INTERNATIONAL GENERIC AND
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Single Global Development of Generic and Biosimilar Medicines: a cornerstone of Patient Access

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For immediate release

A research report resulting from a collaboration between the University of Maryland and University of Michigan (USA) delivers a critical set of recommendations emphasizing the urgent need for policies that foster **single global development** of off patent medicines.

The research concluded that **harmonized regulatory standards** and **streamlined development pathways**, including the acceptance of foreign comparator products, can drastically reduce the cost and time required to bring essential, quality-assured generic, complex generic and biosimilar medicines to patients worldwide, including off-patent versions of orphan drugs.

The analysis identifies four primary areas where policy innovation and international collaboration can yield the most significant public health benefits:

1. Modernize Comparator Product Requirements

The research strongly recommends establishing **clear legislative and regulatory pathways** to permit the use of **foreign comparator products** in generic and biosimilar medicines development.

- This crucial step would significantly **reduce development costs** by eliminating the need to source expensive reference products exclusively from domestic markets, while **maintaining rigorous scientific standards** for establishing therapeutic equivalence and bioequivalence.

2. Align Technical and Scientific Standards

The report calls for global regulatory agencies to urgently **align technical standards** and eliminate scientifically unsupported discrepancies that hinder efficient development.

3. Streamline Development for Complex Generic Products and Biosimilars

To speed access to sophisticated, life-saving therapies, the research recommend the **elimination of redundant clinical study requirements** for complex generic products and biosimilars.

- When sufficient **analytical, physiochemical, non-clinical testing and/or clinical testing evidence** already exists to demonstrate similarity and equivalence, regulatory bodies should leverage this data.

- Global concurrence on acceptance of alternative approaches such as modeling, simulation and other quantitative methods for demonstrate equivalence is essential.
- This data-driven approach will **streamline development pathways**, cutting unnecessary testing without compromising patient safety or product efficacy.

4. Enhance and Expand Global Regulatory Collaboration

A call for strengthened international cooperation is central to the recommendations. Policymakers should **enhance regulatory collaboration** through expanded work-sharing and joint review initiatives.

- The report encourages expanding successful models, such as the **EU's centralized procedure** and programs like the **Access Consortium** and the **FDA-EMA Parallel Scientific Advice Pilot Program**, to include other major regulatory jurisdictions.
- This collaboration will leverage global expertise, avoid duplication of effort, and accelerate the approval of critical medicines across multiple countries simultaneously.

"By adopting these evidence-based, collaborative reforms, and building upon proven harmonization efforts global policymakers can unlock a new era of efficiency, ensuring quality-assured, cost-effective medicines reach the communities that need them most," said Dr. James Polli, Shangraw/Noxell Endowed Chair in Industrial Pharmacy and Pharmaceutics, Department of Pharmaceutical Sciences, University of Maryland. *"The findings are clear: outdated, inconsistent regulations are unnecessarily inflating development costs and delaying patient access,"* commented Dr. Susana Almeida, Secretary General of the IGBA. *"While the harmonisation of the technical requirements for bioequivalence and biosimilar development programs at the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) is a fundamental foundation for global regulatory convergence for off-patent medicines, it is not sufficient to allow single global development, which is a key enabler for patient access to cost-effective and quality-assured medicines. In this context, the acceptance of foreign comparators is of utmost importance, to remove a major barrier to streamlined global development and leverage the benefits of harmonization at ICH level".*

IGBA and its members remain steadfast in their calls to foster a globally aligned regulatory environment, which is critical to ensuring that quality-assured, safe, cost-effective medicines are available to patients around the world.

The full report is available on the IGBA webpage:
IGBA_Report_Importance of Single Global Development of Generic and Biosimilar Medicines for Patient Access.pdf