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Critical medicines act: Council agrees its position on new rules to tackle shortages

The Council has agreed its position on a new regulation that seeks to **strengthen the EU's resilience** in the face of ongoing challenges to security of supply of critical medicines in Europe.

The critical medicines act (CMA) aims to **tackle shortages in key medicines** such as antibiotics, insulin and painkillers by improving security of supply and availability in the EU.

The new rules incentivise **supply chain diversification**, facilitate **collaborative procurement** models, and create incentives to boost **pharmaceutical manufacturing** in EU countries.

“ Today, we have taken an important step towards ensuring that European patients have access to the medicines they need. The critical medicines act will strengthen the availability of vital medicines, reduce shortages, and build a more resilient supply chain for critical health products across Europe.



— Sophie Løhde, Danish Health Minister and Minister for the Interior

The Council's position

The main changes introduced by the Council relate to the **procurement of critical medicines** and their active ingredients. In its position, the Council has:

- introduced a requirement for the Commission to **issue guidance**, including to help member states determine whether a critical medicine or active ingredient has been **produced in the EU**
- facilitated the exchange of information on **contingency stocks of medicinal products**
- streamlined the provisions on **collaborative procurement** and reduced (from nine to six) the **minimum number of member states** needed to submit a joint request to the Commission
- added an obligation to use **criteria relating to resilience** in the public procurement of critical medicines
- improved the legal clarity and coherence of the regulation by **aligning its terminology** with that of the **public procurement directive**

Next steps

Once the European Parliament has established its position, the two institutions will enter into negotiations to agree on the final text.

Background

In recent years, the EU has increasingly faced severe shortages of key medicines such as antibiotics, insulin and painkillers. On 11 March 2025, the Commission sought to address these issues by publishing a proposal for a 'critical medicines act' (CMA).

The CMA complements the proposals to revise the EU's pharmaceutical legislation (the 'pharmaceutical package'), which also contain provisions on shortages and management of supply of medicinal products.

→ [Critical medicines act \(Council's general approach\)](#) 

→ [New rules for critical medicines in the EU \(background information\)](#)


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