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Biosimilars: state of the art in the treatment of rheumatic diseases

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It is a privilege to introduce the special issue "Biosimilars: state of the art in the treatment of rheumatic diseases." The contributions collected here address pressing scientific, clinical, regulatory, and policy questions that have emerged as biosimilars become integral to the management of rheumatic disease. Together, these papers provide a timely synthesis of evidence and experience—from randomized and observational clinical data to regulatory and implementation perspectives—that will inform clinicians, regulators, payers, and policy makers working to optimize patient care and health-system sustainability.

A prominent theme across the issue is the capacity of biosimilars to expand access to highly effective therapies for rheumatic diseases. One review examines how the availability of biosimilars has broadened therapeutic options for rheumatoid arthritis, highlighting their role in increasing treatment uptake and enabling earlier and sustained disease control [1]. Complementing this perspective, an analysis of anti-TNFα biosimilar development draws on a decade of experience to outline technical, clinical, and regulatory lessons learned that have improved biosimilar design, comparability assessment, and post-marketing surveillance [2].

Several papers focus on the clinically relevant question of switching from originator biologics to biosimilars. A Spanish sub-analysis of the PROPER study evaluates outcomes after transition from reference adalimumab to the biosimilar SB5 in patients with rheumatoid arthritis, providing country-specific real-world evidence on effectiveness and safety following a switch [3]. Another 12-month observational study reports on the efficacy of switching from originator adalimumab to adalimumab-AACF in patients with axial spondyloarthritis, offering further longitudinal data on clinical course after interchange [4]. These real-world studies are invaluable for clinicians and patients navigating switching decisions and underscore the importance of ongoing pharmacovigilance and data collection.

The issue also addresses nonclinical but equally consequential dimensions of biosimilar uptake. One contribution focuses on regulatory inconsistencies and the clinical uncertainty they can engender—calling for harmonized frameworks and clearer guidance on interchangeability and naming conventions to reduce confusion among prescribers and patients [5]. Relatedly, a paper examines strategies for selecting best-value biosimilars in emerging countries, recognizing that procurement decisions and value-based selection processes can significantly influence access, affordability, and sustainability in resource-constrained settings [6]. A practical implementation study included here demonstrates that sharing cost information with prescribers can facilitate successful interchange of biologic medications in chronic arthritis clinics,

illustrating how transparent economic data and clinician engagement can enable policy interventions to translate into practice change [7].

Taken together, these contributions point to several actionable conclusions:

- Biosimilars are established as effective options that expand patient access to biologic therapies and support health-system sustainability when accompanied by appropriate regulatory oversight and post-marketing surveillance.
- High-quality real-world evidence on switching and interchangeability is accumulating and should continue to be prioritized; such data are critical for clinician confidence and for refining switching strategies.
- Regulatory harmonization, clear communication about interchangeability, and standardized pharmacovigilance practices will help reduce variability in clinical practice and promote safe, effective adoption of biosimilars.
- Value-based procurement and transparent cost communication are powerful levers—especially in emerging economies—to increase uptake without compromising quality of care.
- Education of prescribers, patients, and other stakeholders remains central: clinical evidence must be paired with outreach and implementation support to achieve intended population-level benefits.

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It is my hope that this collection will aid clinicians in their therapeutic decisions, guide policy makers and payers in designing equitable procurement and reimbursement strategies, and stimulate further research to refine biosimilar use in rheumatic diseases. Continued collaboration among clinicians, researchers, regulators, and patients will be essential to realize the full potential of biosimilars to improve outcomes and broaden access to effective therapy.

Declarations

Author contributions

VFA: Writing—original draft, Writing—review & editing. The author read and approved the submitted version.

Conflicts of interest

Valderilio Feijó Azevedo, who is the Editorial Board Member and Guest Editor of Exploration of Musculoskeletal Diseases, had no involvement in the decision-making or the review process of this manuscript.

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