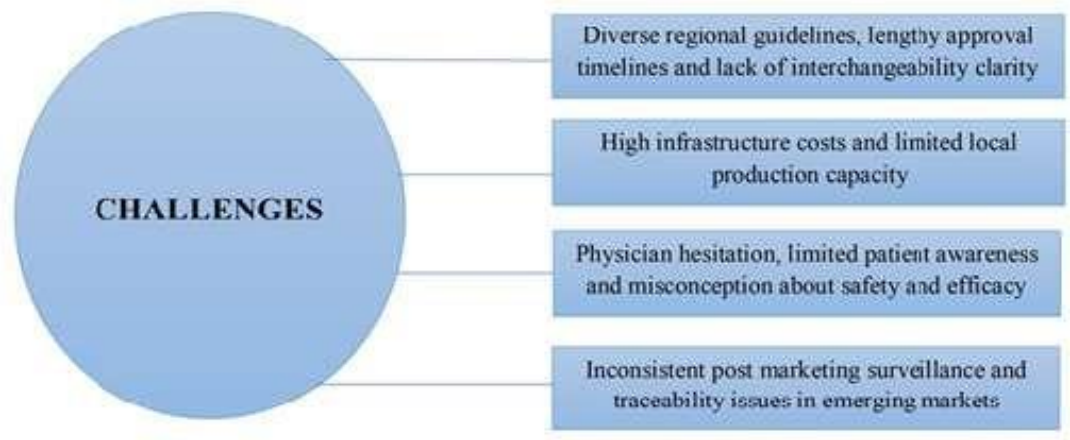

Figure 1. Challenges in global biosimilar adoption

India's 2025 biosimilar guidelines elevate the country from a domestic producer to a proactive global player in biopharmaceutical access, especially for low- and middle-income countries (LMICs). Through harmonisation of the CDSCO guidelines with the WHO's TRS 1043

guidelines, India opens the door to WHO prequalification and streamlines the integration of its biosimilars into international procurement agencies such as UNICEF, GAVI and the Global Fund. Beyond production, India is set to lead the region in capacity building through twinning and South-South exchanges, while also unlocking innovation in biobetters and AI-based manufacturing. Figure 2 presents the opportunities available in the near future. In conclusion, through its diplomatic convenings in the G20 and BRICS, India is bringing together scientific rigour and health equity to become the primary policy maker and supplier of biologics (24).

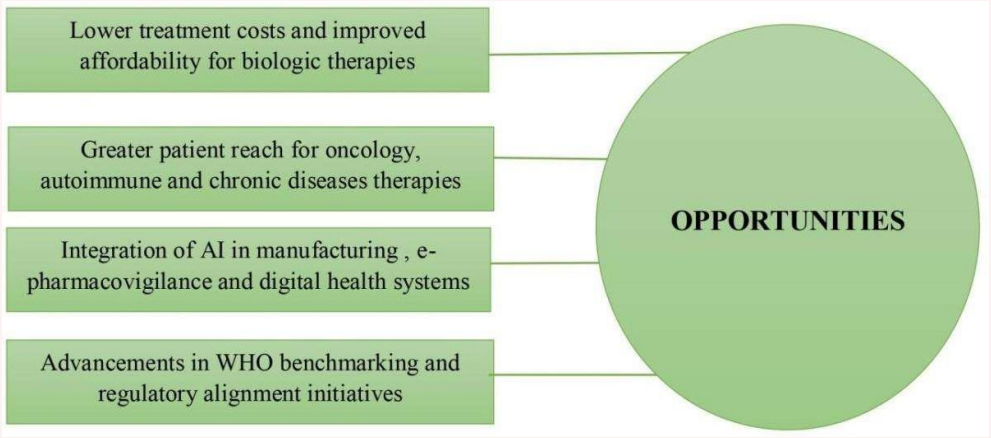

Figure 2. Key opportunities in global biosimilar adoption

A comparison of the biosimilar regulatory framework of developed countries namely US, EU and Japan followed by the examination of the regulatory guidelines in developing countries like India, Brazil and South Africa are depicted in Table 2.

Table 2. Current regulatory landscape of biosimilars (25-33).

Aspects	USFDA	Europe	India	Japan	Brazil	South Africa
Regulatory timeline	351(k)BPCI Act	Art.10(4), Dir.2002/83/EC	Guidelines on Similar Biologics (2020)	PMDA Biosimilar guidelines	RDC 55/2010- RDC 875/2024	Biosimilar guidelines (2019)
Reference Product (RP)	A single FDA-approved RP. A foreign comparator with sufficient scientific support, and bridging data is permissible	Preferably EU - authorized RP is required. Any non-EU comparator is allowed after analytical bridging only	India- licensed RP is preferred. Any foreign RP that is ICH accorded is acceptable with bridging data	Japan approved RP is preferred; Any other RP is allowed if justified	Brazil approved RP; foreign RP allowed if justified	SAHPRA-registered RP; foreign RP allowed
Bridging requirement	When a foreign comparator is employed, a three-way PK bridging study might not be necessary. If sufficient scientific rationale is demonstrated, biosimilar developers can depend on the results evidenced by a non-US licensed comparator without further bridging studies.	Analytical bridging is primary requirement but PK bridging may also be required	Bridging is required when foreign RP is used. Both analytical and comparative PK/PD data is needed	Case by case bridging determination can be affected. Global comparability data may be accepted	Analytical bridging is typically sufficient. Additional PK/clinical data may be requested case by case if desirable	Analytical bridging is usually adequate. Additional information is needed on an individual basis.
Non-clinical requirements	*Focus is on in vitro* studies. In vivo studies are done if needed	*In vitro* data is dominant	*In vitro* + limited *in vivo*	*In vitro* is dominant	May be waived off depending on the totality of evidence	May be waived off depending on scientific justification

Clinical PK/PD requirements	Comparative PK mandatory; PD when relevant	Comparative PK mandatory; PD when applicable	Comparative PK/PD generally required	Comparative PK mandatory; PD when relevant	PK/PD may suffice	Comparative PK/PD generally required
Interchangeability	An "interchangeable" biosimilar status may be granted by the FDA if additional switching studies evidence no risk in terms of safety or diminished efficacy as compared to the RP.	EU-approved biosimilars are interchangeable with their RP. Individual member states oversee the substitution at the pharmacy level.	No formal interchangeability designation recognized.	No separate interchangeability designation recognized. Switching is decided by prescriber	No formal interchangeability designation recognized.	SAHPRA permits interchangeability between biosimilars that have been demonstrated to be equivalent to the same RP as well as between a biosimilar and its RP. The prescribing physician should decide whether to switch.
Pharmacovigilance	Post-marketing surveillance and a risk management plan are necessary. The framework should be same as originators	Post-marketing surveillance and a risk management plan are essential within a framework similar to originators.	Post-marketing surveillance and a risk management plan are essential within a framework similar to originators.	Same pharmacovigilance requirements as originators	Risk management plan is required in a similar framework as the originators	Risk management plan needed in a similar frame work as originators

Naming	International Nonproprietary name (INN)+ 4 -letter suffix	Same INN; brand and batch tracing	Same INN + brand name	Same INN + biosimilar identifier	Same INN	Same INN

3. Recommendations for clinical practice and global regulatory alignment

The project ICH M18 titled as "Framework for determining the utility of comparative efficacy studies in biosimilar development programs" has moved past the approval stage in early 2026, and is currently working on developing the guideline. The guideline's objective is to offer a standardized scientific method for comparative efficacy studies of biosimilar development programs. ICH M18 aims to improve coherence with international regulatory decision-making while supplementing a principled "tailored approach" outlined in the WHO 2022 guidelines. The world's regulatory bodies will remove duplication, standardize the burden of proof, and enable states to rely on common scientific judgments if they adopt the ICH M18 standards.

All things considered, these advancements could speed up access to more reasonably priced biologic medications worldwide and reduce the time and expense of developing new products. Adoption of biosimilars is nevertheless hampered by complicated international patent and legal frameworks, despite regulatory advancements. A fully open-access, centralized digital platform that exclusively compiles data on patent expiration dates, exclusivity periods, litigation status, and regulatory pathways could facilitate prompt and assured clinical adoption. A cross section of ongoing clinical trials on biosimilars is enlisted in Table 3. Education and trust among clinicians is another major issue. Education programs include interactive clinical case discussions, real-world evidence sharing, and authorized online instruction may boost confidence. Particularly in low- and middle-income contexts, additional policy measures including incentives, prescription monitoring, and patient feedback can promote optimal use. Last but not least, enhancing international post-marketing immunogenicity monitoring through cooperative data-sharing networks will guarantee biosimilars' long-term safety, trust, and equitable access (33).

Table 3. Ongoing Clinical Trials on Biosimilars in 2025-26 (33)

Name of Biosimilars	Clinical Trial No.	Company/ Sponsor	Start date	Indication
Trastuzumab biosimilars and Pertuzumab biosimilars plus XELOX	NCT07108127	Peking Union Medical College Hospital, China	2025-06-20	HER2-positive rectal cancer
Ocrelizumab	NCT06847724	Sandoz, USA	2025-06-10	Relapsing multiple sclerosis

Ipilimumab Biosimilar HLX13 vs. YERVOY®	NCT07176650	Shanghai Henlius Biotech, USA	2025-11-25	Hepatocellular carcinoma
Ustekinumab	NCT06997055	Celltrion HealthCare, France	2025-03-17	Crohn's disease
Aflibercept (MY-1701P)	NCT07235527	Saglik Bilimleri Universitesi, Turkey	2025-11-20	Age related macular degeneration
Bevacizumab	NCT06860490	Fudan University, China	2025-03-18	Advanced hepatocellular carcinoma.
Rituximab	NCT06890884	Merck Sharp & Dohme LLC, USA	2025-04-11	Lymphoma
Ranibizumab	NCT07520045	Osijek University Hospital, Croatia	2026-03-12	Diabetic Retinopathy
Sintilimab combined with bevacizumab biosimilar	NCT07324824	Sun Yat-sen University, China	2026-01-14	Hepatic Carcinoma
SCD411	NCT07501052	Sam Chun Dang Pharm. Co. Ltd., USA	2026-05-08	AMD, RVO, DME, or Diabetic Retinopathy (DR)

4. Conclusion

The advent of biosimilars represents a game-changing opportunity to reduce healthcare expenditure and enhance access to biologic medicines globally, but it cannot be achieved through science alone. To guarantee safety and sustainability over time, the global community needs to focus on regulatory alignment, including the establishment of a global safety data platform to monitor real-world data and immunogenicity. Overcoming the global health divide between developed and emerging markets is vital to health equity, and demands international collaboration in surveillance and capacity development. In both the short and long term, the benefits of biosimilars can only be fully harnessed by a comprehensive approach that includes evidence-based education for medical professionals alongside harmonised regulatory pathways to ensure all patients can benefit from these life-saving therapies, wherever they live.

5. References

1. Musti K, Yarra SP, Munukutla KS, Kavala NR. Possible Guidelines and Regulatory Issues on Biosimilars in INDIA, USA, EU. World J Pharm Biotechnology. 2023;10(02):51-6.
2. Tiwari NJ, Narkhede KB, Prajapati A, Narkhede SB, Luhar S. Biologics and biosimilars: Navigating production, approval, applications and challenges. Asian J Res Pharm Sci. 2025;15(2):167-71.
3. Biosimilars Basics for Patients | FDA(2026) Accessed 26 April
4. Biosimilar medicines: Overview | European Medicines Agency (EMA)(2026) Accessed 26 April
5. Guidelines on Similar Biologics | NFS (2026) Accessed 26 April
6. Klein K, Gencoglu M, Heisterberg J, Acha V, Stolk P. The Global Landscape of Manufacturers of Follow-on Biologics: An Overview of Five Major Biosimilar Markets and 15 Countries: K. Klein et al. BioDrugs. 2023;37(2):235-45.
7. Bhardwaja B, Klocke S, Ekinci E, Jackson A, Kono S, Olson KL. Switching from biologic to biosimilar products: insight from an integrated health care system. BioDrugs. 2022;36(1):1-1.
8. Khoo T, Sidhu N, Marine F, Lester S, Quinlivan A, Rowett D, Buchbinder R, Hill CL. Perceptions towards biologic and biosimilar therapy of patients with rheumatic and gastroenterological conditions. BMC Rheumatology. 2022;6(1):79.
9. Car E, Barbier L, Huys I, Simoens S, Vulto AG. Evolving global regulatory landscape for approval of biosimilars: current challenges and opportunities for convergence. Expert Opinion Biology Therapy. 2025;25(6):649-68.
10. Rathod JA, Amthaniwala BK. Comparative insights into biosimilar development in the UAE and India: Opportunities, challenges, and global trends. Ind J Pharm Pharmacology 2025;12(4):194–205.
11. Biosimilar Product Information | FDA Accessed on 26 April 2026
12. European Medicines Agency (EMA) Accessed on 26 April 2026
13. PMDA Approved Biosimilars. https://www.pmda.go.jp/files/000278462.pdf. Accessed on 26 April 2026
14. Mascarenhas-Melo F, Diaz M, Gonçalves MB, Vieira P, Bell V, Viana S, et al. An overview of biosimilars—development, quality, regulatory issues, and management in healthcare. Pharmaceuticals. 2024;17(2):235.
15. Sheridan M, Massich M, Ashourian N. Biosimilars: from production to patient. J Infusion Nursing. 2024;47(1):19-29.
16. Nupur N, Joshi S, Gulliarme D, Rathore AS. Analytical similarity assessment of biosimilars: global regulatory landscape, recent studies and major advancements in orthogonal platforms. Front. Bioeng. Biotechnology. 2022;10:832059.
17. Niazi SK. The coming of age of biosimilars: a personal perspective. Biologics. 2022;2(2):107-27.
18. Jarab AS, Abu Heshmeh SR, Al Meslamani AZ. Bridging the gap: The future of biosimilars regulations. Hum Vaccine Immunotherapy. 2024;20(1):2362450.
19. Cordeiro MA, Vitorino C, Sinogas C, Sousa JJ. A regulatory perspective on biosimilar medicines. Pharmaceutics. 2024;16(3):321.
20. Amaral C, Rodrigues AR, Veiga F, Bell V. Biosimilar medicines: From development process to marketing authorization by the EMA and the FDA. Appl Sci. 2024;14(17):7529.
21. Patel N, Prajapati H, Joshi N, Movaliya V, Kanaki N, Deshpande S, Zaveri M. Regulatory requirements for approval and registration procedure of biosimilar in US and European Union (EU). Int J Drug Regulatory Affairs. 2024;12(1):70-82.
22. CDSCO. Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India. Available from: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf documents/DgSimilaBiologics25.pdf.
23. Vadehra S, Arora A. Biosimilars in India: Regulatory, legal and industry landscape. Kan & Krishme. 2024. Available from: https://kankrishme.com/biosimilars-in-india-regulatory-legaland industry-landscape/
24. Samajdar SS, Husain N, Dikshit H, Suvarna VR, Maheshwari A, Mohan L, Joshi SR. India's biosimilar reform and the global shift away from redundant clinical trials. Perspect Clin Res. 2026:10-4103.
25. Monga A, Gagan, Jamwal P, Sharma S, Kaur A. Biosimilars: a critical review of development, regulatory landscape, and clinical implications. AAPS PharmSciTech. 2025;26(1):46.
26. Mandhare AS. *Biosimilars 2024* (Doctoral dissertation, Thesis. Blue Marble University, India).
27. Kaur S, Yadav S, Sahu V, Sharma N, Shukla VK. Biosimilar regulations: Current framework and future prospects. Curr Drug Safety. 2025 May 23.
28. Haritwal P, Lohani A. Regulatory and safety challenges of biosimilars: insights from developed and emerging economies. Eur J Clin Pharmacol. 2026;82(5):125.
29. Kurki P, Barry S, Bourges I, Tsantili P, Wolff-Holz E. Safety, immunogenicity and interchangeability of biosimilar monoclonal antibodies and fusion proteins: a regulatory perspective. Drugs. 2021;81(16):1881-96.
30. Ubendran J, Kumar S. A Comparative Study of Regulatory Compliance for Biosmilars in US, EU and INDIA. World J Pharm Biotechnol. 2023;10(02):79-84.
31. Kasana H, Chander H, Mathur A. A Systematic Review of Regulatory requirements of Biosimilar Products: WHO, India, European Union and USFDA. Res J Pharm Technol. 2024;17(5):2413-20.
32. Rizwan A, Dubey K, Malhotra V, Bhatnagar S. Biosimilars: Bridging the Gap in Biologics, Access, and Affordability. J Pharm Bio Tech Ind. 2026;3(1):2.
33. ClinicalTrials.gov. U.S. National Library of Medicine. 2020. Available from: https://ClinicalTrials.gov. Accessed on 36 April 2026.

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ONCOLOGY
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HUMOG
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EPOFER
BASALOGONE

PHARMA NEWS ROUND-UP

12th January, 2026: Alembic Pharmaceuticals has received tentative approval from the U.S. Food and Drug Administration for its Bosutinib tablets (400 mg), a medication used in the treatment of Chronic Myelogenous Leukemia. This approval represents an important milestone for Alembic's expansion in the U.S. oncology market. The company had already secured final approvals for other strengths of Bosutinib, and this latest development strengthens its overall product portfolio. Tentative approval indicates that the product meets regulatory standards but cannot be marketed until patent or exclusivity protections expire, positioning Alembic for future entry into the U.S. market.

23rd January, 2026: The Indian government has introduced a major regulatory reform to accelerate pharmaceutical innovation by reducing the review period for manufacturing applications of new drugs to just 45 days. Under the updated framework overseen by the Central Drugs Standard Control Organization, manufacturers can now initiate clinical trials or bioequivalence studies through a prior notification system, eliminating the earlier requirement for explicit regulatory approval. This shift is expected to significantly shorten development timelines, lower entry barriers, and encourage faster innovation, particularly in complex areas like biologics and biosimilars. By streamlining approvals while maintaining regulatory oversight, the reform aims to enhance India's competitiveness as a global hub for pharmaceutical research, development, and manufacturing.

23rd January, 2026: Zydus Lifesciences, Ahmedabad, has launched **Tishtha**, the world's first biosimilar of nivolumab, in India. This landmark development is expected to significantly reduce the cost of immunotherapy for cancer patients, improving access to advanced oncology treatments. The launch follows a favorable decision by the Delhi High Court, which allowed the company to market the biosimilar prior to the original patent expiry. This move highlights India's growing capabilities in complex biologics and biosimilars, while also setting an important precedent for balancing innovation, patent law, and patient affordability.

01st February, 2026: India is set to strengthen its position in the global biopharmaceutical sector following the announcement of the **Biopharma Shakti initiative** in the Union Budget 2026. Finance Minister Nirmala Sitharaman revealed plans to invest ₹10,000 crore over the next five years to boost the development and manufacturing of biologics and biosimilars. This initiative aims to enhance domestic production capacity, reduce dependence on imports, and

support innovation in complex biologics. By improving infrastructure, encouraging research, and fostering industry growth, the program is expected to position India as a major global hub for affordable and high-quality biopharmaceuticals, while also strengthening healthcare access both domestically and internationally.

04th February, 2026: AstraZeneca Pharma India has received approval from the Central Drugs Standard Control Organization for the use of Durvalumab, marketed as Imfinzi, in combination with chemotherapy for the treatment of gastric and gastroesophageal junction cancers. This approval introduces a perioperative immunotherapy approach for adult patients with resectable disease, where the drug is used alongside standard chemotherapy before and after surgery. The goal is to enhance treatment outcomes and improve survival rates, marking a significant advancement in the use of biologic immunotherapies for gastrointestinal cancers in India.

06th February, 2026: Zydus Lifesciences has announced a significant milestone, with the U.S. Food and Drug Administration granting Orphan Drug Designation to Desidustat for the treatment of Sickle Cell Disease. Desidustat, a novel oral therapy, is being explored for its ability to address the underlying needs of patients with limited treatment options.

10th February, 2026: AstraZeneca Pharma India has received approval from India's drug regulator, the Central Drugs Standard Control Organization, for a new indication of Durvalumab, marketed as Imfinzi. This approval enables its use in the treatment of advanced or recurrent endometrial cancer. Under the new regimen, Durvalumab will be administered in combination with other therapies as part of the initial treatment, followed by its use as maintenance therapy in selected patients. This development expands the role of immunotherapy in gynecological cancers and highlights ongoing advancements in targeted biologic treatments in India.

12th February, 2026: Biological E Limited has reached a major milestone with the World Health Organization granting phase II prequalification for its Novel Oral Polio Vaccine type 2 (nOPV2). This approval enables vaccine manufacturing at a dedicated production site, strengthening global supply capacity. The development is significant in the ongoing fight against polio, as nOPV2 is designed to be more genetically stable than earlier oral polio vaccines, helping reduce the risk of vaccine-derived outbreaks. It also highlights India's growing contribution to global immunization efforts and its leadership in vaccine innovation and large-scale biologics manufacturing.

30th April, 2026: Dr. Reddy's Laboratories has achieved a major milestone by securing market authorization from Health Canada for its generic semaglutide injection, a high-demand GLP-1 receptor agonist, becoming the first company to receive such approval for this therapy in Canada. The authorization covers 2 mg/pen and 4 mg/pen dosage strengths, positioning the company for an imminent launch in the Canadian market. The strengthens Dr. Reddy's presence in international markets and reinforcing India's role as a key player in the evolving biologics and biosimilars landscape.

30th April, 2026: A recent clinical trial involving adults with alcohol use disorder suggests that GLP-1 receptor agonists such as semaglutide, commonly used for diabetes and obesity, may also help reduce alcohol consumption. In this study, the participants receiving weekly semaglutide injections demonstrated a significant reduction in heavy drinking (nearly 50% decrease in heavy-drinking days) compared to placebo. The mechanism is believed to involve modulation of brain reward pathways, particularly those linked to dopamine, which reduces cravings and the reinforcing effects of alcohol. Although these findings indicate a potential new therapeutic application of GLP-1 drugs beyond metabolic diseases, long-term studies are required before such drugs can be routinely recommended for alcohol use disorder.

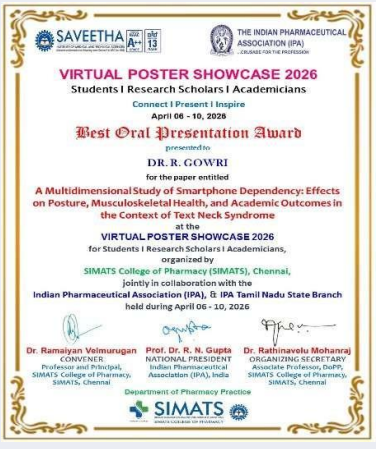
https://economictimes.indiatimes.com/

APTI Forum News

1. **Academic Excellence Award - Souhard 2026**

Ms. Nikita Dhanaji Gidde was honored with the Academic Excellence Award at the prestigious Souhard 2026 event, organized by the All India Journalist Association in association with the Sanjay Bhokare Group of Institutes, Miraj. The award was presented by Hon'ble Mr. Murlidhar K. Mohol, Minister of State for Civil Aviation and Cooperation, Government of India, in recognition of her outstanding academic achievements. The event aimed to celebrate excellence across diverse fields while highlighting the importance of inspiring youth towards nation-building, in line with the vision of "Developed India 2047." The occasion was attended by several eminent dignitaries from media, academia, and public service, making it a significant platform for recognizing and encouraging academic and professional excellence.

2. **Dr. R. Gowri**, Associate Professor, Department of Pharmaceutics, GRT Institute of Pharmaceutical Education and Research (GRTIPER), Tiruttani, Tamil Nadu, received the Best Oral Presentation Award for the research paper titled "A Multidimensional Study of Smartphone Dependency: Effects on Posture, Musculoskeletal Health and Academic Outcomes in the Context of Text Neck Syndrome," at an event organized by SIMATS College of Pharmacy, Chennai, in collaboration with the Indian Pharmaceutical Association and IPA Tamil Nadu State Branch, held from April 6-10, 2026.


SAVEETHA
THE INDIAN PHARMACEUTICAL ASSOCIATION (IPA)
VIRTUAL POSTER SHOWCASE 2026
Students I Research Scholars I Academicians
Connect I Present I Inspire
April 06 - 10, 2026
Best Oral Presentation Award
presented to
DR. R. GOWRI
for the paper entitled
A Multidimensional Study of Smartphone Dependency: Effects on Posture, Musculoskeletal Health, and Academic Outcomes in the Context of Text Neck Syndrome
at the
VIRTUAL POSTER SHOWCASE 2026
for Students I Research Scholars I Academicians,
organized by
SIMATS College of Pharmacy (SIMATS), Chennai,
jointly in collaboration with the
Indian Pharmaceutical Association (IPA), & IPA Tamil Nadu State Branch
held during April 06 - 10, 2026
Dr. Ramaiyan Velmurugan
CONVENER
Professor and Principal,
SIMATS College of Pharmacy,
SIMATS, Chennai
Prof. Dr. R. N. Gupta
NATIONAL PRESIDENT
Indian Pharmaceutical
Association (IPA), India
Dr. Rathinavelu Mohanraj
ORGANIZING SECRETARY
Associate Professor, DoPP,
SIMATS College of Pharmacy,
SIMATS, Chennai
Department of Pharmacy Practice
SIMATS

3. **Sandhya V** and **Dr. Soumya**, Assistant Professors from Yenepoya Pharmacy College & Research Centre, Yenepoya (Deemed to be University), were awarded the Best Poster Presentation at Pharma Anveshan 2026, a state-level academia–industry conclave organized by the Pharmacy Council of India on March 30, 2026, at Manipal College of Pharmaceutical Sciences, MAHE, Manipal. The event, held in celebration of National Pharmacy Education Day, witnessed participation from 135 delegates across 12 institutions.

4. **Dr. Disha Kesharwani**, Assistant Professor at Columbia Institute of Pharmacy, Raipur, has earned her Ph.D. in August 2024 in Pharmacy, Biomedical Sciences, and Biotechnology from CSVTU, Bhilai, under the guidance of Dr. Swarnali Das Paul and co-supervision of Dr. Rishi Paliwal and Dr. Trilochan Satapathy. Her research focused on the development of a nanocarrier system of diacerein for topical application. She has over 12 years of experience and has published 20 research articles, along with 2 book chapters and 2 patents, and is a lifetime member of IPA, IPGA, and the Society of Pharmacognosy.

5. **Dr. Monika Bhairam**, Assistant Professor at Columbia Institute of Pharmacy, Raipur, has earned her Ph.D. in December 2023 in Pharmacy, Biomedical Sciences, and Biotechnology from CSVTU, Bhilai, under the guidance of Dr. Ravindra Kumar Pandey and Dr. Shiv Shankar Shukla. Her research focused on nanocarrier-mediated systems to enhance the solubility of poorly soluble drugs. She has over 15 years of experience and has published 25 research articles, along with 6 books, 10 book chapters, and 2 patents, and is a lifetime member of IPA, IPGA, and the Society of Pharmacognosy.

6. **Dr. Neha Dubey**, Assistant Professor at Columbia Institute of Pharmacy, Raipur, has earned her Ph.D. in September 2023 in Pharmacy under the guidance of Dr. Om Prakash Agrawal and co-supervision of Dr. Bina Gidwani. Her research focused on the formulation and evaluation of a nanoparticulate system of rivastigmine for the treatment of Alzheimer's disease. She has over 12 years of academic and research experience and has published more than 22 research articles, along with 1 book, 8 book chapters, and 3 design patents.

7. **Columbia Institute of Pharmacy, Raipur**, organized a two-day National Seminar on "Sustaining Comprehensive Feat of the Conservation Approaches for Endangered Species of Medicinal Plants of Chhattisgarh State Using Artificial Intelligence" on October 30-31, 2025. Sponsored by the Chhattisgarh Tribal Local Health Traditions and Medicinal Plant Board, the seminar witnessed participation from over 160 delegates, with active poster presentations by 49 students focusing on conservation strategies and AI applications in medicinal plant research.

8. International Conference on Global Health and Innovation

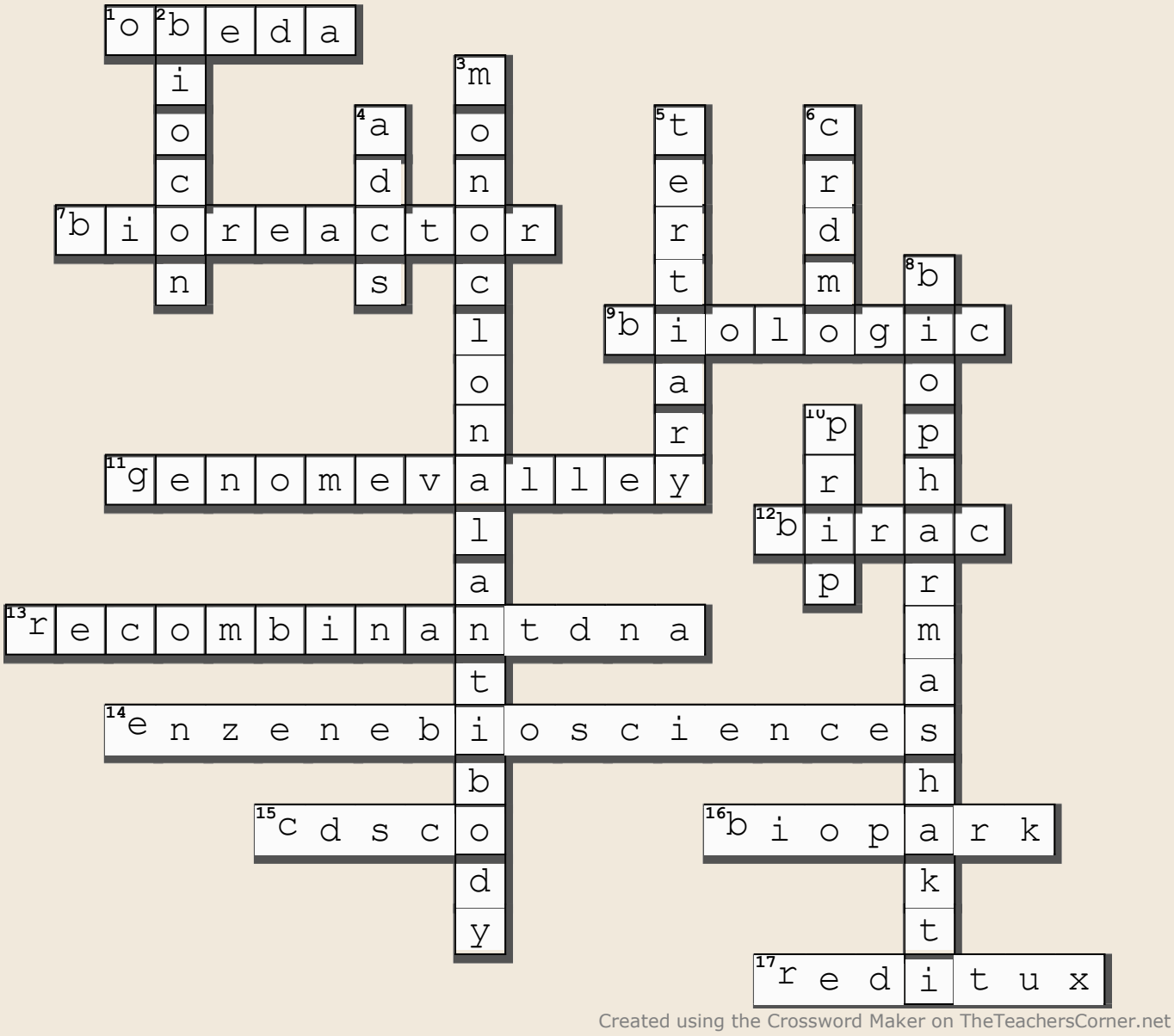
Himachal Institute of Pharmacy, Paonta Sahib, in association with the Himachal Pradesh State APTI Branch, organized a two-day International Conference on "Pharmacy Beyond Borders: Translating Innovation into Impact for Global Health" on February 27–28, 2026. The conference witnessed participation from over 1,200 delegates across 22 states and five countries, providing a platform for academicians, researchers, and industry experts to discuss emerging trends and global health challenges. The event featured eminent national and international speakers, along with over 400 research presentations through oral and poster sessions. Academic books and a pharmacy inventory management software were also launched, making the conference a significant step toward promoting innovation and collaboration in pharmaceutical sciences.

9. Greenness Challenge Activity

Sri Adichunchanagiri College of Pharmacy, Adichunchanagiri University, organized a "Greenness Challenge: A Game-Based Learning Activity" on March 17, 2026. The session, conducted by Dr. Yenduri Suvarna, focused on enhancing students' understanding of Green Analytical Chemistry metrics through interactive group activities. The program promoted collaborative learning, critical thinking, and analytical skills, while encouraging the application of sustainable practices in pharmaceutical education.

Name:_____

Complete the crossword puzzle below



Across

1. Generic semaglutide launched by Dr. Reddy's Laboratories (**obeda**)
7. Large-scale cell-based system used for producing biologics (**bioreactor**)
9. Complex protein drugs produced from living cells (**biologic**)
11. Indian Biotech Cluster Renowned as a vaccine hub (**genomevalley**)
12. Organization funding biotech startups in India (**birac**)
13. Technique enabling high-yield protein production via gene insertion (**recombinantdna**)
14. Indian CDMOs Specializing in ADCs (**enzenebiosciences**)
15. Regulatory authority approving biologics in India (**cdsco**)
16. Industrial parks supporting biotech manufacturing (**biopark**)

Down

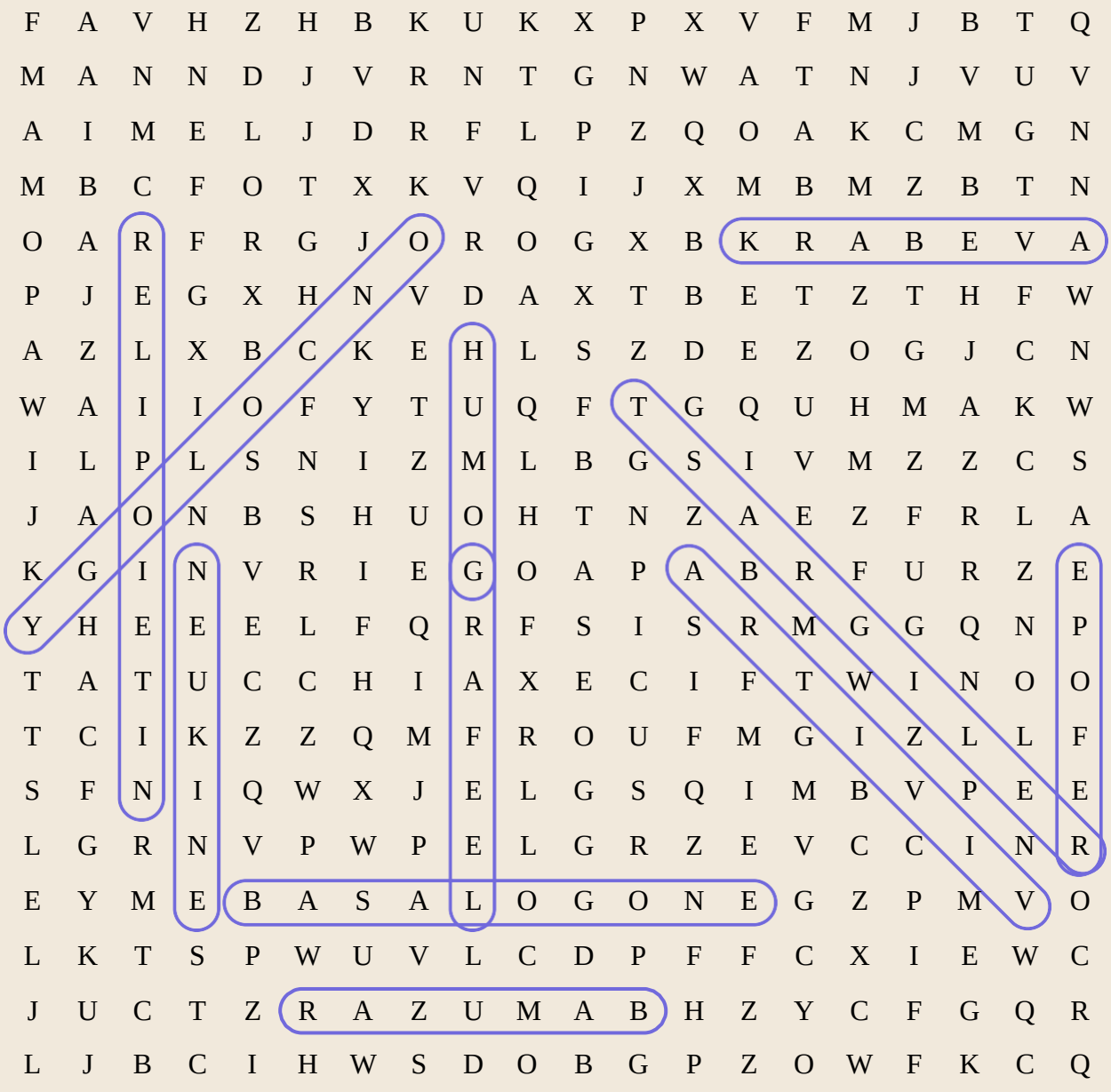
2. Indian company known for insulin biosimilars (**biocon**)
3. Fastest-growing class dominating biosimilars by type (**monoclonalantibody**)
4. Antibody-drug conjugates abbreviation (**adcs**)
5. Structural level crucial for biologic function (**tertiary**)
6. Outsourcing model where India supports global biologics manufacturing (**crdmo**)
8. Government scheme to support biologics and biosimilars (**biopharmashakti**)
10. Promotion of Research and Innovation in Pharma-MedTech Scheme (abbreviation) (**prip**)

17. India's first rituximab biosimilar (**reditux**)

ANSWER KEY

1. Biocon Biologics
2. Intas Pharmaceuticals
3. Dr. Reddy's Laboratories
4. Zydus Lifesciences
5. Lupin Limited
6. Wockhardt
7. Hetero Drugs
8. Emcure Pharmaceuticals
9. Reliance Life Sciences
10. Panacea Biotec

Name:_____



F A V H Z H B K U K X P X V F M J B T Q
M A N N D J V R N T G N W A T N J V U V
A I M E L J D R F L P Z Q O A K C M G N
M B C F O T X K V Q I J X M B M Z B T N
O A R F R G J O R O G X B K R A B E V A
P J E G X H N V D A X T B E T Z T H F W
A Z L X B C K E H L S Z D E Z O G J C N
W A I I O F Y T U Q F T G Q U H M A K W
I L P L S N I Z M L B G S I V M Z Z C S
J A O N B S H U O H T N Z A E Z F R L A
K G I N V R I E G O A P A B R F U R Z E
Y H E E E L F Q R F S I S R M G G Q N P
T A T U C C H I A X E C I F T W I N O O
T C I K Z Z Q M F R O U F M G I Z L L F
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L G R N V P W P E L G R Z E V C C I N R
E Y M E B A S A L O G O N E G Z P M V O
L K T S P W U V L C D P F F C X I E W C
J U C T Z R A Z U M A B H Z Y C F G Q R
L J B C I H W S D O B G P Z O W F K C Q

ONCOLOGY
NEUKINE
RELIPOIETIN
RELIGRAST
VIVITRA
GRAFEEL
KRABEVA
HUMOG
RAZUMAB
EPOFER
BASALOGONE

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APTI SECRETARIAT: Krupanidhi College of Pharmacy, # 12/1 Chikka Bellandur, Carmelram Post, Varthur Hobli, Bangalore- 560035, Karnataka, India, Phone: +91 9008888415

LOTUS LOGO STORY

As a lotus is able to emerge from muddy waters un-spoilt and pure it is considered to represent a wise and spiritually enlightened quality in a person; it is representative of a woman who carries out her tasks with little concern for any reward and with a full liberation from attachment. Lotus-woman in the modern sense of women's qualities: she is superbly intelligent, highly educated, and totally committed to individualism. She is exquisite in her taste for music, art and culture, abounds in social graces and performs brilliantly in communication.