

**Category: Health Professionals in Rheumatology Practice and Clinical Care**

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**Systematic Literature Review on the use of Biosimilars in the Treatment of Rheumatic Diseases in the Gulf Region**

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**Abstract Title:** Systematic Literature Review on the use of Biosimilars in the Treatment of Rheumatic Diseases in the Gulf Region

**Objective(s):**

The treatment of rheumatic diseases with biologic agents has significantly improved disease management and patient outcomes; however, innovator reference products are associated with high costs which may limit access. Biosimilars, which are highly similar to reference products in terms of quality, safety and efficacy can reduce the financial burden and underutilization of medication while still being effective and safe.

The objective of this initiative was to conduct a systematic review of clinical evidence that would support the development of evidence-based consensus recommendations aimed at standardizing and driving alignment on best practices for the use of biosimilars in the treatment of adult patients with rheumatoid arthritis, psoriatic arthritis, spondyloarthritis, and ankylosing spondylitis in the Gulf region.

**Method(s):**

A scientific committee comprising expert rheumatologists, pharmacists, and healthcare economists convened to formulate specific PICO questions that address key topics of interest concerning biosimilars: comparability of the efficacy, safety, and immunogenicity of biosimilars to their reference products, extrapolation of indications, switching from reference products to biosimilars and between biosimilars, cost-savings with biosimilars, retention rates with biosimilars, the nocebo effect among patients, and the general awareness and perceptions of biosimilars in the Gulf region.

A systematic literature review was conducted using PubMed with the aim to identify, select, and critically appraise the quality of the overall body of evidence which demonstrates the value proposition of biosimilars in rheumatic disease. This was performed using defined eligibility criteria to include meta-analyses, clinical trials, and systematic reviews of adult patients aged 19 years or older with rheumatoid arthritis, psoriatic arthritis, spondyloarthritis, and ankylosing spondylitis who received biosimilars at some point during their course of treatment. Publications that did not meet the eligibility criteria, including studies in healthy subjects and patients with other inflammatory conditions, were excluded from the systematic review. As the data before 2017 has already been reviewed in another publication, the current review focused on data that was published between 2017 and 2022. The systematic review was registered on PROSPERO with registration ID CRD42022364002.

### **Result(s):**

The search yielded 1,111 results which included meta-analyses, clinical trials, and systematic reviews published between 2017 and 2022. After screening by publication type, relevance, and duplicates, 1,004 records were excluded, and a total of 107 relevant publications were incorporated in the summary of evidence. All methods were fully reported following the recommended reporting guidance (PRISMA 2020).

### **Conclusion(s):**

The systematic review allowed for a transparent and reproducible methodology to aggregate clinical evidence, and address the defined PICO questions to subsequently support the development of overarching principles and recommendations. The aim is to facilitate the integration of clinical evidence with clinical expertise to optimize decision-making for the use of biosimilars in patients with rheumatic diseases in the Gulf region.