

Question for written answer E-004151/2026
to the Commission
Rule 144
Stanisław Tyszka (ESN)

Subject: Critical Medicines Act – legal bases, safeguarding competition and costs for Poland

The Critical Medicines Act proposed by the Commission in March 2025 aims to strengthen the resilience of critical medicines supply chains and reduce the EU's dependence on imports of active substances from third countries. The proposal is presented primarily as a measure to regulate the internal market; at the same time, however, it introduces binding operational mechanisms relating to public procurement, the designation of strategic projects and the joint purchasing of medicines – areas directly linked to the organisation and funding of healthcare. In accordance with Article 168(7) TFEU, the organisation, management and financing of health services and medical care fall within the exclusive competence of the Member States, and the Union's actions in this area are of a purely supportive, coordinating or complementary nature.

With this in mind:

1. On what legal basis is the Commission introducing operational and binding mechanisms in an area which largely concerns the organisation of healthcare systems and which is reserved for the Member States?
2. What specific mechanisms is the Commission envisaging to ensure that the Critical Medicines Act does not favour large Western European producers at the expense of Polish generic producers, and does not restrict competition in the medicines market?
3. What is the estimated impact of the implementation of the Critical Medicines Act on the Polish healthcare budget, and does the Commission envisage any compensation or support mechanisms for Member States with lower incomes?

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