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A Targeted Literature Review to Identify the Dimensions of Sustainable Global Biosimilars Markets

Victoria W. Dayer, PharmD[1,2], Joshua A. Roth, PhD, MHA[2,3], Mireia Jofre-Bonet, PhD[4,5], Alistair McGuire, PhD[6], Sean D. Sullivan, PhD[1,2,6]

[1]Curta, Inc., Seattle, WA, USA , [2]School of Pharmacy, University of Washington, Seattle, WA, USA, [3]Pfizer, Inc., New York, NY, USA, [4]Office of Health Economics, London, England, [5]Department of Economics, City, University of London, [6]Department of Health Policy, London School of Economics and Political Science, London, England

Background

- Biosimilars are biologic medications that are highly similar to, and have no clinically meaningful differences from, existing approved biologics known as “reference products”.[1]
- Typically, biosimilars are priced below their reference products, creating an economic incentive for use to reduce expenses.[2-4]
- However, a variety of challenges to biosimilar uptake have arisen across global markets, threaten market sustainability, and may create disincentives to pursue development of additional biosimilars in the future.

Objective

To conduct a targeted literature review (TLR) of the biosimilars literature to identify key sustainability dimensions of this market to inform future research, stakeholder interactions, and policy initiatives aimed at ensuring the long-term viability of global biosimilars markets.

Conclusions

- A contemporary review of the global biosimilars literature was used to identify key dimensions of biosimilar market sustainability that should be considered by stakeholders looking to ensure the long-term viability of the market.
- This framework that will be developed using the findings of this TLR will help facilitate research, collaboration, and policy focused on optimizing the cost-saving potential while promoting a sustainable biosimilars market.

References: 1. Center for Drug Evaluation and Research. Biosimilars. FDA. Published June 16, 2023. Accessed March 20, 2024. https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars; **2.** Aitken M. Biosimilars in the United States 2023–2027. IQVIA Institute for Human Data Science; 2023.; **3.** Aitken M. Assessing the Biosimilar Void. IQVIA Institute for Human Data Science; 2023. https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/assessing-the-biosimilar-void; **4.** Car E, Vulto AG, Houdenhoven MV, Huys I, Simoens S. Biosimilar competition in European markets of TNF-alpha inhibitors: a comparative analysis of pricing, market share and utilization trends. Front Pharmacol. 2023;14:1151764. doi:10.3389/fphar.2023.1151764

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Methods

- We searched publications in PubMed and EMBASE for the period January 2013 to September 2023 to identify literature addressing aspects of biosimilar market sustainability
  - Terms: ‘biosimilars’, ‘market sustainability’, ‘market access’, ‘pricing and reimbursement’, ‘market dynamics’, ‘market trends’, and ‘price erosion’
- We also searched conference abstracts in those databases and relevant policy documents and white papers from 2019 onward.
- Among included publications, we documented study year, countries or regions of focus, design/methodology, therapeutic area, key findings, and noted the stated objectives.
- We iteratively refined lists of stakeholder and sustainability dimension themes into combined groupings. After arriving at the groups, we re-reviewed all full texts to document which specific stakeholder and sustainability dimension groups were discussed in each publication

Results

PubMed, EMBASE, and grey literature (n=790)
566 (71.6%) published 2019 or later

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Identified for full text review (n=192)
151 (78.6%) published 2019 or later

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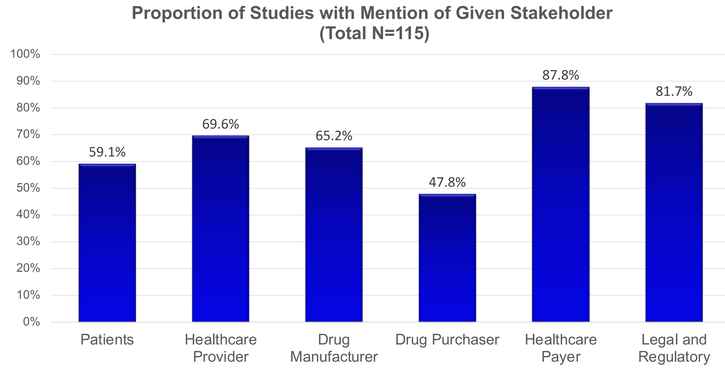
Included in study (n=115)
90 (78.2%) published 2019 or later

Most prevalent stakeholders identified

- **Patients**
- **Healthcare Providers**
- **Drug Manufacturers**
- **Drug Purchasers**
- **Healthcare Payers**
- **Legal & Regulatory Authorities**



Most prevalent sustainability dimensions identified

Pricing & Cost Savings
- Magnitude of potential savings with biosimilars compared to their reference products is substantial
- Policies such as pricing, switching, quotas, and procurement requirements affect savings
- Savings are not always passed on to patients
- Pricing being driven down too quickly may discourage market entry

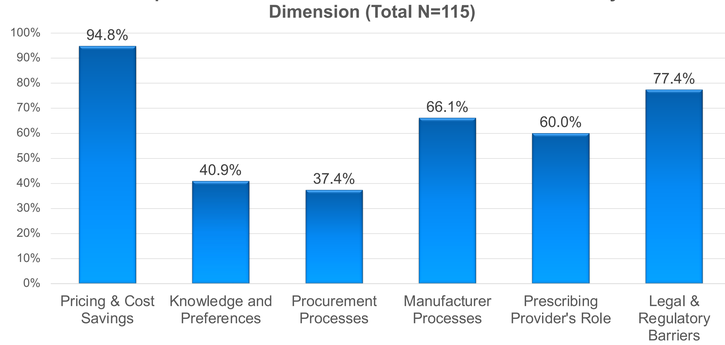
Knowledge & Preferences
- Knowledge gaps about safety, efficacy, and/or interchangeability have the potential to result in sub-optimal biosimilar coverage, uptake, and adherence
- ‘Nocebo’ effect—a phenomenon where stakeholders believe that a biosimilar product has less favorable outcomes than a reference product because it is not the originator biologic and/or costs less
- Policies and initiatives to educate providers and patients are important for improving biosimilar utilization

Procurement Processes
- Evaluation criteria to determine winner(s) of competitive contracts and tenders often includes large emphasis on price
- Quality assurance processes, supply chain robustness, and environment sustainability practices may suffer
- Procurement processes that select only one or two manufacturers can exacerbate declines in price

Manufacturer Processes
- Development process is complex, expensive, and time consuming
- Financial risk of entering the market amidst uncertainty about competition and potential for prices to be driven down quickly
- Patent extensions and thickets
- Price setting can be difficult amidst these uncertainties

Prescribing Provider’s Role
- Prescribers are often the key decision-makers in biosimilar choice
- Many still have concerns or uncertainty around biosimilar safety or efficacy
- Providers are often the targets for policies and interventions to incentivize biosimilar use, but conflicting policies can create disincentives to prescribing biosimilars
- Institutional rules and payer policies may limit prescriber choice

Legal & Regulatory Barriers
- Complex and expensive evidence requirements to establish similarity to and/or interchangeability with reference products and extrapolation to reference product indications, with differing requirements across countries
- Laws determining whether or not pharmacists may substitute differ across jurisdictions, even within countries
- Patent laws and litigation from originator manufacturers can delay market entry of biosimilars



Discussion

- We did not undertake a full systematic literature review, resulting in findings are likely less reproducible as compared to those generated by more formal SLR methods.
  - The phrase ‘market sustainability’ rarely appears across the 113 studies that we identified.
- Our categorization of themes relied on a simple binary (yes/no) classification system based upon ≥1 mention.
  - However, the themes identified were based on a wide body of research conducted in markets across the world.
- We believe that the findings of our literature review provide a unique centralized resource that can help stakeholders to identify sustainability-related publications over the period 2013 to 2023.

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