

(English version)

Question for written answer E-000902/25
to the Commission
Dimitris Tsiodras (PPE)
(4 March 2025)

Subject: Ensuring availability of critical medicines and addressing shortages in ‘small markets’

Access to critical medicines varies greatly from one Member State to another due to factors such as market size. Many innovative medicines are either not on the market or they are made available after significant delays in some markets, creating inequalities between patients across the EU, with smaller Member States tending to pay higher prices. In addition, the EU faces shortages in 33 medicines ⁽¹⁾ and depends on a limited number of third-country suppliers for raw materials and active substances. The consequences of this reliance were felt during the recent COVID-19 pandemic.

In view of this, can the Commission answer the following:

1. How will it encourage the joint procurement of critical medicines and other medicines of common interest, with a special focus on ‘small markets’, and is it considering creating a voluntary joint mechanism for procurement cooperation between Member States facing similar challenges with regard to availability and access to innovative medicines and avoidance of shortages?
2. How will it encourage investment and the development of a framework that is more conducive to enhancing the EU’s production capacity?
3. What steps will it take towards reducing reliance on third-country trading partners and strengthening the security and resilience of pharmaceutical supply chains?

Submitted: 4.3.2025

Answer given by Mr Várhelyi on behalf of the European Commission
(20 May 2025)

On 11 March 2025, the Commission adopted a proposal for a Critical Medicines Act ⁽²⁾ to improve the availability of critical medicines in the EU and access to other medicines of common interest.

The proposed Act provides a framework for Member States to request Commission support, under certain conditions, to use voluntary collaborative procurement tools for critical medicines and other medicines of common interest. Such procurements would help to make smaller markets more attractive to pharmaceutical companies, improving access and availability through economies of scale.

In addition, the proposed Act supports investments for companies that increase EU manufacturing capacity of critical medicines through the designation of Strategic Projects. These industrial projects may benefit from facilitated access to funding and fast-tracked administrative, regulatory and scientific support.

The proposed Act also provides measures to reduce reliance on third countries and strengthen the security and resilience of pharmaceutical supply chains through public procurement. For critical medicines, procurers would have to include a broader set of requirements in their procurement procedures. In case of high dependency on a single or a limited number of countries, they would also have to use procurement requirements that favour critical medicines production in the EU. This would also be possible for other medicines of common interest, when justified. Finally, strategic partnerships with other countries and regions would be explored to diversify the supply chains and reduce dependencies on single suppliers.

⁽¹⁾ European Medicines Agency (EMA).

⁽²⁾ COM(2025)0102 final. 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.