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P-001924/2024

Answer given by Ms Kyriakides
on behalf of the European Commission
(12.11.2024)

In December 2023, the Commission with Member States and the European Medicines Agency (EMA) published the first version of the Union List of Critical Medicines¹. The publication follows the commitment made in the Commission's Communication on addressing medicine shortages in the EU² to accelerate the work on this list, originally announced in the EU's pharmaceutical reform proposal.

The publication of the Union List aimed to support and expedite the analysis of vulnerabilities in the supply chains of the critical medicines. An assessment of the supply chain vulnerabilities of a first subset was published in June 2024³. On the basis of this assessment, the Critical Medicines Alliance will propose recommendations to address the identified challenges in Q1 2025, with the aim to mitigate structural risks and to reinforce supply.

Member States have the responsibility to manage shortages in their own territory. At the EU level, the Executive Steering Group on Shortages and Safety of Medicinal Products, consisting of representatives of Member States, the EMA and the Commission, monitors and responds to ongoing shortages of medicines that cannot be resolved at Member State level. If needed, Member States can deploy the Voluntary Solidarity Mechanism to redistribute stocks available in another Member State.

All these actions are taken ahead of the adoption of the new EU pharmaceutical legislation⁴, which includes stronger obligations for companies and a framework for EU coordination to manage ongoing critical shortages and enhance security of supply of critical medicines. Finally, the Commission will propose a Critical Medicines Act⁵ to tackle shortages of critical medicines and reduce the dependencies.

¹ https://ec.europa.eu/commission/presscorner/detail/en/ip_23_6377; https://health.ec.europa.eu/health-emergency-preparedness-and-response-hera/overview/critical-medicines-alliance_en

² https://commission.europa.eu/system/files/2023-10/Communication_medicines_shortages_EN_0.pdf

³ https://health.ec.europa.eu/document/download/67294e68-3a9a-4a73-8c9f-899338bac7f9_en?filename=hera_scv-critical-medicines_1t_assessment_en.pdf

⁴ https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/reform-eu-pharmaceutical-legislation_en

⁵ https://commission.europa.eu/document/download/b1817a1b-e62e-4949-bbb8-ebf29b54c8bd_en?filename=Mission%20letter%20-%20VARHELYI.pdf