Biomedical Alliance in Europe

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The BioMed Alliance calls for a strong and ambitious Critical Medicines Act

Medicine shortages continue to disrupt patient care and place significant strain on healthcare systems across the European Union. Record levels of shortages were reported in 2023 and 2024[1], leading to treatment delays and interruptions and undermining healthcare professionals' ability to deliver timely and appropriate care. The BioMed Alliance, representing 34 European Medical Societies, believes that this is a structural, EU-wide challenge that requires a coordinated and futureproof European response.

The Critical Medicines Act (CMA), which is currently in trilogue negotiations, may represent a decisive step towards strengthening the availability, supply and production of critical medicines in the EU. The Commission's proposal provides an important starting point, but the final Regulation must be ambitious and firmly rooted in transparency, cooperation, and public accountability.

European Parliament position

The European Parliament's position introduces important improvements to enhance EU-level coordination in stock management, supply monitoring, and crisis response. Common approaches to stockpiling and improved monitoring of availability and distribution across Member States are essential to address cross-border shortages effectively, coordinate the management of stocks and supplies and strengthen crisis resilience and response.

The Parliament's position also reinforces the importance of joint procurement (Article 23) as a structural tool to improve resilience, affordability, and fairness. Crucially, it strengthens public procurement rules (Article 18) by requiring that healthcare professionals be consulted when defining the scope of procurement procedures and by ensuring that price is no longer the sole or dominant award criterion, in favour of resilience, quality and diversification of supply sources.

Council approach and remaining concerns

By contrast, the Council has opted for increased discretion and flexibility for Member States, at the expense of a strong Union approach. The security of supply and availability of critical medicinal products for patients should remain a strategic EU objective, as originally envisaged in the Commission proposal (Article 4).

It is particularly important for the BioMed Alliance that public investment under the CMA, notably through Strategic Projects (Article 5), is clearly tied to public returns. Industry support must be transparent and accompanied by binding supply obligations that deliver tangible benefits for EU patients. In parallel, procurement requirements should actively incentivise production in Europe (Article 18).

To ensure that the implementation of the CMA and the advice provided to the European Commission reflect clinical realities, the Critical Medicines Coordination Group (Article 25) must work closely with healthcare professionals (including nurses and pharmacists) and patient organisations. Coherence with other EU health legislation, including the European Health Data Space, is equally important.

Key shortcomings that must be addressed

- **Weak linkage between public funding and binding supply obligations:** While the CMA foresees substantial public support for Strategic Projects (Articles 5–8), obligations attached to this funding remain insufficiently binding. Even with Parliament improvements, guarantees on EU supply prioritisation and availability during shortages are not consistently ensured. Without clear conditions, public investment risks failing to deliver tangible benefits for patients and healthcare professionals.
- **Limited operationalisation of affordability:** Although affordability is listed among the objectives of the CMA (Article 1(2)), the Regulation lacks concrete mechanisms to ensure that increased resilience does not undermine the sustainability of health systems. Procurement provisions focus primarily on security of supply, with insufficient safeguards against excessive pricing. Availability without affordability risks perpetuating access disparities in practice.
- **Risk of fragmentation due to excessive national discretion:** The Council's approach, including the deletion of Article 4 on strategic coordination, undermines the collective approach set by the EC's proposal Excessive flexibility may lead to unequal access, uncoordinated stockpiling and competition between national systems, disproportionately affecting smaller and less resourced Member States.
- **Insufficient formal role for healthcare professionals and patients:** While consultation is referenced in procurement (Article 18), healthcare professionals and patient organisations are not sufficiently featured in governance structures such as the Critical Medicines Coordination Group (Article 25). Decisions on preparedness, prioritisation and crisis response risk being disconnected from clinical realities if these stakeholders are not structurally involved.

Conclusion

The BioMed Alliance calls on all EU institutions to maintain a high level of ambition, as reflected in the European Parliament's position, throughout the interinstitutional negotiations. A strong and forward-looking Critical Medicines Act is essential to safeguard patient care, strengthen Europe's resilience, and ensure that critical medicines reach those who need them, when they need them, everywhere in the EU. A forward looking Critical Medicines Act that maintains a European approach is essential to safeguard patient care, strengthen Europe's resilience, and ensure that critical medicines reach those who need them, when they need them, everywhere in the EU.