EN
E-004765/2025
Answer given by Mr Várhelyi
on behalf of the European Commission
(25.2.2026)

Medicine shortages is a growing issue that poses a serious threat to patients and public health. It has been high on the EU's political agenda for years. Several legislative proposals have been introduced by the Commission to address this problem.

In March 2025, the Commission has proposed a Critical Medicines Act[1] which aims at reducing EU dependencies on third countries and single suppliers. Proposed measures include fast-tracking administrative procedures and financial support for strategic projects that will increase the EU manufacturing capacity of critical medicines, their active pharmaceutical ingredients and other key inputs.

This initiative complements the regulatory measures on shortages introduced in the reform of the pharmaceutical legislation[2]. This reform introduces concrete measures to prevent and mitigate critical shortages through EU coordinated actions, better monitoring and stronger obligations such as early notification of interruption of supply and shortage prevention plan for prescription medicines. While an EU stockpile of medicines was not considered a cost-effective measure outside crisis preparedness to tackle shortages, the Commission proposed an empowerment to impose EU-wide contingency stocks of critical medicines.

Finally, pricing and reimbursement of medicines is a national competence. Nevertheless, in the recent years, the Commission has supported the voluntary cooperation between national competent authorities on pricing and reimbursement of medicines. In this context, a new joint action gathering more than 10 countries[3] has been launched in December 2025. The three-year project aims to promote affordability, sustainability and access to medicines.

[1] 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.
[2] COM(2023) 193 final and COM(2023)192 final.
[3] Cyprus, France, Hungary, Italy, Latvia, Malta, Poland, Romania, Slovenia, Spain, Bosnia and Herzegovina.