# Critical Medicines Act

2025/0102(COD) - 20/01/2026 - Text adopted by Parliament, partial vote at 1st reading/single reading

The European Parliament adopted by 503 votes to 57 and 108 abstentions **amendments** on the proposal for a regulation of the European Parliament and of the Council laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795.

The issue has been referred to the relevant committee for interinstitutional negotiations.

The main amendments adopted in plenary session concern the following points:

***Objectives***

Members clarified that the regulation aims to **strengthen the security of supply and the availability of critical medicinal products within the Union**, thereby reducing its dependency on third countries and thereby ensuring a high level of public health protection, maintaining patient safety and supporting the security of the Union. Strengthening manufacturing capacities and the resilience of supply chains, as well as competitiveness, strategic autonomy and innovation in the Union's pharmaceutical sector, is also an objective of this Regulation.

In order to achieve these objectives, the regulation should:

- **facilitate, support and incentivise investments in new manufacturing capacity** and strengthen existing manufacturing capacity for critical medicinal products and, where applicable, medicinal products of common interest, with a priority given to medicinal products that can become critical if vulnerabilities affect their supply chain, by making available any accelerated permit granting processes related to the strategic projects;

- **prevent shortages and strengthen availability of medicinal products** by facilitating the adoption of common standards governing contingency stocks and national stockpiles of critical medicinal products and medicinal products of common interest, and by enhancing transparency and coordination among Member States in this regard;

- **facilitate investments in critical distribution infrastructure capacity** for critical medicinal products ensuring security of supply, availability and accessibility in the Union;

- **strengthen the resilience of supply chains** and maintain a continuous and demand-oriented supply of medicinal products, active substances, API starting materials, and key inputs in the Union, even during disruptions or external shocks.

**The security of supply, availability and affordability** of critical medicinal products and, where applicable, medicinal products of common interest, for patients should be considered a strategic objective of the Union.

***Strategic projects***

Members support the creation of industrial 'strategic projects' within the EU to create, modernise, and improve production capacity. Companies benefiting from public financial support must meet clear obligations. If a project promoter has received financial support for a strategic project from Union

funding, it should prioritise supply to the Union market and should ensure that the critical medicinal product or, where applicable, medicinal product of common interest, remains available in the Member States where it is being marketed.

Within three months of the entry into force of this regulation, each Member State must designate an authority responsible for assessing and verifying whether a project qualifies as a strategic project. The Commission should provide a simple, accessible, and user-friendly webpage serving as the central hub for project promoters. It should act as a coordinator for cross-border strategic projects and should ensure effective cooperation between the designated authorities of the Member States concerned, to avoid duplication of efforts in bordering Member States.

Where the development of Strategic Projects or their related infrastructure has potential cross-border implications, the Member States concerned should **coordinate their planning and assessment procedures**, with the support of the Commission, in order to avoid duplication of efforts.

***EU financial support***

Subject to a Council regulation laying down the multiannual financial framework for the years 2028 to 2034 (MFF 2028–2034), strategic projects may be supported by Union funding, including any relevant Union instrument financed within the limits of the ceilings established in the MFF 2028–2034, provided that such support is in line with the objectives set out in the regulations establishing any such relevant instrument.

A **critical medicines security fund** should be established within the framework of MFF 2028–2034, in coordination with other relevant Union instruments, to support the achievement of the objectives of this Regulation.

Where there is a substantiated risk that export of a critical medicinal product would undermine supply within the Union, and upon request by at least one Member State, the Commission may require the project promoter benefiting from financial support to obtain an **export authorisation** before transferring such products outside the Union.

***Procurement by the Commission on behalf of or in the name of Member States***

Members want to lower the number of countries that may engage in joint procurement procedures to at least **five** (compared to nine in the Commission's initial proposal).

***Improved coordination of national stockpiles***

To better anticipate and manage shortages, Members called for the creation of a **European coordination mechanism** for national stockpiles and contingency stocks of critical medicines. They also want the Commission to have the power to decide on, as a last resort, the **redistribution** of medicines from one national stockpile to one or more other countries, in instances where a shortage or a supply disruption has been identified.

In order to ensure the timely and effective availability of critical medicinal products with identified vulnerabilities in their supply chains, a **Union Stockpile** may be established as a last-resort mechanism to be activated in situations where the Union coordination mechanism for critical medicinal products indicates the existence of a recurrent or persistent shortage in national stockpiles and contingency stocks.