EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

2.1 Union list of Critical Medicines

Industry Standing Group (ISG) meeting, 23 November 2023

Agenda point 2.1

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

Outline

1. Background
2. Objectives & scope
3. Methodology
   - Criteria, risk matrix and workflow
4. Process to establish the list
5. Phase 1 outcome – *at a glance*
6. Planned Communication
7. Next steps

Background

March-July 2021

- **EC Structured Dialogue** (SD) on security of medicines supply takes place

October 2022

- Publication of EC **SD staff working document***

May 2023

- Revision of **TF-AAM work programme** to include the development of the EU list
- **"Non-paper"** initiated by Belgium is supported by many national Health Ministers at EPSO meeting.

June 2023

TF-AAM endorsed final **methodology** and agreed **process** to set up the list

August 2023

Phase 1 of EU list rollout launched

October 2023

Member State categorisation **deadline** (Phase 1)

EC Communication on Tackling Shortages

December 2023

Planned publication of the **first version** of the Union list (Phase 1 outcome)

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

Objectives & scope (1/2)

1. Ensuring medicines considered most **critical for health systems** are always available.

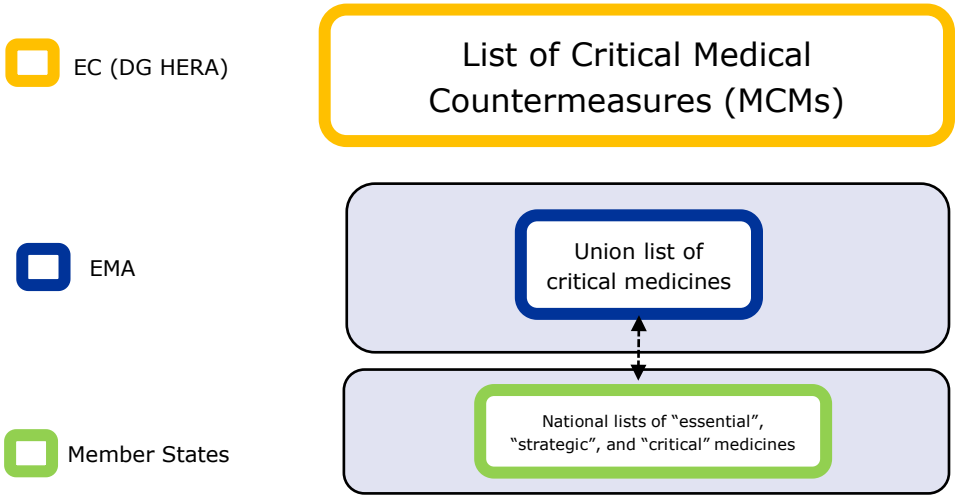
2. Provide **industrial capacity/ support** where medicines' supply chain vulnerabilities and dependencies are identified.

3. Enable Short- to Medium[1*] and long-term[2*] **Supply Security measures**

1. Suppliers' diversification or increase production within the EU,
2. Investment incentives,
3. Additional regulatory obligations for companies,
4. Procurement with strong contractual obligations for delivery.

1) October 23 - EC Communication in addressing critical shortages of medicines in the EU (short-/medium-term proposals): https://ec.europa.eu/commission/presscorner/detail/en/ip_23_5190
2) April 2023 - Proposal for Regulation (long-term proposals): https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023PC0193

Objectives & scope (2/2)



Methodology: criteria

Categorization of medicines in three groups

Critical medicines | Medicines at risk | Other medicines

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

Criterion 1

Therapeutic indication

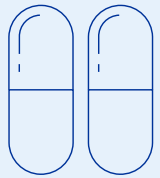
High, medium, low risk

Criterion 2

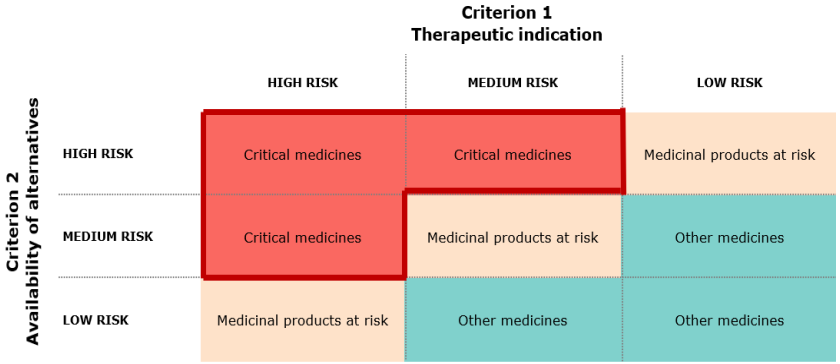
Availability of alternatives

High, medium, low risk

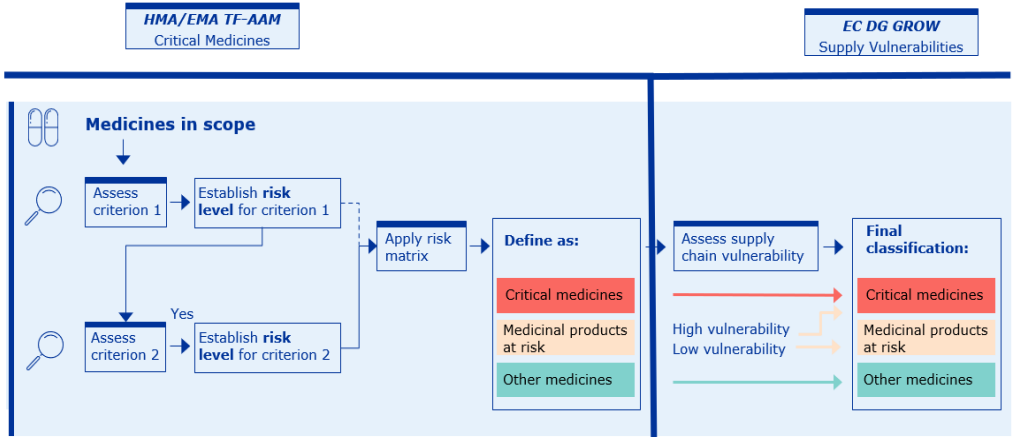
Categorization according to a risk matrix



Methodology: risk matrix and workflow



Risk matrix



Workflow*

Continuous review: Methodology can be fine-tuned while EU list evolves.

** Supply chain vulnerabilities assessment to be undertaken by DG GROW*

Process to establish the list

Progressive release: Considering the volumes of authorised medicines in the Union (~500k) the "Union list of critical medicines" is being released in 2 phases:

Phase 1

Release of first version, based on (6) national lists of critical medicines

(planned release: **December 2023**)

Phase 2

Release of subsequent versions, prioritising review of therapeutic groups of major interest

(planned release: **throughout 2024**)

Maintenance: The EU list of critical medicines will be a "living document" and subject to continuous review and potential refinement.

Phase 1 outcome – initial version *at a glance* (1/2)

National clinical experience

- Leverages work from 6 existing national lists
- Starting point:
  600 active substances/ combinations
  = 71K medicines

Member State review timelines

- August – October 2023
  (3 months)
- 2 batches subject to review

EU-wide data analysis

- 29 EU/EEA countries reviewed data sets
- Medicines included if critical in at least 1/3 of EU/EEA countries

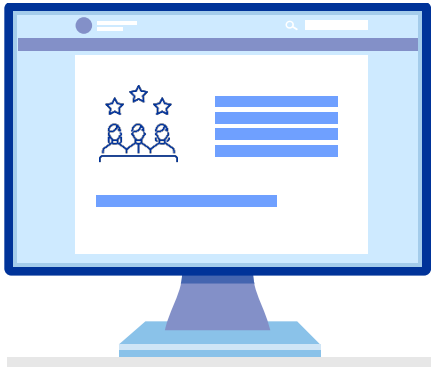
Projected figures

- 240+ active substances and combinations

Planned communication

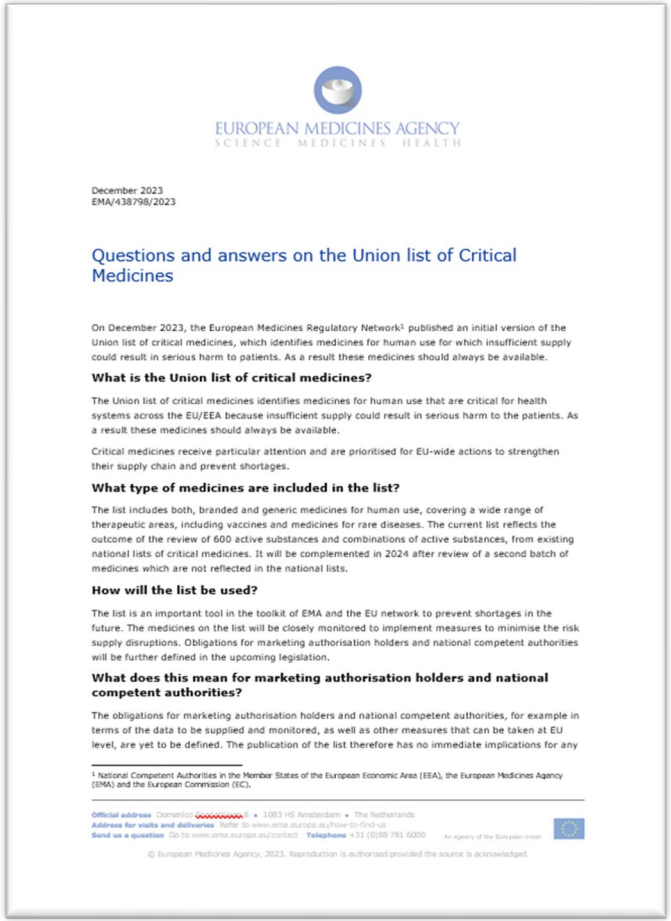
Communication package (5 items):

1. Initial version of the list (outcome of Phase 1)
2. Methodology adopted by the HMA/EMA TF-AAM (public-friendly version)
3. “Union list” EMA & HMA website sections
4. The news item/press release
5. FAQ document



Questions & Answers

- What is the Union list of critical medicines?
- What type of medicines are included in the list?
- How will the list be used?
- What does this mean for marketing authorisation holders and national competent authorities?
- What does the list mean for patients and healthcare professionals?
- How was the Union list drawn up?
- Were stakeholders involved in the list?
- Will the list replace national lists of critical medicines?



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

December 2023
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Questions and answers on the Union list of Critical Medicines

On December 2023, the European Medicines Regulatory Network[1] published an initial version of the Union list of critical medicines, which identifies medicines for human use for which insufficient supply could result in serious harm to patients. As a result these medicines should always be available.

What is the Union list of critical medicines?

The Union list of critical medicines identifies medicines for human use that are critical for health systems across the EU/EEA because insufficient supply could result in serious harm to the patients. As a result these medicines should always be available.

Critical medicines receive particular attention and are prioritised for EU-wide actions to strengthen their supply chain and prevent shortages.

What type of medicines are included in the list?

The list includes both, branded and generic medicines for human use, covering a wide range of therapeutic areas, including vaccines and medicines for rare diseases. The current list reflects the outcome of the review of 600 active substances and combinations of active substances, from existing national lists of critical medicines. It will be complemented in 2024 after review of a second batch of medicines which are not reflected in the national lists.

How will the list be used?

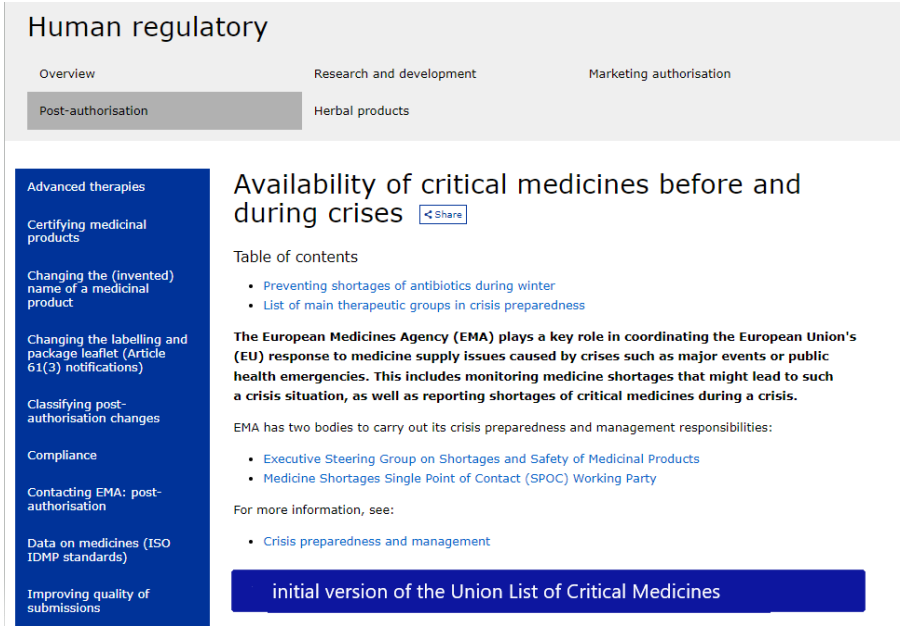
The list is an important tool in the toolkit of EMA and the EU network to prevent shortages in the future. The medicines on the list will be closely monitored to implement measures to minimise the risk supply disruptions. Obligations for marketing authorisation holders and national competent authorities will be further defined in the upcoming legislation.

What does this mean for marketing authorisation holders and national competent authorities?

The obligations for marketing authorisation holders and national competent authorities, for example in terms of the data to be supplied and monitored, as well as other measures that can be taken at EU level, are yet to be defined. The publication of the list therefore has no immediate implications for any

[1] National Competent Authorities in the Member States of the European Economic Area (EEA), the European Medicines Agency (EMA) and the European Commission (EC).

Union list vs other lists



Topic	Name of List	Responsible body	Scope	Purpose
Security of supply	Union list of critical medicines	EMA/HMA	Medicines (active ingredients) critical for public health at the EU level	Support tracking of EU manufacturing capacity and ensure security of supply and availability of critical medicines at EU level.
Crisis preparedness	List of main therapeutic groups of medicines	MSSG	Main therapeutic groups that are necessary for emergency care (hospital setting)	This list informs the preparation of critical medicines lists for a public health emergency and major event.
Crisis response	List of critical medicines for a major event	MSSG	Medicines authorised for the major event	To ensure supply of medicines relevant for the major event. Medicines on the list will be subject to close monitoring of supply and demand.
	List of critical medicines for a public health emergency	MSSG	Medicines authorised for the public health emergency	To ensure supply of medicines relevant for the public health emergency. Medicines on the list will be subject to close monitoring of supply and demand.

Next steps

- Engagement with PCs/HCPs & Industry during platform meetings in Q4 2023
- HMA& EMA Management Board will adopt the first version by December 5th
- Release of the first version of the EU list of critical medicines based on published national lists of critical medicines (Phase 1), planned for w/c December 11th 2023
- EU list of critical medicines to be a living document, subject to continuous review and potential update.
- List will expedite the EC's exercise to analyse the supply chain of critical medicines to determine potential vulnerabilities.

Any questions?

Further information

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