

THE CRITICAL MEDICINES ACT

NEXT STEPS

Why it matters to consumers

Europe faces persistent shortages of critical medicines, affecting patients' access to essential treatments. COVID-19 and the geopolitical context have exposed the fragility of medicine supply chains and the EU's reliance on limited sources of production. If well designed, the Critical Medicines Act can be decisive in strengthening supply security, ensuring timely and uninterrupted access to critical medicines and reinforcing health system's resilience.

This two-pager sets out BEUC's key recommendations for trilogue negotiations to deliver real benefits for patients. For more information, see our [key recommendations](#), the [Commission's proposal](#), the [EU Parliament's](#) and [Council's](#) positions.

Check our
recommendations



TOPICS

BEUC POSITION

OBJECTIVES

The EU must recognise the security of supply and availability of critical medicines as a **strategic objective**, ensuring that shortage prevention is a core priority (**Commission**).

DESIGNATION OF 'STRATEGIC PROJECTS'

Strategic projects' scope should focus only on critical medicines. It is crucial to targetedly intervene on vital medicines for which there are no or very few alternatives (**Commission**).

The following **Parliament's** proposals are key:

- Including as eligible projects those creating medicine formulation capacity within pharmacies and hospitals to address shortages.
- Adopting guidelines to ensure consistency and coordination for the assessment of strategic projects, to avoid fragmentation and ensure that projects strengthen supply security.

PROVISION OF PUBLIC FUNDING

To ensure maximum return on investment, public funding should focus only on strategic projects addressing vulnerabilities and dependencies in the supply chain of critical medicines (**Commission**).

We support the following **Parliament's** proposals:

- Requiring public financial support to be proportionate and transparent.
- Requiring the financial beneficiary to adopt measures contributing to critical medicines' availability and affordability on the EU market.
- Suspending, revoking, or recovering the financial support granted to the strategic project if companies breach their contractual and supply obligations.
- Introducing additional fines or exclusion from future funding in cases of non-compliance.

COLLABORATIVE
PROCUREMENT

The number of required Member States to request the Commission to *procure on their behalf* should be lower (Council and Parliament).

Facilitating *joint procurement* is necessary to strengthen the EU's bargaining power, equitable access to critical medicines and those of common interest (Commission). Joint procurement should also include products for rare diseases, antimicrobials and other high-cost treatments (e.g. oncology) (Parliament). However, it should be open as of minimum five participating Member States (Parliament).

Affordability should be explicitly listed as a benefit of the different procurement procedures alongside availability (Parliament).

We **do not** support the Parliament's proposal to require flexibilities such as electronic packaging information (e.g. QR codes) for collaborative procurements. It risks undermining patients' easy access to comprehensive safety information.

AWARD CRITERIA
IN PUBLIC
PROCUREMENT

Public buyers (e.g., hospitals) procuring medicines should apply supply security criteria on top of medicines prices when choosing their supplier (Award criteria) (Commission).

Exceptionally, Member States may apply price-only criteria when justified by market analysis or pressures on public health finances (Commission). Exceptions should include situations where medicines are disproportionately expensive (Parliament and Council). The Commission should issue award criteria guidelines for an effective implementation, and there should be some verification mechanisms (Parliament).

SAFETY STOCKS

The text should reflect the importance of safety stocks to mitigate shortages.

The CMA should prioritise coordination on *contingency stocks* rather than on national stockpiling. The latter are mostly linked to medical countermeasures (e.g. security threats, pandemic, crisis) and national coordination should be part of HERA's crisis preparedness and response strategies. (Commission).

We support the following Parliament's proposals:

- Establishing guidelines and common standards for contingency stocks. Efforts to minimise waste and environmental impact are essential, and so is the need to avoid measures in one country that could impact others negatively (e.g. set thresholds as necessary).
- Introducing a digital reporting system for better information-sharing amongst Member States and the Commission.

Stock redistribution mechanisms are important to ensure solidarity and equitable access. Member States should make their very best efforts to assist others in need (BEUC).

CRITICAL
MEDICINES
COORDINATION
GROUP (CMCG –
COMMISSION AND
MEMBER STATES)

We support the following Parliament's proposals:

- Ensuring the representation of patient and healthcare professional organisations in the CMCG, to ensure its decisions are better aligned with patient's and consumers' real-life needs.
- Requiring declarations of interest from members of the CMCG.
- Issuing guidelines on measures to support availability and affordability of critical medicines receiving public financial support.

INVOLVEMENT
OF PATIENTS AND
HEALTHCARE
PROFESSIONALS

Policymakers should systematically involve and consult patient, consumer and healthcare organisations as their direct experience of shortages is essential to better reflect patients' needs. (Parliament).

TRANSPARENCY

When implementing pricing and public procurement practices, Member States and the Commission should seek to achieve transparency in medicine pricing formation. This will result in increased consumer trust in medicines market and affordability (2019 World Health Assembly Resolution on transparency) (Parliament).