Critical Medicines Act

2025/0102(COD) - 11/03/2025 - Legislative proposal

PURPOSE: to establish a framework to strengthen the availability and security of supply of critical medicinal products within the Union and to improve the availability and accessibility of medicinal products of common interest through coordinated and targeted action of Member States.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: the EU has a strong and competitive pharmaceutical sector, which is a global leader in the production of medicines and a major contributor to the EU economy and directly employs around 800 000 people. However, in recent years, the Union has experienced an increasing number of shortages of medicinal products, including shortages of medicinal products for which insufficient supply results in serious harm or risk of serious harm to patients. Shortages of medicinal products can have very different and complex root causes, with challenges identified along the entire pharmaceutical value chain. In particular, shortages of medicinal products can result from supply chain disruptions and vulnerabilities affecting the supply of key ingredients and components. These include existing dependencies on a limited number of suppliers globally and lack of Union capacities to produce certain medicinal products, their active substances or key raw pharmaceutical materials. Through diversification of supply sources and investment in local production, the Union can **reduce its risk of exposure to shortages** of medicinal products.

CONTENT: the Commission proposal consists of a proposal for a new regulation. It seeks to strengthen the **security of supply and the availability of critical medicinal products within the Union**, thereby ensuring a high level of public health protection and supporting the security of the Union. The objective of this Regulation is also to **improve the availability and accessibility of other medicinal products**, where the functioning of the market does not otherwise sufficiently ensure the availability and accessibility of those medicinal products to patients, whilst giving due consideration to the appropriateness to ensure the affordability of medicinal products.

To achieve the objectives, the proposed Regulation sets out a framework to:

- **facilitate investments** in manufacturing capacity for critical medicinal products, their active substances and other key inputs in the Union;

- **lower the risk of supply disruptions** and strengthen availability by incentivising supply chain diversification and resilience in the public procurement procedures of critical medicinal products and other medicinal products of common interest;

- leverage the aggregated demand of participating Member States through **collaborative procurement procedures**, and;

- support the **diversification of supply chains** also by facilitating the conclusion of strategic partnerships.

Key elements of the Critical Medicines Act include:

Strategic Projects

Strategic Projects will create, increase or **modernise EU manufacturing capacity** for critical medicines or their ingredients. These industrial projects may benefit from easier access to funding and fast-tracked administrative, regulatory and scientific support.

Financial incentives

It should be possible for Member States to prioritise financial support for strategic projects that address a supply chain vulnerability and requires due consideration to the outcome of vulnerability evaluations and the strategic orientations of the Critical Medicines Group. Strategic projects may be supported by EU funding under the current MFF, if strategic projects fulfil the conditions and requirements of the calls under the available programmes.

Procurement requirements

The proposal imposes the use of procurement requirements other than price in the context of public procurement procedures by contracting authorities in the Member States, unless justified by market analysis and considerations related to the financing of health services. The proposal also requires, in specific cases, when justified by a **vulnerability analysis**, that the contracting authorities apply procurement requirements that favour suppliers that manufacture a significant portion of these critical medicines in the EU. The compliance with Union's international commitments should be ensured.

Furthermore, Member States will be required to develop national programmes to ensure security of supply of critical medicines via procurement, and, possibly, pricing and reimbursement practices. When imposing contingency stocks on supply chain actors, Member States will ensure these requirements are proportionate and respect the principles of transparency and solidarity.

Collaborative procurements

It is proposed that the Commission should support **collaborative procurement** among different Member States at the request of Member States, to address availability and access disparities of critical medicines and other medicines of common interest throughout the EU.

Critical Medicines Coordination Group

A Critical Medicines Coordination Group is established, which is composed of the Commission and Member States' representatives. Its main task being to facilitate the application of the Regulation including by facilitating: (i) discussion on strategic orientation for financial support of Strategic Projects; (ii) exchanges and, where appropriate, cooperation on national procurement policies; (iii) discussion on a need for collaborative procurement initiatives; (iv) advice on the order of priority for the vulnerability evaluation of critical medicines.

International cooperation

The proposal requires the Commission to investigate the possibility of establishing strategic partnerships with a view to broadening the supply chain and reducing dependencies on single or limited numbers of suppliers.