

# Press release: Industry unites for a bold Critical Medicines Act that prioritises secure supply of medicines for patients

Brussels, 24 September 2025

Over the past decade, the European Union has faced increasing concerns regarding the availability of medicines and APIs, with medicines shortages becoming a systemic issue that threatens public health and the resilience of health systems across Member States. Factors contributing to these shortages are vast and complex, and Covid-19 crisis, geopolitical tensions combined with inflation, increased dependency on a small number of suppliers / regions and increased pricing pressures have accentuated the discussion on security of pharmaceutical supply.

Speaking today in the European Parliament, at a dedicated event hosted by MEP Tomislav Sokol, (EPP) and MEP Vlad Vasile-Voiculescu (RE), health leaders shared their vision for a bold critical medicines act, as the legislative process continues. The Act should enable Europe to achieve open strategic autonomy in healthcare and boost stable supply of API's and medicines for patients.

To achieve this, the Critical Medicines Act must:

- Include mandatory non-price criteria such as security of supply or social and environmental standards in procurement, and improve procurement practices by ensuring appropriate lead times, minimum quantities, as well as multi-winner tenders, where appropriate
- Implement a holistic view in national plans, by including procurement as well as pricing and reimbursement and other measures applicable to critical medicines such as cost-containment measures, price freezes and stockholding obligations.
- Ensure a robust investment security partnership between the EU, Member States and industry to invest in medicine and active pharmaceutical ingredients (API) production: this should aim at increase manufacturing capacity, modernise existing production sited and develop new innovative production processes technologies.
- 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.

## Quotes

Bork Bretthauer, Executive Committee member of Medicines for Europe and Director General of ProGenerika: *“For years, we have known that unsustainable pricing policies applied to off patent medicines have aggravated medicines supply chains and led to shortages. Just to provide an example, a defined daily dose of medicine in Germany now averages at 0.06EUR<sup>1</sup>. Now is the time to reverse this race to the bottom trend, with an ambitious Critical Medicines Act. I hope to see the act strengthen generic medicines by mandatory non-price criteria in tenders, as well as including pricing and reimbursement policies in national plans to create healthy competition, economic sustainability, market stability and predictability. Furthermore, the European Commission's good intentions should be reflected in national policy. To strengthen security of supply, we need a comprehensive and harmonised strategy.*

Maggie Saykali, Director of EFCG: *“The availability of medicines is crucial for maintaining a sustainable standard of healthcare for all European citizens and preventing undue strains on our healthcare systems. By bolstering and supporting local manufacturing capabilities throughout the supply chain, the EU can reduce its dependency on other regions and ensure uninterrupted access to essential medicines for patients. The Critical Medicines Act presents a unique opportunity for the EU to implement ambitious measures to reinforce its strategic autonomy. We must act together to build a reliable and future-proof supply chain of essential medicines and their key inputs, in the interest of all EU patients.”*

Nathalie Moll, Director General of EFPIA: *“The Critical Medicines Act shows real momentum to act on shortages, and we support that goal. However, adding complexity and duplication to an already fragmented system will not deliver resilience. Europe is already losing ground in global R&D and we cannot afford policies that push investment away. The Act will only be an opportunity if it is risk-based, proportionate and aligned with existing rules. What we need are predictable measures that strengthen competitiveness, support manufacturing and build trusted international partnerships to keep medicines flowing to patients.”*

## About 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. 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 <https://www.medicinesforeurope.com/> and on LinkedIn and X @medicinesforEU.

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<sup>1</sup> <https://www.progenerika.de/en/topics/security-of-supply/supply-shortages/>

## About EFCG

**EFCG, The European Fine Chemicals group**, represents the European manufacturers of Fine Chemicals, Intermediates and Active Pharmaceutical Ingredients (APIs). Our members are the backbone of the pharmaceutical supply chain, supplying its essential building blocks and our vision is to help create a world where access to safe and good quality nutrients and innovative medicines is guaranteed for all. We promote a fairer and safer environment for future generations and we champion sustainable processes and enforced regulations that deliver safe products and enhance growth, employment and environmental performance. EFCG upholds the highest quality and safety standards in our industry and strongly advocates for all companies producing and selling in the EU to be held to the same high standard.

EFCG operates as a Sector Group within Cefic, the European Chemical Industry Council. Founded in 1972, Cefic is the voice of large, medium and small chemical companies across Europe, which provide 1.2 million jobs and account for 13% of world chemicals production.

## About EFPIA

The **European Federation of Pharmaceutical Industries and Associations (EFPIA)** represents the biopharmaceutical industry operating in Europe. Through its direct membership of 36 national associations, 39 leading pharmaceutical companies and a growing number of small and medium-sized enterprises (SMEs), EFPIA's mission is to create a collaborative environment that enables our members to innovate, discover, develop and deliver new therapies and vaccines for people across Europe, as well as contribute to the European economy. Our vision is for a healthier future for Europe. A future based on prevention, innovation, access to new treatments and better outcomes for patients.