Press Release

Pharma reform brings new opportunities for better regulation, access and security of medicines supply

Brussels, 27 February 2025

Simplified regulatory processes needed to boost competitiveness and patient access to off-patent medicines

The review of the EU pharmaceutical legislation provides an opportunity to update the regulatory framework for pharmaceuticals in Europe. The legislation should integrate modern tools to make science-based regulation more digital, agile and efficient. The legislation should be forward-looking and flexible to manage the challenges and opportunities of the next 20 years.

As the European Council focuses on regulatory aspects of the legislation, it should focus on improvements that will increase access to medicines, while reducing the administrative burden, simplifying procedures for the generic sector which supplies 7 out of 10 prescription medicines. The EMANS 2028 Strategic Plan for the EU regulatory network to 2028 should prioritise policies that encourage access to generic and biosimilar medicines, which are essential for sustainable healthcare for all Europeans. The EMANS should ensure that enough resources are dedicated to the regulatory approval and maintenance requirements for off-patent medicines and scientific support to adapt evidence generation requirements. These must be fit for modern times and science, supporting single development and avoiding duplications of studies.

With a renewed focus on competitiveness, medicine agencies are in a unique position to safeguard access to medicine for patients. The regulatory framework should be more responsive to challenges, interconnected between EU and national medicine agencies, and a flexible to partner to solve issues before they affect patients. For example, by connecting the EMVS and SPOR to help monitor medicines shortage risks, digitalising regulatory processes by accelerating and investing in PMS/SPOR, allowing the opportune implementation of electronic patient information (ePI) and phasing out the paper leaflet once the system is fully operational.

Speaking at Medicines for Europe's Regulatory and Scientific Affairs conference, association Director General Adrian van den Hoven said "*The EU must seize the opportunity of the Pharma Review to update regulatory affairs in the pharmaceutical sector. In an unpredictable and turbulent geopolitical environment, we have no time to waste in transforming our regulatory system in the world's most agile, efficient and digital network– built on our strong scientific foundation.*"

For more information on Medicines for Europe's Regulatory and Scientific Affairs conference, see https://www.medicinesforeurope.com/events/rac25/

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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.