EMA
EUROPEAN MEDICINES AGENCY

# Union list of critical medicines: launch of 2026 annual review

## Joint PCWP/HCPWP meeting

Presented by Siofradh McMahon on 4 February 2026

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

# Agenda

- What is the Union list of critical medicines
- Summary of Annual review 2025
- Overview of annual review 2026
  - Process
  - Key dates
  - Expected outcomes
- Impact of the new pharmaceutical legislation implementation

# 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)

# 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

# Summary of annual review 2025

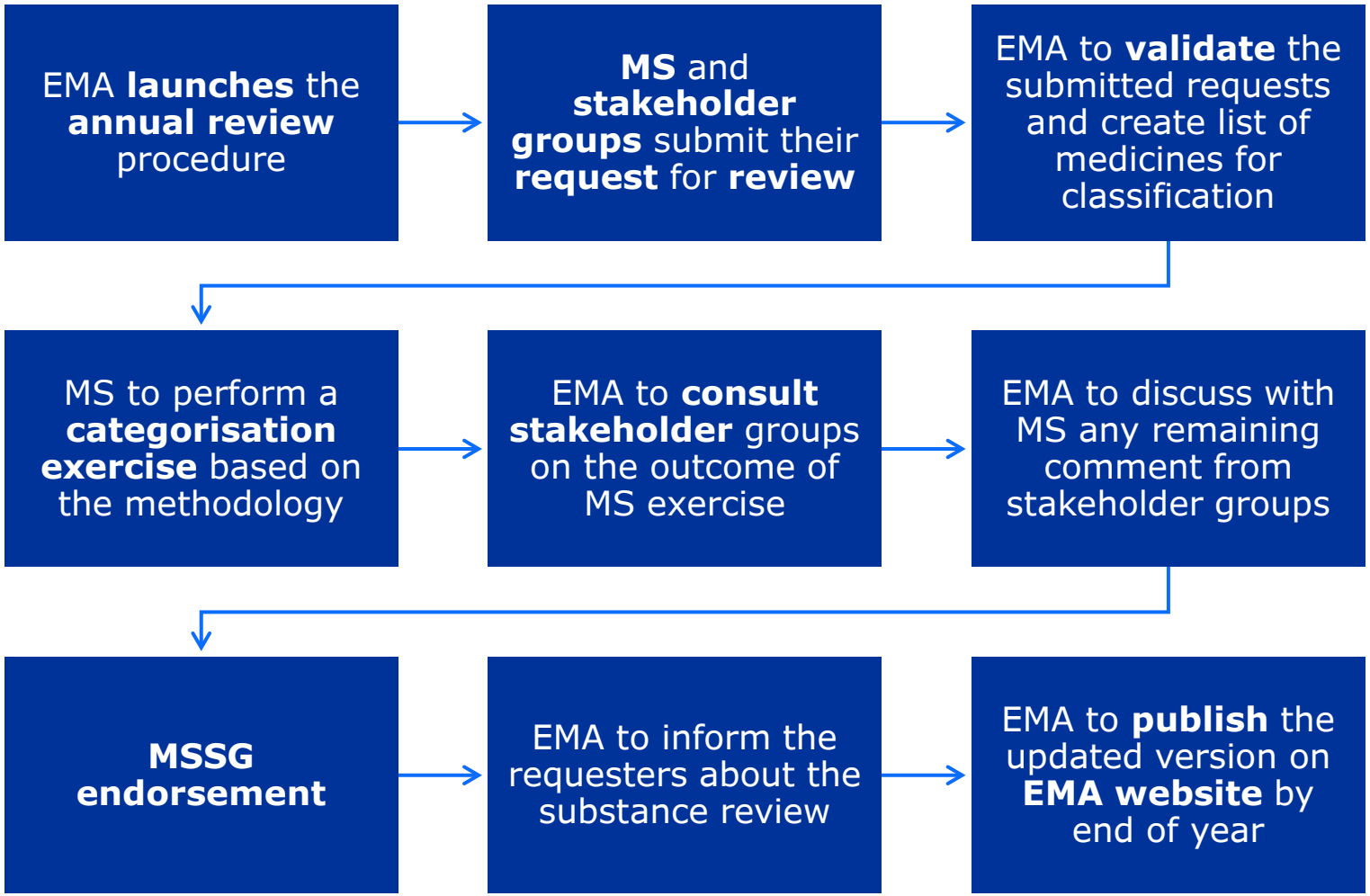
- First annual review
- Member states were asked to suggest active substances to be reviewed
- **61 Active Substance Groups** were assessed by member states
  - Outcome of this assessment reviewed by stakeholders and feedback shared with member states
- **9 active substance groups** added to the final Union list of critical medicines
  - Published December 2025 (revised January 2026 with no changes to substances included but editorial changes made to improve interoperability with other systems)
    - Union list of critical medicines | European Medicines Agency (EMA)

- Valuable feedback received from stakeholders during this first annual review helped inform the approach to all future annual reviews
  - Expanded process implemented from 2026 onwards
  - Methodology for annual reviews published on EMA website January 2026
    - Methodology for the annual review of the Union list of critical medicines

# 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
- **Process to be followed:**
  - Member states and stakeholders to use templates to suggest medicines for inclusion or removal from the Union list, taking into account guidance included in the published methodology
    - Deadline **27 March 2026**
  - EMA to consolidate all submissions and prepare for member state classification
  - 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)

# Union list annual review: workflow



# 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.

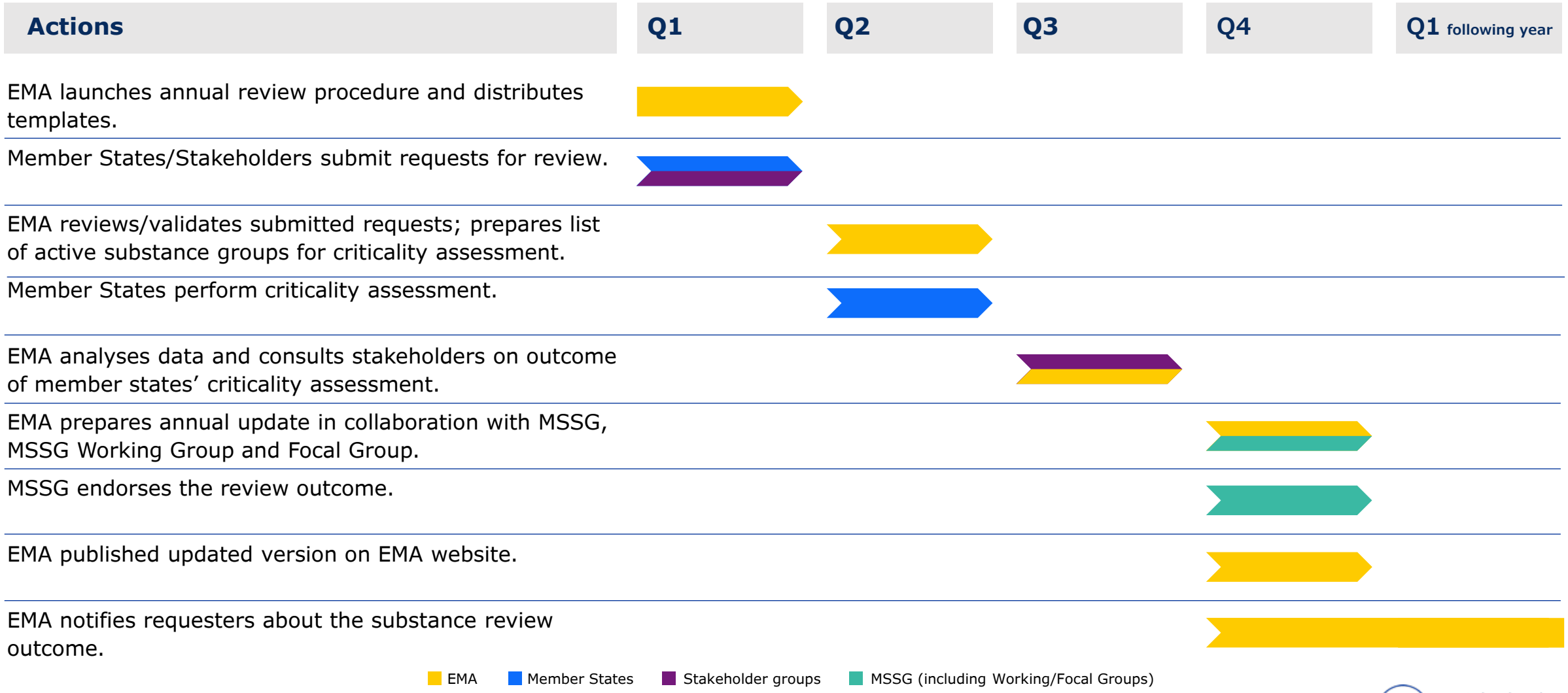
3. A change in the market dynamic:

    - **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”).

# Union list annual review: timeline



# Template for request for review: example

| International Non-proprietary Names (INN) | ATC level 5 | Route of administration *mandatory* | Rationale for inclusion *mandatory* |
|---|---|---|---|
| International Nonproprietary Names (INN) identify pharmaceutical substances or active pharmaceutical ingredients. Each INN is a unique name that is globally recognized and is public property. A nonproprietary name is also known as a generic name. | In the Anatomical Therapeutic Chemical (ATC) classification system, the active substances are divided into different groups according to the organ or system on which they act and their therapeutic, pharmacological and chemical properties. Drugs are classified in groups at five different levels. ATC level 3 and 4 are chemical, pharmacological or therapeutic subgroups; level 5 is the chemical substance. | | Please provide a detailed reasoning for the inclusion of the active ingredient in the Union list, supported by a strong clinical rationale and scientific evidence. Please consider the two criteria (therapeutic indication and availability of alternatives) for risk categorisation included in methodology of the Union list of critical medicines (EMA, 2023) to strengthen their position. |
| **INSULIN ASPART** | A10AB05 | intravenous, subcutaneous use | Example: A number of Marketing authorisation holders (MAHs) have decided to cease marketing some presentations of human insulins in all EU/EEA countries where they were previously marketed. Insulin treatment must be administered within regular dosing intervals and unavailability of these medicines can have serious implications for the health of patients. Human insulins are already included in the Union list, however considering the criticality of these medicines and the discontinuations of some human insulin products, analogue insulin medicines should be considered for inclusion in the Union list. Insulins must remain available to all patients who need them, and unavailability greatly impacts glycaemic control, risk of hypoglycaemia, and other serious complications for this patient group. Scientific evidence and strong clinical rationale that support this request for inclusion has been provided as part of this request. |

# Next steps

- MSs and stakeholders to **submit the requests** for review or removal **by Friday 27 March 2026**.
    - EMA will perform additional review of medicines to consider for removal based on changes in market dynamics and availability
- Stakeholders will be consulted again in Q3 2026 regarding the outcome of the member state classifications
- Final updated list to be published Q4 2026, and next annual review procedure will start in Q1 2027

- *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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# Thank you

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