Press Release

New EU Pharma Legislation to safeguard patient access and boost off-patent medicines efficiency

Brussels, 26 February 2026

In the current unpredictable geopolitical environment, there is no time to lose in making the EU pharmaceutical regulatory system more agile, efficient and digital. This is one of the major objectives of recently concluded and ongoing EU pharmaceutical legislation.

The implementation of the recently agreed **Pharma legislation** should deliver:

- A fully digitalised regulatory network, for responsive and interconnected agencies.
- A regulatory network that strives to reduce bureaucracy and redundancies when applying requirements such as shortage prevention plans, Environmental Risk Assessments or the transfer of marketing authorisations in the case of withdrawals, for a competitive off-patent pharmaceutical sector.

Health industrial policies, such as the **Critical Medicines** and **Biotech Acts,** must boost generic and biosimilar medicine manufacturing supply chains via:

- Robust market reforms that privilege most economically advantageous tender (MEAT) award criteria and multi-winner tenders as the rule rather than the exception to reduce industrial consolidation and improve security of supply.
- Strong financial incentives in the EU budget to invest in generic and biosimilar medicines production.

Medicines agencies also have a unique opportunity to safeguard patient access to medicines in other policies impacting the sector. Given the critical role they play in ensuring medicines supply to patients, their engagement is needed in **horizontal, environmental and chemical** regulations, which may inadvertently undermine the secure supply of medicines.

Speaking at Medicines for Europe's 2026 Regulatory and Scientific Affairs Conference, the Association's Director General, Adrian van den Hoven, said "*The European Union cannot sit on the sidelines while the US, Japan, India and China are heavily investing in and clearly supporting their off-patent pharmaceutical industry. As we build the pharmaceutical regulatory framework of the future, we need bold reforms to encourage investments in EU medicines development and production. The digitalisation of the regulatory network and pharmaceutical regulation offers hope for a dynamic and efficient single market for medicines. At the same time the EU must reconsider poorly designed regulation like the Urban Waste Water Treatment Directive (UWWTD), which will undermine the viability of essential and critical medicines supply for Europe.*"

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Conference information

For more information on Medicines for Europe's Regulatory and Scientific Affairs conference **#RAC26** you can consult the following pages:

- Programme and speakers

Relevant documents

More information on Medicines for Europe's positions on the legislative proposals can be found at the following links:

- Critical Medicines Act
- Biotech Act
- Urban Waste Water Treatment Directive

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. 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.