

Vulnerability Assessment of Critical Medicines

European Medicines Agency (EMA)

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Agenda

Shortage Prevention Plan and Shortage Mitigation Plan

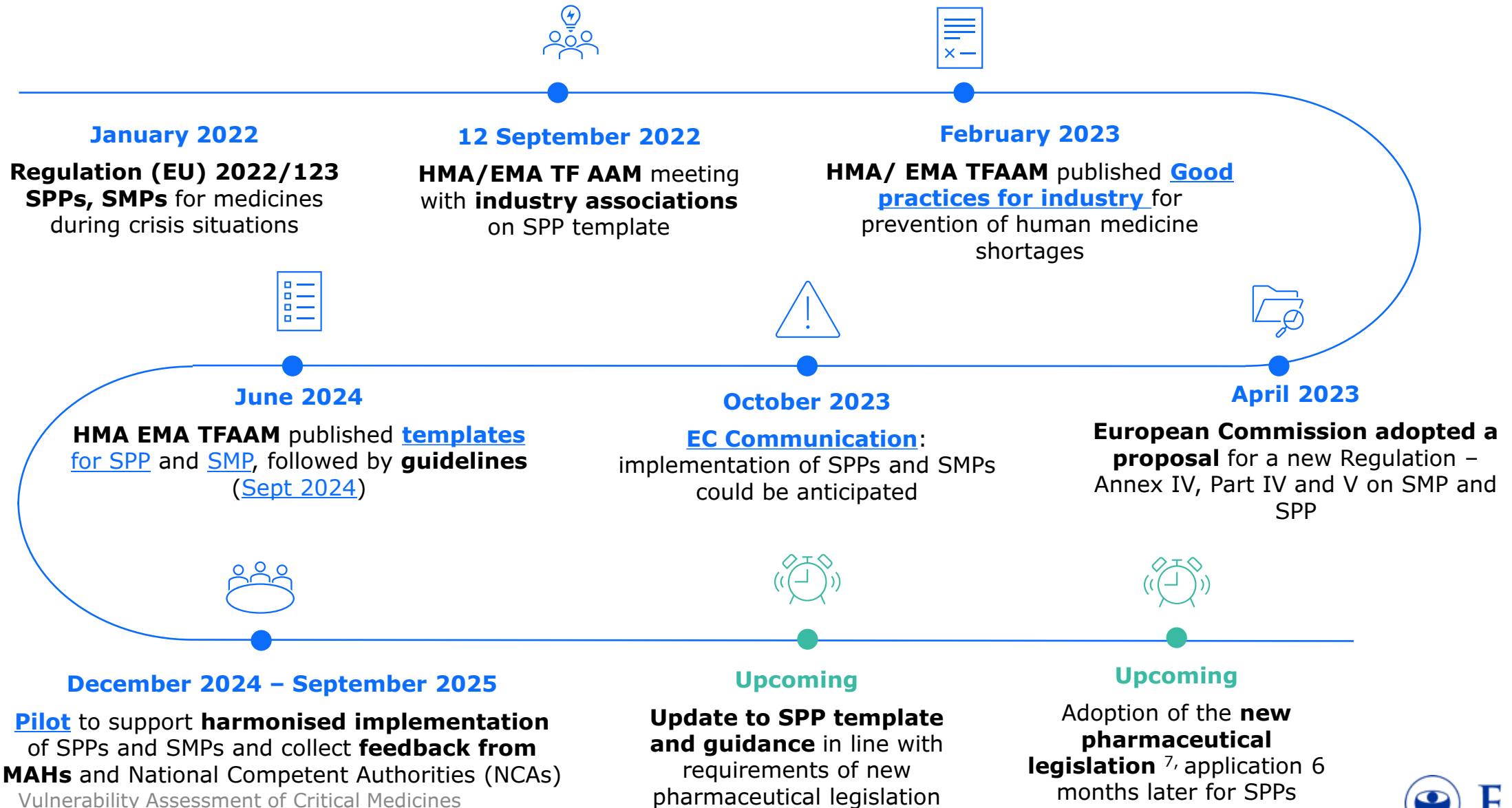
Vulnerability Assessment Methodology

Vulnerability Assessment on first set of INNs

Key takeaway messages

Shortage Prevention Plan and Shortage Mitigation Plan

Shortage Prevention / Mitigation Plan: background



Vulnerability Assessment methodology (VAM)

Vulnerability Assessment under Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) governance



Legal requirements

New pharmaceutical legislation:

- **MSSG propose Union list of critical medicines**
- **EMA to develop a common methodology to evaluate vulnerabilities**
- **MSSG to evaluate the vulnerability with respect to the supply chains of the critical medicinal products**

Associated provisions included in the proposed Critical Medicines Act



Actions to date

- MSSG established a dedicated Working Group, to **build on work already completed at EU and national level**
- **Developed** a vulnerability assessment **methodology**, with input from industry representative associations. Adopted in November 2025 and published on EMA website
- **Identified priority INNs** for application of the methodology this year
- Scheduled workshop to provide **information to MAHs in scope**; further support will be provided throughout the process and feedback will be provided once finalised

New Pharmaceutical Legislation and Critical Medicines Act implementation will lead to tangible outcomes

New Pharmaceutical Legislation

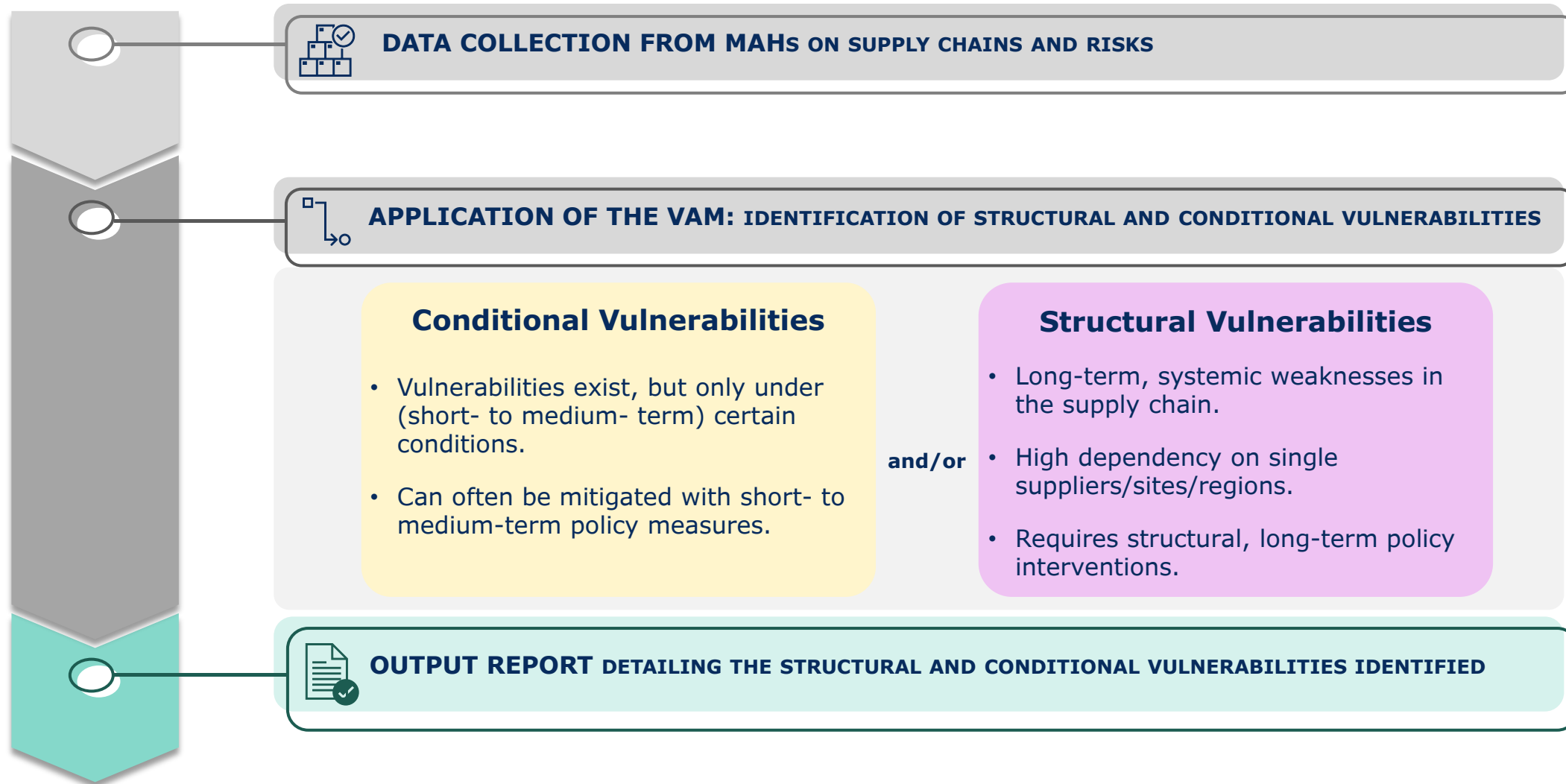
- MSSG Recommendations in line with MSSG [Guidance](#).

Critical Medicines Act

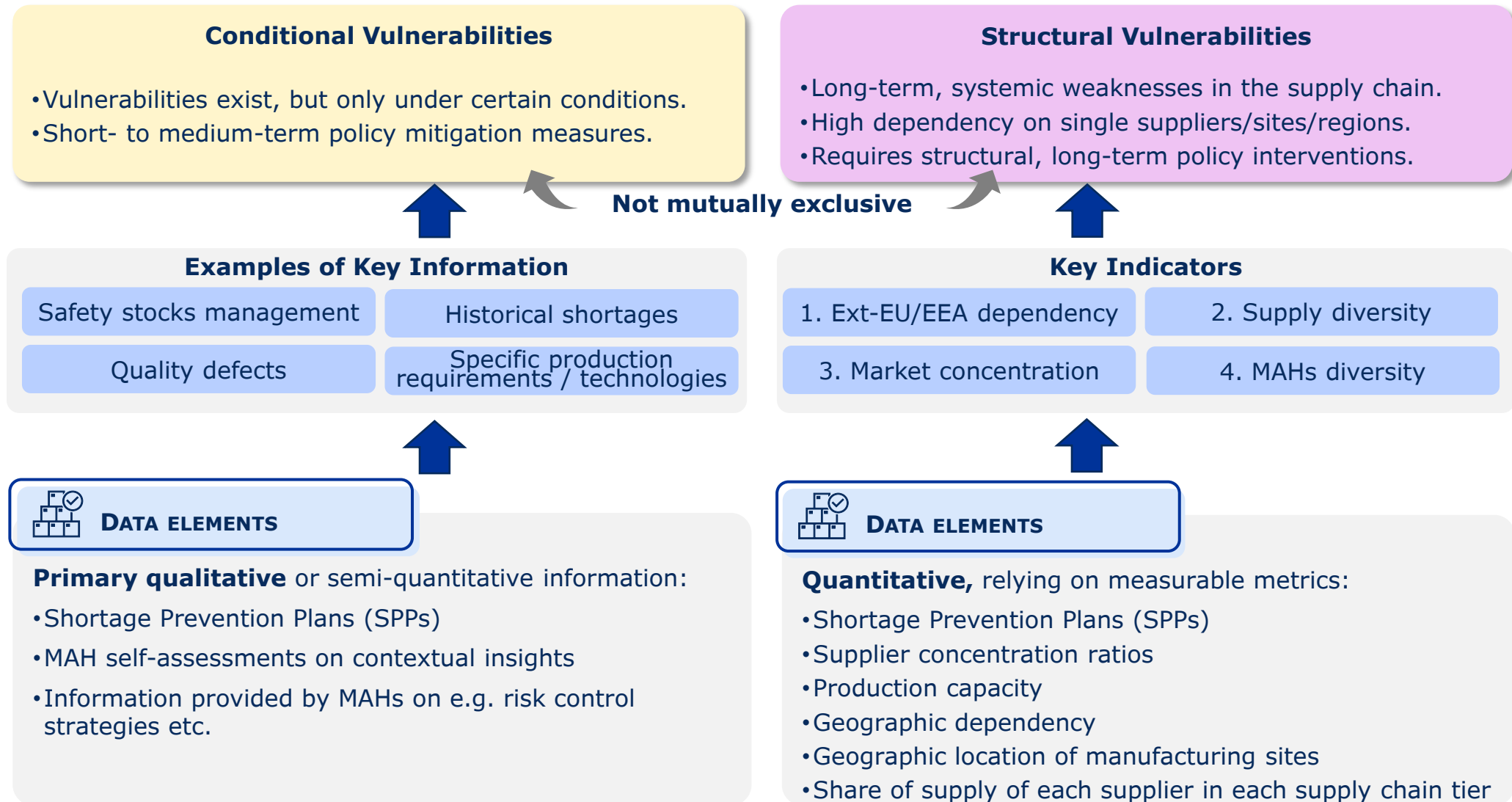
To ensure that the **measures are applied where justified and proportionate**, it is necessary to demonstrate that some measures **address a vulnerability in the supply chains** of a given critical medicinal product (recital 16).

- Financial incentives, Strategic Projects — **supply chain resilience**: possibility for Member States (**designated authorities**) to **prioritise financial support** for **strategic projects** that address a supply chain vulnerability.
- Procurement requirements — **diversification and reshoring**:
 - Necessary to procure in a way that **promotes diversification of suppliers** where dependency on a single or a limited number of third countries, threatening the security of supply, established through a vulnerability evaluation.
 - In specific cases, **contracting authorities** should apply **procurement requirements** that **favour suppliers that manufacture a significant portion of these critical medicines in the EU**, when justified by a vulnerability analysis.
 - **Commission procurement** on behalf of MS/**Joint procurement** where a vulnerability evaluation has identified a vulnerability in the supply chains or for which the MSSG has recommended a common procurement initiative.
- **Inform Critical Medicines Coordination Group** discussions on **strategic orientation**, cooperation and coordination of EU activities.

VAM Implementation: Overview



VAM: Key Principles



Vulnerability assessment on first set of INNs

Vulnerability Assessment of a first set of INNs



Context

The associated provisions of the **new pharmaceutical legislation** will be introduced **earlier than anticipated (from Q4 2026)**.



Alignment to requirements

The information provided by marketing authorisation holders to carry out the Vulnerability Assessment for the first set of INNs is based on the **obligations to supply data** in the new pharmaceutical legislation, including Shortage Prevention Plans.



Assessment by Member States, in collaboration with EMA

Each INN will be assigned to one **Member State** for **assessment**, with support from EMA. The outcomes will be shared with MSSG, at medicinal product and aggregate level to inform MSSG recommendations.

Feedback will be provided to participating marketing authorisation holders.

Criteria deployed for identification of INNs

A first set of INNs has been selected **to use the Vulnerability Assessment Methodology** in 2026.



Medicines in scope

Criteria for selection of INNs:

- Medicines that have been subject to **critical shortages at EU level since 2023**
- Medicines with **known vulnerabilities**, including dependencies, identified either as a result of shortage management or vulnerabilities identified by Member States

MAHs' ROLE

MAHs responsible for the INNs in scope will be required to provide structured supply chain data via the excel template, submitted via Eudralink, in line with the obligations set out in the NPL and CM Act.

Personal data protection: Any personal data submitted in the context of this exercise shall be processed strictly in accordance with the applicable Union data protection framework, in particular Regulation (EU) 2018/1725 as applicable to the European Commission and the European Medicines Agency and Regulation (EU) 2016/679, applicable to national Competent Authorities in the EEA.

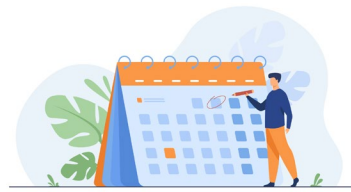
Protection of commercially confidential information: Only EMA and the competent authority of the Member States in charge of a vulnerability assessment for an INN will have access to the data submitted by Marketing Authorisation Holders (MAHs) in the context of this exercise. Without prejudice to the application of Regulation (EC) No 1049/2001, MAHs shall indicate whether the information submitted contain any commercially confidential information, identify the relevant parts of that information having a commercially confidential nature and explain why that information is of such nature. The Agency will assess the merits of each confidentiality claim and protect commercially confidential information against unjustified disclosure, as foreseen under Chapter X of the upcoming new pharmaceutical Regulation.

INNs included in the 2026 vulnerability assessment

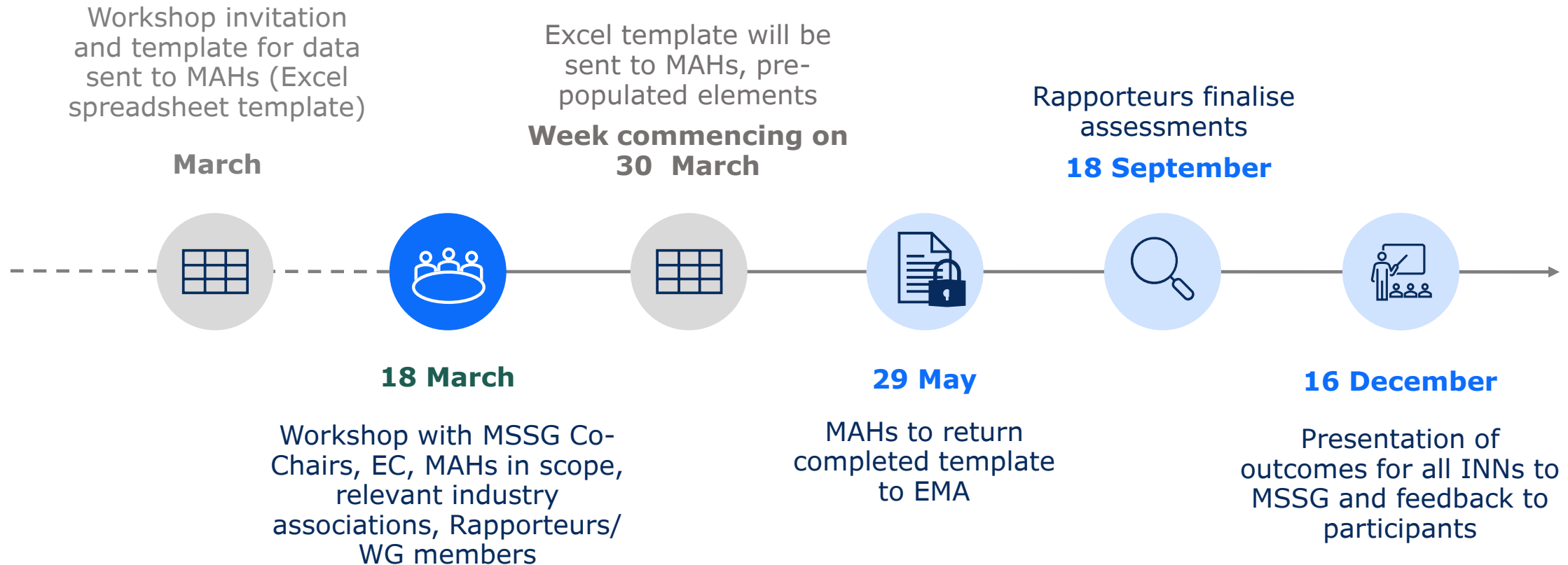
The **INNs in scope** are listed below, at level of **ATC level 5 and pharmaceutical form**.

INNs	ATC code	Pharma Form	INNs	ATC code	Pharma Form
Hydroxocobalamin	V03AB33 B03BA03	Solution for infusion, solution for injection	Vinblastine	L01CA01	Solution for injection, solution for injection/infusion
Erythromycin	J01FA01	Solution for infusion, solution for injection	Vincristine	L01CA02	Solution for injection, solution for injection/infusion
Clarithromycin	J01FA09	Solution for infusion, solution for injection	Etoposide	L01CB01	Capsule (soft), solution for infusion, solution for injection, solution for injection/infusion
Azithromycin	J01FA10	Solution for infusion, film-coated tableted, coated tablet, capsule (hard), oral suspension, dispersible tablet	Cisplatin	L01XA01	Solution for injection, solution for infusion, solution for injection/infusion
Human Anti-D Immunoglobulin	J06BB01	Solution for injection	Epinephrine	C01CA24	Solution for injection, solution for injection/infusion
Ifosfamide	L01AA06	Solution for infusion, solution for injection, solution for injection/infusion	Cyclophosphamide	L01AA01	Film-coated tablet, solution for injection, solution for injection/infusion
Peginterferon Alfa-2A	L03AB11	Solution for injection	Fludarabine	L01BB05	Film-coated tablet, solution for injection/infusion
Olanzapine	N05AH03	Solution for injection, prolonged release formulation for injection	Oxaliplatin	L01XA03	Solution for infusion, solution for injection/infusion
Methotrexate	L01BA01 L04AX03	Solution for infusion, solution for injection, solution for injection/infusion, tablet, film-coated tablet	Valproic acid	N03AG01	Oral solution, oral drops (solution), prolonged release tablet, modified release tablet, gastro-resistant tablet, film-coated tablet, prolonged release granules, modified-release granules, syrup, solution for injection, solution for injection / infusion, gastro-resistant capsule (soft), prolonged release capsule (hard)
Fluorouracil	L01BC02	Solution for injection, solution for infusion, solution for infusion/injection			

Vulnerability assessment: envisaged steps



The **vulnerability assessment** for the first set of INNs will follow the steps outlined below, until the end of 2026.



Questions received during the Workshop

Template specific technical questions, with reference to specific data fields (majority)

Process related questions

e.g. deadline, timelines, support throughout process, frequency of exercise/ updates, management of data gaps, assessment of quality of data

Marketed/non-marketed medicines in scope

Access to data from CMOs, API suppliers, other third parties

Out-of-scope questions

e.g. on time to approve national phase of a DCP, low ex-factory pricing (US preference), market attractiveness

Key messages



The **vulnerability assessment on the first set of INNs** aims to **inform policy measures** under the **New Pharmaceutical Legislation** and the proposed **Critical Medicines Act, with data requests** aligned with new obligations in those texts.



The commitment of MAHs is key to the success of this assessment. On week commencing on 30 **March** MAHs will receive the **Excel template** including pre-filled cells, with medicinal product specific information. The template needs to be filled and sent back to EMA to Rapporteurs **by 29 May**.



Data will be treated in accordance with applicable **EU data protection legislation**, including Regulation (EU) 2018/1725, and the Agency's established rules on **confidential** and **commercially sensitive information, with no unjustified disclosure**.



MSSG/ EMA will keep **MAHs** and **industry representative associations informed** throughout the process, and **upon completion** of this exercise.



EUROPEAN MEDICINES AGENCY
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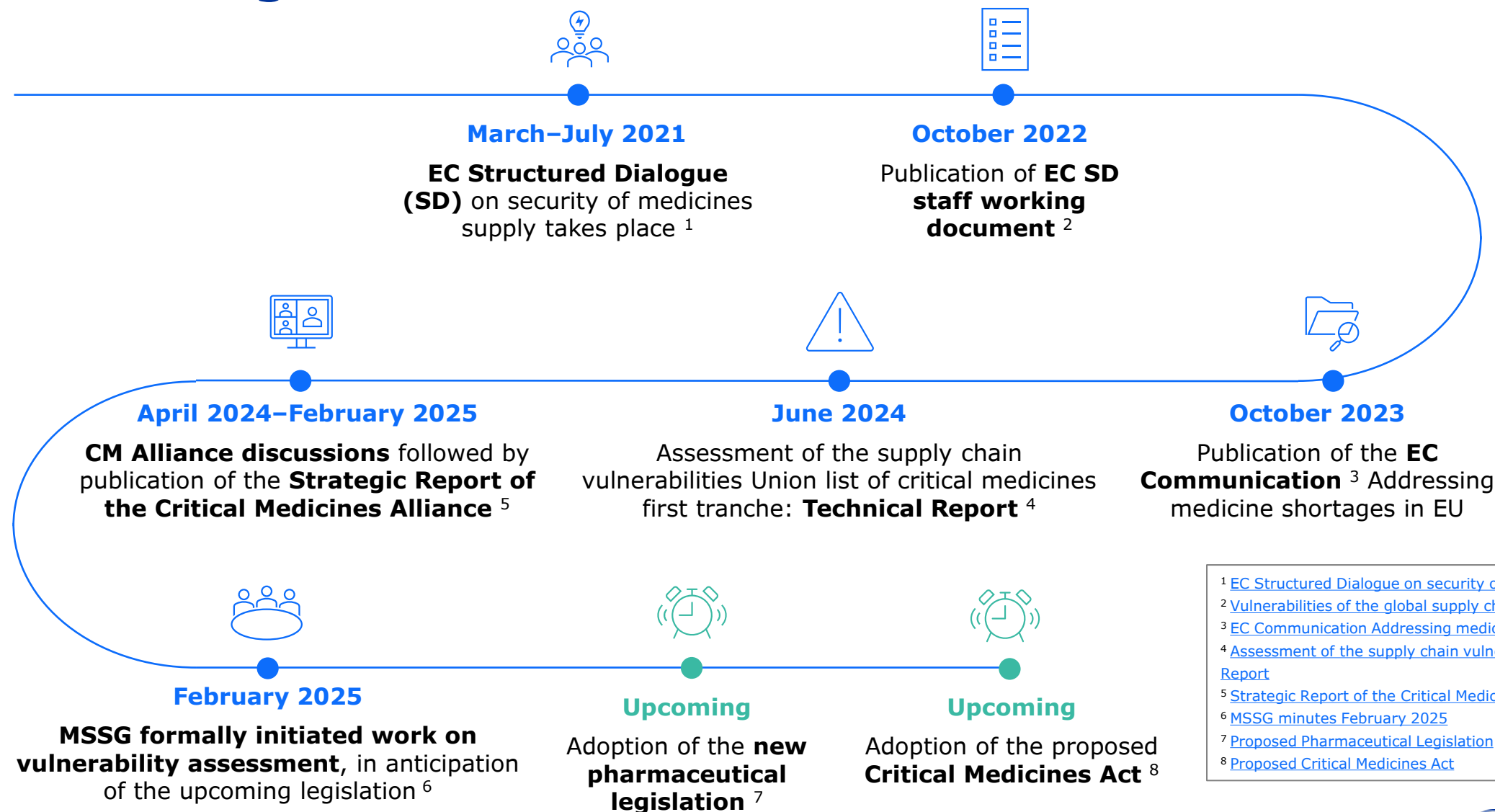
Thank you

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VAM background



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 [MSSG minutes February 2025](#)
⁷ [Proposed Pharmaceutical Legislation](#)
⁸ [Proposed Critical Medicines Act](#)

VAM: Key Indicators for Structural Vulnerabilities

Entity	Indicator	What it captures/why it matters
 Manufacturers (Per tier of the supply chain)	1. ext-EU/EEA dependency	<p>Definition: Share of production located outside the EU/EEA for each supply-chain tier (API, F&F)</p> <ul style="list-style-type: none"> • 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
	2. Supply diversity	<p>Definition: Effective number of production sites per tier (API, F&F) calculated with the Simpson diversity index (S)</p> <ul style="list-style-type: none"> • Redundancy and geographical spread of the manufacturing network. • The resilience of the supply chain against localised disruptions in one country
 MAHs	3. Market concentration	<p>Definition: Herfindahl-Hirschman Index (HHI) of MAH market shares</p> <ul style="list-style-type: none"> • Commercial concentration of a product`s supply • High market concentration = Single-point failure = High risk of supply disruptions
	4. MAHs diversity	<p>Definition: Effective number of MAHs calculated with the Simpson diversity index (S)</p> <ul style="list-style-type: none"> • 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