EU list of Critical Medicines

ISG meeting
21 September 2023

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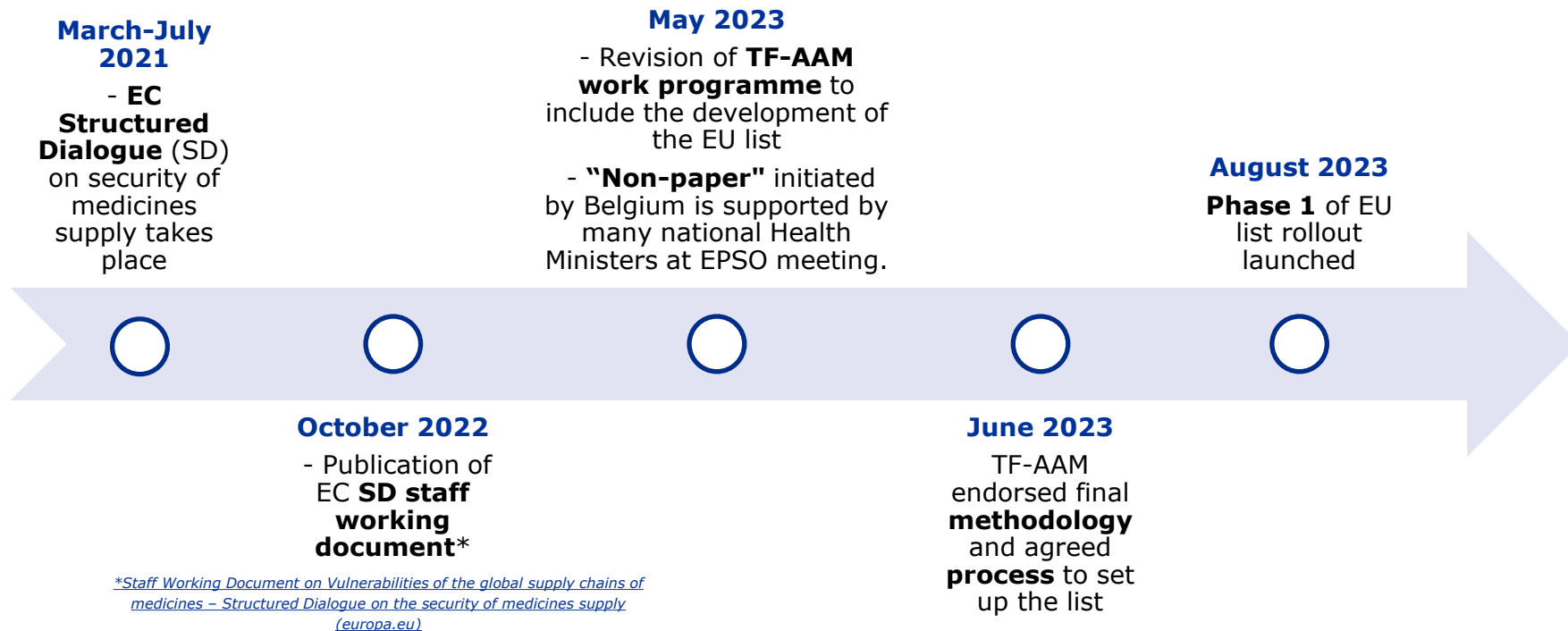
Outline

1. Background

2. Objectives & scope

3. Methodology

   ▪ Criteria, risk matrix and workflow

4. Process to establish the list

5. Next steps

Background

March-July 2021

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

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.

August 2023

Phase 1 of EU list rollout launched

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)

June 2023

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

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"

Prevention of shortages

EU List of critical medicines

Scope
Medicines considered critical for public health taking into consideration the therapeutic indication of the medicines, the availability of alternative treatments and the vulnerability of the supply chains.

Purpose
- Ensure security of supply and availability of critical medicines during normal conditions.
- Support tracking of EU manufacturing capacity for critical medicines.

Crisis Preparedness

List of Critical Medical Countermeasures (MCMs)

Scope
Medicines, personal equipment, medical devices.

Purpose
Improve preparedness and response to serious cross-border threats.

complementary lists

List of Main Therapeutic Groups of medicines

Scope
Main therapeutic groups of medicinal products that are necessary for emergency care, surgeries and intensive care.

Purpose
To inform the preparation of the critical medicines lists for a public health emergency or major event.

informs preparation of

informs preparation of

Crisis response

List of Critical Medical Countermeasures in a Public Health Emergency

Purpose
Ensuring supply of crisis-relevant medical countermeasures in the event of a public health emergency.

List of critical medicines for a Major Event (MECM)

Purpose
Supply and demand for the medicines on this particular list are closely monitored so that potential shortages can be avoided or managed early.

List of critical medicines for a Public Health Emergency (PHECM)

Purpose
Supply and demand for the medicines on this particular list are closely monitored so that potential shortages can be avoided or managed early.

☐ European Commission (DG HERA)   ☐ European Medicines Agency

4

EU list of Critical Medicines: status update

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

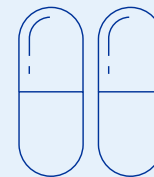Therapeutic indication

High, medium, low risk

Criterion 2
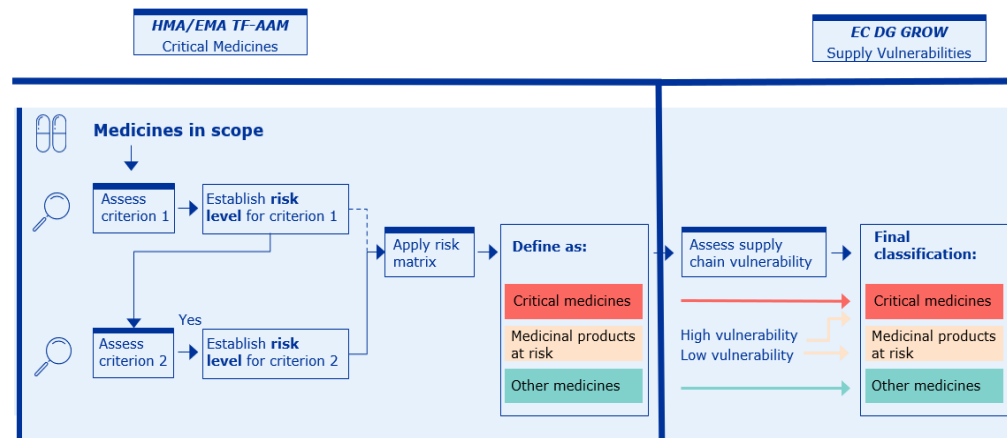
Availability of alternatives

High, medium, low risk

→ *Categorization according to a risk matrix*

Methodology: risk matrix and workflow

Risk matrix

Workflow*

<u>Continuous review</u>: Methodology can be fine-tuned while EU list evolves.

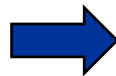** Supply chain vulnerabilities assessment to be undertaken by DG GROW*

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 Industry (ISG 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

Follow us on @EMA_News