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# A Critical Medicines Act to secure Europe's pharmaceutical independence



21/12/2023



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**In a recently adopted opinion (<https://www.eesc.europa.eu/en/our-work/opinions-information-reports/opinions/securing-europes-medicine-supply-envisioning-critical-medicines-act>), the European Economic and Social Committee (EESC) warns that the EU's overreliance on imports of active pharmaceutical ingredients and finished medicines from Asia poses threats to the health and well-being of EU citizens. The EESC therefore proposes a Critical Medicines Act.**

The European Union faces a growing challenge in securing its supply of essential pharmaceuticals, with the majority of its active pharmaceutical ingredients (APIs) and finished medicines currently imported from Asia, with China being the single largest supplier. This reliance on external suppliers has raised concerns about the EU's resilience to supply chain disruptions, price volatility and potential geopolitical risks.

“We are jeopardising our citizens' health by relying on external suppliers for essential pharmaceuticals. Europe cannot afford to gamble with the lives of its citizens. We must act now to ensure that Europeans have access to the medications they need,” stated **Lech Pilawski**, EESC rapporteur for the opinion.

To address these concerns, the EESC recommends that the EU take a number of steps to strengthen its domestic pharmaceutical production capacity. These include:

**Establishing a new EU mechanism** to support the production of APIs and finished medicines in Europe. The proposed **Critical Medicines Act** is envisioned as a comprehensive EU mechanism, presented in the form of a regulation, to actively support the production of APIs and finished medicines within the European Union. This mechanism would provide funding for research and development, infrastructure development and operating costs.

**Encouraging the development of innovative production technologies.** This could involve investment in research and development, collaboration with academia and industry and the adoption of cutting-edge manufacturing practices.

**Promoting the use of APIs and finished medicines produced in Europe.** Public procurement policies, subsidies and other incentives should be implemented to encourage the use of APIs and finished medicines produced in Europe.

**Adopting fair pricing mechanisms** for APIs and finished medicines to ensure that patients have access to affordable healthcare. This could involve measures such as price controls, competitive bidding processes and the promotion of generic medicines.

The implementation of these recommendations will require significant investment and cooperation between EU Member States. The EESC is calling on the European Commission to take the lead in coordinating this effort and to develop a comprehensive strategy that can protect Europe's health security, promote economic prosperity and ensure the affordability of medicines for EU citizens.

## Work organisation

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Adopted on 13/12/2023 - Bureau decision date: 25/01/2023



### **Securing Europe's medicine supply: envisioning a Critical Medicines Act** (</en/our-work/opinions-information-reports/opinions/securing-europe-s-medicine-supply-envisioning-critical-medicines-act>)

Reference: CCMI/212-EESC-2023

Rapporteur: Lech PILAWSKI (Employers - GR I/Poland), Lech PILAWSKI (Employers - GR I/Poland)

Co-rapporteur  [Thomas STUDENT](#)

(<http://memberspage.eesc.europa.eu/Search/Details/Person/2021250?onlyActiveMandate=True&isMinimal=False>) / (Germany)

Plenary session number: 583 - Dec 13, 2023 -  Dec 14, 2023

The Covid 19-pandemic has drawn attention to the role of the pharmaceutical industry and to production, availability and affordability of medicines and medicinal products on the European market.

Dependency on critical ingredients, such as active pharmaceutical ingredients (APIs), became obvious when China and India limited exports. According to current data, up to 80% of APIs used in Europe and about 40% of finished medicines sold in Europe come from China or India. The European Union's increasing dependence on API supplies has led to a partial loss of capability to manufacture active substances independently, which poses a potential threat to public health in the countries of the European Union.

**Download — EESC opinion: Securing Europe's medicine supply: envisioning a Critical Medicines Act**



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(<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1000000/>)

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BG does not affect the rate of conversion of Fmoc-protected amino acids to their corresponding amine (the end product).

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