



INTERNATIONAL GENERIC AND
BIOSIMILAR MEDICINES ASSOCIATION

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For immediate release

IGBA Contributes to Global Discussion on Tailored Clinical Biosimilar Development with New Peer-Reviewed Scientific Paper

The International Generic and Biosimilar medicines Association (IGBA), which represents global manufacturers of generic and biosimilar medicines, today announces the publication of its first peer-reviewed scientific paper on biosimilar medicines development: **The Path Towards a Tailored Clinical Biosimilar Development** ([Biodrugs](#)).

This peer-reviewed paper is the result of scientific collaboration and dedicated work by the IGBA Biosimilars Committee and is a substantive contribution to the advancement of biosimilar regulation and standards globally. It presents data in support of the possible evolution of regulatory science in the comparability exercise, specifically regarding the clinical comparability paradigm, established since 2006.

Building on the vast clinical experience and scientific knowledge accrued through the evaluation of over 42 unique biosimilar candidates authorized in the EU and US, this paper proposes revisiting the existing development paradigm to ensure that a tailored clinical approach is adopted, as supported by science, while maintaining the high level of quality, safety and effectiveness established by current regulatory pathways.

Erika Satterwhite, Chair of the IGBA Biosimilars Committee, underlined *“This peer-reviewed work by IGBA scientific experts clearly articulates the imperative for a tailored clinical biosimilar development paradigm, without the routine need for comparative efficacy and/or pharmacodynamic studies, that is founded on scientific evidence and compatible with both existing EU and US biosimilar regulatory standards.”*

“We look forward to working with IGBA global partners to bring this paradigm to life”, commented Hanan Sboul, IGBA Chair. *“Considering the remaining global access needs in biologic therapies, IGBA considers the tailoring of clinical biosimilar development a significant and achievable step in fostering earlier and broader access to safe and effective biologic therapies in the future,”* concluded Sboul.

About IGBA

The International Generic and Biosimilar medicines Association (IGBA) strengthens cooperation between associations representing manufacturers of generic and biosimilar medicines from around the world. The IGBA is at the forefront of preserving sustainable competition within our industry, by stimulating competitiveness and innovation in the pharmaceutical sector; thereby, ensuring millions of patients around the world have access to high quality, pro-competitive medicines. For more details, regarding IGBA and its member associations, see the IGBA website at: www.igbamedicines.org.