

EAHP Opinion on the Critical Medicines Act

On 11 March 2025 the European Commission published the proposal for a Critical Medicines Act. The European Association of Hospital Pharmacists (EAHP) acknowledges and supports the proposal as a step forward to address some of the root causes of shortages. However, in order to ensure full and meaningful access to medicines, further efforts are needed to guarantee that these measures address the daily needs of patients and healthcare professionals, in the overarching interest of public health.

The proposal for a Critical Medicines Act, is part of a comprehensive approach adopted by the European Commission to face the growing challenge of critical medicines shortages, and it is aimed at complementing the measures included in the proposal for the revision of the pharmaceutical legislation, currently under discussion in the Council¹.

The proposal includes several categories of actions, such as:

- Incentivising strategic projects to strengthen EU manufacturing capacities and reduce dependency on the import of critical medicines and active pharmaceutical ingredients (APIs), through EU funding and State aid;
- Rethinking public procurement models by applying award criteria beyond price, in line with the Most Economically Advantageous Tender (MEAT) approach;
- Promoting collaborative procurement of medicines, provided certain specific conditions are met;
- Creating a Critical Medicines Coordination Group;
- Fostering the development of strategic partnerships to diversify supply chains.

EAHP welcomes the incorporation of several measures stemming, in part, from recommendations elaborated through multi-stakeholder initiatives in which EAHP actively participates, including the Structured Dialogue² and the Critical Medicines Alliance³.

EAHP is also pleased to observe that, while the main emphasis is on enhancing the security of supply and boosting the availability of medicines included in Union List of Critical Medicines, the new proposed regulation also incorporates some measures intended to improve the access and availability of other medications in situations where market failure occurs.

EAHP supports the efforts and initiatives aimed at enhancing the APIs (Active Pharmaceutical Ingredients) production in Europe to secure supply chain and ensure the availability of finished pharmaceutical products. Nevertheless, **EAHP calls for a regular assessment on the correct use of EU funds and State aids accorded to industries having applied for Strategic Projects, in order to ensure that public resources are used for adopting a person-centred holistic approach, prioritising patient needs and public health objectives.**

EAHP is pleased to see that the Commission's proposal promotes the use of MEAT criteria rather than a selection process solely based on the cheapest price, nor on a single-winner takes all concept. EAHP appreciates that the outlined criteria consistently include stockholding obligations, the number of diversified suppliers, monitoring of supply chains, their transparency to the contracting authority, and

¹ More information on the ongoing Revision of the Pharmaceutical legislation is available here: https://health.ec.europa.eu/medicinal-products/legal-framework-governing-medicinal-products-human-use-eu/reform-eu-pharmaceutical-legislation_en

² More information on the Structured Dialogue on Security of Medicines Supply is available here: https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/structured-dialogue-security-medicines-supply_en

³ More information on the Critical Medicines Alliance is available here: https://health.ec.europa.eu/health-emergency-preparedness-and-response-hera/overview/critical-medicines-alliance_en

contract performance clauses related to timely delivery. However, further progress would be desirable. For instance, the text merely mentions that contracting authorities are not precluded from using additional qualitative requirements, such as environmental sustainability and social rights, rather than actively promoting these criteria. Additionally, one essential criterion to ensure optimal procurement of medicines is not mentioned: the involvement of healthcare professionals responsible for prescribing, managing, and dispensing medications, primarily hospital pharmacists, in the tendering procedures. These professionals are the only ones who regularly have an up-to-date, comprehensive view of patients' needs, as well as the quality and characteristics of the medicines ordered. For this reason, their involvement in the procurement of medicines is crucial, both at the national level and in cases of cross-border collaborative procurements managed or facilitated by the European Commission on behalf of Member States. Therefore, **EAHP calls for the regular involvement of hospital pharmacists and other healthcare professionals in all procurements of medicinal products in order to ensure a safe, of best quality, efficient, cost-effective and data-driven procurement.**

Furthermore, the Critical Medicines Act provides for the establishment of a "Critical Medicines Coordination Group", composed of representatives of the European Commission and Member States, with the European Medicines Agency having an observer status. EAHP wishes to express its concern regarding the establishment of this new group, which, while well-intentioned, may inadvertently lead to a fragmentation of communication and information. Moreover, the absence of civil society representation - even in an observer capacity- risks creating a disconnect from the real-world needs. **EAHP therefore strongly recommends ensuring close coordination, collaboration, and transparent information sharing among involved institutional stakeholders. In addition, EAHP calls for the inclusion of civil society representatives -at minimum from key categories such as hospital pharmacists, community pharmacists, doctors, nurses, hospitals, and patients- by granting them observer status in the Critical Medicines Coordination Group, with the opportunity to be heard and to provide advice grounded in the daily experience of their respective communities.**

EAHP welcomes the recommendation to explore strategic partnerships for diversifying sourcing of critical medicinal products. **EAHP calls for building these partnerships taking into account the criteria and methodology outlined in the Strategic Report of the Critical Medicines Alliance and in its Annex III⁴.**

Finally, **EAHP calls for a more coordinated and strengthened approach to stockpiling**, including mechanisms that allow for the sharing of medicine stocks to reinforce supply security. Additionally, EAHP advocates for **more frequent updates of the Union List of Critical Medicines, with the possibility for healthcare professionals to report shortages of essential medicines not currently included in the list, as well as of their therapeutic alternatives** - thereby enabling a timely review and revision of the list.

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⁴ Including, among others, previous successful collaborations to mitigate medicine shortages, geopolitical factors, alignment with the EU in terms of social and environmental standard, etc. The strategic report and its annexes are available here: https://health.ec.europa.eu/document/download/3da9dfc0-c5e0-4583-a0f1-1652c7c18c3c_en?filename=hera_cma_strat-report_en.pdf