INTERNATIONAL GENERIC AND
BIOSIMILAR MEDICINES ASSOCIATION

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Global Roadmap for Tailored Clinical Biosimilar Development: Instrumental for Sustainable Access to Biologics

Following its first peer-reviewed scientific paper on biosimilar medicines development: the Path Towards Tailored Clinical Biosimilar Development (Biodrugs), the International Generic and Biosimilar medicines Association (IGBA), which represents global manufacturers of generic and biosimilar medicines, today released a new policy paper: "***Developing a Regulatory Framework Supporting Biosimilar Competition: The Opportunity for Tailored Clinical Biosimilar Development***"

Today, healthcare systems are facing unprecedented challenges. The development of new strategies for resilient structures requires renewed focus on optimisation and efficiency.
"*The Covid-19 pandemic has further highlighted and deepened inequalities in patient access to medicines globally. Biosimilar medicines are a must-have resource for health systems to ensure equitable access to finite healthcare resources. This access crisis has taken centre stage in the health care agenda and regulatory authorities must swiftly find sustainable solutions*", Hanan Sboul, IGBA Chair, commented.

In its new policy paper, the IGBA focuses on two main areas in which regulatory authorities can uniquely contribute to building a conducive environment for sustained biosimilar competition, a critical component of more equitable access to biological medicines.

- Firstly, vast regulatory experience with biologics, including biosimilar medicines, supports the **streamlining of biosimilar regulatory requirements**, particularly concerning clinical biosimilar development. The IGBA recent analysis revealed the limited value of comparative efficacy clinical data in the overall biosimilarity assessment. There have been significant advances in the level of detail and clinically relevant information derived from analytical science since the introduction of biosimilar frameworks globally, and regulatory requirements must keep pace with the scientific developments.
- Secondly, regulators have a **pivotal role in informing and educating healthcare community stakeholders** that will demand **renewed efforts** as the biosimilar regulatory framework evolves further. Greater reliance on analytical data over clinical studies will require a fundamental shift in understanding among healthcare professionals to ensure that biosimilar approvals translate into utilisation and patient access.

Julie Maréchal-Jamil, Co-Chair of the IGBA Biosimilars Committee, stated "*We need a global effort to revise the current requirements for clinical biosimilar development while maintaining uncompromised biosimilarity standards, including safety, and acceptance by stakeholders. We have shown that the science is there. What remains is action from regulatory policymakers. A global implementation roadmap from regulatory authorities is needed to put this evolution in motion."*

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.