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Short communication

Biosimilar medicines in North Macedonia: availability, therapeutic distribution and registration trends

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Introduction

Biosimilar medicines play an increasingly important role in expanding access to biological therapies while supporting the sustainability of healthcare systems. Since the approval of the first biosimilar in the European Union (EU) in 2006, their availability has increased substantially across major therapeutic areas, including rheumatology, oncology, hematology and endocrinology (European Medicines Agency, EMA 2022). The EU has established a comprehensive regulatory framework for the evaluation and approval of biosimilar, providing the basis for their widespread adoption in clinical practice (European Parliament and Council, 2001).

In North Macedonia, the regulatory framework for biosimilar has been aligned with European regulatory principles through the national Rulebook on the Procedure for Marketing Authorization for Medicinal Products adopted in 2015. Biosimilar approval requires demonstration of quality, safety and efficacy in accordance with European Medicines Agency (EMA) standards and the corresponding EU marketing authorization (Macedonian Agency of drugs and medical devices, MALMED 2015).

The aim of this study was to provide an overview of biosimilar medicines registered in North Macedonia and to evaluate their availability according to therapeutic area, mechanism of action and year of registration. In addition, the study assessed the interval between EU authorization and national registration to examine trends in biosimilar market entry and the degree of alignment with the European biosimilar landscape.

Materials and methods

A descriptive analysis of biosimilar medicines registered in North Macedonia was performed using data obtained from the National Register of Medicinal Products and Medical Devices. All biosimilars with a valid marketing authorization up to April 2026 were included. Data on active substance, therapeutic area, mechanism of action, year of European Union authorization and year of national registration were collected and analyzed. The time interval between EU authorization and registration in North Macedonia was calculated, and the findings were descriptively compared with the European biosimilar landscape.

Results and discussion

As of April 2026, a total of 59 marketing authorisations for biosimilar medicines representing 13 active substances were registered in North Macedonia.

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Oncology and hematology accounted for the largest proportion of registered biosimilar products. Oncology-related biosimilars included trastuzumab (n=4), bevacizumab (n=3), rituximab (n=2) and denosumab (n=2), while hematology-related biosimilars comprised filgrastim (n=3), pegfilgrastim (n=1) and epoetin alfa (n=1). In addition, biosimilars authorized for rheumatologic and autoimmune indications included adalimumab (n=2), infliximab (n=1), etanercept (n=1) and rituximab (n=2), with approved indications encompassing rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, psoriasis, inflammatory bowel disease and systemic vasculitis. The prominent representation of these therapeutic areas parallels the European biosimilar landscape, where monoclonal antibodies and supportive oncology therapies have experienced substantial growth in recent years (EMA, 2026). Analysis according to mechanism of action demonstrated that monoclonal antibodies represented the dominant class of registered biosimilars. These included anti-TNF agents (adalimumab and infliximab), a TNF-receptor fusion protein (etanercept), anti-CD20 monoclonal antibodies (rituximab), anti-VEGF monoclonal antibodies (bevacizumab), anti-HER2 monoclonal antibodies (trastuzumab) and anti-RANKL monoclonal antibodies (denosumab). Additional biosimilar classes included granulocyte colony-stimulating factors (filgrastim and pegfilgrastim), erythropoiesis-stimulating agents (epoetin alfa), recombinant hormones (somatropin and follitropin alfa), long-acting insulin analogues (insulin glargine) and low-molecular-weight heparins (enoxaparin).

Notably, diabetes-related indications, identified as one of the major therapeutic areas for biosimilars in the European Union, were represented in North Macedonia exclusively by insulin glargine biosimilars (Abasaglar and Semglee), corresponding to a single biosimilar molecule. This contrasts with the broader range of diabetes-related biosimilars currently available on the European market.

The temporal analysis revealed a gradual expansion of biosimilar availability over the analized period. The first biosimilar registered in North Macedonia was the filgrastim biosimilar Nivestim in 2011, followed by Omnitrope in 2014 and Inflectra in 2015. More than half of all identified biosimilar products (52.0%) were registered during the period 2020–2022, with the highest number of registrations recorded in 2021 (n=5). The most recent additions were the denosumab biosimilars Enwylma and Zadenvi, registered in 2026.

By April 2026, 178 Marketing Authorisations for biosimilar medicines had been approved in the European Union, compared with 59 biosimilar products that had received Marketing Authorisation in North Macedonia (EMA 2026, MALMED 2026). The average interval between EU marketing authorization and national authorization was approximately 2.4 years for biosimilars authorized after 2015, compared with approximately 5 years for biosimilars authorized between 2006 and 2015, when no specific regulatory provisions for biosimilar medicines were in place. The shorter interval between EU and national authorization observed after 2015 suggests improved regulatory alignment and facilitated market entry of biosimilars following the adoption of the dedicated biosimilar regulatory framework.

Conclusion

The introduction of the biosimilar regulatory framework in 2015 facilitated biosimilar market entry and was accompanied by a growing number of registrations in North Macedonia.

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