

Press Release

Ambitious Critical Medicines Act vital to secure supply

Brussels, 11 March 2025

The <u>publication of an EU Critical Medicines Act</u> is a major milestone for increased strategic autonomy in Europe. Alongside EU Member States and the European Parliament, our industry has been calling for this Act to secure access to high-quality, safe, effective and affordable off-patent medicines and we appreciate the high priority given to the Act by the recently appointed Commission.

The Critical Medicines Act adds to the pharmaceutical legislation review by tackling the economic and industrial root causes of medicines shortages in line with recent Commission studies¹ and the Critical Medicines Alliance strategic report².

The most essential components of the Act for legislators should be to support:

- Real procurement reform by including **MEAT (most economically advantageous tender) criteria and multi-winner tendering** in tandem with national market reforms, so that security of supply is rewarded in pricing and purchasing policies.
- An **investment partnership** between the EU, Member States and our industry to invest in EU competitiveness for medicine and active pharmaceutical ingredients (API) production. This requires a new approach to EU state aid and IPCEI rules to allow investments in manufacturing innovation and production, a dedicated EU critical medicines manufacturing fund the future Multiannual Financial Framework (EU Budget) and more flexible regional aid funding to support EU-wide 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.

Speaking on the adoption of the Commission's proposal for a Critical Medicines Act, Medicines for Europe's Director General Adrian van den Hoven said "We have lived experience from COVID-19 and a myriad of European and national level studies have underlined the need for this Critical Medicines Act. Today's geopolitical reality is uncertain, and the EU must now take bold steps to secure its medicines supply and manufacturing. The Commission has prioritised the Critical Medicines Act as its first major legislation, and we call on the Parliament and Council to advance much-needed reforms to make security of supply a central component of medicines policy across the EU."

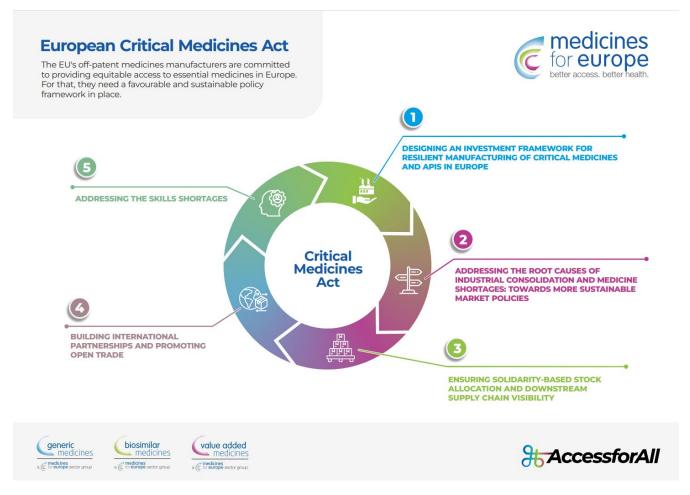
¹ European Commission, <u>Study on best practices in the public procurement of medicines</u>, September 2022.

² European Commission, <u>Critical Medicines Alliance strategic report</u>.



Resources

- * Medicines for Europe position paper on a Critical Medicines Act <u>https://www.medicinesforeurope.com/wp-</u> <u>content/uploads/2024/09/Critical-Medicines-Act-delivering-a-secure-supply-of-critical-medicines-and-active-</u> <u>pharmaceutical-ingredients-in-Europe.pdf</u>
- * Medicines for Europe_position paper on Medicines Procurement Reform, October 2023.
- * European Commission:
 - Study on best practices in the public procurement of medicines, September 2022.
 - o <u>Critical Medicines Alliance strategic report</u>, March 2025.
- * Potential measures to facilitate the production of active pharmaceutical ingredients (APIs) (European Parliament).
- * EU Fine Chemical Commercial KPI, Executive Summary (European Fine Chemicals Group and IQVIA).
- * The anatomy of the current antibiotics shortage (Supply Chain Intelligence Institute Austria).
- * Study on API Dependency "<u>Where do our API come from</u>"? (Pro Generika, the German Association of generic and biosimilar medicines).
- * The ongoing project on 'Initiative against Drug Shortages' (Universität Würzburg).



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.