

EN

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Answer given by Mr Várhelyi
on behalf of the European Commission
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Addressing medicine shortages is a priority for the Commission. The Commission's objective is to ensure that medicines are available to patients across the EU when needed. The European Medicines Agency (EMA) and its Medicines Shortages Steering Group, which includes representatives from Member States, monitor and address ongoing shortages escalated to the EU level by national authorities, including shortages of antivirals. For critical shortages unresolved at the Member State level, the Medicines Shortages Steering Group and the EMA coordinate actions to mitigate their effects as much as possible. Additionally, a Member State may request assistance from others in urgent situations under the Voluntary Solidarity Mechanism. In the past, the procedures under this mechanism have successfully led to redistributing stocks available in other EU countries.

The provisions addressing prevention of shortages under the new Pharmaceutical Regulation¹, on which co-legislators found a political agreement in December 2025, will provide a robust EU framework for managing critical shortages and improving access to medicines. Specifically, the new Regulation will strengthen early notification obligations for shortages by companies and require them to have shortage prevention plans for medicines sold under prescription. This new regulatory framework would be complemented by the Critical Medicines Act², as proposed by the Commission in March 2025, which aims to address upstream supply chain vulnerabilities and offer additional tools to enhance supply security.

¹ COM(2023) 193 final.

² COM(2025) 102 final.