

Biologics And Biosimilars: Bridging Innovation And Affordability In India



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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

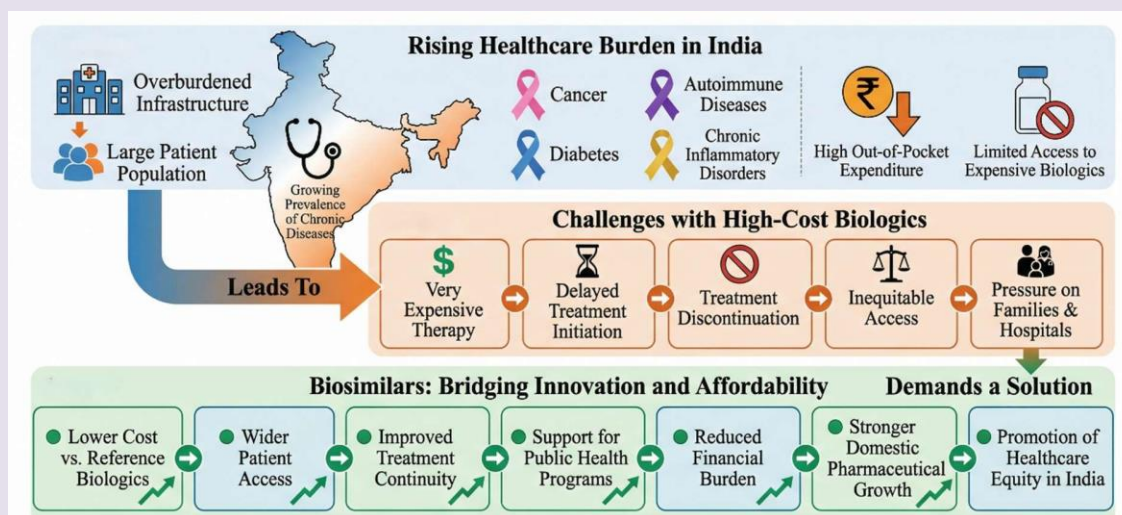


Figure 1. Why India needs the shift to Biosimilars

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 Pharmagenetics. *Vaccines*. 2023 Jan;11(1):110–110. doi:10.3390/vaccines11010110 PubMed PMID: 36679955.
10. Prinja S, Dixit J, Gupta N, Dhankhar A, Katak 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, Mitra 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.