
STATEMENT ON THE EUROPEAN COMMISSION CALL FOR EVIDENCE ON THE CRITICAL MEDICINES ACT

The International Association of Mutual Benefit Societies (AIM) welcomes the potential implementation of a Critical Medicines Act as a crucial step toward ensuring equitable access to medicines across Member States. While innovation is important, the Act should primarily focus on addressing shortages, which mainly affect off-patent medicines. AIM strongly supports measures that enhance affordability and availability while ensuring the sustainability of solidarity-based healthcare systems. We also welcome the fact that the Act complements, rather than overlaps with, existing pharmaceutical legislation, ensuring coherence and efficiency in addressing medicine shortages and enhancing supply chain resilience.

Medicines are an essential component of disease treatment and should not be considered goods like any other. Their price must not become a barrier to access, as high costs can lead to governments and competent authorities (e.g., health security institutions) being unable to provide medicines to all eligible patients or force patients to pay out-of-pocket. In the case of specialty medicines, this can result in patients either foregoing treatment or enduring catastrophic healthcare expenditure.

AIM calls for the Critical Medicines Act to address the following key priorities:

- Ensuring transparency in medicine pricing, research, and production costs.
- Reinforcing data requirements and standardization for registration of shortages at the European Medicines Agency (EMA) level. A coordinated reporting system for medicinal products, accessible to national authorities, would increase transparency regarding current and future stocks and shortages.
- Diversifying the production of pharmaceuticals globally, as well as increasing investments in European manufacturing capacities, will contribute to greater supply security, provided the relocation of production capacities does not lead to renewed concentration elsewhere.
- Utilizing EU financial resources to promote pharmaceutical production in Europe. Contributions from statutory health insurance funds or mutuals should not be diverted for industrial policy task.
- Expanding new production locations, including in Europe should aim for the highest economic efficiency criteria, e.g., by taking new production methods into account and achieving the highest level of global competitiveness. It should also follow highest sustainability and

environmental criteria. These requirements must not lead to the costs being passed on to the medicines and the prices of medicines rising as a result.

- Incentivizing European production through joint public procurement policies and competitive bidding processes to enhance transparency and efficiency. Promoting generic and biosimilar medicines to foster competition and lower costs while ensuring high quality and safety. Transparency regarding financial and other incentives granted by the authorities for research, development and production is crucial for informed price negotiations and reimbursement decisions.
- Prioritizing the production of active pharmaceutical ingredients (APIs) and finished medicines within Europe to strengthen supply chain resilience and reduce dependency on third countries as part of Europe's industrial policy.
- Reinforcing joint European strategic stockpiles of essential medicines and APIs to prevent shortages and supply disruptions.
- Proportionating commitments for beneficiaries of financial incentives, such as prioritizing supply, affordability, and long-term supply resilience. A robust monitoring mechanism to ensure adherence to these commitments, along with clear enforcement measures, should be in place to ensure compliance.

A crucial aspect in ensuring medicine availability across Europe is the establishment of a comprehensive EU list of critical medicines. AIM welcomes the publication of a list of critical medicines and strongly supports the creation of an EU-wide database, regularly updated by Member States, to monitor the supply of essential medicines. This database should remain under the management of the EMA to ensure a coordinated and reliable response to medicine shortages.

By diversifying supply chains, including European pharmaceutical production, and implementing fair pricing mechanisms, healthcare systems can reduce vulnerabilities, strengthen supply security, and improve access to essential medicines. AIM's vision is rooted in collaboration, innovation, and humanity, ensuring that pharmaceutical policies contribute to a sustainable future for generations to come.