

Press release

Pharma legislation deal important for the future EU pharmaceutical industry but most importantly for access to medicine

Brussels, 12 December 2025

The deal agreed between Parliament and Council on the general pharmaceutical legislation review is an important step forward for the European pharmaceutical industry at a time of great geopolitical uncertainty.

Medicines for Europe has supported the objectives of the reform from the start: improving equity of access for all Europeans, ensuring timely access to generic, biosimilar and value added medicines, and modernising the regulatory framework through more digitalisation, harmonisation and optimisation.

The deal between the Parliament and Council represents real progress on:

- **Equitable access**, we would have supported a more ambitious reform for better access to medicines in Central and Eastern European and smaller member states and will work with the EU to play our role in filling the access gaps as much as possible.
- **Timely access**, Bolar harmonisation will reduce frivolous litigation and the misuse of, for example, divisional patents to create artificial delays to competition and to wider access to medicines for all Europeans.
- The **digitalisation and harmonisation** of pharmaceutical regulation will align the pharmaceutical legislation with the objectives of the EMA extended mandate legislation to prevent and mitigate medicine shortages although longer shortage notification periods will increase shortages 'false alerts' and overload national competent authorities.

While the legislation represents real progress, we recognise the limits of what could be achieved in a political compromise. We will therefore engage strongly in the implementation of the legislation and in other pharmaceutical policy fields to support more equitable access to medicines, to partner for much needed health security and to work with healthcare systems, providers and stakeholders to support better public health for all Europeans. In this time of great geopolitical uncertainty, the strength of the European Union lies in its ability to work together in solidarity, to focus on the core strategic concerns of patient access and health outcomes, security of supply and resilience, and ensuring that European policies support rather than undermine the industries, like ours, that are investing in Europe for patients, public health and health security.

Association President, Markus Sieger said: *"I am particularly satisfied with the result of trilogues on Pharmaceutical Package published today. It confirms that EU institutions have EU patients in their hearts and minds. This is great step in ensuring earliest possible access to generic and biosimilar medicines thus reinforcing medicines security in Europe."*

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.