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2ND BIOEQUIVALENCE WORKSHOP
THE HOTEL, BRUSSELS | 26 APRIL 2023
#BIOEQ23

Harmonised bioequivalence guideline paves the way for global generic medicine development and access to medicines

For Immediate Release
Brussels, 26 April 2023

The International Council for Harmonisation (ICH) has initiated the process for a new guideline on bioequivalence requirements for the approval of medicines, which is an important milestone for global convergence. The EU Pharmaceutical Strategy for Europe can build on this to enable global generic medicine development which is needed for better access to medicines and security of supply.

At the 2nd Bioequivalence Workshop, Gerald Beuerle, Chair of the Medicines for Europe Bioequivalence working group, emphasised the importance of maintaining the principle of extrapolation of bioequivalence study results between different populations and that the current language in the sections on fed and fasting studies and pH dependency should be clarified to avoid unnecessary additional studies. Conflicting requirements between M13A and existing guidelines and product-specific guidance should also be addressed.

Adrian van den Hoven, Director General of Medicines for Europe and Vice-Chair of the International Generic and Biosimilar medicines Association, highlighted the critical importance of the M13A guideline for scientific alignment among global regulatory authorities and industry.

Susana Almeida, Clinical Development and Safety Director of Medicines for Europe concluded that the M13 Guideline should be a building block for global development to avoid the unnecessary repetition of bioequivalence studies when the comparator product is similar across highly regulated regions. Switzerland, Canada, Australia, Singapore, and the UK have already established criteria for global development. The EU should do the same to deliver on its access goals in the Pharmaceutical Strategy for Europe.

Resource hub
These issues and other key topics in the field of bioequivalence were discussed during the Medicines for Europe 2nd Bioequivalence Workshop, which was held on 26 April 2023, in Brussels, Belgium, with around 120 participants, comprising regulators from Europe and the United States (including members of the ICH M13 Expert Working Group), industry leaders and experts from around the world. For more information on the event, see
https://www.medicinesforeurope.com/events/bioeq23/

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Medicines for Europe represents the generic, biosimilar and value-added medicines industries across Europe. Its vision is to provide sustainable access to high quality medicines, based on 5 important pillars: patients, quality, value, sustainability and partnership. Its members directly employ 190,000 people at over 400 manufacturing and 126 R&D sites in Europe and invest up to 17% of their turnover in R&D. Medicines for Europe member companies across Europe are both increasing access to medicines and driving improved health outcomes. They play a key role in creating sustainable European healthcare systems by continuing to provide high quality, effective generic medicines, whilst also innovating to create new biosimilar medicines and bringing to market value added medicines, which deliver better health outcomes, greater efficiency and/or improved safety in the hospital setting for patients. For more information, please follow us at www.medicinesforeurope.com and on Twitter @medicinesforEU.