EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EU list of Critical Medicines

PCWP/HCPWP joint meeting
19 September 2023

Presented by Joao Ferreira
Supply and Availability of medicines and devices, EMA

Outline

1. Background
2. Objectives & scope
3. Methodology
   - Criteria, risk matrix and workflow
4. Process to establish the list
5. Status update (as of 18 September 2023)
6. 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***

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

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

Objectives & scope (1/2)

1. Ensuring medicines considered to be most **critical for health systems** are available at all times.

2. Critical medicines may be subject to coordinated Union level actions to **improve security of supply**.

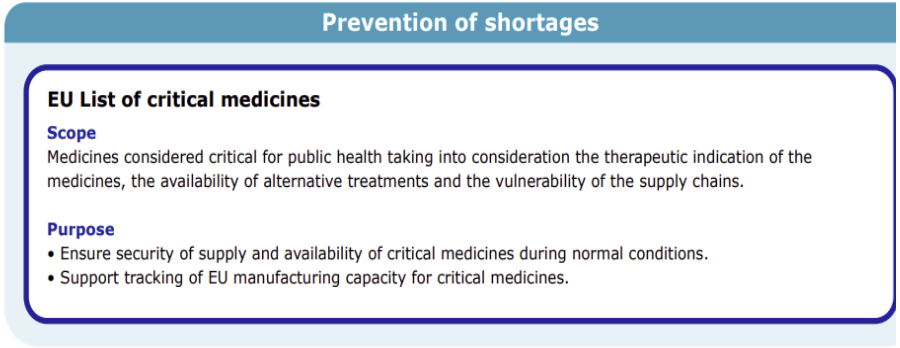
3. Provide **industrial capacity/ support** where medicines' supply chain vulnerabilities and dependencies are identified.

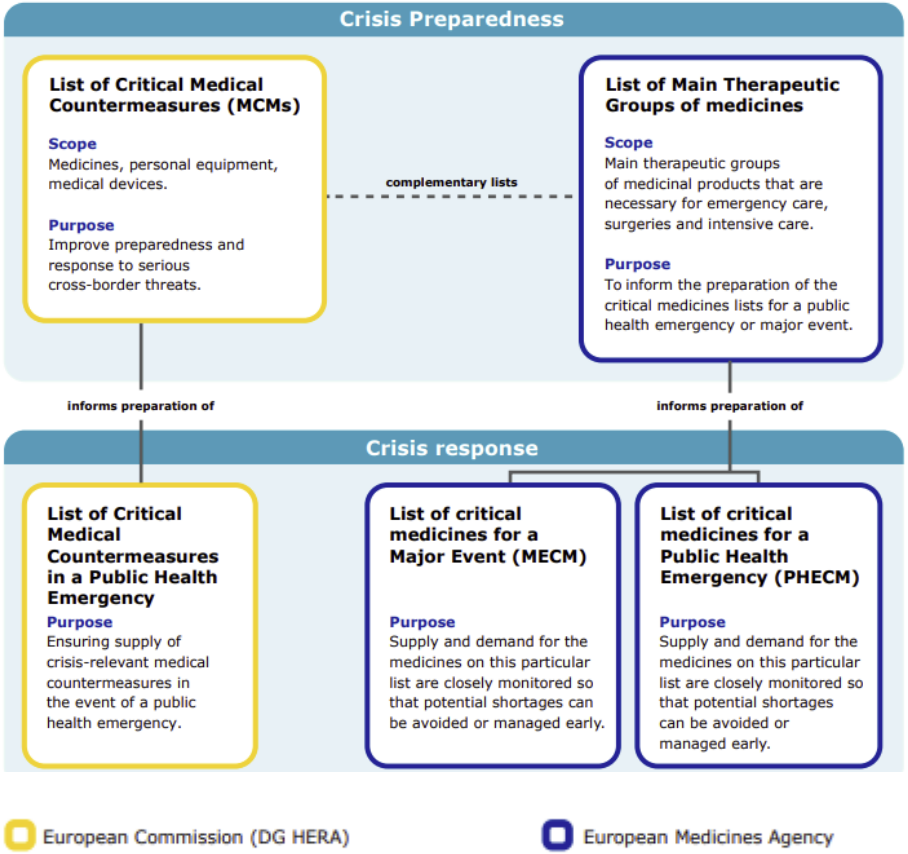
4. Security of supply measures may include **recommendations to Industry** on *"diversification of suppliers and inventory management"*

*Proposal for Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023PC0193

Objectives & scope (2/2)

- Visualising the scope of the ***NEW*** "EU list of critical medicines"





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

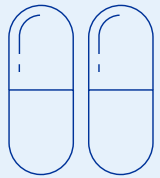
High, medium, low risk

Criterion 2

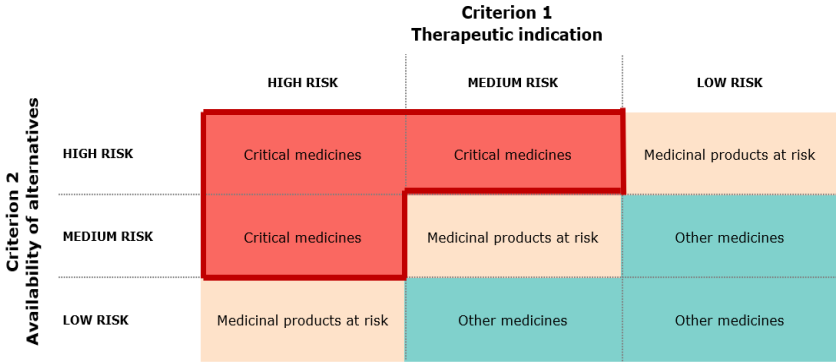
Availability of alternatives

High, medium, low risk

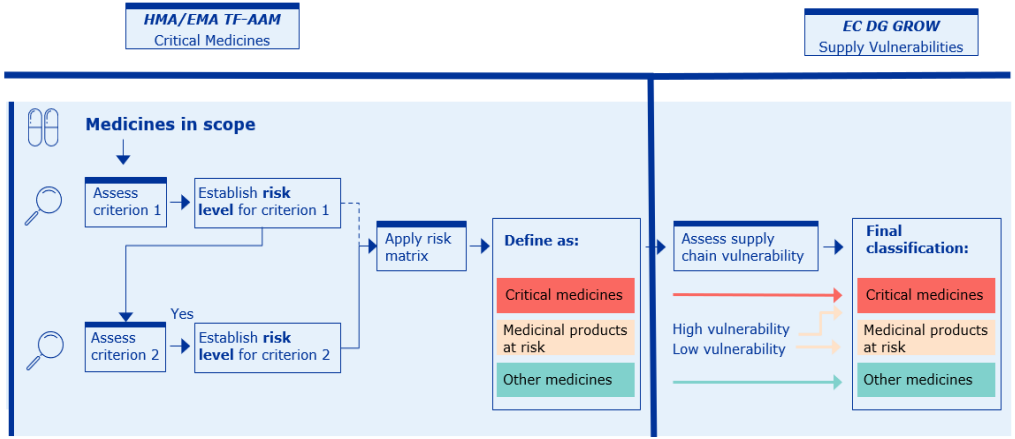
Categorization according to a risk matrix



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*

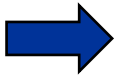
Process to establish the list

Staggered release: the "EU list of critical medicines" will be released in 2 phases:

Phase 1

Release of first version, based on published national lists of critical medicines or lists currently under development

(planned release: **Q4 2023**)



Phase 2

Release of subsequent versions, prioritising review of therapeutic groups of major interest (ATC code-led review)

(planned release: **2024**)

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

Next steps

- Continue engagement with PCs/HCPs & Industry during platform meetings in Q3/Q4 2023
- Release of first version of the EU list of critical medicines based on published national lists of critical medicines (Phase 1), expected before the end of this year
- EU list of critical medicines to be a living document, subject to continuous review and potential update.

Any questions?

Further information

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Telephone +31 (0)88 781 6000
Send us a question Go to www.ema.europa.eu/contact

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Criteria and risk levels

Therapeutic indication (criterion 1)

HIGH

- **Indications with very serious implications:** general life-threatening acute conditions, specific life-threatening acute conditions, or irreversibly progressive conditions.
- **The treatment must be administered immediately** or within regular dosing intervals.
- The product is as part of a national disease control program (vaccination campaign).

MEDIUM

- **Indications with serious implications:** chronic, severely limiting diseases, vulnerable patient groups (e.g., pediatric medicines).
- **If the disease is left untreated**, it may induce potentially irreversible disease progression or hospitalization or intensified treatment, but no fatality is expected.

LOW

- **Other indications**.
- A medicinal product should be allocated to the "low-risk" level if it does not fulfil any of the above-mentioned conditions for "high" or "medium" risk.

Availability of alternatives (criterion 2)

HIGH

Quantitative risk-classification:

- **No** appropriate alternative available; OR,
- **Only one** appropriate alternative (product) on ATC level 4 or 5.

Qualitative risk-classification:

- Alternative treatment is **not clinically possible**.
- Alternative treatment would **require extensive clinical consultations**, not applicable for high-risk indications
- Alternative treatment is **not available**.

MEDIUM

Quantitative risk-classification:

- **At least two** appropriate alternatives (products) on ATC level 4 or 5

Qualitative risk-classification:

- Alternative treatment is clinically possible **but requires input from medical personnel**.
- Alternative treatment is available in **limited quantities**.
- Substitution of treatment is **not expected to affect** patient safety or disease prognosis

LOW

Quantitative risk-classification:

- **More than two** appropriate alternatives (products) available on ATC level 4 or 5

Qualitative risk-classification:

- Alternative treatment is clinically possible and **requires little to no input** from medical personnel.
- Alternative treatment is readily available, **and no supply issues are expected** due to increased demand.