ESIP Position on

the European Commission's Proposal for a Critical Medicines Act

European Social Insurance Platform (ESIP)

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Position Paper
on the European Commission's Proposal for a Critical Medicines Act

Executive summary

The European Social Insurance Platform (ESIP) shares the growing concern over shortages of critical medicines across the EU and welcomes the objective of the proposal for a Critical Medicines Act to address vulnerabilities in the pharmaceutical supply chain. Any intervention to strengthen supply chain resilience must be evidence-based and accompanied by appropriate incentives and conditionalities. In this context, ESIP calls for:

- A **thorough, evidence-based evaluation of current market dynamics, potential supply chain vulnerabilities and their root causes.** This should inform the development of a European List of Critical Vulnerable Medicines, identifying products based on both their public health importance and risk of supply disruption. This list should guide the allocation of financial incentives under the Critical Medicines Act.

- A **timely evaluation of the proposal's economic effects**, particularly regarding the cost implications of the proposed criteria for public procurement.

- **Industrial policy measures that demonstrably contribute to higher supply security and the reduction of medicine shortages**. Incentives should be granted based on economic efficiency criteria, as well as on the ability to maintain adequate stock levels and/or ensure flexible and efficient production to meet European market needs. Penalties for non-compliance with these conditions should also be established.

- **Predictable and appropriate national and EU-level budgets to support industrial policy measures** aimed at building, expanding, or modernising production capacity for critical medicines – while ensuring that financial support is provided without further straining the budgets of health insurance funds.

- **Transparency regarding financial and other incentives granted by public authorities**.

- **Guidelines, rather than binding criteria, for public procurement** that prioritise security of supply and the resilience of EU-based manufacturing.

- **Continuous EU-wide monitoring of supply and shortages**, in coordination with other legislative files addressing medicine shortages.

- **Strategic EU reserves of critical medicines** and/or active pharmaceutical ingredients (APIs), **complementing but not replacing national stockpiling obligations.**

- **Fair and balanced representation in the Critical Medicines Coordination Group**, including participation from national authorities responsible for procurement, pricing, and reimbursement of both critical and other medicines of common interest.

Introduction

On 11 March, the European Commission presented the proposal for a **Critical Medicines Act** titled "Regulation laying down 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 proposal aims to promote the continued availability of critical medicines, as well as other medicines of common interest, across the EU, when insufficient supply and/or unavailability in some Member States create health risks for patients.

The proposal follows the recent publication of the strategic report of the Critical Medicines Alliance[1] and complements other legislative files addressing medicine shortages in the EU, notably the reform of the EU pharmaceutical legislation[2,3] as well as Regulation (EU) 2022/123 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices.[4]

General remarks: Clarify the scope and impact of the Critical Medicines Act

The European Social Insurance Platform (ESIP) shares concerns about the shortages of critical medicines within the EU. ESIP members play a pivotal role in procuring critical medicines, a core component of the proposal for a Critical Medicines Act (CMA), always keeping patient access to affordable healthcare at the core of their activities.

While it is crucial to prevent supply disruptions, ESIP urges to keep public health, rather than market dynamics, at the core of European health policies. Preserving affordable patient access and the financial sustainability of healthcare systems should remain primary targets, together and beyond 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.**

First, the scope of the Critical Medicines Act, particularly with a view to pharmaceutical products and their ingredients eligible for incentives, should be further clarified based on a **thorough, evidence-based evaluation of current market dynamics, potential supply chain vulnerabilities and their root causes**.

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[1] Strategic Report of the Critical Medicines Alliance (February 2025)

[2] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006

[3] Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC

[4] Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices

ESIP supports the creation of a **European List of Critical Vulnerable Medicines**, as recommended by the Critical Medicines Alliance. Medicines on this list should be identified based on an evaluation of both their relevance for public health – for instance with a view to unmet medical needs and/or absence of viable alternatives on the market – and of supply vulnerabilities and dependence to single or limited suppliers. The list should be subject to regular reviews and should be the primary target for financial incentives within the Critical Medicines Act.

Beyond financing, ESIP acknowledges the inclusion of incentives such as **expedited administrative, regulatory, and scientific support**. While this could be useful for accelerating the manufacturing of critical medicines, it is important to **carefully define and limit the types of strategic projects eligible for these incentives**. This would ensure that the support provided by competent national authorities is better targeted and more effective. ESIP also cautions against expanding strategic projects beyond critical medicines and their active ingredients. Allowing incentives for the roll-out of other technologies related to the manufacturing of critical medicines could divert the focus of the Critical Medicines Act, generating unpredictability.

In parallel, the **definition and processes for designating a medicine as critical or of common interest** within the Critical Medicines Act should be transparent and involve stakeholders including healthcare payers. A **clear distinction** should be made between the two categories, with different legal implications for each.

Furthermore, the Critical Medicines Act was presented without a formal impact assessment, citing the urgent need to address shortages of critical medicines. This resulted in a lack of clarity regarding the budgetary implications of the proposal's complex financing mechanisms. Hence, essential information is missing as to how the proposed measures will affect national as well as European budgets. It also remains to be further clarified whether the measures proposed will effectively ensure stable supply, without disproportionately increasing the cost of medicines. **A timely evaluation of the proposal's economic effects is paramount**, not only aiming to serve the competitiveness of the pharmaceutical sector but also the financial sustainability of healthcare systems. Clear information is needed on the expected financial contributions from Member States for strategic projects, the budget allocation from the European Union and its sources, as well as the cost implications of new procurement criteria for purchasing critical medicines.

Finally, many provisions of the Critical Medicines Act are based on the ongoing EU pharmaceutical reform, which has not yet been finalised. It is essential that both initiatives align to ensure an EU-wide system, with early warning mechanisms, that enhances transparency and effectively prevents supply shortages. A general obligation should be established for marketing authorisation holders to report potential shortages and develop prevention strategies. Additionally, existing and future extended obligations for marketing authorisation holders to ensure the continuous supply of their medicines must be accompanied by clear and enforceable penalties for noncompliance.

Optimise conditions for financial support: Guarantee public return on multi-layered public investment

The Critical Medicines Act proposes industrial policy measures, such as strategic projects aimed at building, expanding, or modernising the production capacity for critical medicines within the EU.

ESIP supports these measures and emphasises that the EU and its Member States are jointly responsible for active and coordinated industrial policies to strengthen supply security. This responsibility cannot be delegated to other institutions that lack the necessary legal authority and financial leverage. **The already strained budget of health insurance funds should by no means be redirected towards financing production capacity.**

In addition to national public funding, strategic projects are expected to receive co-funding from the EU budget. Therefore, it is essential to maintain a **separate budget, similar to the EU4Health programme** in the current Multiannual Financial Framework (MFF), and potentially expand it.

The proposal for a Critical Medicines Act also sets **conditions regarding the priority supply in Europe** for products that have received financial support from Member States, as long as they remain on the Union List of Critical Medicines. This provision is generally welcomed as it could contribute to **public return on multilayered public investment**.

In fact, **the industrial policy measures outlined in the proposal must be designed to demonstrably contribute to higher supply security and the reduction of medicine shortages.** Currently, whether these measures are fit for purpose remains unclear, due to the lack of a prior impact assessments.

To maintain efficiency and cost-effectiveness, the incentives for the development or improvement of production sites should be granted based on the highest economic efficiency criteria, such as considering new production methods. Manufacturers of critical medicines who have received incentives for production should be required to maintain adequate stock levels, including for health crises, prioritise supply to the European market and/or develop efficient and flexible production capacity to meet potential surges in demand within the EU. **These conditionalities should be extended to cover any form of incentive, whether financial, scientific, or regulatory, both at the EU and national levels. Penalties should be imposed on companies that fail to fulfil their obligations.**

Overall, **transparency around the financial and other incentives** provided by public authorities for research, development, and production is crucial for informed pricing negotiations and reimbursement decisions. Such information should be made publicly available. In this context, ESIP welcomes provisions in the proposal for a Critical Medicines Act that foster the exchange of information on financial support for strategic projects at both national and EU levels, which could prove useful in tenders and in pricing and reimbursement negotiations.

Refine procurement criteria: A balanced approach that respects national competences

The proposal introduces **new binding requirements for the procurement** of critical medicines, prioritising **security of supply and resilience**. These criteria could potentially extend to other medicines of common interest, where their availability is at risk, if justified.

ESIP Members support the possibility to value access and European manufacturing as well as environmental and social aspects in procurement. Some of these criteria are already taken into account in public procurement, except for the new legal preference for EU production, which ESIP Members generally support in the context of the Critical Medicines Act.

Nevertheless, they express reservations regarding hard provisions for the procurement of critical medicines. The identification and selection of procurement criteria should remain in the remit of the responsible national and regional procurers. **Mandating specific procurement criteria would interfere with the competence of individual Member States on public procurement. Therefore, guidelines would be preferred, with the possibility to apply the defined criteria voluntarily at the discretion of individual Member States**, both in procurement and in pricing and reimbursement negotiations.

ESIP acknowledges that the proposal for a Critical Medicines Act allows for deviations from these procurement criteria, for example due to market analysis or financial considerations. However, requiring formal justification for these deviations, along with implementing national programmes to promote the consistent application of procurement criteria, risks adding administrative strain to already overburdened healthcare systems.

Of particular concern is the potential for the new binding procurement requirements to drive up prices, consequently affecting the sustainability of healthcare systems. At present, the proposal fails to guarantee affordable access to critical medicines, especially when promoters of strategic projects receive public funding, state subsidies and other incentives for manufacturing. Therefore, **it is essential that the proposed criteria are carefully assessed, particularly their economic impact, through a formal evaluation**. Notably, the costs associated with the new procurement criteria should be estimated also considering the other incentive mechanisms included in the legislation.

Finally, ESIP supports **clear requirements on producers** in the procurement contracts and welcomes the inclusion of **performance clauses** on timely delivery and pre-agreed supply requirements as well as measures in case of noncompliance.

Support the proposed framework for voluntary collaborative procurement

The proposal describes different **collaborative procurement mechanisms** where the Commission will be involved, or act on behalf of Member States. ESIP welcomes the possibility for Member States to engage in joint procurement **on a voluntary basis and without impeding parallel national procurement**.

Establish a balanced monitoring and stockpiling system

In coordination with other legislative files addressing medicine shortages, ESIP strongly recommends **continuous EU-wide monitoring of supply and shortages**. The European Commission, in cooperation with the European Medicines Agency (EMA), Member States and relevant healthcare stakeholders, should be responsible for this exercise. A coordinated reporting system shared between national competent authorities would enhance transparency regarding current and future stocks and shortages. A thorough overview of data is essential for implementing measures to improve supply security. Since the current proposal for a Critical Medicines Act does not include provisions on this matter, **it is crucial to incorporate such measures into the reform of European pharmaceutical legislation**.

Additionally, ESIP invites to consider **strategic EU reserves of critical medicines and/or active pharmaceutical ingredients** within the scope of the Critical Medicines Act, without prejudice to national stockpiling obligations. The voluntary EU solidarity mechanism for medicines should continue to be used for redistributing existing stocks that exceed national supply needs. Regulatory efforts should focus on creating multinational pharmaceutical packages that can be efficiently distributed across Member States as required.

Ensure fair representation in the Critical Medicines Coordination Group

Finally, ESIP acknowledges the proposal to establish a **Critical Medicines Coordination Group** responsible for facilitating coordination on strategic projects and discussions for collaborative procurement, alongside providing recommendations on the vulnerability evaluations to be prioritised.

ESIP recommends ensuring **fair and balanced representation in this Group, involving national authorities responsible for the procurement of critical medicines as well as for the pricing and reimbursement of critical and other medicines of common interest**.

About the European Social Insurance Platform (ESIP)

The European Social Insurance Platform (ESIP) represents 46 national statutory social insurance organisations in 18 EU Member States and Switzerland, active in the field of health insurance, pensions, occupational disease and accident insurance, disability and rehabilitation, family benefits and unemployment insurance. The aims of ESIP and its members are to preserve high profile social security for Europe, to reinforce solidarity-based social insurance systems and to maintain European social protection quality. ESIP builds strategic alliances for developing common positions to influence the European debate and is a consultation forum for the European institutions and other multinational bodies active in the field of social security.

ESIP members support this position insofar as the subject matter lies within their field of competence.

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