Union list of Critical Medicines

PCWP/HCPWP and all eligible organisations meeting

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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. Next steps
7. Planned Communication

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.

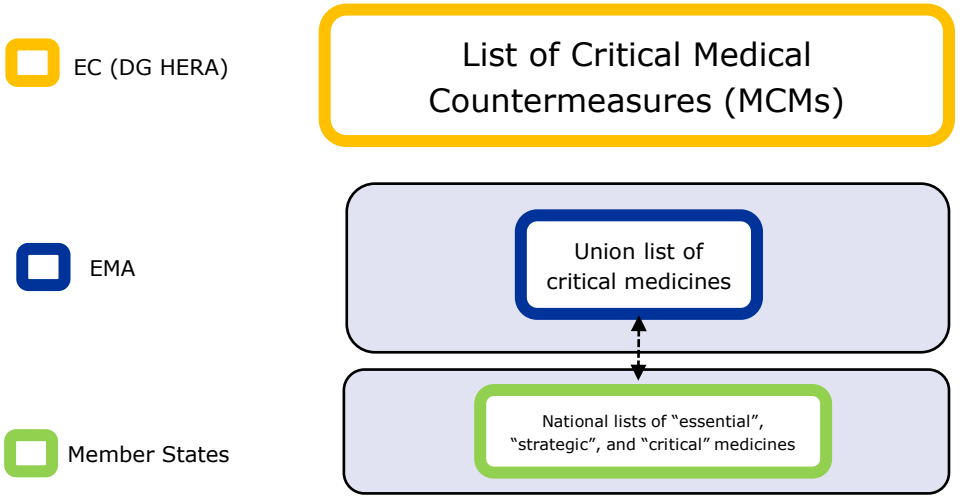
2. Provide **industrial capacity/ support** where medicines' supply chain vulnerabilities and dependencies are identified.

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

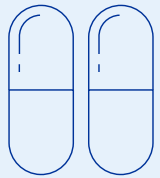
High, medium, low risk

Criterion 2

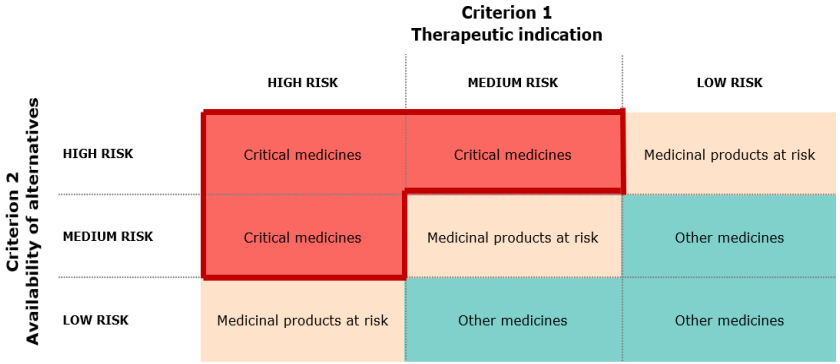
Availability of alternatives

High, medium, low risk

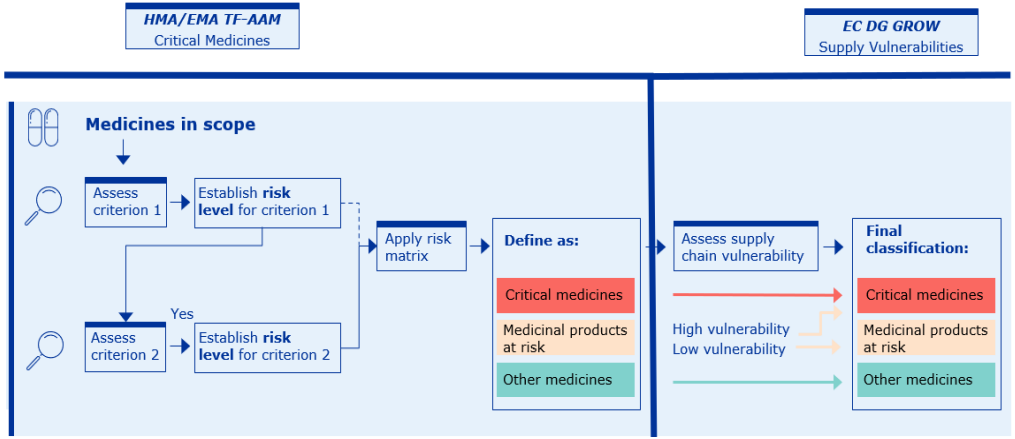
Categorization according to a risk matrix



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*

Clinical National 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

- 200-220 active substances and combinations

Requirements

- No obligations to MAHs immediately
- Applicable when EU law comes into effect

What does the list mean for patients and healthcare professionals?

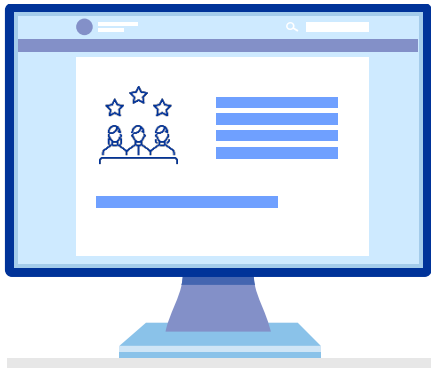
- The list is an important tool in the **toolkit** of EMA and the EU network to prevent shortages in future.
- There is **no action needed** from patients and healthcare professionals as a result of the publication of the list.
- Medicines on the list can continue to be prescribed and used as usual.

Next steps

- Engagement with PCs/HCPs & Industry during platform meetings in Q4 2023
  - Expanded stakeholder consultation is planned for Phase 2.
- 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.
  - In a second phase, additional INNs will be categorised and analysed from January 2024.
- List will expedite the EC's exercise to analyse the supply chain of critical medicines to determine potential vulnerabilities.

Planned communication

- Publication of methodology and list planned for: week c/11 December 2023 (tbc)
- Joint EMA/HMA & EC press release with dedicated Q&A
- Web update



Key messages for communication material

What's new

List identifies medicines for which **no alternatives** are available and for which insufficient supply could result in **serious harm**. The medicines should always be available and prioritised for shortage prevention actions.

Progressive release: List reflects **initial review** of 600 active substances from six national lists of critical medicines. Review to continue through 2024.

The review carried out with **all EU member states**. Criticality assigned based on methodology agreed with **key stakeholder groups.**

There is no impact on existing **national lists** and the Union list will support the network's efforts in drawing up national lists where these doe not exist.

Key messages (cont.)

List will expedite European Commission's **analysis of supply chain** of critical medicines to determine potential vulnerabilities. For medicines with vulnerable supply chain measures can then be taken to better anticipate and mitigate shortages.

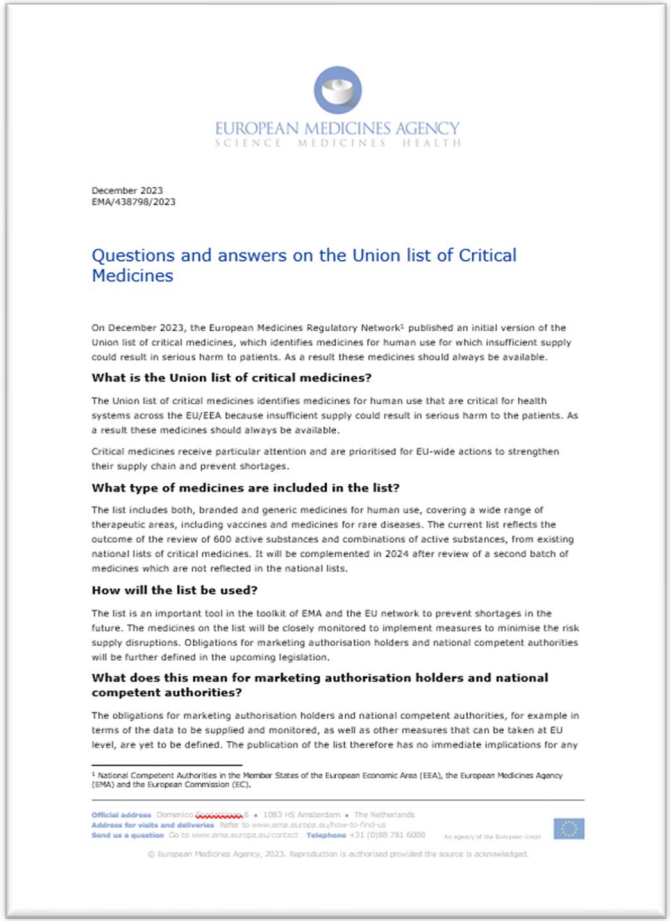
Medicines are included in list if critical in at least **one third** of EU/EEA countries.

Currently no obligations on marketing authorisation holders and national competent authorities.

Reporting requirements will be set and become mandatory once the **new legislation** is adopted.

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
EMA/438798/2023

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).

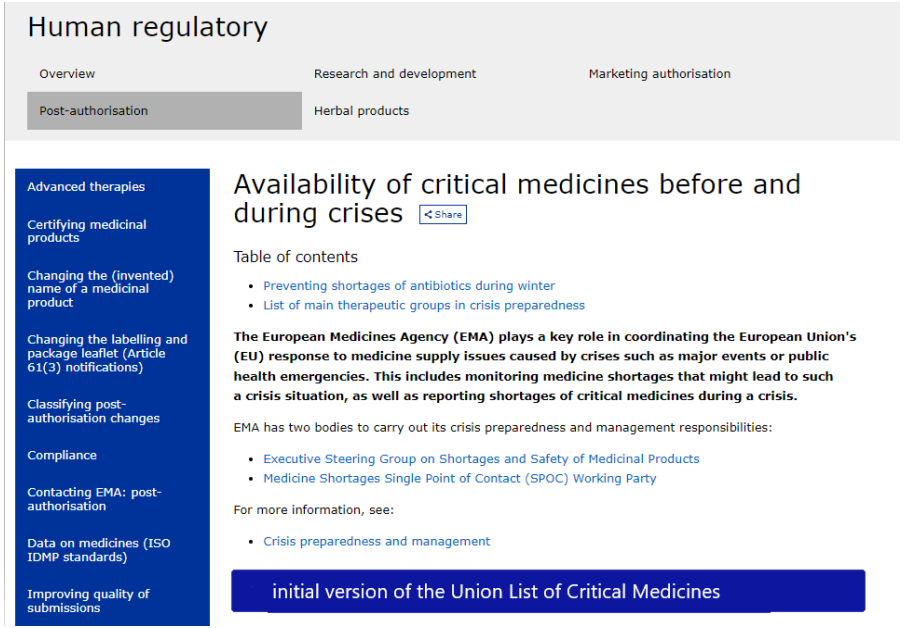
Questions and Answers (cont.)

- Will the publication of the list lead to fewer shortages?
- What is the difference between a critical medicine and a critical shortage?
- The Union list does not include some medicines that are included on national lists of critical medicines – why not?
- The Union list does include some medicines that are not included on a particular national lists of critical medicines – why?
- Are medicines from the WHO list of essential medicines automatically included in the Union list?

Questions and Answers (cont.)

- Why are only few orphan medicines included in the list?
- When will the list be complete?
- How will the list be maintained?

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.

Feedback

Are the messages clear?

Are there any questions or messages missing?

Volunteers for closer review?

Any questions?

Further information

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