26 January 2024

Joint statement Association for Accessible Medicines - Medicines for Europe ahead of 5th EU-U.S. Trade and Technology Council Ministerial meeting

The Association for Accessible Medicines (AAM), representing generic and biosimilar medicines manufacturers in the United States, and Medicines for Europe, the voice of generic, biosimilar and value-added medicines manufacturers in Europe, recognise the EU-U.S. Trade and Technology Council (TTC) as a crucial opportunity to increase pharmaceutical regulatory convergence between transatlantic partners.

In both regions, generic and biosimilar medicines are a key asset for patient access and healthcare sustainability, accounting for 70% of medicines prescribed in the EU and 91% of medicines prescribed in the U.S.

Ahead of the 5th TTC Ministerial meeting on 30th January, we call on the EU and the U.S. to allow **faster patient access** through a regulatory framework enabling a **Single Development Programme** for complex generic medicines.

The current regulatory practice entails the unnecessary repetition of the same or very similar clinical studies across regions, using local comparator products in each case. This is not only time and resource-consuming, but also scientifically unethical, as it involves superfluous testing on human subjects with no added benefit.

Such practices also increase the cost of medicines for patients and can impede the actual development in certain cases, such as follow-on orphan drugs or very complex generic products.

An EU-U.S. Single Development Programme for complex generic medicines would avoid study duplications, cut development program inefficiencies and better respond to patient needs.

There is no legal barrier either on the EU or U.S. side to establish this Programme, which would be coherent with the use of foreign comparator products in clinical trials supporting biosimilar dossiers.

Furthermore, this initiative would allow leveraging the benefits of international harmonisation on bioequivalence currently underway at the International Council for Harmonisation (ICH) of Technical Requirements for Pharmaceuticals for Human Use.

Notably, highly regulated regions such as Australia, Canada, Singapore, Switzerland and the United Kingdom already accept foreign comparator products in clinical trials supporting generic dossiers.

We call for the EU and the U.S to seize this key opportunity for regulatory convergence, in order to facilitate regulatory acceptance, strengthen trade flows and improve patient access to medicines.

David Gaugh, AAM's interim President and CEO, and Adrian van den Hoven, Director General of Medicines for Europe, said "*Improving patient access to generic medicines whose development is becoming more and more complex and enhancing the competitiveness of this critical industrial sector on both sides of the Atlantic is crucial. The establishment of a single development programme for complex generic medicines is a shared objective of EU and U.S. health authorities. We hope the TTC Ministerial will give a clear message to advance this working line with the TTC's goals of securing supply chains and avoiding unnecessary technical barriers to trade".*

Association for Accessible Medicines (AAM)

AAM is driven by the belief that access to safe, quality, effective medicine has a tremendous impact on a person's life and the world around them. Generic and biosimilar medicines improve people's lives, improving society and the economy in turn. AAM represents the manufacturers and distributors of finished generic pharmaceuticals and biosimilars, manufacturers and distributors of bulk pharmaceutical chemicals, and suppliers of other goods and services to the generic industry. Generic pharmaceuticals are 90 percent of prescriptions dispensed in the U.S. but only 17.5 percent of total drug spending.

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 for Europe, 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 Twitter @medicinesforEU.