INTERNATIONAL GENERIC AND
BIOSIMILAR MEDICINES ASSOCIATION

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IGBA Applauds UK MHRA Biosimilar Guidance Revision: Science-driven Evolution for Sustainable Access to Biologics

The International Generic and Biosimilar medicines Association (IGBA), which represents global manufacturers of generic and biosimilar medicines, welcomes the UK MHRA publication of its updated guidance on the licensing of biosimilar products (10 May 2021). This publication marks a positive milestone in the evolution of evidence requirements for biosimilar approval through the removal of the default need for a comparative efficacy trial, instead basing approval on a comprehensive comparability exercise, including a comparative pharmacokinetics (PK) trial.

This evolution is driven by the growing clinical evidence accrued from biosimilar medicines regulatory pathways after more than 15 years on the market and billions of patient treatment days of experience, as well as improvements in regulatory processes, analytical science and characterisation technology.

Julie Maréchal-Jamil, Co-Chair of the IGBA Biosimilars Committee, stated "*The UK MHRA is leading the way in translating the vast cumulative experience with biologic medicines into fit-for-purpose regulatory-science requirements that better serve patients and healthcare systems. We call on the international regulatory community to embrace this evolution and agree on a global implementation roadmap to progress this science-based efficiency. International convergence and consistent communication are essential to maintain trust in biosimilar approval frameworks.*"

While disparities in access to biologic therapies continues to grow globally, this science-driven evolution provides a significant opportunity for faster, more efficient biosimilar medicines development to accelerate equitable access for patients around the world.

IGBA Chair Sudarshan Jain further commented: "*Biosimilar medicines help in delivering greater patient access to biologic therapies and healthcare efficiency. The healthcare system will benefit from regulatory simplification and efficiency. The UK MHRA pioneers the simplification of biosimilar approval process underlining its anticipated positive impact on availability and access to biosimilar medicines going forward. We call on the international regulatory community to further advance this simplification process in continuous dialogue with patients and physicians among stakeholders*."

"The UK MHRA move is a milestone and a logical next step in the biosimilar medicines regulatory framework. We trust that the same updated scientific and regulatory approach will be included in the WHO guidelines on evaluation of similar biotherapeutic products (SBP), currently under revision." concluded Suzette Kox, IGBA Secretary General.

For more information on the IGBA Biosimilars Committee work on biosimilar medicines and streamlined development see:

- *IGBA Policy Paper: Developing a Regulatory Policy Framework Supporting Biosimilar Competition: The Opportunity for Tailored Clinical Biosimilar Development (September 2020).*
- *IGBA Peer-Reviewed Scientific Paper on "The Path Towards a Tailored Clinical Biosimilar Development" (07 April 2020)*

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.