INTERNATIONAL GENERIC AND
BIOSIMILAR MEDICINES ASSOCIATION

Info: info@igbamedicines.org

IGBA identifies streamlined development through reduced comparative clinical studies and appropriate use of global comparator product as key to greater biosimilar access

For immediate release
Geneva, 12 July 2024

The mandate to conduct routine comparative clinical efficacy studies for biosimilar medicines, compounded by duplicative regional requirements, serves as a barrier to greater medicine access for patients. The International Generic and Biosimilar Medicines Association (IGBA) has issued two position papers; the first proposing streamlined development through reduced clinical studies and the second proposing use of the same comparator product across jurisdictions.

Avoiding scientifically unnecessary studies, and their repetition using locally sourced reference materials, does not compromise the quality, safety and efficacy of the approved biosimilar medicines. This can facilitate more efficient development of more affordable medicines, enabling biosimilar access for more patients in more jurisdictions (see IQVIA Biosimilar Void report).

"Comparative clinical studies lack scientific validity and offer no new information to regulators or health care providers. The savings in time and resources from eliminating these duplicative requirements could have a meaningful impact on patient access. Education of all stakeholders will continue to be important," says Gillian Woollett, Co-Chair, IGBA Biosimilars Committee.

Well established regulatory science supports the development of biosimilars based on analytical (physicochemical and functional) data and a clinical pharmacokinetic study, which includes safety and immunogenicity data. Clinical comparative efficacy studies using conventional efficacy and/or pharmacodynamic endpoints are much less sensitive to detect meaningful differences between a candidate biosimilar and the reference product, and do not provide additional regulatorily-relevant information. The recently issued IPRP Biosimilars Working Group (BWG) Report *Increasing the Efficiency of Biosimilar Development Programs — Reevaluating the Need for Comparative Clinical Efficacy Studies* reaches similar conclusions on behalf of regulators from around the world.

The IGBA position to forego the mandate for routine comparative clinical efficacy studies is applicable to all well-characterized biosimilars. Such an approach is consistent with the established regulatory science for all biologics. This position aligns with the revisions to the WHO Guideline on Biosimilars (April 2022), and would support global access to quality-assured, safe, and effective biosimilars.

"State of the art science-based regulatory decision-making that consistently applies the same data expectations fairly across all sponsors, all biologics, and for all regions is the best way to foster access and trust in quality-assured, safe, and effective medicines by patients. Such reliance also helps build regulatory capacity everywhere. It is time for a shared solution.," says Giuseppe Randazzo, Co-Chair, IGBA Biosimilars Committee.

About us: 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.