Pro-competitive policies matter for public health, for security and for strategic autonomy

Brussels, Belgium
25 June 2025

As the EU adapts to global geopolitical tensions and a renewed focus on simplifying EU legislation, Medicines for Europe calls for targeted support for the off-patent medicines sector. Medicines for Europe members account for 70% of medicines dispensed in Europe and represent over 90% of the EU Critical Medicines List. The sector has mobilised in the toughest of circumstances such as the COVID pandemic, the onset of war in Ukraine, and in responding to natural and humanitarian disasters.

The reform of the EU pharmaceutical framework is an opportunity to modernise our regulatory system, to make it fit for purpose for the digital age. As trilogue negotiations begin, we call on co-legislators to:

- Conclude a balanced agreement on regulatory and market incentives to ensure that more patients benefit from access to medicine and innovation in all Member States. Along these lines, the repurposing clause should be extended to sustain investment in public health needs like AMR and cardiovascular disease.
- Harmonise the Bolar exemption to encourage active pharmaceutical ingredient development in Europe and to stop unjustified and anti-competitive delays to generic or biosimilar competition at loss of exclusivity.
- Increase competitiveness with global regulatory measures such as single global development, timely generic and biosimilar marketing authorisation procedures and clear deadlines for setting up a system for electronic product information, which will improve access for millions of Europeans.

The launch of the EU Critical Medicines Act is a milestone for health security. We call on the European Parliament to prioritise:

- Rewarding security of supply in procurement by including MEAT (Most Economically Advantageous Tender) criteria and multi-winner tendering and in national market reforms of pricing and purchasing policies.
- An investment security partnership between the EU, Member States and our industry to invest in medicine and active pharmaceutical ingredients (API) production. Key reforms must be made to EU state aid and IPCEI rules to allow investments in manufacturing innovation and production, the future Multiannual Financial Framework (EU Budget) to create a dedicated EU critical medicines manufacturing fund and regional aid funding should be allowed to support investments in production.
- More EU solidarity on strategic EU reserves and national stockpiling mandates to ensure that patient access to medicines takes precedence over hoarding in the event of a medicine shortage.

The EU must also move boldly and swiftly to make the region more competitive. The Urban Waste Water Treatment Directive (UWWTD) is based on a flawed impact assessment, with incorrect calculations that will have disastrous consequences on access to essential medicines. As the Commission begins its reassessment, the implementation of the UWWTD should be paused at country level, so that patients are not impacted by the inevitable shortages that this directive will cause.

Speaking at the Medicines for Europe annual conference, association **President Markus Sieger** said: "*The EU has an*

Medicines for Europe AISBL
Rue d'Arlon 50 - 1000 Brussels - Belgium
T: +32 (0)2 736 84 11- E : info@medicinesforeurope.com
www.medicinesforeurope.com

opportunity to support essential industries like ours to deliver access to medicines and health security. The EU pharmaceutical legislation is a once in 20 year opportunity to make our regulatory framework more access-friendly, efficient and digitalised. The Critical Medicines Act focuses on the necessity to invest in manufacturing for our health security needs. The Urban Waste Water Treatment Directive, which is based on flawed scientific studies, must be urgently amended to protect the availability of essential and critical medicines. We will continue our close cooperation with the healthcare community to prioritise better access to medicine for patients and a resilient manufacturing sector for health security."

Commission perspective

EU Commissioner for Health and Animal Welfare, Olivér Várhelyi, said "*The security of medicines has never been as critical as it is today. Without security of supply, there is no guarantee that our citizens will have access to the essential medicines. We need to help our industry to remain and prosper in Europe, so that we have a robust European manufacturing base. With the Critical Medicines Act, we aim to bring manufacturing closer to home, through strategic projects, procurement and international partnerships.*"

Resource hub

For more information on the Medicines for Europe annual conference, see https://www.medicinesforeurope.com/events/annual25/

Conference photos are available for use at https://www.flickr.com/photos/196629723@N07/albums/

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.

Medicines for Europe AISBL
Rue d'Arlon 50 - 1000 Brussels - Belgium
T: +32 (0)2 736 84 11- E : info@medicinesforeurope.com
www.medicinesforeurope.com