Critical medicines. The Commission’s proposal to make supply chains more resilient

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EU AND COMPETITION LAW, PHARMACEUTICAL AND LIFE SCIENCES, PERSPECTIVES

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On 11 March 2025, the Commission proposed a Regulation[1] to improve the availability of critical medicines in Europe and to protect human health by incentivising supply chain diversification and boosting pharmaceutical manufacturing.

The Proposal finds its rationale in the fact that, over the past decade, several categories of medicines have become increasingly prone to shortages due to challenges arising along the pharmaceutical chain such as, amongst others, manufacturing hurdles and vulnerabilities in the supply of key ingredients. More particularly, the *coronavirus* pandemic and the recent geopolitical tensions, which are unfortunately ongoing, highlighted that shortages can be extremely problematic in crisis situations, where demand increases sharply, thereby putting patients' lives at risk and placing a significant stress on healthcare systems. By complementing the reform of the Union's pharmaceutical legislation and the enhanced role of the European Medicines Agency in managing shortages, the Proposal aims to reduce that risk and prevent supply chain vulnerabilities and market failures as well as coping with Europe's dependency on single suppliers and third countries.

In the first place, the Proposal defines the criteria for projects located in the Union and related to creating or increasing manufacturing capacity

[1] Com. Comm. COM(2025) 102 final of 11.03.2025, *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.*

considered as strategic. More particularly, industrial ventures could be recognised as Strategic Projects if they create, increase or modernise the European manufacturing capacity of critical medicines and their key ingredients[2]. Such Projects will be awarded incentives such as, amongst others, fast-track permit procedures, streamlined environmental assessments[3], administrative and scientific support[4] as well as easier access to EU funding[5].

In the second place, the Proposal introduces measures related to public procurement as a way to incentivise secure supply chains and make markets more attractive for manufacturers, whilst giving Member States access to a stable supply of medicines. Procurers will be expected to also apply procurement requirements other than price in their public procedures for critical medicines, such as, amongst others, criteria aimed at the diversification of sourcing of input material, and improving stockpiling and monitoring of supply chains. In case of high dependency on a single or a limited number of source-countries, however, procurers should be also encouraged to design requirements that favour critical medicine production in the Union[6]. Moreover, Member States will be required to develop national programmes to ensure secure supply of critical medicines via procurement, and, possibly, coherent pricing and reimbursement practices[7]. Finally, the Proposal provides Member States with several options to request the Commission's support in the engineering of different collaborative procurement tools for critical medicines and other medicines of common interest, depending on the context and respecting the principles of subsidiarity and proportionality[8].

In the third place, the Proposal establishes a Critical Medicines Coordination Group, composed of the Commission and Member States' representatives and whose main task will be to facilitate the application of the Regulation and enable discussions on strategic partnerships[9]. Without prejudice to the prerogatives of the Council, the Commission shall actively explore the possibility of concluding such partnerships[10].

The Proposal will now need to be discussed and approved by the Council and the Parliament, and will enter into force once the legislative process will be over.

[2] See Article 5 of the Proposal.
[3] See Article 12 of the Proposal.
[4] See Article 11 of the Proposal.
[5] See Article 16 of the Proposal.
[6] See Article 18 of the Proposal.
[7] See Article 19 of the Proposal.
[8] See Articles 21-24 of the Proposal.
[9] See Article 26 of the Proposal.
[10] See Article 27 of the Proposal.

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