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Answer given by Mr Várhelyi
on behalf of the European Commission
(14.4.2025)

On 11 March 2025, the Commission adopted the Critical Medicines Act¹ to strengthen the availability and security of supply of critical medicines. Its main goal is to address supply chain vulnerabilities and reduce the EU's dependencies. In particular, strategic projects which create, increase or modernise EU manufacturing capacity of critical medicines, their active substances and other key inputs may benefit from easier access to funding and fast-tracked administrative, regulatory and scientific support. In addition, it incentivises the diversification and resilience of supply chains through public procurement. Collaborative procurement, including joint procurement at EU level, is also one of the tools proposed to improve the availability of critical medicines. This Act complements the regulatory measures to address shortages and improve the security of supply of medicines proposed in the reform of the EU Pharmaceutical legislation², currently under negotiation.

Furthermore, the scope of the Union Civil Protection Mechanism³ was extended in 2020 to include the stockpiling of medical counter measures aimed at combating serious cross-border threats to health, through the EU level stocks under rescEU. The Commission has invested EUR 1.65 billion in medical and chemical, biological and radio-nuclear (CBRN) stockpiles, which now offer a safety net in cases where Member States' national response capacity is insufficient. In June 2025, an EU stockpiling strategy and a medical counter measures strategy will be published, covering strategic stockpiling for medical countermeasures.

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 https://health.ec.europa.eu/medicinal-products/legal-framework-governing-medicinal-products-human-use-eu/reform-eu-pharmaceutical-legislation_en

³ https://civil-protection-humanitarian-aid.ec.europa.eu/what/civil-protection/eu-civil-protection-mechanism_en