INTERNATIONAL GENERIC AND
BIOSIMILAR MEDICINES ASSOCIATION

Info: info@igbamedicines.org

IGBA Welcomes ICH New Topic for Harmonisation: Framework for Determining Utility of Comparative Efficacy Studies in Biosimilar Development Programs

For immediate release

Geneva, 21 May 2025

The International Generic and Biosimilar medicines Association (IGBA) commends the General Assembly of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) for its adoption of a new topic focused on the harmonisation of "**Framework for Determining Utility of Comparative Efficacy Studies in Biosimilar Development Programs**." This significant development, which took place at the recent ICH meeting in Madrid, Spain, marks the introduction of a new ICH Multidisciplinary Guideline, which aims to further strengthen consensus and harmonisation among ICH members regarding reducing or eliminating routine for Comparative Efficacy Studies (CES) for biosimilar medicines. These efforts build upon the advancements in analytical technologies, the nearly three decade long experience with biosimilar development and regulation and existing harmonisation initiatives found in the context of the ICH Q5E guideline that describes factors that may influence when additional clinical data is needed.

The harmonisation of the criteria for determining the need for CES in biosimilar development programs will help to avoid conducting CES which do not provide meaningful data for regulatory decision making, increase efficiency in biosimilar development and therefore ultimately increase the availability and accessibility of important biologic therapies for patients. By providing a unified scientific framework to justify when such studies are not routinely required, this guideline will help reduce the cost and duration of biosimilar development—ultimately benefiting patients around the World.

IGBA emphasizes the critical importance of making biosimilar development more efficient as a cornerstone of global healthcare progress and has previously issued a press release highlighting two position papers in support of this goal. This position is also aligned with the 2022 revisions to the WHO Guideline on Biosimilars and supports global access to quality-assured, safe, and effective biosimilars. Given the potential for a significant reduction in the time and costs of biosimilar development, the guideline would serve as a key enabler in ensuring broader access to affordable, high-quality medicines.

“We commend the ICH Assembly for their commitment to advancing global harmonisation in the field of biosimilars," commented Dr. Nicholas Cappuccino, ICH Assembly and Management Committee member

representing IGBA. “CES lack scientific value and offer no added benefit to regulators or healthcare providers. Robust regulatory science supports biosimilar development based on analytical data and a clinical pharmacokinetic study including safety and immunogenicity. Consistent science-driven decisions for all biologics are key to ensuring access to and trust in high-quality, safe, and effective medicines.” added Gillian Woollett, Chair, IGBA Biosimilars Committee.

IGBA looks forward to contributing to the development and implementation of the new ICH Multidisciplinary Guideline, in collaboration with regulatory authorities and other stakeholders. IGBA and its members remain committed in their mission to supporting a globally aligned regulatory framework, that ensure access to safe and affordable medicines to patients worldwide.

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. Adopting a patient centric approach, IGBA works to improve patients’ access to quality assured, safe and cost-effective medicines by promoting competition and enabling innovation in the pharmaceutical sector and sustainable economic contributions for all stakeholders. For more details, regarding IGBA and its member associations, see the IGBA website at: www.igbamedicines.org