

EN
P-001596/2025
Answer given by Mr Várhelyi
on behalf of the European Commission
(26.6.2025)

Certain medicinal products and active pharmaceutical ingredients (APIs) are imported into the EU from third countries, including the United States, and some of these imports play a critical role in the EU healthcare system.

While comprehensive data or classification of such pharmaceutical dependencies for each medicinal product is not yet available, the Commission is aware that, in specific cases, there may be limited or no immediately adequate substitutes produced within the EU. This is for instance the case for certain plasma-derived medicinal products, where supply chains are highly complex, with different stages of production processes often happening in several different countries.

Broader supply chain vulnerabilities were examined under the Structured Dialogue on security of medicines supply¹, with findings presented in the 2022 Commission Staff Working Document on the vulnerabilities of the global supply chains of medicines². In April 2023, the Commission proposed a new EU pharmaceutical legislation³, which introduces the EU-level identification of critical medicines and the analysis of the vulnerabilities in their supply chains. It also includes regulatory measures to strengthen their supply security.

To complement these efforts, the Commission adopted the proposal for a Critical Medicines Act⁴ on 11 March 2025, which proposes additional measures to reinforce EU manufacturing capacities and diversify supply sources for critical medicines. Together, these initiatives aim to increase the resilience of the EU pharmaceutical sector while supporting patient access to critical medicines.

¹ https://ec.europa.eu/health/human-use/strategy/dialogue_medicines-supply_en.

² https://health.ec.europa.eu/system/files/2022-10/mp_vulnerabilities_global-supply_swd_en.pdf.

³ COM/2023/193 final; COM/2023/192 final.

⁴ COM(2025) 102 final.