

EPF's Position on the Critical Medicines Alliance's Strategic Report

3 March 2025

EPF welcomes the Critical Medicines Alliance (CMA) Strategic Report published on Friday as a step towards identifying the root causes of medicines shortages and an important contribution to the democratic debate on how to address them. The Report outlines a set of recommendations developed at fast pace from a multi-stakeholder perspective. As such, it is based on a wide range of positions and interests and cannot reflect all the views of each individual CMA member. As a next step, the economic impacts of these recommendations as well as their ability to effectively improve the availability of medicines for all patients across the EU must be further assessed.

As the European Commission considers the Strategic Report in view of an upcoming proposal on a Critical Medicines Act, EPF would like to reiterate some key aspects communicated as part of our work in the CMA:

1. **Shortages are first and foremost a public health issue:** they can harm patients' health, safety, and quality of life, professionals' ability to deliver care, and health systems' functioning. Impacts of shortages on patients range from having no treatment at all, to treatment delays or having to use an alternative treatment that may not be equally suitable. **All measures to address shortages should be driven by one public health imperative: ensuring that all patients have access to the medicines they need across the EU.**
2. **Strict conditionality, obligations, and transparency requirements are needed** to ensure that any financial incentives provided by public authorities benefit patients. Evidence-based decision-making and accountability are key to ensuring public trust. In addition, **assessing the impacts of investment in production relocation is important** to avoid any unintended consequences, such as increased out-of-pocket costs for patients and deprioritising other healthcare needs. At the same time, patient safety and strong regulatory oversight must be at the heart of diversification strategies.
3. **Patient involvement and patient information must be strengthened** at all stages, from the definition of "critical medicines" to assessment of public procurement criteria that prioritise long-term impacts on patients, co-creation of information campaigns and guidelines, as well as reporting of shortages. We support a patient-centred EU Health Union that includes strengthened solidarity mechanisms and joint procurement.
4. **At global level, emphasising health equity is essential to ensure that international partnerships do not negatively impact patients in third countries.** Maintaining patients' trust in medicines requires alignment of international standards and strong regulatory oversight.

EPF is ready to support all efforts to put in place a comprehensive, patient-centred system to address shortages and ensure equitable access to medicines. From the EMA’s extended mandate to the pharmaceutical legislation and the future Critical Medicines Act, a comprehensive and coherent strategy is needed to address this crucial public health issue. In the meantime, we look forward to working with the EU institutions and continuing to convey the voice of the patient community in this critical debate.

EPF has been a member of the Critical Medicines Alliance since its creation in April 2024. As such, we were part of subgroup 2 of Working Group 1 *“on stockpiling, public procurement and joint procurement”* and of Task Force 3 of Working Group 2 *“on the extension of the Voluntary Solidarity Mechanism”*, set up by the Alliance. We contributed to the CMA outputs to the extent our limited resources allowed and in close collaboration with a taskforce of EPF members active on shortages issues.

ABOUT EPF

The European Patients’ Forum (EPF) is an independent non-profit, non-governmental umbrella organisation of patient organisations across Europe and across disease areas. Our 80 members include disease-specific patient groups active at EU level and national coalitions of patients. To read about our vision, mission, and strategy, visit: www.eu-patient.eu