EuropaBio response to the Call for Evidence on the Critical Medicines Act (26.02.2025)

EuropaBio, the industry association for biotechnology in Europe, welcomes the opportunity to provide feedback on the future Critical Medicines Act (CMA). Strengthening the security of supply and availability of critical medicinal products in the EU is essential to ensure resilience and autonomy.

EuropaBio believes that achieving these objectives broader policy agenda aimed at boosting the competitiveness of the wider biotech and pharmaceutical value chains. This agenda should reflect the need for resilient global supply chains for the biotech and pharmaceutical industries, including beyond manufacturers.

General Comments

In line with the Strategic Report of the Critical Medicines Alliance, it is essential that the CMA duly reflects the differences between the innovative and off-patent industries as regards resilience. In that respect, EuropaBio believes that the scope of the Act should be focused on where vulnerabilities exist and additional requirements on companies should be imposed on a risk-based approach only in cases where companies MAHs have experienced significant shortages and do not have implemented mitigation strategies. EuropaBio believes that medicines for rare diseases and for small populations should be specifically excluded from the scope of the CMA due to their unique characteristics and heterogeneity of the patient population. If serious shortages for such products were to occur in the EU, these should be addressed through tailored measures. EuropaBio calls on the Commission to carefully consider the additional administrative and regulatory burden, as well as costs, of implementing the Act. EuropaBio underlines the importance of ensuring policy coherence across a rising number of legislations that will impact the biotech and pharmaceutical industries, including the General Pharmaceutical Legislation as well as environmental legislations.

Facilitating Investments to Increase Manufacturing Capacities

EuropaBio believes that investments to strengthen production capacities should be targeted towards real needs, deliver strategic advantages for the EU, and be coupled with other measures (such as incentives) to anchor capacity in the EU. EuropaBio believes that investments should target investments contributing to the EU's strategic objectives, including on competitiveness, sustainability, and jobs, and boost EU attractiveness for foreign direct investment.

This should include addressing the vulnerabilities of the existing manufacturing base, including for innovative products for which the existing capacity will make investments more impactful and deliver long-term benefits. Such investments should take an end-to-end value chain

approach (beyond API production), strengthening areas where Europe already has critical mass (e.g., Europe has one of the world's largest fermentation capacities which can be used to produce APIs),[1] and promoting greener and digitalised manufacturing. EuropaBio highly recommends that investments focus on upstream vulnerabilities with dedicated funding to strengthening supply chains for intermediates, key components, raw materials, and feedstocks.

Improving Resilience of Supply Chains

The diversification of supply chains is an important step towards resilience, however, any measures should consider the importance of global supply chains and shifting geopolitical context. Therefore, diversification measures should not only focus on locations of supply chains but on improving resilience and mitigating actual risks. EuropaBio believes that any additional requirements on marketing authorisation holders should be proportionate to the actual risks and to what companies can control. In view of the Commission's simplification agenda, data submission should be user-friendly and not include data already available to the EMA and national authorities. On contingency stocks of finished products, EuropaBio believes it should be used in limited and proportionate manner to respond to short-term needs while longer-term needs are better addressed by strengthening global supply chains and manufacturing capacities. For manufacturing inputs, the Commission should evaluate where such measures can strengthen supply chain and accelerate response time during crises.

In line with the Alliance's recommendations, EuropaBio supports efforts to conclude strategic partnerships with like-minded countries to further strengthen resilience and security and suggests that where similar outcomes can be secured, strategic partnerships should be preferred over legislative interventions. The development of future strategic partnerships should cover access to raw materials and key components to strengthen the overall biotech and pharmaceutical value chain. With respect to biotech, this would be aligned with the actions announced in the Commission Communication on biotech and biomanufacturing of March 2024.

Leveraging Procurement Practices

EuropaBio agrees that virtuous public procurement practices can help increase security, resilience, and improve sustainability of manufacturing. However, EuropaBio considers that discussions on new procurement practices and criteria should take place as part of a continuous dialogue between competent authorities and industry. As regards the planned revision of the Public Procurement Directives, EuropaBio stresses the need to carefully consider the different needs of the sectors covered by those Directives and refrain from adopting a one-size-fits-all approach.

EuropaBio welcomes considerations of using procurement in the Act, including Most Economically Advantageous (MEAT) criteria. On this, EuropaBio underlines that the overall aim

[1] What's new on the State of Global Fermentation? - Blue Horizon

should be to improve resilience and sustainability by supporting actors which have invested to secure their supply chains and/or improve the sustainability of their production chains. We believe that the Act should include clear language, supported by possible guidelines, on the application of MEAT criteria, including any exemptions, to achieve these objectives.

On collaborative procurement, EuropaBio underlines that the current EU joint procurement agreement (JPA) framework was designed to respond to cross-border health threats, such as pandemic. It should also be stressed that joint procurement is not a silver bullet, and that EU-level joint procurement should fully respect the competences set out in the Treaties and focus on improving existing procedures. As such, any update to the JPA scope should be based on a thorough impact assessment, dialogue between competent authorities and industry, and learning from previous joint procurement experiences in the EU.