INTERNATIONAL GENERIC AND
BIOSIMILAR MEDICINES ASSOCIATION

Info: info@igbamedicines.org

IGBA Welcomes ICH New Topic for Harmonisation: "Bioequivalence for Modified-Release Products"

Geneva, 26 June 2023
For immediate release

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 "**Bioequivalence for Modified-Release Products**." This significant development, which took place at the recent ICH meeting in Vancouver, Canada, marks the introduction of a new ICH Multidisciplinary Guideline, which aims to further strengthen consensus and harmonisation among ICH members regarding bioequivalence standards for more complex dosage forms. These efforts build upon the existing harmonisation initiatives found within the upcoming M13 series of bioequivalence guidelines.

The scientific harmonisation of study designs for bioequivalence studies involving modified-release products holds great promise for streamlining important aspects of trial conduct and optimising product development. By providing a unified framework, these guidelines will enable greater efficiency in the evaluation of these products, ultimately benefiting patients.

IGBA emphasises the crucial role of bioequivalence harmonisation as a fundamental cornerstone for global development, serving as a key enabler in ensuring access to affordable and quality-assured medicines.

"We commend the ICH Assembly for their commitment to advancing global harmonisation in the field of bioequivalence," commented Dr. Nicholas Cappuccino, ICH Assembly and Management Committee member representing IGBA. "*The adoption of this new topic underscores the importance of collaboration and consensus-building among regulatory bodies to optimise drug development processes. By unifying guidelines and standards, we can unlock the full potential of affordable and quality-assured medicines, making a positive impact on patients worldwide*," Cappuccino continued.

IGBA looks forward to actively participating in the development and implementation of the new ICH Multidisciplinary Guideline, alongside regulatory authorities and other stakeholders.

IGBA and its members remain steadfast in their mission to foster a globally aligned regulatory environment, which is critical to ensuring that safe and affordable medicines are available to patients around the world.

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.