

# Press statement

## Europe must act now to protect patients and medicines supply

A call to conclude EU pharmaceutical reform and boost Europe's ability to produce essential medicines

07 May 2025, Brussels

Public health is not optional – it is a basic right. In this moment of unprecedented geopolitical uncertainty, as EU Health Ministries approach the final stages of negotiations on the future of Europe's pharmaceutical rules, Medicines for Europe, which represents the companies supplying 70% of prescription medicines across the continent, calls to ensure health is at the centre of all political decisions and to conclude the reform and take bold steps to strengthen Europe's health security.

This is not just another technical EU policy. It is about ensuring that every European, wherever they live, can access the medicines they need. It's about avoiding shortages, bringing production back to Europe, and making our health systems more resilient and fair. It is also about making the industry robust for the future, recognising investments in sustainability like reducing carbon emissions and increasing the use of renewable energy at our manufacturing sites.

The European Commission's proposal offers a strong foundation to:

- End the disparities for patients and ensure fair access to medicines across Europe. The reform of regulatory incentives should deliver on that promise with a balanced compromise between member states and allow earlier and more equitable access to off patent medicines.
- Support affordable treatment by boosting competition on Day 1 once patents expire. The harmonisation and clarification of the Bolar clause is critical to achieve this.
- Prevent medicine shortages with better EU coordination and digital tools.
- Encourage smarter and affordable innovation on off-patent medicines that can change lives and address major health issues, such as antimicrobial resistance by also allowing "new pharmaceutical forms" to be considered as a repurposed medicinal product.

This reform must go hand in hand with determined progress on the **Critical Medicines Act (CMA)**. Political will is not enough. Europe must equip this plan with the necessary **financial and strategic tools** to truly rebuild its capacity to produce essential off-patent medicines for public health, via securing funds for critical medicines in the upcoming EU budget and deliver bold state aid reforms for critical medicines and API production. We also call for an urgent review of the EU Urban Wastewater Treatment Directive (UWWTD), that will put unworkable pressure on essential generic medicines and ultimately jeopardise their availability, accessibility and affordability.

We urge Member States to support the needed reforms on the CMA and UWWTD and importantly, to resist pressure to stall negotiations on the pharmaceutical legislation over transatlantic trade tensions. Europe already

grants the longest monopoly protections for medicines globally, yet announced investments in R&D and manufacturing have flowed elsewhere. The Draghi Report evidence is overwhelming that competition stimulates productivity, investment and innovation. Now, some companies are shifting production to the US. **That is no reason to delay reforms that serve European patients.**

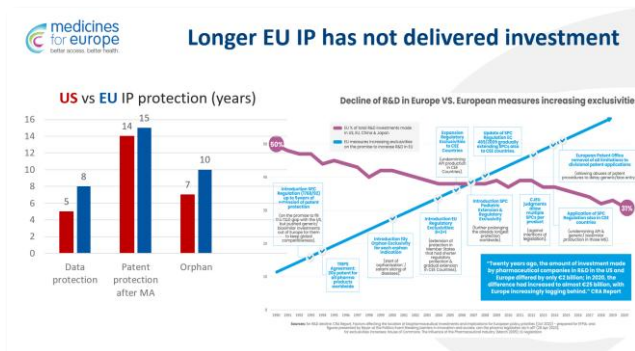
Medicines for Europe asks the EU to:

- Advocate a US and EU deal for the free movement of pharmaceuticals, which is critical for the benefit of patients.
- Support the Critical Medicines Act which strengthens the resilience of supply chains, facilitating investment into Europe. The off patent industry is investing into Europe (while others are moving away)
- Ensure timely entry of generics to strengthen competition, improve access to medicines and alleviate the impact on health budgets. We believe not only that there is no reason to extend exclusivity periods in Europe, there is actually a strong case to reduce – from 11 to 9 years could save 10bn EUR per year, and it would increase access to medicines in Eastern European countries.

Our industry is rooted in Europe—for patients and for supply security. But we need the right policies to make it work.

**It's time for Europe to take responsibility. Finalise the pharmaceutical reform. Empower the Critical Medicines Act. Protect patients.**

## Supporting documents



Economic impact of extension of regulatory protection beyond 11 years on only 15 blockbuster molecules

	EU	GERMANY	FRANCE	SPAIN	POLAND	CZECH REPUBLIC
13.5 years of total regulatory protection	19.5 BN EUR	5 BN EUR	5.35 BN EUR	2.25 BN EUR	552.8 MN EUR	141.6 MN EUR
18 years of total regulatory protection	99.5 BN EUR	23 BN EUR	24 BN EUR	13.2 BN EUR	3.8 BN EUR	1 BN EUR

[5-Point Pharmaceutical Action Plan to Sustain Investment in Europe, for Europe](#)

[Medicines for Europe factsheet on incentives](#)

[Medicines for Europe Factsheet on Bolar clause](#)

[MEMO on UWWTD](#)