EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Next phase to complete and extend the Union list of critical medicines

Joint PCWP-HCPWP meeting
28 Feb 2024

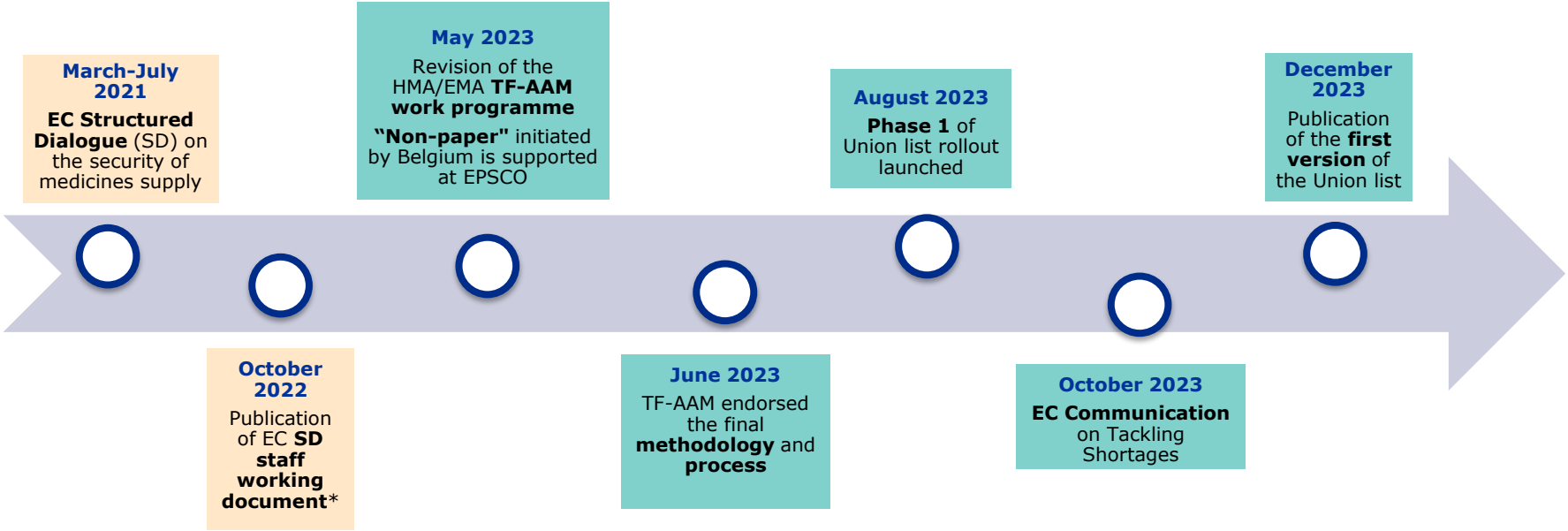
Agenda point 10. Shortages

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

Union list of critical medicines - background

2023 in retrospective

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



Staff Working Document on Vulnerabilities of the global supply chains of medicines – Structured Dialogue on the security of medicines supply (europa.eu)

Publication of the first version (outcome of Phase 1)

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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)]

Process to implement the Union list (1/2)

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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

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Phase 2 - 2024 Delivery Roadmap

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
- Outcome of stakeholder consultation is transmitted to Member States
- Missing substances are added to MSs' review backlog

NEW:* Targeted consultation

Objective: **1)** Provide stakeholders with an opportunity to identify substances important for criticality review (rationale needed). Those will be included in the MSs' review backlog. **2)** Flag critical medicines in advance of MSs' (Phase 2) classification (reasoning required).

Supporting materials: EMRN will share with stakeholders the full mapping of substances reviewed in Phases 1 and 2, inc. 1/ INN/therapeutic area and 2/ criticality & review statuses.

H2 2024

September 2024
- Member States conclude the active substance review
- EMA initiates data processing activities

November 2024
- The outcome of 2nd version of the list is shared with Stakeholder Groups
- Adoption of the 2nd version by HMA and EMA Management Board

December 2024
- EMA/HMA/EC published the 2nd version of the Union list
- The list will be maintained annually thereafter

Next steps

- Expanded review throughout 2024 with NCAs/MoHs
- Targeted consultation with stakeholder groups on missing substances will be launched in March 2024
- Until April 2024, EC (DG HERA/GROW) is currently undertaking a pilot to assess supply chain vulnerabilities for critical medicines (11 INNs will be prioritised).
  - The outcome of this work will provide the scope of the mandate of the "Critical Medicines Alliance" (CMA), which will start in April 2024.
- MSSG may propose recommendations for critical medicines with vulnerabilities to prevent shortages ultimately.
- Yearly review and potential update of the list ("living document")

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?

Further information

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Step 2: Member States categorisation exercise: methodology[1] to identify critical medicines

Categorization of medicines in three categories

Critical medicines | Medicines at risk | Other medicines

Risk classification based on two criteria (with three risk levels each)

Criterion 1

Therapeutic indication

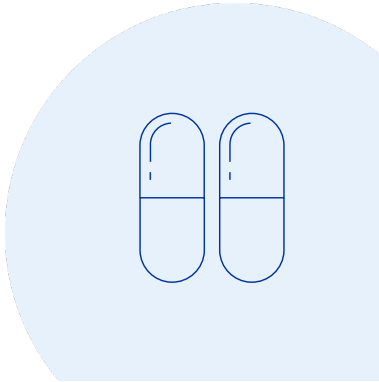
High, medium, low risk

Criterion 2

Availability of alternatives

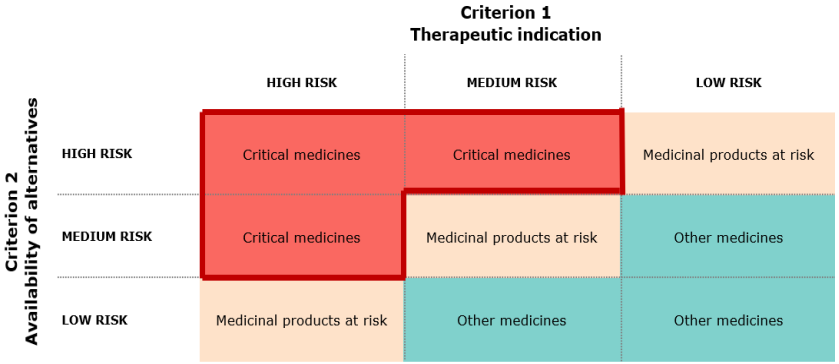
High, medium, low risk

Categorization according to a risk matrix

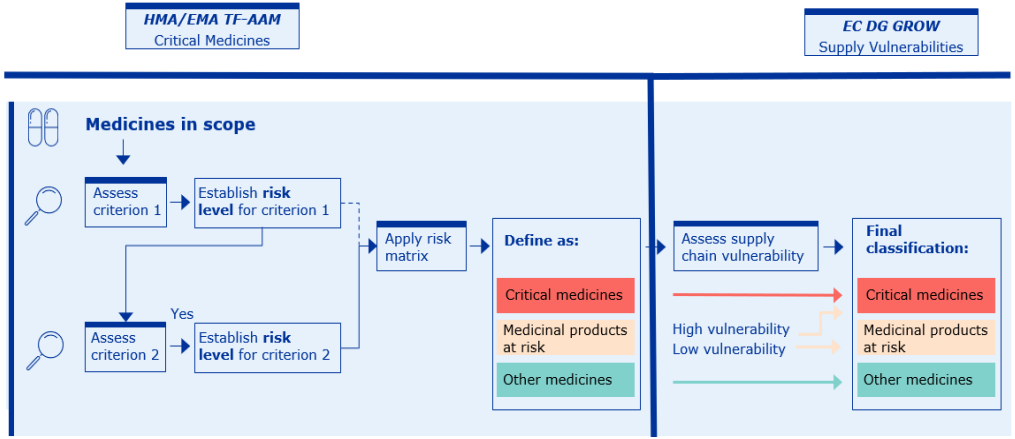


1 Methodology to identify critical medicines for the "Union List of critical medicines" (europa.eu)

Methodology: risk matrix and workflow



Risk matrix



Workflow