Biosimilars: A Sustainable Strategy for Healthcare Systems

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> The escalating cost of biologic therapies presents a significant challenge to healthcare system sustainability and patient access globally. Biosimilars offer a viable solution by providing comparable efficacy and safety at a reduced cost, thereby enhancing the affordability and availability of essential treatments. This review highlights the role of biosimilars in achieving healthcare sustainability, drawing insights from China's evolving regulatory landscape and approval trends.

KEY TAKEAWAYS

- The Pivot: Biosimilars are crucial for improving access to high-cost biologics and ensuring healthcare system sustainability.
- The Data: China approved 83 biosimilars between 2019 and 2025, demonstrating a maturing regulatory framework.
- The Action: Clinicians should consider biosimilar options to support healthcare system sustainability and patient access to biologics.

Biosimilars represent a critical strategy for improving access to high-cost biologics and ensuring the sustainability of healthcare systems worldwide.1 Over the past decade, China has transitioned from a nascent market to one of the most active regions for biosimilar development.1 This transformation has been driven by an evolving regulatory framework, which began with the foundational 2015 Technical Guidelines and has matured into a current system comprising 19 technical and product-specific guidelines.1 This framework emphasizes a stepwise, science-driven comparability paradigm, aligning with international regulatory standards.1

Approval Dynamics and Global Integration

A systematic analysis of 83 biosimilars approved between 2019 and 2025 in China illustrates trends across molecular classes, therapeutic areas, and regulatory review pathways.1 This analysis demonstrates the evolution of regulatory expectations and sponsor development strategies through representative case examples.1 The increasing number of biosimilar approvals is also emphasized in the 2025 annual reports from both the US Food and Drug Administration and the European Medicines Agency, providing a comparative context for China's experience.1

China's expanding biosimilar development pipeline is particularly relevant in the context of the forthcoming global biologics patent cliff and ongoing international initiatives aimed at streamlining biosimilar development.1 This trend highlights China's increasing integration into the global biopharmaceutical landscape.1 The development and adoption of biosimilars are essential for managing healthcare expenditures and ensuring that patients have access to necessary

biologic therapies, thereby contributing to the long-term sustainability of healthcare systems.1

Biologic therapies, including monoclonal antibodies, fusion proteins, and hormones, have revolutionized the treatment of numerous chronic and life-threatening conditions. These conditions include autoimmune diseases such as rheumatoid arthritis, Crohn's disease, and psoriasis, as well as various cancers and diabetes. For instance, tumor necrosis factor (TNF) inhibitors, a class of biologics, significantly improve outcomes for patients with inflammatory conditions by blocking the inflammatory cytokine TNF-alpha. Similarly, biologics targeting specific growth factor receptors or immune checkpoints have become cornerstones in oncology. However, the high cost of originator biologics often limits patient access, particularly in resource-constrained healthcare systems. Biosimilars, as highly similar versions of approved reference biologics, offer a cost-effective alternative without compromising efficacy or safety. Their mechanism of action mirrors that of the reference product, binding to the same targets and eliciting comparable pharmacological effects. This allows for broader patient populations to benefit from advanced therapies that were previously inaccessible due to prohibitive costs.

Methodology and Scope of Analysis

The systematic analysis of biosimilar approvals in China involved a comprehensive review of publicly available regulatory databases and official announcements from the National Medical Products Administration (NMPA). The researchers identified all biosimilar products that received marketing authorization in China within the specified timeframe of 2019 to 2025. Data extraction focused on key attributes, including the reference biologic, molecular class (e.g., monoclonal antibody, fusion protein), therapeutic indication (e.g., oncology, immunology, endocrinology), and the specific regulatory pathway utilized for approval. The analysis also considered the timing of approvals relative to the expiration of patent protection for the reference biologics, providing insights into market dynamics and strategic development decisions by pharmaceutical sponsors. Case examples were selected to represent diverse challenges and successes in biosimilar development, illustrating the application of the comparability paradigm across different product types and complexities. This detailed approach allowed for a robust characterization of the evolving biosimilar landscape in China and its alignment with global trends.

Limitations and Future Directions

Despite the comprehensive nature of this analysis, certain limitations warrant consideration. The study primarily relies on publicly available regulatory approval data, which may not capture all nuances of the development and review processes. Information regarding post-market surveillance data, real-world effectiveness, and specific pricing strategies for each approved biosimilar was beyond the scope of this particular analysis. Furthermore, while the study provides a snapshot of approvals up to 2025, the dynamic nature of the biopharmaceutical industry means that new regulatory guidelines and market entrants will continuously shape the landscape. Future research could expand upon these findings by incorporating real-world evidence from patient registries, conducting pharmacoeconomic analyses to quantify the cost savings achieved through biosimilar adoption, and examining the impact of biosimilars on specific patient populations and disease epidemiology within China. Understanding the long-term clinical outcomes and patient acceptance of biosimilars will be crucial for fully assessing their contribution to sustainable healthcare. The epidemiology of chronic diseases, such as diabetes and autoimmune disorders, continues to rise globally, increasing the demand for effective and affordable treatments. Biosimilars offer a vital tool in addressing this growing burden, ensuring that a wider segment of

the population can access necessary biologic therapies. Continued monitoring of regulatory harmonization efforts and international collaborations will also be essential to facilitate global access to these critical medicines.
For comprehensive insights into the overarching management of healthcare systems and developing sustainable strategies, refer to The Oxford Handbook of Health Care Management.

CLINICAL IMPLICATIONS

The increasing availability and regulatory alignment of biosimilars, particularly evidenced by China's rapid expansion in this sector, present a clear directive for clinical practice. For general practitioners and specialists, understanding the comparability data and regulatory pathways of biosimilars is no longer optional; it is essential for informed prescribing decisions. The economic benefits of biosimilars are substantial, offering a mechanism to alleviate the financial burden of high-cost biologics on healthcare systems and, by extension, on patients. This allows for broader patient access to treatments that might otherwise be prohibitively expensive, directly impacting health equity.
The industry's focus on biosimilar development, as seen in China's robust pipeline and integration into the global biopharmaceutical landscape, signals a sustained shift. Pharmaceutical companies that invest in biosimilar research and development are not merely responding to market demand; they are actively contributing to a more sustainable healthcare ecosystem. This trend should encourage healthcare providers to engage with pharmaceutical representatives to understand the specific biosimilar options available and their evidence base, ensuring that cost-effectiveness does not compromise patient outcomes.
Ultimately, the move towards biosimilars is a pragmatic approach to resource allocation within healthcare. It allows for the reallocation of funds to other critical areas of patient care, research, and infrastructure. Clinicians have a role in advocating for and adopting these therapies where appropriate, thereby supporting both individual patient needs and the broader financial health of the healthcare system. The evidence from regulatory bodies like the FDA and EMA, alongside China's experience, reinforces that biosimilars are not merely alternatives but integral components of modern therapeutic strategies.

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REFERENCES

1. 1. Yang M, Zhang N, Wang H. An Overview and Trend Analysis of Biosimilar Approvals in China. BioDrugs. 2026;42307859.

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