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E-002365/2025

Answer given by Ms Lahbib
on behalf of the European Commission
(22.8.2025)

Critical medicine is defined as medicines for which insufficient supply may result in serious harm or risk of serious harm to patients. It is identified by combining two criteria: the seriousness of the disease concerned, and the availability of appropriate alternative treatments. A medicine must also meet additional criteria to be included in the list, such as a defined number of Member States that consider the medicine to be critical or the marketing status of the medicine.

The common methodology to draw up the list was developed with input from key stakeholder groups, including patient and healthcare professionals' organisations, and pharmaceutical industry associations. Once the proposed reform of the pharmaceutical legislation will enter into force, the methodology and Union List will be formalised.

The Union List of critical medicines is important to prioritise EU actions on security of supply, including through the measures foreseen under the proposed Critical Medicines Act. Nevertheless, medicines that are not included in the Union list may also be important for healthcare systems and the Member States and the European Medicines Agency (EMA) will continue to address the risk of supply disruptions through the existing framework for handling shortages.

In accordance with Article 168(7) of the Treaty on the Functioning of the European Union, Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care; this includes sexual and reproductive health services, including abortion and emergency contraception.