International Journal of Pharmaceutical Research and Development

ISSN Print: 2664-6862
ISSN Online: 2664-6870
Impact Factor: RJIF 8.55
IJPRD 2026; 8(1): 33-37
www.pharmaceuticaljournal.net
Received: 16-11-2025
Accepted: 18-12-2025

Hari Krishnan M
UG Scholar, Department of Pharmaceutics, GRD College of Pharmacy, Affiliated to the Tamil Nadu Dr. MGR Medical University, Chennai, Tamil Nadu, India

Abinaya M
UG Scholar, Department of Pharmaceutics, GRD College of Pharmacy, Affiliated to the Tamil Nadu Dr. MGR Medical University, Chennai Tamil Nadu, India

Vani PS
UG Scholar, Department of Pharmaceutics, GRD College of Pharmacy, Affiliated to the Tamil Nadu Dr. MGR Medical University, Chennai Tamil Nadu, India

Pooja S
Assistant Professor, Department of Pharmacognosy, GRD College of Pharmacy, Affiliated to the Tamil Nadu Dr. MGR Medical University, Chennai Tamil Nadu, India

Dhanesh Kumar MR
Assistant Professor, Department of Pharmaceutics, GRD College of Pharmacy, Affiliated to the Tamil Nadu Dr. MGR Medical University, Chennai Tamil Nadu, India

Corresponding Author:
Hari Krishnan M
UG Scholar, Department of Pharmaceutics, GRD College of Pharmacy, Affiliated to the Tamil Nadu Dr. MGR Medical University, Chennai, Tamil Nadu, India

Biosimilars in Modern medicine: A Comprehensive Review

Hari Krishnan M, Abinaya M, Vani PS, Pooja S and Dhanesh Kumar MR

DOI: https://doi.org/10.33545/26646862.2026.v8.i1a.265

Abstract
The introduction of biosimilars has transformed the treatment options for chronic diseases, including cancer, autoimmune disorders, and various conditions that necessitate biologic therapies. As healthcare systems around the globe work towards providing affordable treatments, the role of biosimilars in clinical practice is increasingly significant. Biosimilars are closely comparable to reference products, featuring slight variations in non-active components, while exhibiting no clinically relevant differences regarding safety, purity, and effectiveness. This review seeks to offer a thorough examination of biosimilars in contemporary medicine, emphasizing their development, regulatory guidelines, clinical effectiveness, and safety assessments. By exploring the existing situation of biosimilar approvals, their influence on healthcare systems, and the obstacles that hinder their acceptance. Our findings indicate that biosimilars can enhance access to essential therapies, lower healthcare expenses, and better patient outcomes. Nevertheless, challenges related to interchangeability, naming practices, and the education of healthcare providers and patients deserve attention. This review concludes that biosimilars are an essential element of modern medicine, presenting a hopeful remedy to the rising costs of biologic therapies, and highlights the necessity for ongoing research, education, and policy advocacy to fully capitalize on their advantages.

Keywords: Biosimilars, Biologic therapies, Chronic illnesses, Affordable healthcare

Introduction
In the treatment of chronic illnesses like cancer, autoimmune disorders, and other problems needing biologic treatments, biosimilars have become an important aspect of modern medical care. The use of biosimilars in clinical practice is becoming more and more important as healthcare systems throughout the world strive to provide more affordable therapies.
According to the FDA, “The biologic product is highly similar to the reference product notwithstanding minor differences in clinically inactive components, and there are no clinically meaningful differences between the biologic product and the reference product in terms of safety, purity, and potency of the product.” [1]. As a result, it is evident that biosimilars are not exact replicas of reference products and that any variations in potency and purity must not be clinically significant. Biosimilar drugs are "similar" to their referenced products but not "identical." Following the expiration of patent protection and regulatory data protection for biological products, or biologics, some drug manufacturers or other biotech companies have succeeded in marketing biologic product replicas or similar items [2]. Developing and producing high-quality biosimilars requires both inherent scientific knowledge and manufacturing expertise.

Historical development and regulatory landscape: Omnitrope (somatropin [rDNA origin]; Sandoz, Holzkirchen, Upper Bavaria, Germany) was the first biosimilar drug. Pfizer's Genotropin (somatropin [rDNA origin]; Pfizer, Cary, NC), which was first approved in the EU in 1988, was the reference medication referenced for Omnitrope [3]. Shortly after Omnitrope, another biosimilar, Valtropin (somatropin rDNA origin for injection, USP; BioPartners, Lithuania), a Biopartner product and recombinant HGH, received approval. [4] Numerous biosimilar companies were made possible by the two approved drugs, Omnitrope and Valtropin, which led the way in the expanding biosimilar industry.

For assurance of safety, effectiveness, and comparability with reference biologics, biosimilar approval is subject to strict regulatory standards. The FDA, EMA, World Health Organization (WHO), and International Council for Harmonization (ICH) are important regulatory bodies. [5] Mass spectrometry, chromatography, and functional bioassays are used for physicochemical characterization in analytical comparability evaluations. Pharmacokinetic (PK) and pharmacodynamic investigations are commonly used in clinical trials to evaluate biosimilar equivalency; these studies are frequently complemented by immunogenicity assessments and empirical data [6]. Programs for post-marketing pharmacovigilance keep an eye on long-term efficacy and safety.

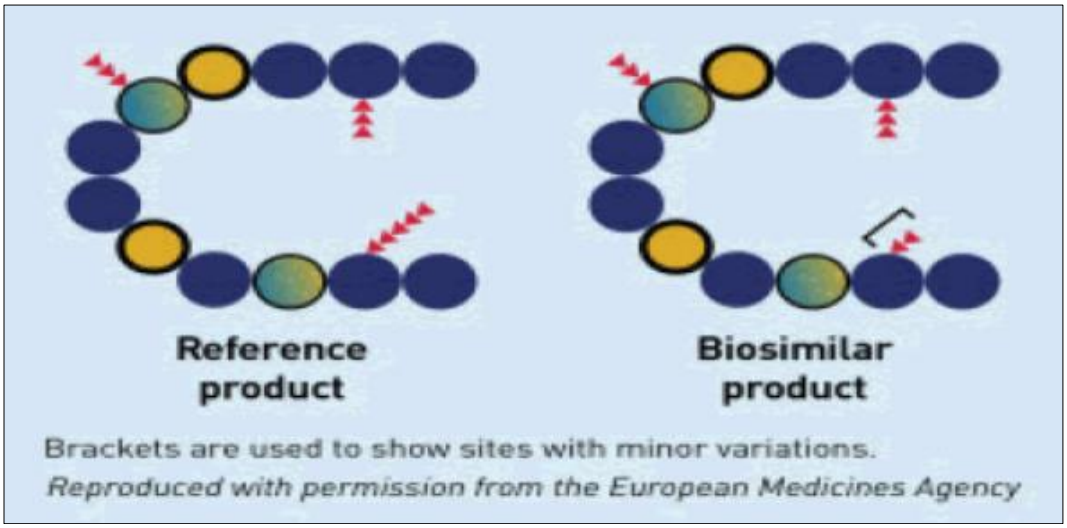

Fig 1: Reference product and biosimilar product

Table 1: Biosimilar and Biologics

Properties	Biosimilar	Biologic
Molecular weight	> 140,000 Daltons	< 1000 Daltons
Manufacture	Manufactured from genetic material of living cell cultures or DNA technologies	Biologically produced in host cell lines
Origin	Similar regarding the reference biologic	Equivalent to the brand-name drug
Cost	Less expensive	Less expensive
Savings	More savings	More saving than brand drug
Adverse immune reaction	Higher potential and unpredictable	Higher potential and predictable

Production of biosimilars

It is permitted for other manufacturers to produce a biosimil ar once the original biologic product's patent expires.

The manufacturers of biosimilars must start from scratch be cause the original biologics company is not required to discl ose its production process.

The various processes that go into making biosimilars are

- In order to replicate the fundamental structure of the bio logic, biosimilar manufacturers must analyze the origin al biologic brand using published data.
- The functional or clinically active components of the 3 D medication are then replicated.
  This technique is really complex.
- For the combination of the drugs together, scientists mu st rely on cultures of living cells.
- After production, the biosimilar must pass stringent test ing to ensure that its chemistry and functionality are comparable to those of the original biologics.
- To ensure that they canbind to their target in the same w ay as their original biologics, biologics must also go through functional testing.
- To ensure that the biosimilar functions as well as the ori ginal biologic and does not cause anyunanticipated side effects in the body, it must be compared to the original biologics in clinicalstudies.

Manufacturers of biosimilars must adhere to strict safety, pu rity, and potency requirements.

Over ten years may pass during this entire procedure

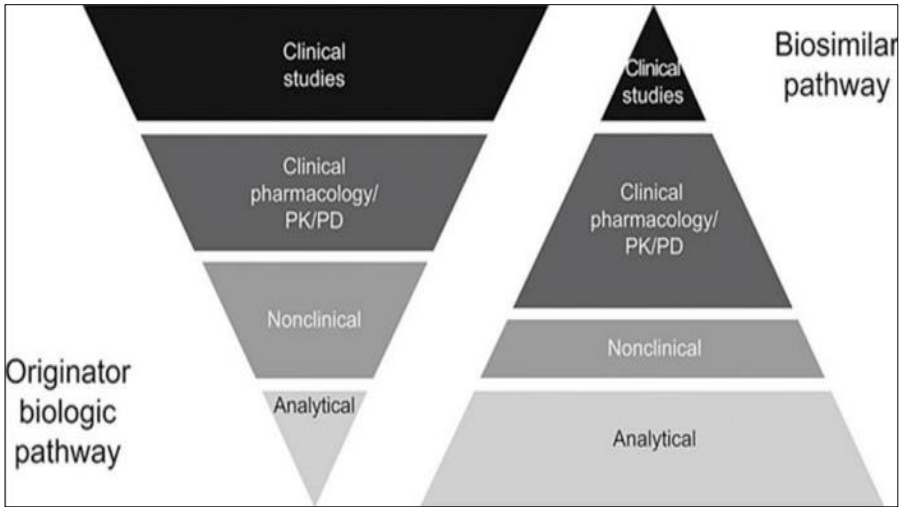

Fig 2: Structure of biosimilar pathway

Characterization of biosimilars

To register biosimilar drugs, it is essential to verify the authenticity of "biosimilarity" between the physiochemical and biological frameworks of the biosimilar and its reference product. To assess the safety and efficacy of biosimilars in comparison to reference products, numerous medical, preclinical, and clinical studies must be conducted according to the regulatory guidelines established by the EMA and FDA.

Table 2: Characterization of biosimilars

S. No.	Characteristics	Analytical tests
1	Primary amino acid structure	Peptide mapping, and tandem mass spectroscopy
2	Potency	Bioassay
3	Target binding	Surface plasmon resonance
4	Protein concentration	Content determination
5	Higher order structures	Circular dichroism spectroscopy
6	High molecular aggregates	Size-exclusion chromatography
7	Oxidized variants	Reverse-phase chromatography
8	Subvisible particles	Light obscuration

Interchangeability

It signifies that:

- The biologic product is proven to be biosimilar to the reference product.
- It is anticipated to yield the same clinical outcomes as the reference product in any specific patient.
- For a product administered multiple times to an individual, the safety risk or decreased efficacy related to alternating or switching between the biosimilar and its reference product is not greater than the risk associated with using the reference product alone.

Immunogenicity

Immunogenicity refers to a therapeutic protein's capacity to provoke an immune response. Similar to reference products, immunogenicity can potentially affect the pharmacokinetics, clinical effectiveness, and safety profile of a biosimilar. A thorough systematic review was carried out to examine the immunogenicity of biologic agents, highlighting that the incidence of anti-drug antibodies (ADAbs) differs significantly across various biologics. In particular, infliximab and its biosimilar, CT-P13, showed high immunogenicity, raising concerns over possible adverse effects such as infusion-related reactions and diminished treatment effectiveness. The review stressed the importance of continuous monitoring of immunogenicity in clinical settings, especially for individuals with conditions like rheumatoid arthritis and inflammatory bowel disease (IBD). This finding underscores the vital need to evaluate the immunogenic profiles of biosimilars to ensure patient safety and effective treatment results [7]. The overall risk linked to immunogenicity-related safety issues is low; individual evaluations of biosimilars are crucial. The combined evidence indicates that although biosimilars can offer therapeutic advantages, careful examination of their immunogenicity profiles is necessary to enhance patient safety [8, 9].

Clinical evidence and therapeutic applications Oncology

Biosimilars have been incorporated into the treatment protocols for metastatic colorectal cancer (mCRC), as emphasized by the NCCN Guidelines. These guidelines highlight the potential of biosimilars to provide cost-effective alternatives to original biologics, thereby enhancing patient access to crucial therapies. [10] This indicates a wider trend in oncology, where biosimilars are increasingly acknowledged for their role in improving treatment outcomes while also considering economic factors. The introduction of monoclonal antibodies (MAbs) has transformed cancer treatment, and the development of biosimilars is expected to allow more patients to benefit from these advancements [11]. The progress of treatment strategies has been aided by the growing approval of MAbs, which can offer comparable efficacy and safety profiles to their reference counterparts. This change is especially vital for patients who could gain from targeted therapies.

Rheumatology

Biosimilars have been acknowledged for their potential to enhance treatment outcomes for patients undergoing anti-TNF-α therapies. [12] The accessibility of biosimilars has made these crucial treatments easier to acquire, addressing some of the financial hurdles linked with biologic therapies. The launch of anti-TNF-α biosimilars is particularly important in treating autoimmune diseases, where continued research into biomarkers for predicting treatment responses is essential [13].

Table 3: Recently FDA approved biosimilars in 2025

S. No.	Biosimilar Name	Reference Product	Approval Date
1	Osvyrti and Jubereq (denosumab-desu)	Prolia and Xgeva (denosumab)	October 2025
2	Eydenzelt (aflibercept-boav)	Eylea (aflibercept)	October 2025
3	Enoby and Xtrenbo (denosumab-qbde)	Prolia and Xgeva (denosumab)	September 2025
4	Aukelso and Bosaya (denosumab-kyqq)	Prolia and Xgeva (denosumab)	September 2025
5	Bildyos and Bilprevda (denosumab-nxxp)	Prolia and Xgeva (denosumab)	August 2025
6	Kirsty (insulin aspart-xjhz)	Novolog (insulin aspart)	July 2025
7	Starjemza (ustekinumab-hmny)	Stelara (ustekinumab)	May 2025
8	Jobevne (bevacizumab-nwgd)	Avastin (bevacizumab)	April 2025
9	Bomyntra and Conexxence (denosumab-bnht)	Prolia and Xgeva (denosumab)	March 2025
10	Omlyclo (omalizumab-igec)	Xolair (omalizumab)	March 2025
11	Stoboclo and Osenvelt (denosumab-bmwo)	Prolia and Xgeva (denosumab)	February 2025
12	Merilog (insulin aspart-szjj)	Novolog (insulin aspart)	February 2025
13	Ospomyv and Xbryk (denosumab-dssb)	Prolia and Xgeva (denosumab)	February 2025
14	Avtozma (tocilizumab-anoh)	Actemra (tocilizumab)	January 2025

Regulatory framework and pharmacovigilance

The regulatory landscape for biosimilars has undergone substantial changes, largely due to the necessity for stringent standards that prioritize patient safety and product effectiveness. The European Medicines Agency (EMA) has implemented detailed guidelines outlining the approval pathway for biosimilars, highlighting the importance of demonstrating similarity to reference products through comprehensive scientific evaluations [14]. This process includes assessing structural, functional, and clinical data, which collectively contribute to the totality-of-evidence approach essential for regulatory endorsement [15]. The rigorous regulatory framework for biosimilars was examined, asserting that they must show no significant differences in safety, efficacy, and immunogenicity compared to their reference products. This regulatory oversight is vital for ensuring patient safety, confidence and trust in biosimilars [16].

Pharmacovigilance, which refers to the scientific and procedural activities related to detecting, assessing, understanding, and preventing adverse effects or other drug-related issues, is especially important for biosimilars. As biosimilars are implemented in clinical settings, establishing strong pharmacovigilance systems is crucial for tracking their long-term safety and effectiveness. This surveillance becomes increasingly critical considering the risk of immunogenicity and other adverse events that may not be apparent during pre-marketing evaluations. The need for continuous pharmacovigilance to assess long-term safety and efficacy, particularly as new biosimilars are introduced in the marketplace. This ongoing observation is essential to address any potential safety issues associated with biosimilars [17].

Ethical considerations

The introduction of biosimilars has the capacity to greatly enhance access to biologic treatments, especially for conditions such as metastatic colorectal cancer (mCRC) and autoimmune disorders. The ethical considerations surrounding biosimilars also encompass aspects of safety and effectiveness. The necessity for thorough testing and the development of a strong regulatory framework was emphasised. [18]

Economic considerations

The financial implications of biosimilars are substantial, as they can lead to significant cost reductions within healthcare systems. The potential savings can help mitigate the financial strain on these systems and enhance access to vital therapies. The anticipated savings from introducing biosimilars, like the rituximab biosimilar CT-P10, could enable thousands more patients to receive treatment, thereby improving health outcomes and overall quality of life. [19]

Future directions

The future of biosimilars offers a landscape rich with opportunities to enhance patient access to biologic therapies while keeping healthcare expenses in check. Nonetheless, considerable knowledge gaps persist, especially regarding long-term efficacy, safety, and economic repercussions. As the biosimilars market continues to grow, it is crucial to work on aligning regulatory frameworks, educating stakeholders, and investigating the broader implications of biosimilars beyond merely cost reductions. Future research should focus on examining biosimilars across various therapeutic areas, their integration into current treatment protocols, and their long-lasting effects on patient outcomes. By tackling these research gaps, the healthcare sector can better leverage the potential of biosimilars to improve treatment accessibility and elevate patient care.

Conclusion

Biosimilars mark a significant breakthrough in contemporary medicine, promising enhanced access to effective therapies while addressing the financial challenges associated with expensive biologics. Current literature indicates that biosimilars can be safely incorporated into clinical practice, with no major issues related to efficacy or safety. However, continuous research and education are essential to bridge existing knowledge gaps and ensure that biosimilars are applied effectively and safely in patient healthcare. As the field of biologic therapies progresses, the importance of biosimilars in influencing the future of healthcare is likely to grow.

References

1. US Food and Drug Administration. Guidance for industry: scientific considerations in demonstrating biosimilarity to a reference product. Silver Spring (MD): FDA; 2015.
2. Hariprasad SM, Gale RP, Weng CY, Ebbers HC, Rezk MF, Tadayoni R. An introduction to biosimilars for the treatment of retinal diseases: a narrative review. Ophthalmol Ther. 2022;11(3):959-982.
3. Romer TE. The role of recombinant human growth hormone biosimilars in the management of growth disorders. Eur J Endocrinol. 2009;160(5):47-50.
4. Knezevic I, Griffiths E. Biosimilars—global issues, national solutions. Biologicals. 2011;39:252-255.
5. World Health Organization. Biosimilars: regulatory considerations for global markets. Geneva: WHO; 2019.
6. Weise M, Bielsky MC, De Smet K, *et al*. Biosimilars—why terminology matters. Nat Biotechnol. 2012;30(12):1187-1190.
7. Strand V, Balsa A, Al-Saleh J, Barile-Fabris L, Horiuchi T, Takeuchi T, *et al*. Immunogenicity of biologics in chronic inflammatory diseases: a systematic review. BioDrugs. 2017;31(4):299-316.
8. Egeberg A, Ottosen MB, Gniadecki R, Broesby-Olsen S, Dam TN, Bryld LE, *et al*. Safety, efficacy and drug survival of biologics and biosimilars for moderate-to-severe plaque psoriasis. Br J Dermatol. 2018;178(2):509-519.
9. Danese S, Fiorino G, Raine T, Ferrante M, Kemp K, Kierkus J, *et al*. ECCO position statement on the use of biosimilars for inflammatory bowel disease—an update. J Crohns Colitis. 2017;11(1):26-34.
10. Benson AB, *et al*. Colon cancer, version 2. NCCN clinical practice guidelines in oncology. J Natl Compr Canc Netw. 2021;19(3):329-359.
11. Singh S, Kumar NK, Dwivedi P, Charan J, Kaur R, Sidhu P, Chugh V. Monoclonal antibodies: a review. Curr Clin Pharmacol. 2017;13(2):85-99.
12. Dörner T, Strand V, Castañeda-Hernández G, Ferraccioli G, Isaacs J, Kvien T, *et al*. The role of biosimilars in the treatment of rheumatic diseases. Ann Rheum Dis. 2013;72:322-328.
13. Kirchhoff CF, Wang XZ, Conlon HD, Anderson S, Ryan A, Bose A. Biosimilars: key regulatory considerations and similarity assessment tools. Biotechnol Bioeng. 2017;114:2696-2705.
14. Casadevall N, Edwards I, Felix T, Graze P, Litten J, Strober BE, Warnock D. Pharmacovigilance and biosimilars: considerations, needs and challenges. Expert Opin Biol Ther. 2013;13:1039-1047.
15. Kozlowski S, Woodcock J, Midthun K, Sherman R. Developing the nation's biosimilars program. N Engl J Med. 2011;365(5):385-388.
16. Kurki P, van Aerts L, Wolff-Holz E, Giezen T, Skibeli V, Weise M. Interchangeability of biosimilars: a European perspective. BioDrugs. 2017;31(2):83-91.
17. Dörner T, Strand V, Cornes P, Gonçalves J, Gulácsi L, Kay J, *et al*. The changing landscape of biosimilars in rheumatology. Ann Rheum Dis. 2016;75:974-982.
18. Kvien TK, Patel K, Strand V. The cost savings of biosimilars can help increase patient access and reduce the financial burden of health care systems. Semin Arthritis Rheum. 2022;52:151939.
19. Markus R, Liu J, Ramchandani M, Landa D, Born T, Kaur P. Developing the totality of evidence for biosimilars: regulatory considerations and building confidence for the healthcare community. BioDrugs. 2017;31(3):175-187.