

# Statement

## Council agreement on review of EU pharmaceutical legislation

04 June 2025, Brussels

The Polish Presidency has successfully aligned the Council to advance the EU Pharmaceutical Package to its final phase of negotiations between the Commission, Council and Parliament. This is an important step for progress in pharmaceutical regulation in a turbulent geopolitical environment.

Medicines for Europe supports this reform provided it can truly deliver on equitable access to medicines for all Europeans and it contributes to increasing the security of supply of medicines. We will oppose attempts to extend incentives and intellectual property rights which already provide the longest monopoly protections in the world. We urge the Council, Parliament and Commission to increase the harmonisation of rules for better access and security of supply for patients in all EU Member States.

- The agreement on regulatory and market incentives should ensure that there is more investment in Europe and that more patients benefit from access to innovation in all Member States. The repurposing clause should be extended to ensure more investments in major public health needs like AMR and the upcoming cardiovascular strategy.
- The Bolar exemption must be harmonised to encourage active pharmaceutical ingredient development in Europe and to stop unnecessary and anti-competitive delays to generic or biosimilar competition at loss of exclusivity.
- Regulatory measures to increase the European competitiveness globally such as single global development, timely generic and biosimilar marketing authorisation procedures and clear deadlines for setting up a system for electronic product information will improve access to medicines for millions of Europeans.
- Aligning the pharmaceutical package with the objectives of the EMA extended mandate legislation will facilitate the use of digital tools to prevent and mitigate medicine shortages.

The pharmaceutical package is a necessary step forward to encourage private sector investment to ensure the availability and accessibility of medicines for public health needs.

## 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](http://www.medicinesforeurope.com) and on LinkedIn and X @medicinesforEU.