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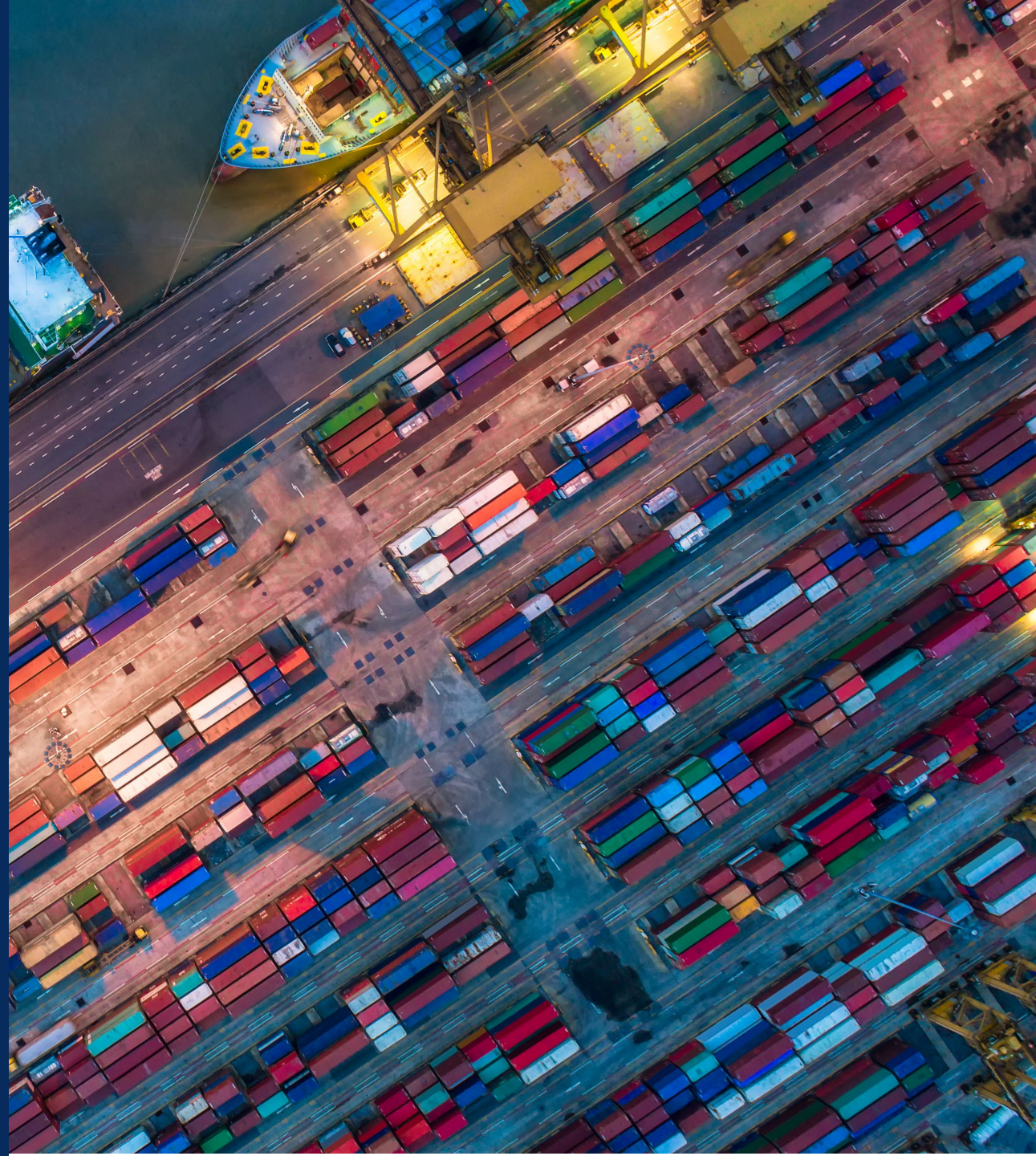
EUROPEAN MEDICINES AGENCY

MSSG Working Group on the Vulnerability Assessment Methodology

Industry Standing Group

Presented Vanessa Bennett (EMA) on 30 September 2025



Disclaimer

The Supply Chain Vulnerability Assessment Methodology as presented is not to be considered complete, nor adopted by the MSSG WG and MSSG. The current proposal must be considered as a preliminary draft and will be subject to change.

Only the MSSG adopted and published Vulnerability Assessment methodology can be considered as the official version.

Vulnerability Assessment Methodology: Background

March–July 2021

EC Structured Dialogue (SD) on security of medicines supply takes place [1]

October 2022

Publication of **EC SD staff working document** [2]

October 2023

Publication of the **EC Communication** [3] Addressing medicine shortages in EU

June 2024

Assessment of the supply chain vulnerabilities Union list of critical medicines first tranche: **Technical Report** [4]

February 2025

Publication of the **Strategic Report of the Critical Medicines Alliance** [5]

Upcoming

Adoption of the **Proposed Pharmaceutical legislation** [6]

Upcoming

Adoption of the proposed **Critical Medicines Act** [7]

[1] *EC Structured Dialogue on security of medicines supply*
[2] *Vulnerabilities of the global supply chains of medicines*
[3] *EC Communication Addressing medicine shortages in the EU*
[4] *Assessment of the supply chain vulnerabilities: Technical Report*
[5] *Strategic Report of the Critical Medicines Alliance*
[6] *Proposed Pharmaceutical Legislation*
[7] *Proposed Critical Medicines Act*

Working Group of the MSSG on the Vulnerability Assessment Methodology: Mandate, Objectives, Goals

Mandate

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. Considering associated provisions included in the Critical Medicines Act.

Objectives

- Build on the work already carried out
- Develop a practical and implementable methodology by the agreed deadline
- Avoid duplication of existing processes or excessive burden on actors involved.

Goals

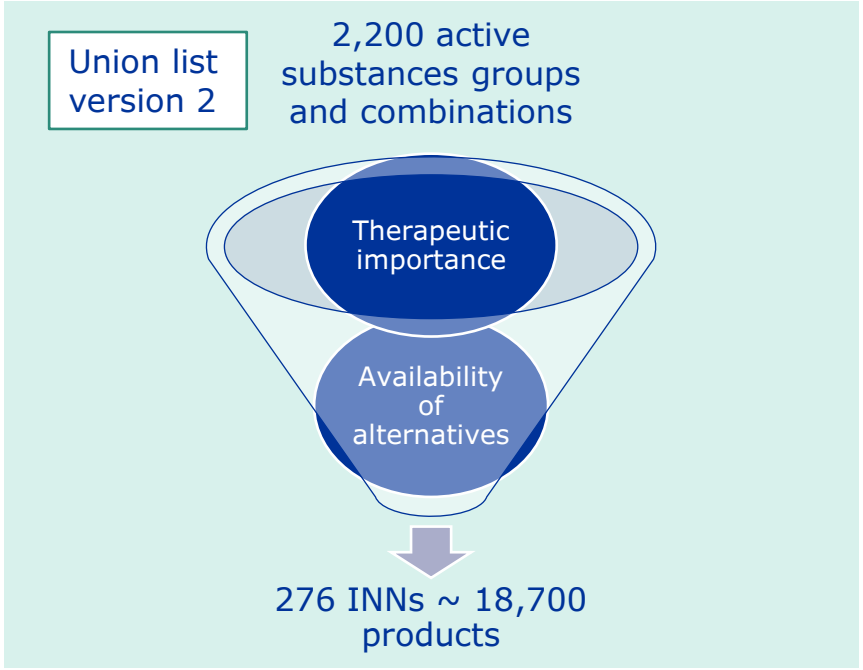
- Input for specific **MSSG recommendations** set out in the proposed pharmaceutical legislation
- Inform certain provisions included in the proposed **Critical Medicines Act**

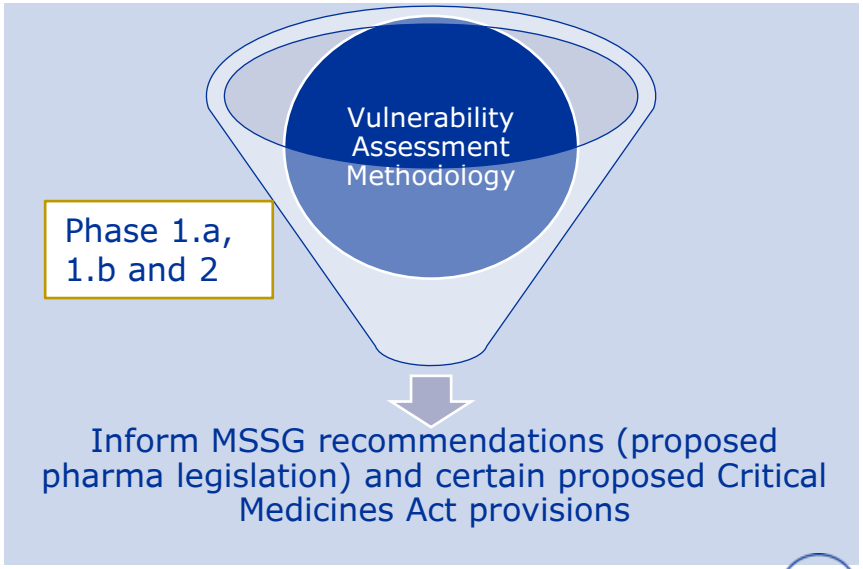
Starting point: Union list of critical medicines

Published on EMA website

Version 2: contains 276 Active substances (International Non-Proprietary name - INN). Review ongoing.

Number of medicinal products: ~18.700 products ; ~95% are authorised through national routes, the remainder through the centralised authorisation route





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Description of the proposed methodology

Phase 1: Proposed indicators and composite Supply Vulnerability Index

Phase 2: Detailed analysis and identification of vulnerabilities

Development of the draft Methodology: a phased approach

Phase 1

Step 1.a

- High level, data-driven screening
- 4 macro-level, quantitative indicators using readily available data in EMAs Substance, Product, Organisation and Reference master data or commercial sales database.
- At the level of **INN + pharmaceutical form** level for medicines on the Union list

Step 1.b

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

Supply Vulnerability Index:
In built ranking to inform prioritisation for Phase 2.

Phase 2

- Detailed and specific analysis, **at medicinal product level**, allowing for identification and clear understanding of specific supply-chain vulnerabilities
- Relies on submission of information from marketing authorisation holders and Member States, as set out in the proposed pharmaceutical legislation and proposed 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 full methodology is not complete without step 2.

Identified vulnerabilities will inform regulatory and industrial policy measures set out in the proposed legislation

Phase 1, proposed indicators and Supply Vulnerability Index (1/2)

Manufacturers:

Ext-EU/EEA dependency:

- The geographical location of manufacturing sites outside the EU/EEA
- Ratio of unique sites outside EU/EEA over total number of manufacturing sites worldwide

The higher the ratio → The higher the dependency on outside EU/EEA countries

Diversity of manufacturing sites:

- Redundancy and geographical spread of manufacturing network
- To what extent is the supply chain reliant on one or a few countries?

$$S = \sum_i c_i^2 \text{ where } c_i = \frac{manufacturing\ sites\ in\ country\ i}{total\ manufacturing\ sites}$$

Simpson diversity index (S)
Higher S → Lower diversity → Higher vulnerability

Phase 1, proposed indicators and Supply Vulnerability Index (2/2)

Marketing Authorisation Holders

Market concentration:

- How dominant is one or a few MAHs on the EU/EEA market
- How commercially concentrated is an INN + Pharmaceutical form's supply?

Diversity of Marketing Authorisation Holders:

- Redundancy and geographical spread of MAHs marketing medicinal products in country and EU-wide
- How many different MAHs are marketing a medicine at country and EU-wide level?
- How evenly spread are the MAHs across the EU/EEA?

$$HHI = \sum_{i=1}^{n} s_i \text{ where } s_i = \text{market share of MAH } i$$

(s_i expressed as fraction 0-1; n = total number of MAHs)

Herfindahl-Hirschman Index (HHI)
Higher HHI → Higher concentration → Higher vulnerability

$$S = \sum_i c_i^2 \text{ where } c_i = \frac{\text{number of MAHs in country } i}{\text{total MAHs}}$$

Simpson diversity index (S)
Higher S → Lower diversity → Higher vulnerability

Culminates in the composite **Supply Vulnerability Index**, that can inform ranking for each substance (INN + pharmaceutical form) on the Union list

Phase 2, detailed analysis and Identification of vulnerabilities

- Informed by the SVI built-in ranking, a detailed and specific analysis will be carried out at the **medicinal product level**, allowing for identification and clear understanding of specific supply-chain vulnerabilities
- Results can be aggregated to **INN + Pharmaceutical form level**
- Information contained in the **Shortage Prevention Plans** set out in Annex IV of the proposed pharmaceutical Regulation and additional information will be important to inform this assessment. (EMA guidance to industry already issued on SPPs and SMPs and pilot)
- Other information (ideally structured data) will be considered in Phase 2 e.g. **Historical shortages** (EU and MS level) related to supply chain vulnerabilities

While the methodology will be developed in advance of adoption of the proposed pharmaceutical legislation and the proposed Critical Medicines Act, implementation of Phase 1b and Phase 2 of the methodology relies heavily on **availability of necessary data** and legal obligations set out in the proposed legislation.

The outcome of the overall methodology will inform regulatory and industrial policy measures set out in the proposed pharmaceutical legislation and proposed Critical Medicines Act.

Key updates

- **15 September: A survey** was circulated **to industry associations**
  - Deadline of **3 October**
  - Replies will be discussed in the next meeting of the MSSG Working Group on VA methodology
- Taking into account feedback from ISG meetings, and the survey, necessary **refinements** will be made to the proposed methodology with further outreach if necessary
- **20 October:** Draft methodology will be presented to MSSG for discussion
- **Post MSSG adoption**
  - Enrichment of EMAs Product Management Service (**PMS**): Manufacturer's data & structured pack size for non-CAPs (Union list of critical medicines) using Product UI (and API from Q3 2025) (Extended to **June 2026**)
  - While the draft methodology may be adopted by MSSG in October, certain elements may require slight adjustments following targeted testing of the methodology. This will ensure a robust, data driven approach.
  - Following this testing, and in preparation for implementation of the proposed legislation the methodology could be **piloted by carrying out vulnerability assessments on selected Union-list critical medicines**, depending on data availability.

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Thank you

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