

PRESS RELEASE

Biocon Biologics' Commissioned Report Highlights Pathways to Increase Adoption of Biosimilars in LMICs

GaBI Publishes Peer-Reviewed Article

Bengaluru, Karnataka, India, October 8, 2024

Biocon Biologics Limited, a fully integrated global biosimilars company, has published the results of a detailed study that provides key insights into creating a more supportive environment for biosimilars in low- and middle-income countries (LMICs), aimed at boosting uptake and expanding access to affordable healthcare solutions.

Biocon Biologics commissioned the study, defined the methodology and collaborated with Clarivate to develop the final report. A peer-reviewed article based on this study has been published in the prestigious *Generics and Biosimilars Initiative (GaBI) Journal*.

The article titled "Increasing Adoption of Quality-Assured Biosimilars to Address Access Challenges in Low- and Middle-Income Countries" outlines six policy recommendations for accessing and using quality-assured biosimilars in LMICs:

- Strengthening regulatory systems;
- Strengthening national policies to increase access and adoption of biosimilars;
- Encouraging local manufacturing;
- Providing guidance for prescribing biosimilars and increasing education on biosimilars;
- Encouraging stakeholders' initiatives promoting access to biosimilars;
- Strengthening pharmacovigilance.

Susheel Umesh, Chief Commercial Officer - Emerging Markets, Biocon Biologics, said, "Clarity in regulatory frameworks and pathways help in preventing delays in accessing quality-assured, affordable medicines. This is important especially in low- and low-middle income countries (LMICs) that already struggle with constrained healthcare systems. Regulatory agencies must consider a paradigm shift towards eliminating redundancies in the approval processes and fast-track commercialization of quality-assured biosimilars. Through this article, we have provided recommendations that can lead to improved adoption of biosimilars in countries with limited resources and who have the most critical need for cost-effective, high-quality alternatives to modern therapies."

Dr Uwe Gudat, Chief Medical Officer, Biocon Biologics, said, "Non-communicable diseases (NCDs) disproportionately impact low- and middle-income countries (LMICs), where healthcare resources



are particularly limited. Our study underscores the potential of biosimilar products to expand access to essential medicines in these regions. By offering more affordable alternatives to originator biologics, biosimilars can significantly improve patient outcomes. This review highlights the benefits of biosimilars in LMICs, drawing on data from emerging markets and proposing a call to action to strengthen regulatory frameworks, to facilitate local manufacturing, and to increase awareness of the potential that biosimilars offer for patients and health care systems."

According to the study, NCDs including cancer and diabetes account for 74% of global deaths, with 41 million people succumbing to them annually. These diseases disproportionately affect LMICs, where 77% of NCD deaths occur. As NCDs disproportionately affect people living in LMICs and these countries have more limited healthcare resources, increasing biosimilar adoption can enable increased patient access to more affordable alternatives to originator biologics and ultimately improve patient outcomes.

In high-income countries (HICs), biosimilars have already demonstrated their value in reducing healthcare costs and increasing patient access to biologic treatments for diseases such as cancer, diabetes, and autoimmune disorders. In LMICs, where healthcare budgets are often stretched and large segments of the population remain underserved, the introduction of biosimilars can be transformative.

Biocon Biologics is committed to ensuring that no patient is left behind when it comes to quality healthcare. By focusing on accessibility and affordability, the Company is bridging the disparities that exist between high-income countries and LMICs in terms of access to cutting-edge biologic therapies. Its biosimilars are providing cost-effective alternatives to expensive biologic drugs, making advances in medical treatment more accessible to patients. By broadening patient access to biosimilars, Biocon Biologics is contributing to improved patient outcomes and sustainable use of healthcare system resources in LMICs.

The abstract and full article (subscription required) are available on the GaBI website: https://gabi-journal.net/increasing-adoption-of-quality-assured-biosimilars-to-address-access-challenges-in-low-and-middle-income-countries.html

About Biocon Biologics Limited:

Biocon Biologics Ltd. (BBL), a subsidiary of Biocon Limited, is a unique, fully integrated, global biosimilars company committed to transforming healthcare and transforming lives. It is capitalizing on its 'lab to market' capabilities to serve millions of patients across 120+ countries by enabling affordable access to high quality biosimilars. The Company is leveraging cutting-edge science, innovative tech platforms, global scale manufacturing capabilities and world-class quality systems to lower costs of biological therapeutics while improving healthcare outcomes.

Biocon Biologics has commercialized eight biosimilars in key emerging markets and advanced markets like U.S., Europe, Australia, Canada, and Japan. It has a pipeline of 20 biosimilar assets across diabetology, oncology, immunology, ophthalmology, and other non-communicable diseases. The Company has many



'firsts' to its credit in the biosimilars industry. As part of its environmental, social and governance (ESG) commitment, it is advancing the health of patients, people, and the planet to achieve key UN Sustainable Development Goals (SDGs). Website: www.bioconbiologics.com; Follow us on X (formerly Twitter): @BioconBiologics and LinkedIn: Biocon Biologics for company updates.

Biocon Limited, publicly listed in 2004, (BSE code: 532523, NSE Id: BIOCON, ISIN Id: INE376G01013) is an innovation-led global biopharmaceuticals company committed to enhance affordable access to complex therapies for chronic conditions like diabetes, cancer and autoimmune. It has developed and commercialized novel biologics, biosimilars, and complex small molecule APIs in India and several key global markets as well as Generic Formulations in the US, Europe & key emerging markets. It also has a pipeline of promising novel assets in immunotherapy under development. Website: www.biocon.com; Follow-us on X (formerly Twitter): @bioconlimited for company updates.

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