Union List of Critical Medicines – first annual update (v2.1)

Presented by Siofradh McMahon on 19 November 2025

Supply and Availability of Medicines and Devices, Regulatory Science and Innovation Task Force (TRS-SAM)

Agenda

- Union List of Critical Medicines – objectives and scope
- Overview of the first Annual Update
- Next steps

Union List of Critical Medicines

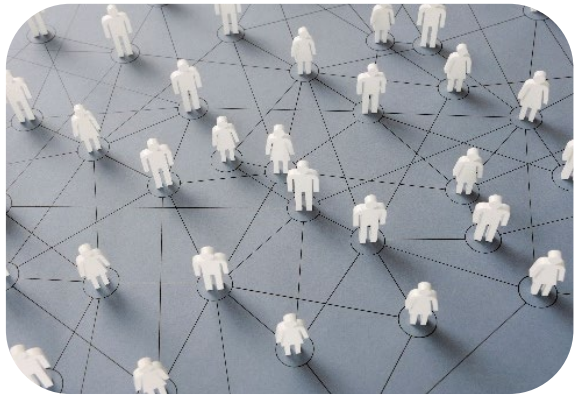
- **Key aim:** To identify **most critical medicines at Union level** that are needed to ensure functioning of health care systems
  - Supply chains of critical medicines will be assessed for vulnerabilities with the aim to reduce the risk of shortages
- **Process used to develop the list:**
  - Medicines reviewed by all member states to determine criticality based on agreed methodology (Methodology to identify critical medicines for the "Union List of critical medicines")
    - **2 criteria**: criticality of therapeutic indication; availability of alternatives
  - Stakeholders requested to comment on criticality and suggest further medicines for review
  - Final review completed by member states before list finalised
- **Annual reviews foreseen**
  - Targeted review to capture medicines where criticality or availability may have changed (e.g. due to new market developments, critical shortages, changes in indication etc)

Objectives and scope – How is the list used?

Availability

Ensure critical medicines for EU health systems are always available.

- Enable short- to medium/ long-term supply security measures.



Regulatory actions

EMA/EMRN monitor medicines on the list to minimise supply disruptions.

- Measures leverage existing processes/ structures defined by EMA's SPOC Working Party and MSSG (based on existing toolkits)

Industrial capacity/support

Industrial and structural policy recommendations for critical medicines e.g. supplier diversification, re-shoring, investment incentives, procurement agreements tied to contractual obligations for supply

Policy/legislation

Planned: The proposed EU pharma legislation revision will define additional obligations for MAHs and Member State NCAs.

Future: The Critical Medicines Act is a key priority of the Commission's mandate (complements new pharma legislation revision with industrial policy measures).

Timeline: 2025 annual update

Annual update 2025: in-scope medicines

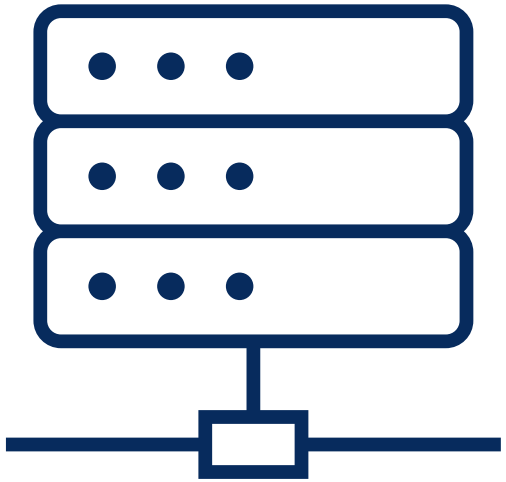
- **61 Active Substance Groups** being assessed
  - Corresponds to approximately **11k authorised medicinal products** from Article 57 database of authorised medicinal products in the Union

- Active substance groups for consideration were **proposed by member states** based on the following criteria:
  - History of critical shortages with potential criticality based on lack of available alternatives
  - New market developments **increasing** demand/criticality for particular medicine
  - New market developments **decreasing** demand/criticality for particular medicine
  - Change in indication of the authorised medicine that **increases or decreases** the previously assessed criticality

Annual updates: reminder of threshold for criticality

Reminder of prerequisites to be met (at the level of pharmaceutical form):

- Data driven threshold
  - Ensure inclusion of medicines critical at **union level**
- Absolute numbers — taking into account all MSs
  - At least 15 countries rated the pharmaceutical form as critical
- Relative numbers — taking into account the MSs where the product is marketed
  - More than two-thirds (67%) of the MSs, where the pharmaceutical form is marketed, assessed it as critical



Reminder: the Union list is intended to capture the **most critical medicines at union level;** a medicine can be essential for clinical use or for one particular country, but would not be appropriate for inclusion in the Union list (Methodology to identify critical medicines for the "Union List of critical medicines")

Stakeholder engagement for 2025 annual update

Call for input was circulated to stakeholders early October 2025	4 weeks to respond
Request to perform targeted review of outcome of member state criticality assessment	Full list of active substance groups considered was shared, along with the outcome of the member state review highlighting which active substance groups are expected to be included in the next version of the union list
No new active substance groups to be considered at this time	Future call for input planned in January 2026 for suggestions of medicines to be considered for inclusion/removal in future annual updates

Summary of stakeholder feedback received

- 15 stakeholder groups responded.

Number of substances (proportion)	Classification	Status
22 (47%)	Disagreement with inclusion/exclusion	MS are reviewing feedback
2 (4%)	Request for clarification	EMA will provide the clarification
12 (13%)	Agreement with inclusion/exclusion	No action needed
17 (36%)	Out of scope for this annual update	Stakeholders will be encouraged to participate in future annual updates

Next steps

- Feedback was shared with member states who performed the criticality assessment
  - Member states will consider whether any change is needed to their previously completed classification
  - EMA will consolidate member state feedback to finalise the updated list
- Union list of critical medicines (v2.1) adoption expected by MSSG in November
  - Publication expected December 2025

- Planning for future annual reviews is underway
  - Request for input to be circulated to stakeholders and member states in parallel January 2026 with responses by end of March 2026
  - Active substances requested to be considered **for inclusion** and **for removal**
  - Draft proposed changes circulated for stakeholder feedback Q3 2026
  - Publication of updated list targeted Q4 2026

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