Shortage Prevention Plan (SPP) and Shortage Mitigation Plan (SMP) Pilot

PCWP/HCPWP meeting

18 November 2025

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EMA

A brief recap…

Good practice guide for industry on prevention/management of shortages of medicinal products for human use

- Document published in May 2023
- Recommendations for MAHs, manufacturers and other actors in the supply chain to draft SPP and SMP

New pharma legislation

- SPMPs included as one of the structural measures to improve availability of medicines

EC communication on shortages published on 24 October 2023 announced the development of SPPs as one of the elements of the upcoming pharmaceutical legislation implementation that could/should be anticipated

SPMP templates published on 18 June 2024

SPMP Pilot

- ☑ Voluntary for MAHs and NCAs (**BE, DE, ES, FI, FR, PT, SE & EMA**)
- ☑ **Pilot** endorsed by the MSSG in November 2024

Objectives

- Facilitate the implementation of SPMPs by MAHs and NCAs
- Collect information from industry on the templates and challenges they might identify during the process

Scope*

- Alteplase
- Amoxicillin
- Amoxicillin with clavulanic acid
- Verteporfin

Timelines

- Starting date: 9 December 2024
- Duration: 6 months

* *Other molecules upon request from the SPOC WP: etoposide, fludarabine, vincristine & peginterferon alfa 2a*

Voluntary participation: trabectedin, amoxicillin and amoxicillin with clavulanic acid

SPMP pilot: data collected and analysis

- **MAHs** in scope of the pilot:
  - 19 MAHs were invited to participate but only **15 MAHs** agreed to participate (~80%)
- Timelines to submit the complete SPP: 3 months. 8 MAHs requested an extension of the DL to submit the SPP
- **SPPs** submitted for review:
  - 37 SPPs included in the pilot but only **29 SPPs** submitted by MAHs (~80%)
- **SMPs** submitted for review:
  - Only **10 SMPs** were submitted by MAHs (requested for active or potential shortages)

→ **All SPMPs** submitted during the pilot were **evaluated** and feedback was provided to MAHs

→ A **SURVEY to MAHs** on the experience with the pilot was undertaken to identify areas for improvement (12/15 replies - 80%)

SPMP pilot: findings

- **SPPs**: different quality and granularity in the information provided by MAHs
  - Different quality and granularity of the information received during the pilot making it difficult to compare the SPPs
  - Information was missing in many SPPs evaluated

- **SMPs**: only a few SMPs received during the pilot. Not linked to ongoing shortages → the proposed mitigation measures nor their adequacy could not be evaluated in the context of an active shortage

Conclusions

- In September 2025, the MSSG agreed with the closure of the pilot with the possibility to request SPPs by the SPOC WP and MSSG
- Highly valuable exercise
- Key areas for improvement identified to support the effective implementation of the new pharmaceutical legislation

Next steps

- SPMP pilot report to be published by the end of 2025
- Templates to be updated and further guidance/clarity about the information requested: Q1 2026
- SPP will be used to inform deployment of the vulnerability assessment methodology

Methodology to identify vulnerabilities in the supply chains of medicines on the Union list of critical medicines

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 (ULCM)**, as set out in **Article 130(1)** of the proposed pharmaceutical legislation. Considering associated provisions included in the Critical Medicines Act.

Objectives

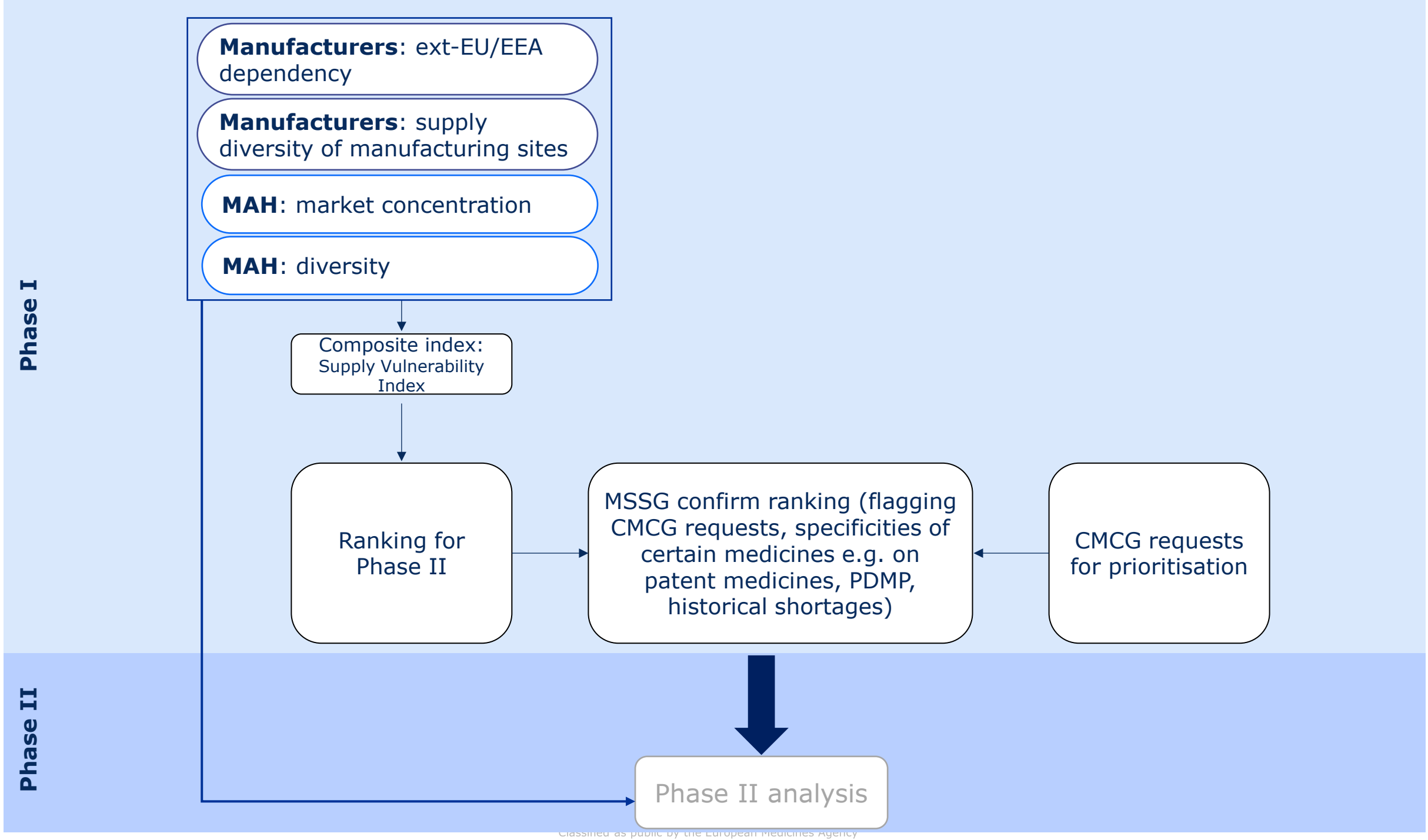
- Build on the work already carried out (EC Structured Dialogue, EC Technical Report (pilot), Critical Medicines Alliance Strategic Report)
- Develop a **practical and implementable** methodology in a 6-month timeline
- **Avoid duplication** of existing processes or excessive burden on actors involved.

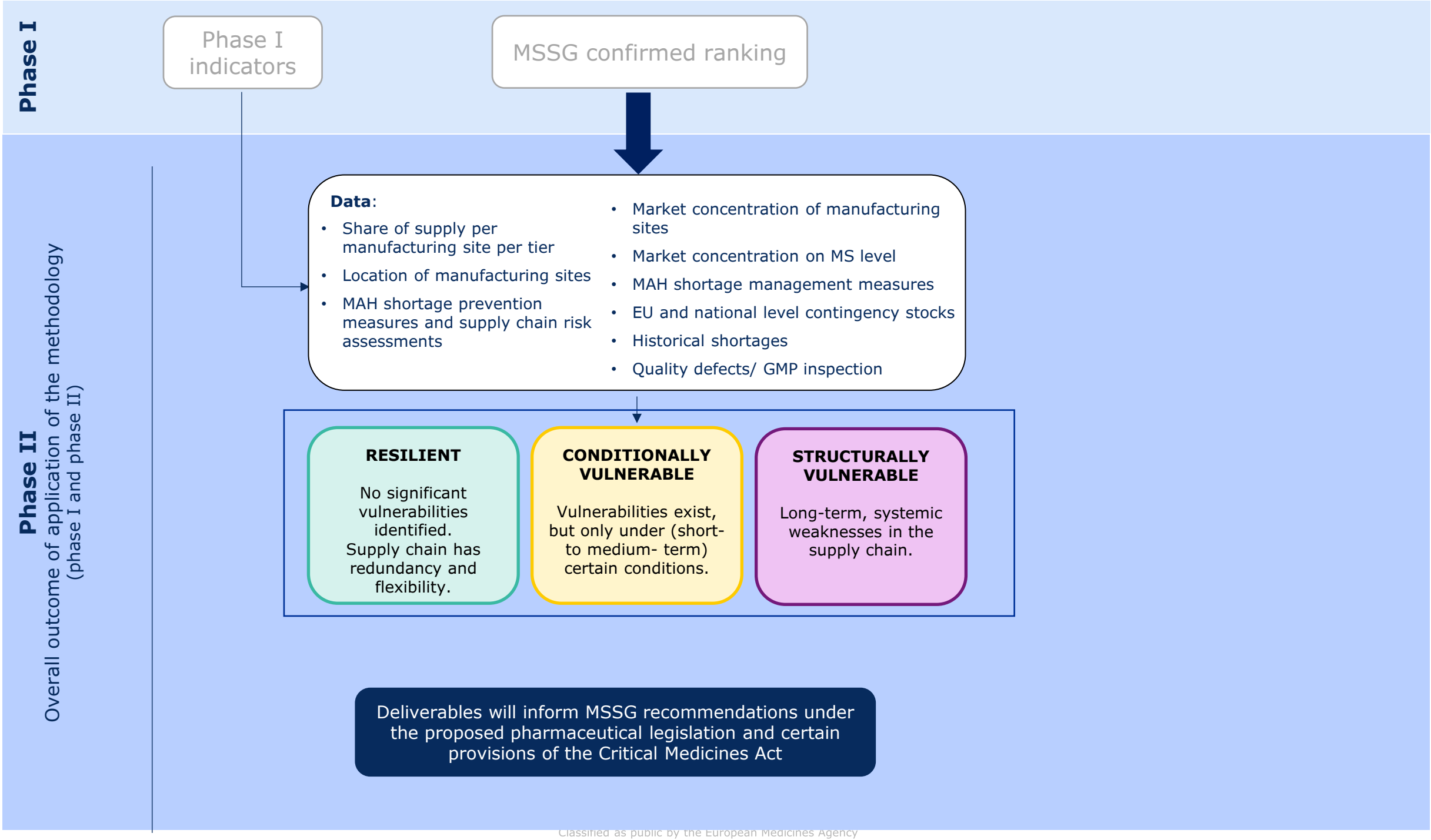
Goals

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

Outcome and next steps

- Methodology presented to MSSG on 20 October; **adopted on 14 November 2025**
- Methodology will be **piloted and updated** accordingly, also in light of the outcome of the co-legislative processes





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