

28 Feb 2025 -12:48

Critical Medicines Alliance issues recommendations for addressing medicines shortages at European level

In April 2024, the Critical Medicines Alliance was established under the Belgian Presidency of the Council of the European Union. The goal of the Alliance is to foster collaboration among policymakers and stakeholders, and develop a robust and responsive system for the supply of critical medicines in the European Union. Today, on 28 February 2025, the Critical Medicines Alliance presents its strategic report. This report will be used as the basis for new European legislation on medicines shortages: the Critical Medicines Act.

The availability of critical medicines is under pressure within the European Union (EU) and globally. In recent years, shortages have become increasingly visible, partly because of geopolitical tensions and a heavy dependence on Asian countries for raw materials. To address this challenge, the Critical Medicines Alliance was established in April 2024 under the Belgian Presidency of the EU Council. This Alliance consists of stakeholders from healthcare, industry and civil society and works with representatives from European Member States to formulate sustainable solutions. The primary goal of the Alliance is to identify bottlenecks in the supply of medicines and formulate recommendations.

The Federal Agency for Medicines and Health Products (FAMHP) played an important role within the Alliance. In early 2023, Belgium wrote a non-paper on the security of medicine supply chain in Europe. Following this document, the Critical Medicines Alliance was created. Our Chief Executive Officer, Hugues Malonne, served as vice-chair of the Steering Board of the Alliance for the past year. Experts from the FAMHP were active within all of the Alliance's thematic working groups to help constructively formulate effective recommendations.

“Recent years have shown that the European Union cannot remain dependent on just a few suppliers outside Europe for critical medicines. The Critical Medicines Alliance has now developed a roadmap to address these vulnerabilities and secure the supply of critical medicines. This report is the result of intensive consultation and in-depth expertise, in which the experts of the FAMHP played a crucial role.”



Hugues Malonne
Chief Executive Officer of the FAMHP and member of the Critical Medicines Alliance Steering Board

The result is impressive: the past year of intensive discussions with all stakeholders has led to the development of [an ambitious strategic report](#). The report provides concrete recommendations to the European Commission, EU Member States and other stakeholders on how to strengthen the production of critical medicines within the EU and ensure strategic partnerships with non-EU countries.

The strategic report forms the basis for the Critical Medicines Act, a legislative initiative currently being prepared by the European Commission. This Act will contribute to a stronger pharmaceutical sector in Europe through a targeted approach.

1. Vulnerability analysis of critical medicines
A methodology has been developed to identify where the greatest risks are in the supply chain. This will help allocate resources more efficiently and ensure that critical supply chains remain intact.
2. Targeted state aid for generic medicines
The Alliance recommends the use of targeted EU funding and particular state aid rules to boost the manufacturing of critical medicines, especially generic medicines.
3. Diversification of supply chains
A methodology is being developed to identify suitable partner countries that will allow Europe to reduce its dependence on a few regions.
4. More sustainable procurement of medicines
The Alliance calls for a new public procurement framework that not only takes into account the lowest price, but also includes criteria such as environmental friendliness, social regulation and security of supply.
5. EU guidelines for national stocks of medicines
Uncoordinated national emergency stockpiling can exacerbate shortages in other Member States. Therefore, a harmonised system based on transparency, proportionality and solidarity is needed.

“ COVID-19 made painfully clear to us how vulnerable Europe is when it depends on other countries for crucial medicines. With a military threat straining our security, we must not repeat that mistake. Europe must guarantee the production of essential medicines itself. It is therefore of great importance that the European Commission quickly presents an ambitious Critical Medicines Act, so that we do not face shortages again in times of crisis.”



Frank Vandenbroucke
Minister of Social Affairs and Health

The Critical Medicines Alliance and the upcoming Critical Medicines Act mark a turning point in European medicines policy. Whereas previously shortages were mainly addressed nationally, a common European policy is now emerging that bolsters the resilience of pharmaceutical supply chains. The Alliance's recommendations will form the basis for a strategic plan that will provide direction to the European Commission, EU Member States and other decision makers.

By working together and implementing structural reforms, the EU is taking a big step towards a more secure, sustainable and resilient system for the manufacturing and distribution of critical medicines. The FAMHP continues to play a central role, also in coordinating negotiations for the upcoming Critical Medicines Act. It promises to be a crucial year for medicines policy as the ongoing review of European pharmaceutical legislation also makes much progress.

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