

Press Release

As Parliament chapter closes, Council chapter opens on EU pharma legislation to deliver equitable access to medicines

Brussels, 10 April 2024

Today, the European Parliament formally endorsed the deal on the revision of the European Pharmaceutical legislation. This compromise is the result of intense and lengthy debate, which aimed to improve the access, availability, and affordability of medicines and to prevent further delays of this much needed reform.

Medicines for Europe supports this step forward. Looking to the next phase of the legislative process, Medicines for Europe calls on Member States to:

- Cap regulatory protection (data and market) to 11 years which is the longest protection in the world and ensure that modulation criteria support better access in Central and Eastern Europe and smaller markets.
- Support the harmonised Bolar provision to prevent delays to generic and biosimilar medicines access at SPC expiry.
- Introduce a comprehensive shortage prevention strategy which uses real-time serialisation data (EMVS), instead of unrealistic shortage notification time frames.
- Back an EU reserve for antibiotic access and dismiss the transferrable exclusivity voucher which rewards monopolies instead of public health.
- Support the full scope of medicines repurposing (new indications, new reformulations and posology) to encourage affordable innovation.
- Fast track regulatory efficiency and digitalisation measures to support medicines availability and ensure that environmental risk assessments can be done efficiently with data referencing.

Following the European Parliament plenary vote, Medicines for Europe Director General Adrian van den Hoven said *“We are happy to see the Parliament advance this important legislation. While imperfect, there are many improvements to the legislation to increase access to medicines for all Europeans. Other elements in the deal like unrealistic shortage requirements and the transferrable exclusivity voucher will work against medicines availability and health system sustainability. We trust the Council focus on the objectives of the review, access, availability and affordability in future work on this legislation.”*

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 Twitter @medicinesforEU.