EUROPEAN SOCIAL INSURANCE PLATFORM

ESIP Feedback to the

Call for Evidence
On the Proposal for a Critical Medicines Act

27-02-2025

The European Social Insurance Platform (ESIP) emphasizes the urgent need to ensure the continued availability of critical medicines within the EU.

ESIP members play a pivotal role in procuring critical medicines, a core component of the upcoming Critical Medicines Act (CMA).

In light of the trend towards increasing pharmaceutical prices, it is crucial to preserve affordable patient access and the financial sustainability of healthcare systems in any future initiative targeting pharmaceutical supply resilience and/or the competitiveness of the EU pharmaceutical sector.

Interventions to strengthen pharmaceutical supply chain resilience must be evidence-based and accompanied by appropriate incentives and conditionalities.

ESIP recommends:

Clarity on the scope and impact of the CMA

Future legislative initiatives aiming to ensure stable pharmaceutical supply should be grounded in a **thorough, evidence-based evaluation of current market dynamics, potential supply chain vulnerabilities and their root causes.**
ESIP expresses concerns about the absence of a comprehensive impact assessment for the CMA. A timely evaluation of its economic effects is paramount, not only targeting the competitiveness of the pharmaceutical sector but also the financial sustainability of healthcare systems. **The cost implications of the potential financing mechanisms within the CMA should be clarified**.
Overall, it is crucial to **determine whether the measures proposed in the CMA will effectively ensure secure and stable supply, without disproportionately increasing the cost of medicines**.

Coordination and consistency across EU instruments addressing medicine shortages

ESIP calls to ensure **consistency and coordination among the various EU initiatives** addressing medicine shortages e.g. the Regulation on a reinforced role for the European Medicines Agency (EMA) and the revision of the EU general pharmaceutical legislation.
It is also crucial to maintain a clear distinction between initiatives designed to bolster the supply of often well-established critical medicines and those intended to foster innovation.

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The scope of the CMA should be restricted to products included in the Union List of Critical Medicines.
ESIP supports the creation of a **European List of Critical Vulnerable Medicines**. Medicines on this list should be identified based on a thorough evaluation of supply vulnerabilities and clear and transparent criteria. The list should be subject to regular reviews. Financial incentives within the CMA should be primarily targeted to critical vulnerable medicines.

Public return on multilayered public investment

Incentives to diversify manufacturing should lead to **tangible improvements of resilience and security of supply**. Any form of financial support should be tied to conditions that maximise **public return on multilayered public investment** and effectively prevent and minimise medicine shortages.
Conditions should include compliance with the obligations set out in the EU general pharmaceutical legislation in terms of reporting potential stock disruptions and developing plans to prevent shortages. Manufacturers of critical medicines who have received incentives for production should also commit to maintaining adequate stocks including for health crises, prioritising supply to the European market and/or developing efficient and flexible production capacity to address potential surges in demand within the EU. **Penalties should be imposed on companies that fail to fulfil these obligations.**

A balanced monitoring and stockpiling system

Responsibility for **continuous EU-wide monitoring of supply and shortages** should lie with the European Commission, in cooperation with the EMA, Member States and relevant healthcare stakeholders. A **coordinated reporting system shared between national competent authorities** would enhance transparency regarding current and future stocks and shortages.
Strategic EU reserves of critical medicines and/or active pharmaceutical ingredients should be considered**,** without prejudice to national stockpiling obligations. Additionally, the voluntary EU solidarity mechanism for medicines could be used to redistribute existing stocks that exceed national supply needs.

MEAT criteria and conditionalities for procurement

ESIP supports **MEAT (most economically advantageous tender) criteria for the procurement of critical medicines, as well as multi-winner tenders** to promote security of supply. These criteria should nevertheless remain implemented **on a voluntary basis**.
Penalties should be introduced if pharmaceutical developers fail to meet their pre-agreed supply requirements.
Importantly, new criteria **should not automatically lead to higher prices during procurement**, particularly when incentives have been granted to enhance manufacturing.
Transparency regarding financial and other incentives received for research, development and production from public authorities is essential for well-informed pricing negotiations and reimbursement decisions. Such information should be made publicly available.