



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

2.1 Union list of critical medicines update

Industry Standing Group (ISG) meeting, 25 March 2024

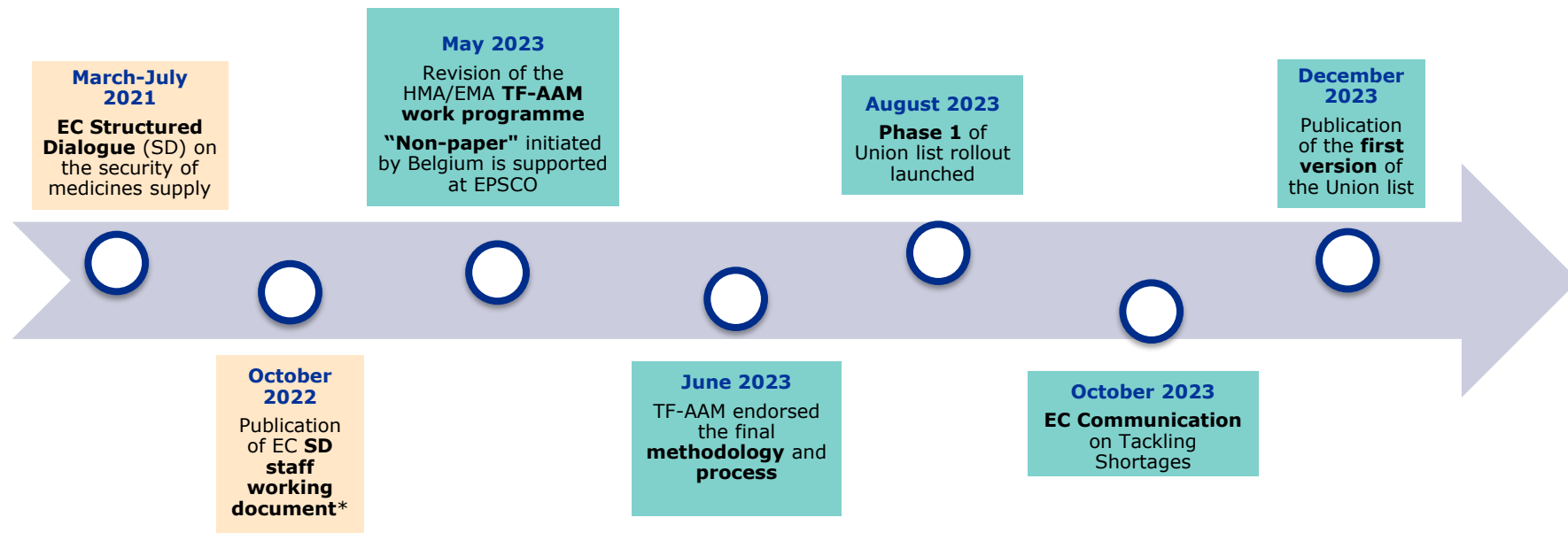
Presented by Joao Ferreira,
Supply and Availability of Medicines and Devices, Regulatory Science and Innovation Task Force (TRS-SAM)





2023 in retrospective

*HMA = Heads of Medicines Agencies
TF-AAM = Task Force on Availability of Authorised Medicines for human and veterinary use*



In **December 2023**, EMA/HMA/EC released:

1. Initial version of the list
2. Methodology adopted by the HMA/EMA TF-AAM (public-friendly version)
3. Updated EMA website page
4. Questions and answers document

- More information available in the EMA website: [Availability of critical medicines | European Medicines Agency \(europa.eu\)](https://www.ema.europa.eu/en/news/first-version-union-list-critical-medicines-agreed-help-avoid-potential-shortages-eu)



The screenshot shows the EMA website's news section. At the top, there is the EMA logo and a search bar. Below the logo is a navigation menu with items: Medicines, Human regulatory, Veterinary regulatory, Committees, News & events, Partners & networks, and About us. The main content area features a news article with a header image of various pills. The article title is "First version of the Union list of critical medicines agreed to help avoid potential shortages in the EU" and the date is "12 December 2023". The text of the article states that the European Commission (EC), the Heads of Medicines Agencies (HMA) and EMA have published the first version of the Union list of critical medicines, containing more than 200 active substances. Below the text are tags for "News", "Human", and "Medicine shortages".

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The list is an important tool to support the EU's efforts in ensuring supply security and preventing shortages of critical medicines. Inclusion in the list does not mean that the medicine is likely to experience a shortage in the near future. It means that the prevention of shortages is particularly important as a shortage could cause significant harm to patients and pose important challenges to health systems. A medicine is considered critical if it is used in serious diseases and cannot be easily replaced by other medicines, for example in case of a shortage. It is included in the Union list of critical medicines if it meets certain criteria, including being critical in more than one third of EU/EEA countries.

<https://www.ema.europa.eu/en/news/first-version-union-list-critical-medicines-agreed-help-avoid-potential-shortages-eu>

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 (throughout 2024)

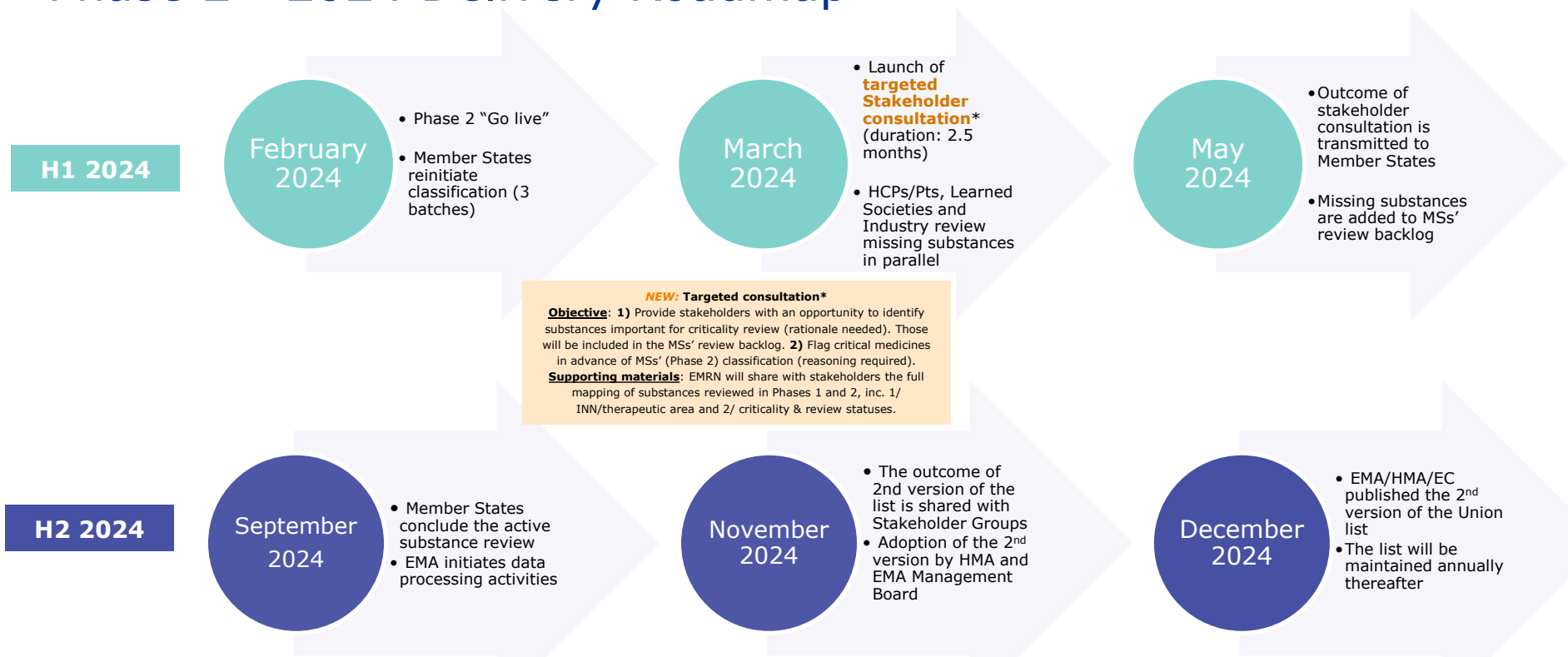
- Scope: ~**1.5K** active substance groups subject to review (>**177K** authorised medicines)
- Source: EMA List of *Main Therapeutic Groups*, HERA MCM Catalogue, French list of essential medicines.
 - Timelines: **7** months



MCM = Medical Countermeasures

Implementation: A phased release has been agreed in light of the volumes of medicines licensed in the Union (~500K)
Methodology: EU countries classify critical medicines in a harmonised manner (based on risk matrix).
Additional criteria (for medicines "to be listed"): inc. being critical in at least one-third (i.e. 10) of EU/EEA countries
Objective: Medicines on this list will be prioritised for EU-wide actions to strengthen their supply chains

Phase 2 - 2024 Delivery Roadmap





Next steps

- **Expanded review** throughout 2024 with NCAs/MoHs (Phase 2 conclusion: December 2024)
- Targeted consultation with **stakeholder groups** has been launched the w/c 18 March 2024
- EC (HERA/GROW) is currently undertaking a pilot to assess **supply chain vulnerabilities** for critical medicines until April 2024 (11 INNs will be prioritised).
- **Yearly review** and potential update of the list (“living document”) beyond 2024

*NCAs/MoHs = National Competent Authorities/ Ministries of Health
DG GROW = Directorate General for Internal Market, Industry,
Entrepreneurship and Small and Medium Enterprises
INNs = International Nonproprietary Names
MSSG = Medicine Shortages Steering Group*



Any questions?

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