EMA
EUROPEAN MEDICINES AGENCY

Union list of critical medicines: 2026 annual review status

Presented by Síofradh McMahon on 30 June 2026

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

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
  - **NB:** Front-loaded new pharmaceutical legislation activity
- **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)

Union list annual review: scope

- To ensure the Union list remains **relevant** and aligned with the evolving needs of the EU/EEA healthcare systems, it is subject to review on an **annual basis**
- The review will consider **new scientific evidence**, **changes** in **public health priorities**, emerging **supply chain challenges**, and **updates** to **EU regulatory** frameworks
- Through this collaborative and continuous process, the Union list will remain a **dynamic tool** for supporting the **security** of medicinal product supply across EU/EEA.

Medicines are expected to be added or removed whenever necessary

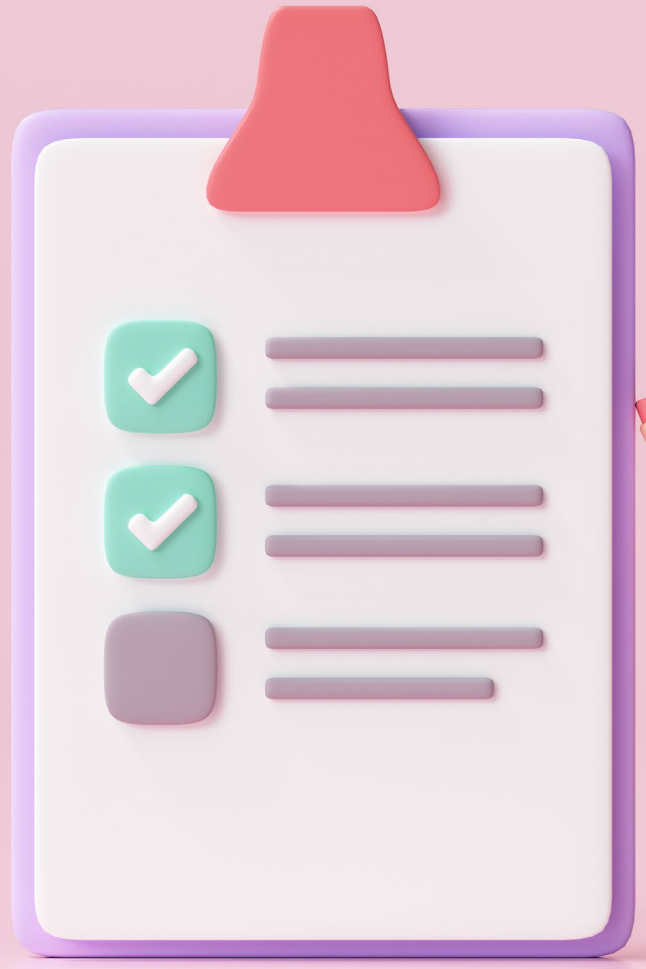
Criteria to trigger a request for review

1. The INN has been the subject of recurrent, **historical critical shortages**, already highlighted due to the **lack of available alternatives**.
2. The INN has **stopped** being the subject of recurrent, historical critical shortages, due to the number/abundance of available alternatives.
3. A change in the market dynamic:
    - **Increasing the criticality** of a medicine at **EU level**, i.e. **new market development** based on evidence.
    - **Decreasing the criticality** of a medicine at EU level.
4. A **change** in the **indication** of an authorised medicine that increases or decreases the criticality of the medicine to individual patients or to public health (linked to assessment criterion 1 of the criticality assessment “Therapeutic indication/importance”).

INN: international non-proprietary name

Annual review 2026

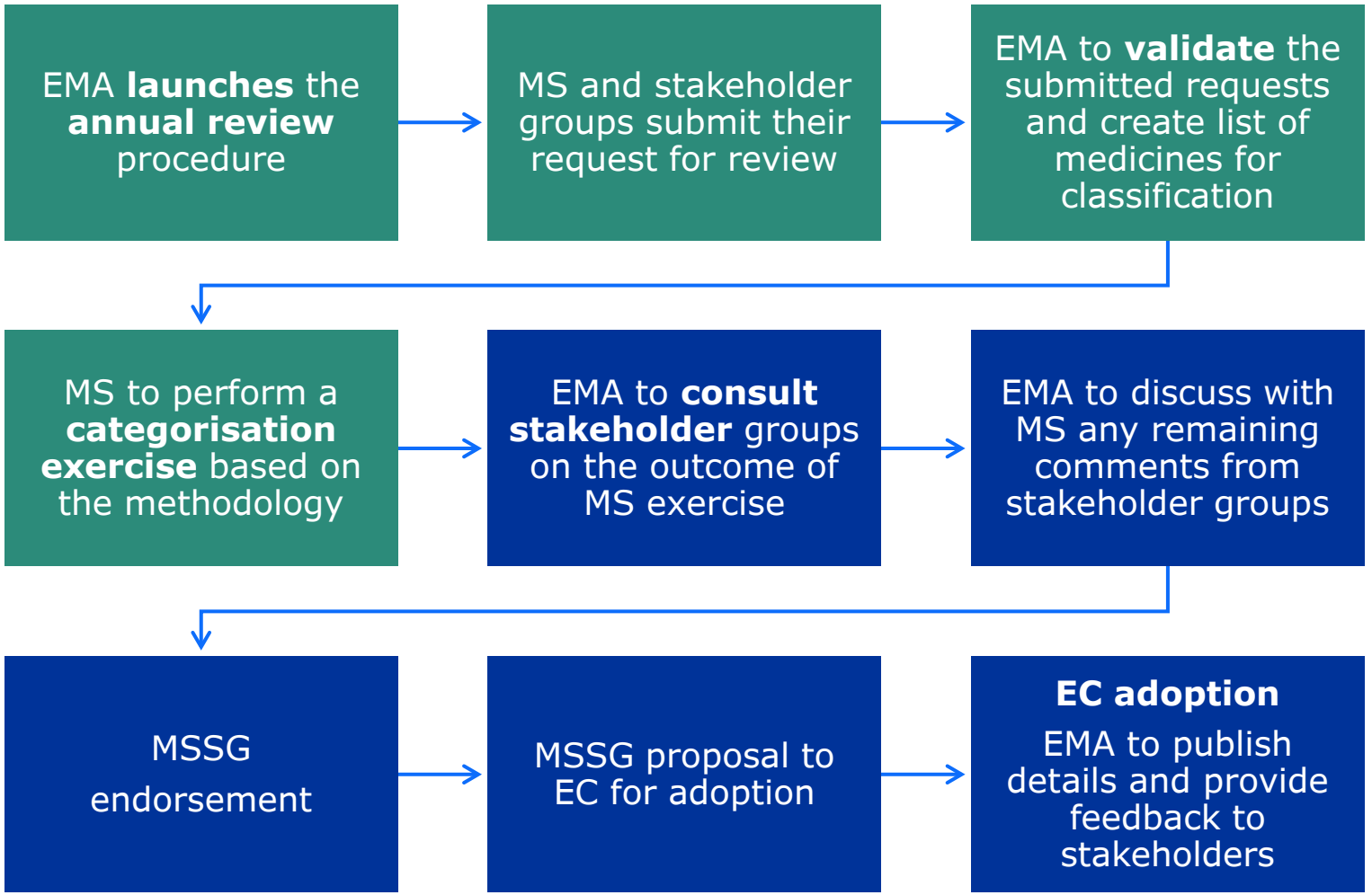
- **Launched 19 January 2026**
  - Publication of annual review methodology on EMA website
  - Direct email to stakeholders and member states in parallel, including the methodology document and templates to be used
- **Feedback received from all stakeholders by 27 March 2026**
  - Member states and stakeholders use provided templates to suggest medicines for inclusion or removal from the Union list, taking into account guidance included in the published methodology
  - EMA reviewed and consolidated all submissions and prepared data for member state classification
- **Member state classification exercise underway – deadline 31 July 2026**
  - Member states to classify all active substance groups based on Methodology to identify critical medicines for the “Union List of critical medicines"
  - Stakeholder consultation on outcome of member state classification
  - Final review completed by member states before list finalised and published on EMA website (expected December 2026)



606 single entries for classification

- Proposals for active substances for addition or removal were consolidated, and in-scope medicinal products were extracted from Article 57 database
  - Includes medicines across all therapeutic areas and populations
- Medicinal products were grouped to allow efficient classification
  - Some grouping is more challenging e.g. for radiopharmaceuticals
  - Grouping is also discussed with member states to ensure it remains appropriate
- Additional entries were included for classification to address identified data issues and ensure accuracy
- Deadline for member state classification is 31 July 2026
  - EMA will consolidate the feedback and identify the medicines to be included or removed
  - Proposed updated list will be sent to stakeholders to provide feedback before member state finalisation and proposal to EC for adoption

Union list annual review: workflow



MSSG: Medicines Shortages Steering Group

Next steps

- Member states will submit their classifications by **31 July 2026**.
  - EMA will review and consolidate the feedback to create the proposed, updated list
- Proposed updated list will be shared with stakeholders in Q3 2026 for final feedback
- Member states will confirm final outcome, and list endorsed by MSSG for proposal to EC for adoption

- *Note: final adoption of the Union list of critical medicines will be the responsibility of EC following implementation of the new pharmaceutical legislation so there may be minor changes to the final adoption and publication process in the future.*
  - *No changes are anticipated in the stakeholder input and review steps*

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