

'Consistency, cooperation and practicality are the watch words'. EuropaBio reacts to provisional agreement on the Critical Medicines Act

PRESS RELEASE

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"2026 is a defining moment for Europe's healthcare framework, with two major legislative reforms set to reshape the regulatory landscape. As implementation moves forward, it is critical that these reforms strengthen — not weaken — Europe's health biotech sector, which is already under significant global competitive pressure and facing increasing cost-containment dynamics that risk limiting patient access to innovation.

The Critical Medicines Act must remain focused on its core objective: addressing shortages and reinforcing supply security. It should not become an instrument for additional cost-containment measures."

Dr Claire Skentelbery, Director General of EuropaBio.

EuropaBio, the association representing Europe's innovative bioindustries, takes note of the provisional agreement reached by co-legislators on the Critical Medicines Act (CMA).

Together with the forthcoming reform of the EU General Pharmaceutical Legislation, the CMA marks a significant shift in the European regulatory and access landscape at a critical time for the health biotech sector.

Whilst the primary objective of the CMA is to address shortages of critical medicines, EuropaBio will continue to monitor the developments closely and engage constructively with co-legislators and stakeholders to ensure that the final provisions and their implementation deliver on the core ambitions of the Act: strengthening supply chains and improving Europe's capacity to anticipate and mitigate shortages.

EuropaBio calls for clear and consistent guidance on the application of the 'Medicinal Products of Common Interest' concept across the EU. It is essential this tool complements – rather than circumvents – established access pathways, ensuring predictability for patients and innovators alike.

Public procurement provisions will be central to achieving more resilient supply systems. EuropaBio welcomes the introduction of a multi-winner approach, which can support diversifying supply chains and reduce risk linked to single supply. At the same time, close cooperation between public authorities and industry will be crucial to ensure that resilience requirements are practical, effective and aligned with how supply chains operate globally.

While recognising policymakers' efforts to strengthen European manufacturing capacity, EuropaBio reiterates that biopharmaceutical supply chains are inherently global. Building new biomanufacturing capabilities require long-term planning, sustained investment and supportive regulatory framework.

EuropaBio cautiously welcomes provisions enabling Member States to share information and improve coordination on contingency stock requirements. A harmonised approach is essential to avoid unintended market distortion and minimise shortages. Engagement with key supply chain actors will be critical for the implementation of this provision.

EuropaBio underlines that joint procurement mechanisms must remain voluntary, ensuring flexibility for Member States while supporting cooperation where it adds value and taking into account the specificities of medicines, their delivery mechanism and how they fit into patient care pathways.

EuropaBio looks forward to further detail on the agreement and remains committed to maintaining a constructive dialogue with policymakers throughout the final legislative and implementation process.

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About EuropaBio

EuropaBio, the European Association for Bioindustries, promotes an innovative and dynamic European biotechnology industry. EuropaBio and its members are committed to the socially responsible use of biotechnology to improve quality of life; to prevent, diagnose, treat, and cure diseases; to improve the quality and quantity of food and feedstuffs and to move towards a biobased and zero-waste economy. EuropaBio represents corporate and associate members, plus national biotechnology associations and bioregions. Read more about our work at www.europabio.org.