

(English version)

**Priority question for written answer P-000606/25
to the Commission
Aurelijus Veryga (ECR)
(10 February 2025)**

Subject: Tackling medicines shortages in the EU

Addressing the issue of medicines shortages in the EU requires taking into account not only the physical shortage of medicines — caused as much by the lack of production of active pharmaceutical ingredients as by disruptions in the production of medicines themselves and the inadequate forecasting of demand — but also the relative shortage of medicines resulting from issues related to the availability of medicines at competitive prices and the reimbursement regime. In most cases, long-established and widely used medicines are considered to be critical, but occasionally new and innovative medicines with different mechanisms for ensuring accessibility should also be considered critical. The completely uneven situation and the opacity of the process lead to very different prices and timelines for inclusion in reimbursement schemes across the EU.

In 2017-2019, the Visegrad + Lithuania initiative to jointly negotiate on medicines and explore opportunities for the joint purchasing of expensive innovative medicines was implemented. The COVID-19 pandemic led to the discontinuation of this initiative. During the COVID-19 pandemic, a mechanism was put in place where not only were the prices and procurement of vaccines agreed at EU level, but Member States also contributed financially to the funding of vaccine development.

1. What measures does the Commission intend to take in the new Critical Medicines Act to ensure the affordability and availability of new and innovative medicines and medical devices?
2. Are there plans to establish a common EU procurement mechanism for innovative medicines based on the voluntary principle?
3. Is consideration being given to entrusting the coordination and implementation of public procurement at EU level to the European Medicines Agency?

Submitted: 10.2.2025

**Answer given by Mr Várhelyi on behalf of the European Commission
(13 March 2025)**

The main goal of the Critical Medicines Act will be to address supply chain vulnerabilities and reduce the EU's dependencies in order to strengthen the supply of critical medicines, and also to improve the availability and accessibility of other medicinal products of common interest, which could include new and innovative medicines.

The measures that will be proposed in the act will further address the specific concerns related to critical medicines. This will complement the proposed revision of the rules on pharmaceuticals under the EU Pharmaceutical Package.

The Commission proposal is still being prepared, so it is too early to communicate on its exact scope and content.
