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).

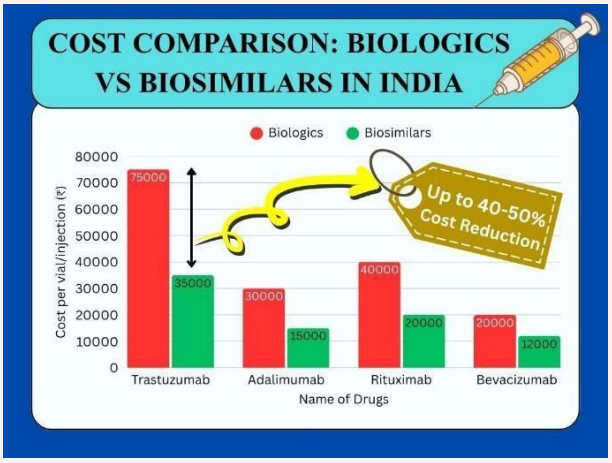

Figure 1. Comparative cost analysis of original medicine and their biosimilars in India

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).

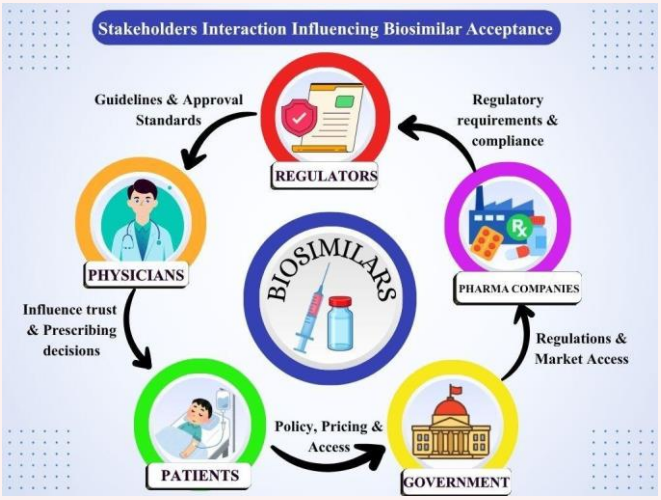

Figure 2. Biosimilar acceptance driven by interactions among key healthcare stakeholders

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.

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