Biosimilar Acceptance In India: Bridging Knowledge Gaps Among Healthcare Professionals


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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).

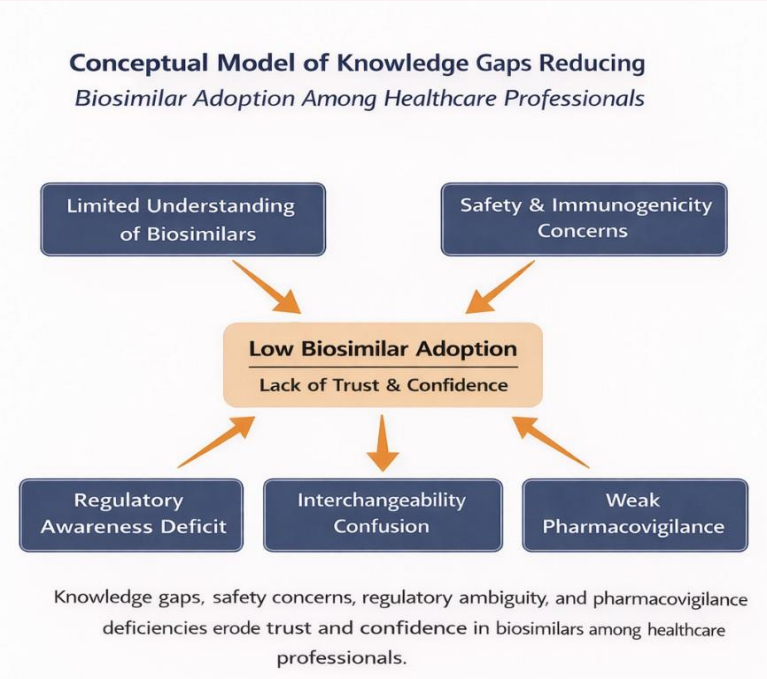

Figure 1: Knowledge Gaps among Indian Healthcare Professionals
*image created from ScholarGPT

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.

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