



INTERNATIONAL GENERIC AND
BIOSIMILAR MEDICINES ASSOCIATION

Info: info@igbamedicines.org

IGBA applauds long-awaited scientific harmonization process of bioequivalence studies

For immediate release
Geneva, 05 December 2019

The International Generic and Biosimilar Medicines Association (IGBA) welcomes the adoption by the International Council for Harmonization (ICH) of a new topic proposal on Bioequivalence for Immediate-Release Solid Oral Dosage Forms (M13)ⁱ. The ICH Assembly approved the Concept Paper Outline in their November Singapore meeting with the establishment without delay of a new Working Group to initiate work on finalizing the concept paper and business plan for this new topic.

Dr. Nicholas Cappuccino, ICH Assembly and Management Committee member representing IGBA commented: *“This is the first topic since the ICH reorganization in 2016 that is specifically focused on the generic medicines industry. The support of both the Regulators and other Industry Members of the ICH Assembly is appreciated given the many priorities for new ICH harmonization topics and the resources necessary from all parties to support guideline development.”*

For immediate-release solid oral dosage forms, bioequivalence studies establish the efficacy and safety of most generic medicines and are an essential part of their development. Scientific harmonization of the study design of bioequivalence studies will allow the streamlining of some important aspects of the conduct of these trials and optimize product development.

IGBA membership therefore awaits with excitement the activation of this topic at ICH which will open the door for subsequent important discussions and ICH guidelines on the global development of affordable generic medicines, which are paramount for increasing patient access.

ⁱ <https://www.ich.org/>

About IGBA

The International Generic and Biosimilar medicines Association (IGBA) was founded to strengthen 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