Editorial Article

Biosimilars in India: Current Status and Future Perspectives with Reference to the Indian Systems of Medicine

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Introduction

The advent of biological medicines has transformed the therapeutic landscape of modern medicine, particularly in the management of malignancies, autoimmune disorders, chronic inflammatory diseases, and metabolic conditions. Unlike conventional chemically synthesized pharmaceuticals, biological medicines are derived from living organisms or biological systems and possess complex molecular structures, sophisticated manufacturing requirements, and unique pharmacological characteristics. Although these therapies have substantially improved clinical outcomes, their high acquisition costs frequently limit accessibility, particularly in developing countries such as India. Biosimilars have consequently emerged as an important strategy to enhance the affordability, accessibility, and sustainability of biological therapies[(1)].

A biosimilar is a biological medicinal product that demonstrates high similarity to an already authorized reference biological product in terms of quality, biological activity, safety, and efficacy. However, biosimilars are not identical copies of their reference products, owing to the inherent structural complexity and variability associated with biological manufacturing processes. Their development requires a comprehensive comparability exercise involving analytical characterization, functional assessment, pharmacokinetic and pharmacodynamic evaluation, immunogenicity assessment, and appropriate clinical investigations[(2,3)].

India has established itself as a significant contributor to the global biosimilar industry, supported by its pharmaceutical manufacturing infrastructure, biotechnology expertise, scientific workforce, and growing emphasis on biopharmaceutical research and development. The development of biosimilars represents not merely an opportunity for pharmaceutical growth but also a potential avenue for strengthening equitable healthcare delivery. In this context, exploring the relationship between biosimilars and the Indian Systems of Medicine presents an emerging interdisciplinary perspective that warrants scientific consideration.

Biosimilars in India: Regulatory Framework and Current Status

India was among the early adopters of a regulatory pathway for biosimilars. The Central Drugs Standard Control Organization (CDSCO), in collaboration with the Department of Biotechnology (DBT), introduced the Guidelines on Similar Biologics in 2012, subsequently revised in 2016. These guidelines established a systematic framework for demonstrating similarity with reference biological products, encompassing manufacturing quality, preclinical evaluation, clinical studies, and post-marketing surveillance.

The World Health Organization (WHO) provided the foundational international framework for the evaluation of similar biotherapeutic products in 2009. The subsequent revision of these guidelines in 2022 reflected advances in analytical science and regulatory experience, emphasizing a science-driven and risk-based approach to biosimilar evaluation[(4,5)]. The updated recommendations support a more flexible approach to clinical development when extensive analytical and functional evidence adequately establishes similarity.

India's revised 2025 Guidelines on Similar Biologics further reflect this evolving regulatory philosophy. The revised framework emphasizes advanced analytical characterization, orthogonal analytical techniques, in-vitro functional assessment, and a scientifically justified approach to nonclinical and clinical investigations[(6)]. Such regulatory modernization may strengthen India's position as a competitive biosimilar development and manufacturing hub.

The Indian biosimilar industry has expanded across several therapeutic categories, including oncology, endocrinology, immunology, and ophthalmology. Biosimilar versions of insulin, erythropoietin, filgrastim, trastuzumab, and rituximab have contributed to the diversification of biological treatment options in the Indian pharmaceutical market[(1,7)].

The National Biopharma Mission, implemented through the Biotechnology Industry Research Assistance Council (BIRAC), has further strengthened the national biotechnology ecosystem by supporting the development of cost-effective biological products, research infrastructure,

process development, analytical capabilities, and clinical research. Its biosimilar portfolio includes therapeutic candidates addressing cancer, diabetes mellitus, rheumatoid arthritis, and age-related macular degeneration[8].

Despite these achievements, several challenges continue to influence the biosimilar ecosystem in India. High capital expenditure, complex manufacturing processes, stringent quality-control requirements, intellectual property considerations, and limited access to advanced analytical infrastructure may increase development costs. Furthermore, the adoption of biosimilars in clinical practice may be influenced by physician familiarity, patient awareness, confidence in manufacturing quality, and concerns regarding switching between reference products and biosimilars[7,9].

Pharmacovigilance remains an essential component of biosimilar development and utilization. The biological nature of these medicines necessitates careful monitoring of immunogenicity, adverse drug reactions, manufacturing-related variations, and long-term clinical outcomes. Strengthening post-marketing surveillance, ensuring transparent adverse-event reporting, and maintaining traceability of biological products are indispensable for maintaining public confidence[4,5].

Indian Systems of Medicine: An Emerging Interdisciplinary Perspective

The Indian Systems of Medicine, particularly Ayurveda, Siddha, Unani, Yoga, Naturopathy, and other AYUSH disciplines, represent longstanding knowledge traditions encompassing health promotion, preventive care, and therapeutic interventions. These systems have increasingly attracted scientific attention through pharmacological investigations, clinical research, pharmaceutical standardization, and integrative healthcare initiatives[10].

However, it is essential to distinguish biosimilars from traditional medicinal formulations. Biosimilars are biotechnology-derived biological medicines developed through rigorous molecular characterization and a defined regulatory pathway. Traditional Indian medicinal formulations, including herbal, mineral, and polyherbal preparations, are governed by distinct pharmaceutical and regulatory principles. Consequently, the term biosimilar should not be applied to Ayurvedic or other traditional formulations merely because they demonstrate similar therapeutic effects or contain biologically active constituents.

Nevertheless, the Indian Systems of Medicine may offer opportunities for complementary research within the broader biological therapeutics ecosystem. Traditional medicinal knowledge may contribute to investigations involving biological response modulation, immunological mechanisms, supportive care, and the identification of pharmacologically active compounds. Such research should be conducted through scientifically validated methodologies rather than assumptions of equivalence between traditional formulations and biological medicines[11].

The interdisciplinary integration of traditional knowledge with contemporary biotechnology could potentially facilitate the discovery of novel therapeutic candidates, development of adjunctive interventions, and investigation of pharmacodynamic interactions. Research involving traditional formulations and biological medicines may also provide opportunities to evaluate drug–herb interactions, potential safety concerns, and complementary therapeutic approaches.

However, these opportunities must be supported by reproducible experimental findings, standardized formulations, appropriate clinical investigations, and robust safety assessments. The WHO benchmarks for Ayurveda emphasize the importance of quality, safety, effectiveness, and appropriate regulatory oversight in the delivery of Ayurvedic healthcare[12].

Future Perspectives

The future of biosimilars in India is likely to be shaped by scientific innovation, regulatory modernization, manufacturing excellence, and interdisciplinary collaboration. Several priority areas deserve consideration.

First, advanced analytical technologies, including high-resolution mass spectrometry, glycan profiling, structural characterization, and sophisticated bioassays, should be increasingly incorporated into biosimilar development. These technologies may enhance product characterization, facilitate comparability assessments, and strengthen manufacturing consistency[3,5].

Second, India should prioritize the development of indigenous biotechnology platforms, including cell-line engineering, upstream and downstream processing, formulation development, and continuous manufacturing technologies. Public–private partnerships involving universities, biotechnology research institutions, pharmaceutical industries, and government agencies could accelerate innovation while reducing dependence on imported technologies.

Third, regulatory harmonization and evidence-based policy development should remain central to the advancement of biosimilars. A transparent and predictable regulatory environment, aligned with international scientific recommendations, may facilitate domestic development and international market access[5,6].

Fourth, interdisciplinary research involving pharmacology, biotechnology, clinical medicine, Ayurveda, Siddha, and other Indian Systems of Medicine should be encouraged through structured collaborative programmes. Such initiatives may investigate the therapeutic potential of traditional formulations as complementary interventions in

appropriate clinical settings. Nevertheless, claims regarding efficacy, safety, compatibility, or therapeutic equivalence must be substantiated through scientifically rigorous research.

Finally, patient-centered healthcare strategies should emphasize affordability, physician education, treatment adherence, pharmacovigilance, and equitable access. Biosimilars have the potential to contribute substantially to the reduction of treatment-related financial burdens, particularly in chronic diseases requiring prolonged biological therapy[13].

The WHO Global Traditional Medicine Strategy 2025–2034 further emphasizes the need for evidence-based integration, appropriate regulation, and scientific evaluation of traditional medicine practices.14 This provides an opportunity for India to establish collaborative research models that preserve the integrity of traditional medicinal knowledge while advancing modern biotechnology.

Conclusion

Biosimilars represent a transformative opportunity for India's pharmaceutical and healthcare sectors. The country's established biotechnology capabilities, expanding manufacturing infrastructure, evolving regulatory framework, and growing research ecosystem provide a strong foundation for future development. The Indian Systems of Medicine may contribute to this broader scientific landscape through the systematic investigation of traditional therapeutic knowledge, discovery of novel bioactive compounds, and development of evidence-based complementary interventions.

However, the integration of biosimilars and Indian medicinal systems must be guided by scientific rigor, regulatory clarity, and a commitment to patient safety. Biosimilars should remain distinct from traditional medicinal formulations in terms of classification, development, and regulatory evaluation.

A collaborative framework that combines biotechnology innovation with validated traditional knowledge may provide new opportunities for therapeutic research and healthcare advancement. India's future leadership in biosimilars will ultimately depend on its ability to translate scientific innovation into safe, effective, affordable, and accessible therapies while preserving the integrity of its diverse medical traditions.

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