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Policy measures and instruments used in European countries to increase biosimilar uptake: A systematic review

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ADMINISTRATIVE INFORMATION

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Review Stage at time of this submission - Formal screening of search results.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 07 December 2023 and was last updated on 07 December 2023.

INTRODUCTION

Review question / Objective What policy measures and instruments are used in European countries to increase the biosimilar market share?

Rationale The aging population in Europe, combined with low birth rates and increased life expectancy, presents economic and social challenges. As chronic diseases become more prevalent with age, high-quality management and cost-efficient drugs is necessary. Biological medicines are a significant component of drug expenditures in Europe. In 2022, representing 35% of drug spending and experiencing above-average annual growth compared to other drug groups. Biosimilar medicines authorized for the European market after the patent of the reference biological medicines has expired. Europe has a well-established market for biosimilars, with a positive experience in the acute and chronic treatment of millions of European patients. However, there are variations in the rates of biosimilars use among and within European countries. Therefore, it is important to systematize information related to this topic to ensure the efficiency and future of healthcare systems.

Condition being studied Biosimilars are designed to be highly similar to reference products (originators). In Europe as of May 2023, 75 biosimilars have been approved and authorized for 19 active substances, spanning various therapeutic areas such as diabetes, inflammatory bowel diseases (IBD), psoriasis, rheumatology, ophthalmology, hematology, and oncology. These biosimilars encompass a range of biological products, including insulins, epoetin, granulocyte-colony stimulating factor (GCSF), heparins, anti-

tumour necrosis factor (Anti-TNF), and monoclonal antibodies. They are an emerging class of biological medicines that have reduced healthcare costs while maintaining similar efficacy and safety as their reference biologicals. Currently, the literature indicates variations in the utilization rates of biosimilars, both among and within European countries, which may be influenced by different policies, medical perspectives, competition among suppliers and prices. Therefore, a comprehensive understanding of the economic policy measures and instruments used in European countries to increase the biosimilars market share is needed to inform policy decisions and optimize the use of these products.

METHODS

Search strategy The study was conducted on February 6, 2023, on Medline-PubMed, Web of Science (Web of Science Core Collection), and ScienceDirect databases. To update the results obtained, a new search was conducted on December 2, 2023, using the same databases.
The search strategy used in the PubMed database is as follows:
("drug substitution/standards"[MeSH Terms] OR "drug substitution/methods"[MeSH Terms] OR "drug substitution/economics"[MeSH Terms] OR "Drug Substitution"[MeSH Terms])
AND
"biosimilar pharmaceuticals/therapeutic use*"[MeSH Terms]) OR "biosimilar pharmaceuticals/standards"[MeSH Terms] OR "biosimilar pharmaceuticals/economics*"[MeSH Terms] OR "biosimilar pharmaceuticals/administration and dosage*"[MeSH Terms])
The search strategy was adapted for each database.

Participant or population The study population consisted of European patients undergoing treatment with biological medicines.

Intervention Intervention involved the use of economic policy measures and instruments in different European countries.

Comparator The comparison involved the absence of policy measures and instruments across different European countries.

Study designs to be included Cross-sectional studies.

Eligibility criteria The inclusion criteria encompassed full-text articles in English, published between January 2006 and November 2023. This timeframe was chosen as the first biosimilar was approved in Europe in 2006. Additionally, the articles had to reference at least one European country, not limited to EU members. Only studies describing policy measures and/or instruments aimed at increasing the biosimilars market share and used in the country were considered. Exclusion criteria included reports, investigative letters, opinion or comment articles, editorials, systematic reviews, reviews, incomplete articles, as well as studies referring to countries outside Europe.

Information sources The study was conducted on February 6, 2023, on Medline-PubMed, Web of Science (Web of Science Core Collection), and ScienceDirect databases. To update the results obtained, a new search was conducted on December 2, 2023, using the same databases.

Main outcome(s) For this systematic review, the primary outcomes include the comprehensive description of economic policy measures and/or instruments implemented to enhance the market share of biosimilars in the European market. These policy measures encompass incentive programs, pricing and reimbursement policies, educational initiatives targeting both physicians and patients, and non-medical switching programs. Additionally, the review seeks to identify existing gaps in the literature and present future perspectives in the field.

Quality assessment / Risk of bias analysis The quality of the included studies will be assessed using the Joanna Briggs Institute (JBI) Checklist for cross-sectional studies. The risk of bias for each study will be independently assessed by two researchers.

Strategy of data synthesis Two researchers independently assessed titles and abstracts to exclude non-relevant articles based on eligibility criteria. The remaining articles underwent full-text screening by two researchers, when significant discrepancies exist, third-party arbitration is required. For the included articles, a data extraction form was created. One researcher filled out the form, and validation was conducted by the entire team. The form included key study details such as title, authors, publication year, covered European countries, study location, objectives, participants, and results (policy measures and/or instruments for increasing biosimilars market share).

Subgroup analysis Not performed.

Sensitivity analysis Not performed.

Language restriction Only articles written in English will be included.

Country(ies) involved Portugal.

Keywords biological products; biosimilar pharmaceuticals; drug substitution; health policy; economics.

Contributions of each author

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