Press Release

Harmonising Bioequivalence: Advancing Global Access to Generic Medicines

Amsterdam, 26 February 2025

The 3rd Bioequivalence Conference, co-hosted by the International Generic and Biosimilar Medicines Association (IGBA) and Medicines for Europe, concluded today at the Hilton Amsterdam Airport Schiphol Hotel, The Netherlands. This landmark event brought together experts from regulatory authorities, industry, and academia to discuss the evolving bioequivalence landscape and its critical role in improving global access to medicines.

The conference took place at a pivotal time, with the ICH M13 guideline series advancing global harmonisation efforts. These developments aim to streamline generic medicine development, reduce duplication of studies, and accelerate access to affordable, quality-assured treatments for patients worldwide. Attendees engaged in in-depth discussions on key topics, including development of ICH M13 guideline series and essential issues, such as the single global development of generic medicines, model-informed approaches supporting bioequivalence, and compliance and oversight in bioequivalence studies.

"The progress in the ICH M13 guideline series is transformative for the global development of generic medicines. This conference was a vital opportunity for stakeholders to align on strategies that ensure harmonisation leads to tangible benefits for patients. There are still real barriers for companies who want to bring their products to patients around the world and it is urgent that these barriers are addressed", stated Lucas Sigman, Chair of IGBA's CEO Advisory Committee, emphasising the collaborative nature of the event.

Commenting on the potential impact of global harmonisation, Susana Almeida, IGBA Secretary General, remarked: *"The effort to harmonise bioequivalence standards and the move towards acceptance of foreign comparators can make generic development much more efficient. By reducing duplication of studies, accelerating timelines, and lowering costs, we can foster broader access to effective, safe and quality-assured medicines. Addressing key gaps is vital to making this vision a reality, ensuring faster access to essential medicines and strengthening global healthcare frameworks."*

Adrian van den Hoven, Director General of Medicines for Europe and member of the IGBA Management Committee, highlighted the broader implications of the conference: *"The 3rd Bioequivalence Conference*

was an opportunity to support a science-based regulatory landscape for equitable and timely access to medicines for patients worldwide. This collaborative approach is key to addressing the healthcare challenges of today and tomorrow."

The discussions and insights shared during the conference reaffirmed the commitment of IGBA and Medicines for Europe to fostering dialogue and global collaboration to address critical challenges and advance harmonisation so that regulatory progress translates into real-world solutions for patients and healthcare systems.

For more information, visit the conference website.

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

About Medicines for Europe:
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 investment. 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 LinkedIn and X @medicinesforEU.