EuropaBio Position on the Critical Medicines Act

EuropaBio supports the goal of the Critical Medicines Act (CMA) to strengthen security of supply for medicines in the EU. Medicine shortages have various causes and require tailored solutions. Addressing long-standing external dependencies and rebuilding manufacturing capacity will require sustained efforts over decades. Delivering the critical medicines of tomorrow demands urgent action today through reinforced global value chains and stronger EU leadership and competitiveness in biotech and life sciences innovation.

EuropaBio actively contributed to the work of the Critical Medicines Alliance to ensure a pragmatic, fit-for-purpose proposal. It is regrettable that many of the Alliance's core recommendations were not taken up. The CMA lacks concrete measures to ensure sustainable access to raw materials and feedstock and to build strategic partnerships, two vital elements for long-term resilience. The absence of a comprehensive impact assessment raises serious concerns. Without a robust analysis of the proposed measures and their interplay with other legislations such as the revision of the EU General Pharmaceutical Legislation (GPL), it is impossible to fully evaluate the cumulative effects of the CMA.

By conflating the distinct challenges of supply security and patient access, the proposal risks unintended consequences for global supply chains, internal market competition, and access conditions across the EU. Proposals on collaborative procurement overlook the diversity of Member States' economic and fiscal characteristics, healthcare systems, and patient access pathways. They also fail to differentiate between access pathways for innovative medicines and those for off-patent products, which could undermine both competition and patient access.

Building upon the Strategic Report of the Critical Medicines Alliance, EuropaBio recommends the following actions to address current gaps in the Commission's proposal:

1. **Ensure proportionate and tailored EU measures** where supply vulnerabilities are most acute, strengthening resilience while preserving fair competition and respecting national access frameworks**.**
2. **Improve EU-level coordination of national responses** to medicine shortages, particularly on contingency stocks, while avoiding creating additional layers of requirements. Fragmented and unaligned stockpiling policies risk creating or exacerbating the shortages they aim to prevent.
3. **Strengthen strategic projects and partnerships** to secure long-term resilience and autonomy by anchoring EU innovation capacity for today's innovative therapies and tomorrow's critical medicines.

Ensuring proportionate and tailored EU action to address supply vulnerabilities

The CMA should focus on areas where vulnerabilities have been established in partnership with manufacturers and where risks are greatest, while providing long-term solutions to address these risks. As currently drafted, the broad scope of the collaborative procurement (CP) framework and the definition of medicinal products of common interest (MPCIs) risk having far-reaching consequences for supply chains, the broader biotech and pharmaceutical ecosystem, and patient access.[1] A more tailored and clearly defined framework for CP, that applies last resort to address cross-border needs only after national measures have not been sufficient or in case of supply chain risks, would better support the CMA's objectives without disrupting existing supply and access mechanisms.

The proposed CP framework does not address the root causes of medicine access challenges at the national level. Instead, it risks introducing an additional layer of complexity to already diverse and sensitive patient access conditions across Member States. The proposal should be complemented to include clear conditions and governance criteria for the operationalisation of CP (detailed in the Annex). Simultaneously, the definition of MPCIs should be reframed to recognise the primary role of allowing for the functioning of national processes first.

EuropaBio believes that Commission-led procurement and Joint Procurement mechanisms (Articles 22 and 23) should be limited to critical medicines for which a vulnerability assessment has confirmed actual supply chain risks. Cross-border procurement by Member States (Article 21) should be reserved as a last resort, used only when a cross-border need persists after all relevant national and EU procedures have been completed, and subject to an assessment confirming its proportionality and necessity.[2]

In all cases, participation in CP procedures should remain voluntary. At the same time, tenders should be designed in a way that does not inadvertently disadvantage smaller innovators, SMEs and mid-caps, and does not stifle innovation and undermine competition between manufacturers. The use of CP procedures should also be avoided where it would delay patient access due to length of procedure. This is particularly important for therapeutic areas where time to treatment is critical, it is difficult to predict volumes, or patient treatment requires advanced facilities and highly trained staff that are not available in all Member States.

Finally, we urge the Commission, the Council, and the European Parliament to ensure that the CMA is coherent with the landmark access-related proposals under the GPL. A coherent legislative approach is essential to avoid duplication, conflicting objectives, or unintended consequences for access and innovation. National cost-containment policies risk undercutting

[1] Collaborative procurement refers to the three types of procedures laid down in Articles 21-23.
[2] EU procedures refer to any access solution such as in the GPL or cross-border access under Directive 2011/24/EU.

the incentives and investments needed to strengthen resilience, support manufacturing, and deliver on the EU's health and industrial ambitions.

Improving EU-level coordination of national responses to medicine shortages

The CMA should be used to strengthen coordination of national contingency stockpiling measures in order to boost EU resilience to medicine shortages, a key priority identified by the Critical Medicines Alliance. Fragmented stockpiling requirements across Member States risk undermining the integrity of supply chains and may contribute to the creation or prolongation of shortages. It is essential to establish common EU-level criteria for the use of contingency stocks in response to short-term needs.

Currently, EU Member States have significant disparities in their stockpiling regimes, including differences in the types of products covered, actors responsible for stockholding, stock sizes, and lead times. This patchwork is unsustainable. Overlapping national requirements strain supply chains, undermine the principle of EU solidarity, and make it increasingly difficult for companies to manage inventories effectively.

Beyond a potential targeted strategic reserve to respond to cross-border health emergencies, EuropaBio does not support EU-level stockpiling unless it replaces the existing 27 national regimes. The CMA should instead establish common EU principles for contingency stocks focusing on agility and risk mitigation, including:

- A principle of EU solidarity, enabling stock transfers between Member States under the Voluntary Mechanism.
- Clear governance arrangements, including responsibilities, financing mechanisms, derogations, and monitoring.
- Minimum EU-level thresholds, based on a robust vulnerability assessment, including product-specific ceilings and allowances for unfinished products.
- Flexibility to reflect product characteristics and feasibility of stockpiling or for products where stockpiling would create additional supply chain tensions (e.g., biologicals, radiopharmaceuticals, or plasma-derived therapies).
- Regulatory flexibilities, including labelling and packaging requirements, to facilitate seamless movement of contingency stocks across Member States.

EU coordination should also extend to key manufacturing inputs such as raw materials, feedstock, APIs, and excipients, where supply chain vulnerabilities have been identified. A coordinated approach to strategic inventory management aligned with real market needs would significantly strengthen EU resilience to external shocks. This must be supported by concrete EU actions on sustainable and resilient sourcing, including strategic projects,

partnerships, the Bioeconomy Strategy, the EU Biotech Act, and a potential Critical Chemicals Act. Finally, cross-sector collaboration, including with technology providers, should be actively encouraged to accelerate the uptake of innovative supply chain solutions.

Strengthening strategic projects and partnerships to secure long-term resilience

Strategic projects and partnerships are essential to building long-term resilience in the EU's pharmaceutical ecosystem, enabling coordinated investment, innovation, and supply security across medicine development and manufacturing.

Strategic projects should be expanded to fully include upstream industrial capabilities essential to the manufacturing of medicines. This includes the sourcing and processing of raw materials, feedstock, and biotech-derived inputs, which underpin the manufacturing of many medicines.

Eligibility for strategic projects should be based on a robust vulnerability assessment, allowing support for infrastructure that, while not directly linked to a single critical medicine, is essential for maintaining the resilience of entire therapeutic classes or manufacturing platforms. To unlock their full potential, such projects should be exempted from EU debt rules and, where dual-use is demonstrated, be eligible for defence-related funding mechanisms. This targeted, risk-based approach would reinforce the CMA's objectives of strategic autonomy, while avoiding the inefficiencies of untargeted industrial policy.

To strengthen resilience and reduce upstream dependencies, the EU must prioritise strategic partnerships with like-minded countries, focused on securing access to raw materials, feedstock, and other essential inputs for pharmaceutical manufacturing. These partnerships should be guided by a clear EU-level framework to avoid uncoordinated national initiatives, ensure alignment with the Union's exclusive competence on trade, and support a unified external approach to health resilience.

In parallel, partnerships should aim to remove trade barriers, including non-tariff barriers, to facilitate the cross-border movement of medicines and critical components. They should also promote regulatory cooperation, reducing friction in supply chains and supporting faster, more predictable market access. All trade-related measures must remain fully consistent with the EU's international obligations, reinforcing the EU's credibility as a reliable and rules-based global partner.

Annex – Conditions and governance for the operationalisation of collaborative procurement

The following have been developed by EuropaBio as a baseline for the conditions and governance for the operationalisation of collaborative procurement (CP):

- **CP should be a last resort after all national procedures have been completed** and should be subject to an assessment confirming that the measure is reasonable and proportionate.
- **CP should remain voluntary** for both Member States and companies. Participation should not impose obligations beyond the agreed scope of the tender.
- **CP procedures should be time-limited**, with a defined duration clearly specified in the tender documents.
- **CP should apply only to individual medicines**, not therapeutic classes. During an active CP process, parallel procurement or shortage mitigation measures for the same product should be temporarily paused in participating Member States.
- **CP tenders should group only Member States with comparable economic and healthcare contexts**, and where there are shared challenges related to access or supply security for vulnerable critical medicines. Participating countries should agree on a common assessment of the clinical, economic, and societal value of the medicine concerned.
- **CP should ensure fair value for innovation** and use MEAT (Most Economically Advantageous Tender) criteria beyond price alone—such as speed of access, supply reliability, and quality. CP products should be exempt from national cost-containment mechanisms (e.g., clawback schemes). Tender specifications must be transparent and include binding commitments on volumes and procurement timelines.
- **CP must protect intellectual property and ensure confidentiality of commercially sensitive information**, including but not limited to contractual terms, pricing, and product-specific data.
- **CP should operate under a common, clearly defined framework** that reflects the characteristics of the products and the contracting Member States. This framework should establish governance structures, roles and responsibilities, purchasing authority mandates, decision-making processes, and conflict resolution mechanisms.
- **CP should allow regulatory flexibilities** to facilitate efficient manufacturing, packaging, and distribution. These may include electronic leaflets, single-language packaging, or common packaging across the full scope of the tender.