Council of the European Union
General Secretariat

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MEETING DOCUMENT

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (Attachés) Working Party on Pharmaceuticals and Medical Devices (Critical Medicines Act)
Subject:	Meeting of the Working Party on Pharmaceuticals and Medical Devices - Presentation by the European Medicines Agency

Delegations will find attached the presentation given by the European Medicines Agency on vulnerability analyses at the meeting of the Working Party on Pharmaceuticals and Medical Devices on 3 September 2025.

EMA
EUROPEAN MEDICINES AGENCY



Update on EMA/MSSG work on vulnerability analyses in the context of the pharmaceutical package

Head of Supply and availability of medicines and devices, EMA

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Provisions in the pharma package

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Tasks for EMA (with support of MSSG and SPOC WP) outlined in pharma package

FRONTLOADED AND PUBLISHED



Develop a methodology to identify critical medicinal products and establish a Union list of critical medicines

FRONTLOADED AND IN PROGRESS



Develop a methodology to evaluate vulnerabilities in the supply chain of products on the Union list



Identify vulnerabilities in the supply chain of critical medicines

Implications on Critical Medicines Act Provisions

- Identification of vulnerabilities at the aggregated level
- Review and/or update of existing evaluations

Purpose: improving availability and securing supply of critical medicines in the EU by identifying supply chain vulnerabilities (especially for critical medicines)

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Union List of Critical Medicines

- Background
- Methodology
- Annual Update
- Figures
- New provisions in the pharma package



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Union list of critical medicines: background

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March–July 2021

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

October 2022

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

June 2023

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

December 2023

Publication of first version of the Union list of critical medicines

December 2024

Release of second version of the Union list of critical medicines***

* *Vulnerabilities of the global supply chains of medicines*
** *Methodology to identify critical medicines for the "Union List of critical medicines"*
*** *Union list of critical medicines | European Medicines Agency (EMA)*

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Union list of critical medicines: methodology

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1) Criteria: for assignment of risk levels (low, medium and high)

1. Therapeutic indication

2. Availability of alternatives

2) Risk matrix: categorisation of medicines under three different groups

Availability of alternatives	Therapeutic indication: High risk	Therapeutic indication: Medium risk	Therapeutic indication: Low risk
High risk	Critical medicines	Critical medicines	Medicinal products at risk
Medium risk	Critical medicines	Medicinal products at risk	Other medicines
Low risk	Medicinal products at risk	Other medicines	Other medicines

3) Threshold

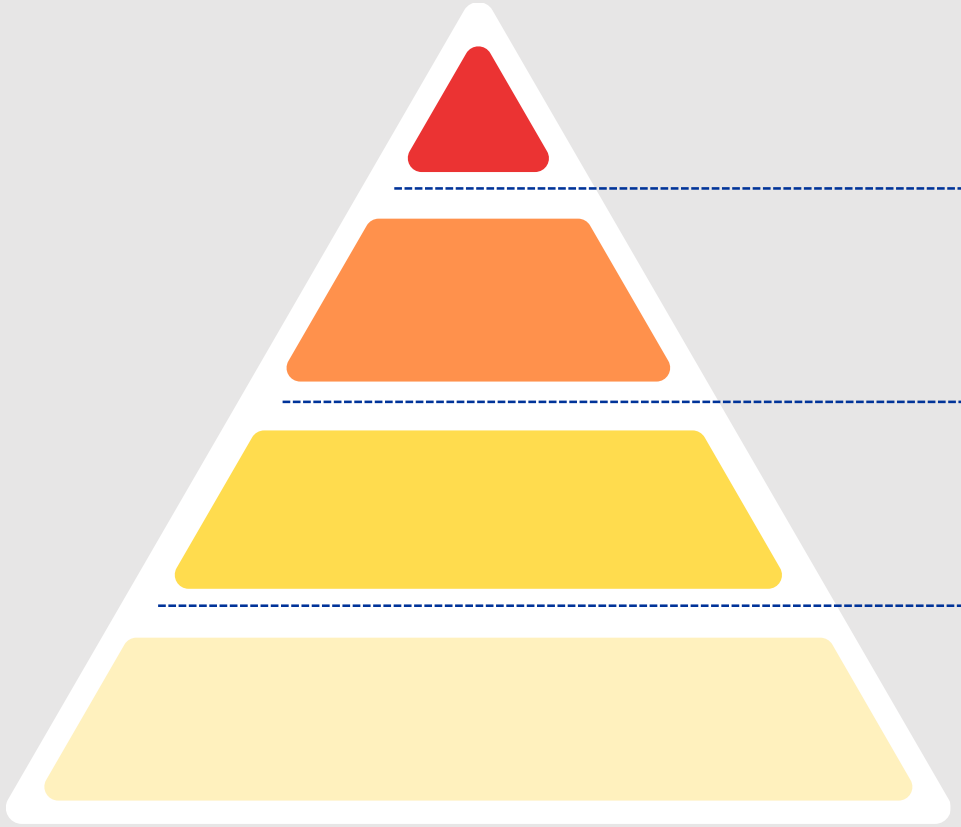
Data driven thresholds: a medicine is included in the Union list only if a set number of Member States considers the medicine critical **and** marketed or imported in more than 2/3rds of those member states.

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Implementation of the methodology

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- Each MS categorised the active substance groups (ASGs) using the agreed methodology
- EMA received **29 individual lists** of ‘critical’ medicines, 'at risk' medicines and 'other' medicines



276 ASGs critical medicines in the Union list corresponding to 17,800 medicinal products

~2700 individual line items categorised as ‘critical’ by MS but did not meet the thresholds for the Union List

3108 individual line items categorised as ‘at risk’ by MS

4777 individual line items reviewed by each MS corresponding to approximately 2200 ASG (75% of medicinal products authorised in the EU).

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Union list of critical medicines: figures

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Version 2: contains 276 ASGs

Number of Products: ~18.700 products ; ~95% are NAPs

Therapeutic areas (top 3): 1. Anti-infectives, incl. vaccines (31%);
2. Antineoplastic and immunomodulating agents (17%);
3. Nervous system (11%)

Critical shortages of critical medicines in 2024: EMA received 63 notifications of critical shortages, of which 29 (~45%) were critical medicines.

Data sources

Phase 1 (H2 2023): lists of critical medicines available at national level (6 countries: DE, ES, FR, PT, SE, FI)

Phase 2 (2024): EMA/ DG HERA crisis lists + input from Stakeholders

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Union list of critical medicines: Annual Update

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Triggers for review

- Historical critical shortages.
- A medicine that becomes the predominant form of therapy or experiences a significant increase in demand.
- Increasing number of available alternatives on the market of a particular medicine.
- A change in the indication of a medicine.

Stakeholder consultation

EMA will consult with stakeholders (HCPs, patients and Industry associations) after the requests from Member States are processed.

MSs will review comments from stakeholders before publication of the updated list.

Review by Member States

Molecules never reviewed: perform a criticality assessment based on the agreed methodology, including the risk matrix.

Molecules already reviewed: review again the criticality of the medicine considering the new information available, using the agreed methodology.

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Union list of critical medicines: outstanding activities

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Completion of the review of all medicines authorised in the EU (review of remaining 25% INNs)

- To be undertaken from the date of application of the NPL
- Annual update to take into account withdrawal of marketing authorisation of medicines included in the Union List medicines as well as newly authorised medicines

Medicines categorised as "at risk" by Member States

- Medicines categorised as "at risk" by MS will be reviewed again in case of historical critical shortages, if they become the predominant form of therapy or if there is a significant increase in demand
- If vulnerabilities in the supply chain are identified in the context of a shortage/critical shortage management, MSSG recommendations will be issued to address those vulnerabilities

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Vulnerabilities in the Supply Chain of Critical Medicines

- MSSG WG on VA methodology
- Timeline
- Stepwise approach and indicators
- Next steps



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MSSG Working Group on Vulnerability Assessment Methodology: mandate, objectives and composition

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Mandate

Progress work to develop a methodology to identify vulnerabilities in the supply chains of medicines on the Union list of critical medicines, as set out in Article 130(1) of the proposed pharmaceutical legislation.

Objectives

To deliver a practical methodology by the agreed deadline without duplication of existing processes or excessive burden on actors involved.

Composition

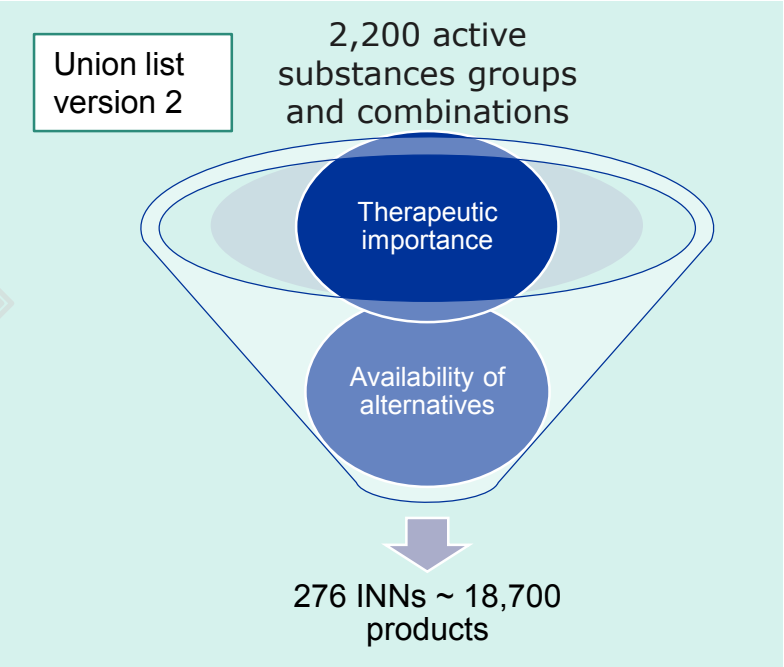
- Co-chairs: Karl Broich (MSSG) and Monica Dias (EMA)
- EMA Experts
- Member State Experts
- European Commission Experts (DG SANTE, HERA and DG ECHO)

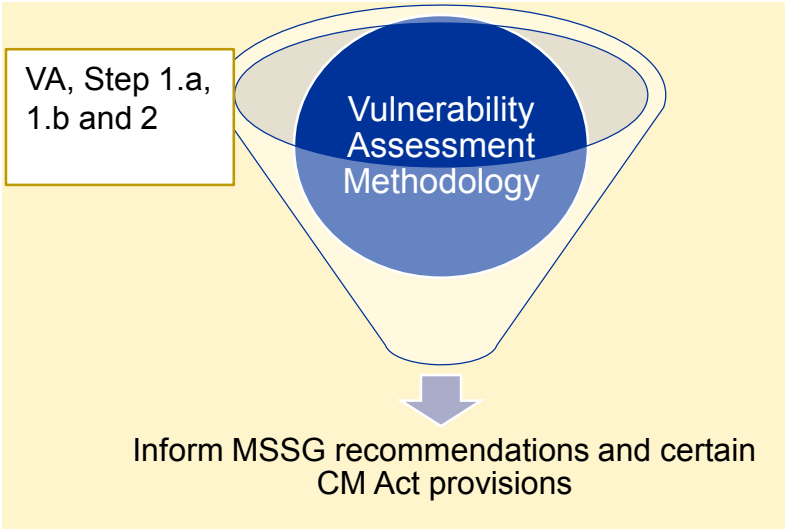
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MSSG Working Group: proposed approach

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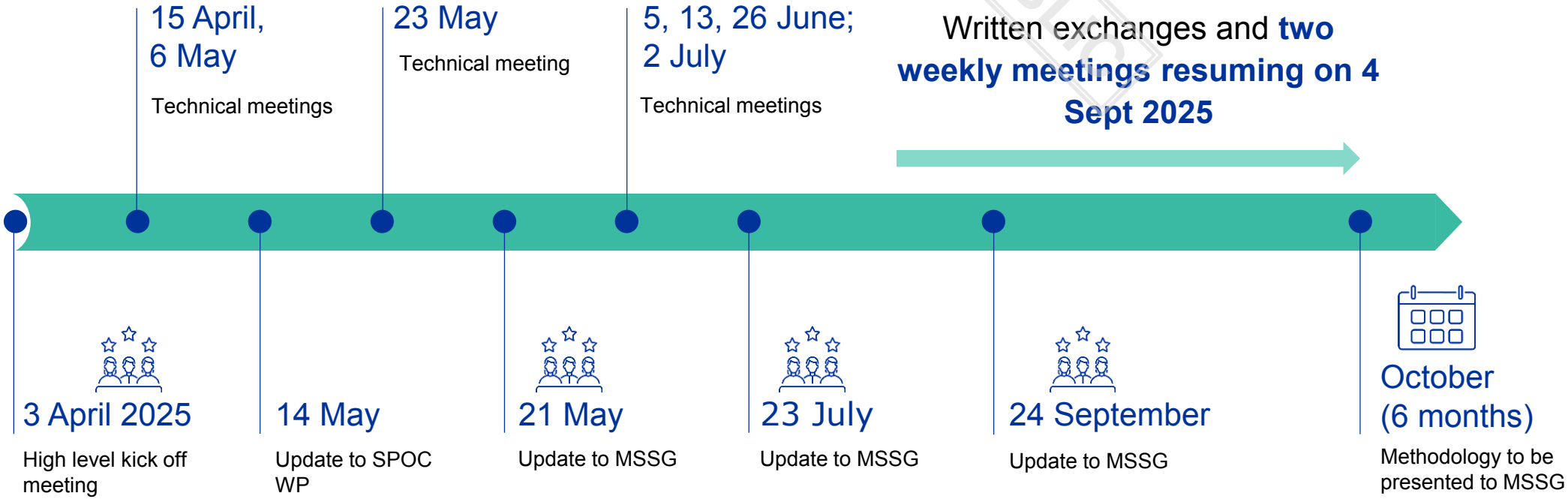
- Take into account work of the European Commission (Technical Report) and Critical Medicines Alliance (Strategic Report)
- Quantitative and qualitative elements, with agreed indicators, thresholds and weights, relying on data available in the European Medicines Regulatory Network, and data available under the proposed pharmaceutical legislation and proposed Critical Medicines Act
- 6-month timeline: draft methodology to be presented to MSSG in **October 2025**





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Timeline



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Step-wise approach

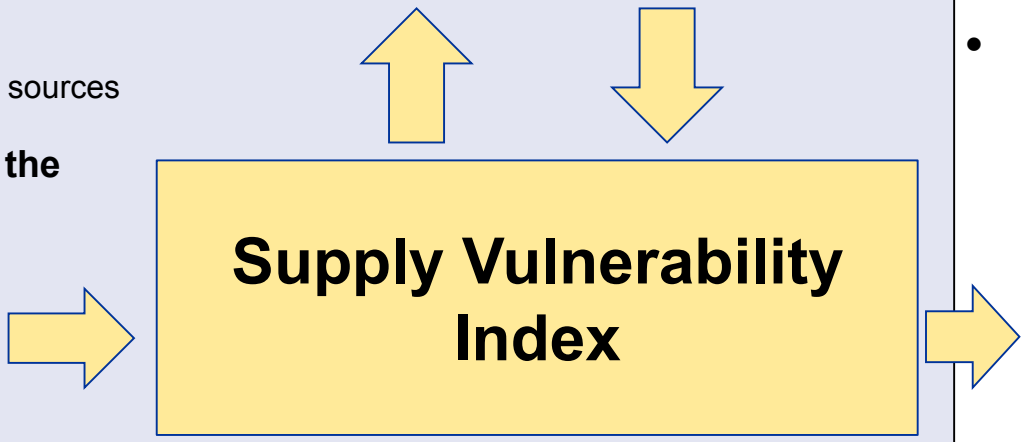
STEP 1

Step 1.a

- Leverages a set of quantitative indicators and readily available data in the EMRN, or publicly accessible sources.
- This could be at the level of the INN and pharmaceutical form.
  - Quantitative Indicators
  - Thresholds, weighting and additional data sources
- **In-built ranking to inform next steps of the approach**.

Step 1.b

- Further refinement, to address potential data/indicator gaps identified in Step 1a
  - Requests to MS and MAHs (or a subset of those), based on the in-built ranking in step 1A.



STEP 2

- Further refinement, allowing for identification and clear understanding of the specific supply-chain vulnerabilities through deeper quantitative and qualitative approach at medicinal product level and per country where necessary, with possibility for aggregation.
- While the complete methodology can be developed in advance of adoption of the legislative texts, implementation of this step of the methodology will rely on compliance with legal obligations set out in proposed pharma legislation and Critical Medicines Act.

Step 1.a misses key supply chain information from MAHs and manufacturers, including on volumes and capacity. This can be complemented in part by 1.b but approach is not complete without step 2.

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Step 1 indicators

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		Indicator	What it captures/Why it matters
Ranking		**Product criticality**	Number of MS reporting the medicinal product as critical at national level (based on therapeutic indication and availability alternatives)
Steps 1a, b	**Manufacturers** (Per tier of the supply chain)	**ext-EU/EEA dependency**	• The share of a product`s production chain that takes place outside the EU/EEA • It reflects the EU's strategic autonomy in critical medicines production
		Supply (manufacturing sites) diversity	• Redundancy and geographical spread of the manufacturing network. • The resilience of the supply chain against localised disruptions in one country
	MAHs	**Market concentration**	• Commercial concentration of a product`s supply • High market concentration = Single-point failure = High risk of supply disruptions
		MAHs diversity	• Number of different MAHs marketing the medicine at country level and their geographical spread across countries • More MAHs = more backup options in case of disruption

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Conclusions

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Union list of critical medicines

- EMA has been tasked with creating, adopting and updating the Union List of Critical Medicines.
- The list serves as the reference point for supply-chain vulnerability assessments.

Vulnerability assessment of critical medicines in the Union list

MSSG mandated to define procedure, prioritization criteria and methodology, combining indicators and MS/industry/expert input.

Progress achieved

Draft methodology under development in the MSSG VA WG; indicators identified, initial pilot foreseen.

Key challenges

Access to data, availability and completeness, in particular for NAPs.

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