

## HMA/EMA Task Force on Availability of Authorised Medicines (TF AAM)

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### **“Union list of critical medicines” working group**

PCWP/HCPWP meeting 3 July 2024

## Progressive release

### Phase 1 (Concluded)

Scope: **600** active substance groups reviewed (**71K** licensed medicines)

Source: leveraged existing work from **6** national lists of critical medicines

Timelines: **3** months



### Phase 2 (ends December 2024)

Scope: ~**1.6K** active substance groups subject to review (>**180 K** authorised medicines)

Source: EMA List of *Main Therapeutic Groups*, HERA MCM Catalogue, French list of essential medicines, stakeholder targeted consultation (new)

Timelines: **7** months



MCM = Medical Countermeasures

# Phase 2 rollout – delivery plan

## H1 2024

February  
2024

- Phase 2 “Go live”
- Member States reinitiate classification (3 batches)

March  
2024

- Launch of **targeted Stakeholder consultation\*** (duration: 2.5 months)
- HCPs/Pts, Learned Societies and Industry review missing substances in parallel

May  
2024

- End of stakeholder consultation
- Missing substances are reviewed & added to MSS’ review backlog

## H2 2024

September  
2024

- Member States conclude the active substance review (Batch 3)
- EMA continues data processing activities

November  
2024

- The outcome of 2nd version of the list is shared with Stakeholder Groups
- Adoption of the 2<sup>nd</sup> version by HMA and EMA Management Board

December  
2024

- EMA/HMA/EC publish the 2<sup>nd</sup> version of the Union list
- The list will be maintained annually thereafter

- **Consultation ended on June 7<sup>th</sup> (feedback being processed)**
- **33 Stakeholder groups** replied until 07/06
  - 18 Learned Societies/ Healthcare professional organisations.
  - 6 Patient/Consumer organisations.
  - 9 from Industry Trades (or individual MAHs).
- **28 Organisations** flagged circa **130 missing substances** for the criticality review.
- Policy, methodology, and implementation-level comments received
- ATC Codes of major interest raised by stakeholders:
  - ATC Code L (*Antineoplastic and immunomodulating agents*): 63 entries.
  - ATC Code C (*Cardiovascular system*): 12 entries.
  - ATC Code J (*Anti-infectives for systemic use*): 10 entries.
  - ATC Code N (*Nervous system*): 9 entries.

- **Ongoing review** of stakeholder groups feedback (July-September 2024)
  - EMA will share consolidated feedback later in October/November 2024.
- Meetings with Stakeholder groups (if required)
- Member States will **finalise the categorisation** of the active substances for **version 2** by September 2024.
- MSSG may propose (regulatory) **recommendations** for **critical medicines** from the Union list, taking into account the vulnerabilities in the supply chain to prevent shortages.
- **Maintenance** of the Union list of critical medicines (“living document”) yearly beyond 2024.

# Any questions?

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## See websites for contact details

**Heads of Medicines Agencies** [www.hma.eu](http://www.hma.eu)  
**European Medicines Agency** [www.ema.europa.eu](http://www.ema.europa.eu)

The European Medicines Agency is  
an agency of the European Union

