

HOPE Position on the Critical Medicines Act

Shortages of medicines have increased in recent years and pose a growing threat to patient care and safety. HOPE then welcomed and joined the European Commission's initiative for a Critical Medicines Alliance launched in 2024.

Overall, HOPE welcomes the ambition to strengthen the resilience of the pharmaceutical supply and is positive about the direction of the proposal "Critical Medicines Act" submitted to consultation. HOPE considers however that:

- The proposed regulation needs a strong impact assessment.
- The proposed regulation needs legal clarity.
- The proposed regulation should stick to a manageable list of critical medicines.
- Procurement criteria should be indicative and not mandatory.
- Participation in joint procurement should be voluntary.
- The support of public money to industry must be conditional on requirements such as safe deliveries.

Impact assessment

The proposed regulation lacks an impact assessment. It makes it difficult to understand the potential economic and organisational impacts. It is unclear to what extent EU-funded incentives will be complemented by national co-financing, how procurement practices will be affected and how medicine prices will evolve. It needs to be ensured that the proposed measures hit the mark so that they really lead to better access and reduced vulnerability.

Legal clarity

There are a number of potential conflicts between the proposed Critical Medicines Act and existing EU and national legislations such as procurement law, state aid rules, data protection rules ...

The ongoing revision of the pharmaceutical reform and the existing mandates of EMA and HERA also overlap in some respects with the structures proposed in the Critical Medicines

Act. There is an obvious risk of ambiguity regarding the division of responsibilities and decision-making mandates.

HOPE would like to emphasise that the regulation should stick to critical medicines, regardless of whether these are new or older. Measures to facilitate the authorisation of urgent medicines, such as medicines for rare diagnoses, are dealt with within the framework of the revision of the pharmaceutical legislation. Where the availability of these medicines is deemed critical, these medicines should be added to the list of critical medicines and thus covered by the Regulation.

HOPE also notes that the European Commission has chosen to write the CMA as a regulation even though the only mandatory measures concern procurement.

Critical medicines

HOPE believes that a common EU list of critical medicines is a necessary prerequisite to enable a coordinated framework for critical medicines. However, it is important that this list is regularly updated in consultation with member states. The selection should be based on transparent criteria of both a medical and supply nature. The list in its current form is very extensive and could be shortened to make it more manageable and to identify the most vulnerable products from a supply perspective and thus requiring action.

HOPE believes that the scope of the proposed regulation, which focuses primarily on the critical medicines included in the list, is an important starting point. But, the Commission proposal also covers medicines of common interest in certain respects. Again HOPE considers that the regulation should focus on critical medicines, regardless of whether they are new or old. Measures to facilitate the authorisation of urgent medicines, such as medicines for rare diagnoses, are dealt with within the framework of pharmaceutical legislation. Where the availability of these medicines is deemed critical, they should be added to the list of critical medicines and thus be covered by the Regulation

Flexible procurement criteria

HOPE fundamentally supports the ambition to integrate criteria on security of supply, environmental sustainability and sustainable production into pharmaceutical procurement. However, HOPE is concerned that these are proposed to be mandatory. Procurement should continue to be based on national and regional assessments of what is effective, appropriate and economically sustainable.

The current management of critical medicines, residues and shortages is administratively burdensome and cost-driving, so joint action is necessary. Financial support for safe access to

critical medicines, having joint procurement or other measures proposed will lead to increased costs for these medicines. There will be cost neutrality and the extent of the cost increase is currently unclear.

HOPE shares the view that multi-supplier agreements can strengthen access and competition, but the regulation should not limit the possibilities in member states to adapt procurement strategies to their specific conditions. HOPE would also like to emphasise that there are differences between patented medicines with only one supplier per substance and the off-patent market where there are often several alternative suppliers.

HOPE welcomes the proposal for an optional framework for joint procurement in which member states themselves can choose to participate. It is important that this complements and does not replace existing national procurement structures.

Public investments

HOPE supports the proposal to continue developing the EU-wide work on risk assessment of supply chains for critical medicines. It is crucial that national and regional authorities have access to relevant information to be able to act in potential shortage situations. This requires clear mechanisms for information sharing. At the same time, HOPE would like to emphasise that it is important that the EU measures complement and do not complicate the member states national preparedness efforts. It should remain voluntary and possible for member states to build up strategic stocks based on their own conditions.

The ambition of incentivising production in the EU is good and important for strengthening security of supply. In practice, no new financial resources will be added as the proposals are to be financed by reallocating the existing budget. Instead, the proposal places great responsibility on the member states to create structures for strategic projects financed by the member states.

HOPE also finds it difficult to see how national projects will be able to strengthen security of supply for the whole of the EU and that the requirements placed on companies that receive financial support are too vague. Incentives should be designed in a way that does not risk distorting competition or leading to inefficient use of resources. Environmental sustainability should also be an integral part of production support.

HOPE believes that public incentives to industry must be conditional on clear requirements for delivery capacity, stockholding and reinvestment in socially beneficial production. Companies receiving support should also be required to prioritise deliveries to the EU market in times of crisis.

At the same time, it is important that the criteria for what constitutes a strategic project are clear and that support is only targeted at those operations that contribute to actual redundancy in the supply chain.

Coordination at EU level

The proposal for a new steering group for critical medicines to coordinate strategic projects and joint procurement, as well as guidance on prioritisation, can improve coordination between member states. HOPE believes that it may be relevant to develop coordination between the member states, but it needs to be clearer what mandate the proposed steering group will have and how the group will be set up.

HOPE wishes to emphasise the importance of continued dialogue on implementation, collaboration between levels, including hospitals, and clear principles for transparency, division of responsibilities and sustainability. Experience from the pandemic shows that local and regional preparedness plays a crucial role in ensuring continuity of care.

HOPE, the European Hospital and Healthcare Federation, is a European non-profit organisation, created in 1966. HOPE represents national public and private hospitals associations and hospitals owners either federations of local and regional authorities or national health services. Today, HOPE is made up of 37 organisations coming from the 27 Member States of the European Union, as well as from the United Kingdom, Switzerland and Serbia as observer members. HOPE mission is to promote improvements in the health of citizens throughout Europe, high standard of hospital care and to foster efficiency with humanity in the organisation and operation of hospital and healthcare services.