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NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795 *- Policy debate*

Delegations will find in Annex a background note from the Presidency to steer the policy debate on the proposal for a Critical Medicines Act at the EPSCO Council (Health) on 20 June 2025.

ANNEX

In March 2025, the European Commission proposed the Critical Medicines Act (CMA) to improve the availability, supply and production of critical medicines within the EU. The CMA also aims to increase access to other medicines of common interest, such as those for rare diseases, and to address the fact that some medicines are not available in certain markets.

The Critical Medicines Act consists of the following components:

- **Strategic Projects** for critical medicines or their ingredients can be designated, so that they benefit from easier access to funding and fast-tracked procedures.
- **Public procurement** to incentivise the resilience of supply chains of critical medicines or to improve access to other medicines of common interest.
- **Collaborative procurement** among different Member States will be supported by the Commission at the request of Member States, to address availability and access disparities of critical medicines and other medicines of common interest.
- **International partnerships** with likeminded countries/regions will be explored, to broaden the supply chain and reduce dependencies on single suppliers.

The CMA will undoubtedly play an important role to address current supply vulnerabilities/improve availability and strengthening EU pharma sector. Financial tools and a catalogue of legislative changes should help rebuild competitiveness and influence the development of the European industry, and thus ensure access to critical medicines within the EU.

The benefits for patients that should result from the implementation of the above tasks are primarily:

- **Guaranteeing the availability** of life-saving medicines even in crisis situations, such as armed conflicts, pandemics or border closures.
- **Protecting public health** through stable supplies of medicines, also during crises.
- **Ensuring the treatment of population diseases**, even with increased demand owing to pandemics or accepting refugees in the event of armed conflicts.

In this context, we need to ensure additional and necessary financing/resources at national and EU level. Financial support should be fair and geographically diversified, also in relation to external threats, such as armed conflicts taking place near the borders of the European Union.
Financing support projects should always be carried out in the public interest. In addition, actions taken at the European level should strengthen critical supply chains to significantly reduce access problems for patients in the EU. Discussions regarding additional and necessary financial support or strengthening the supply are of fundamental importance in the context of the Critical Medicines Act.

QUESTIONS FOR DISCUSSION

- Which parts of the Critical Medicines Act do you see as particularly effective in helping to secure the supply of critical medicines in the EU? Does your Member State see elements in the proposal that could be improved or added to address the availability and supply of medicines?
- What priorities and concerns does your Member State have in relation to the proposed Critical Medicines Act?