

# Industry Standing Meeting Q1 2026

European Shortages Monitoring Platform (ESMP)

31 March 2026



# Agenda

- EMVS-ESMP gap analysis report summary
- ESMP expansion and improvements
- Recent and upcoming events



# Background and context

## 2021

**EMVS considered as a possible source of data** in an **EMA feasibility study** to cover needs under EMA extended mandate. The use of EMVS data was not prioritised due to limitations in data coverage and timing of ESMP MVP implementation, among others.

## 2022-2024

**MfE and EFPIA** carried out a series of **workshops**, with EMA as observers from 2023, to explore opportunities of the EMVS to replace reporting via ESMP. MfE releases a position paper stating that **“70-80% of the information required from MAHs to input ESMP is already uploaded to the EMVS”**

## 2023

In light of the post-MVP ESMP expansion, **EMA requested MfE and EFPIA to undertake a proof-of-concept exercise**, to demonstrate that EMVS data could be used predict shortages of antibiotics ahead of the '24/'25 autumn/winter season.

## 2024

**MfE and EFPIA presented the proof of concept to the MSSG**, and it was concluded EMVS **supply data** could be used as a complementary data source to the ESMP. However confirmation was deemed necessary through a gap analysis study with the participation of ESMP and EMVS team. The gap analysis was **endorsed by the MSSG**.

## 2025

**Execution of a comprehensive and actionable gap analysis** between ESMP and EMVS to enable informed decision-making. This was **led by EMA** with participation of **MfE, EFPIA** and **EMVO**.

# Goals and scope of the gap analysis

The Gap analysis aimed to deliver a **comprehensive and actionable gap analysis** between ESMP and EMVS to enable an informed decision that considers **three fundamental points**:

- The **existing overlap** between ESMP and EMVS data fields.
- What are the viable **options for data migration** from EMVS to ESMP.
- Estimate the impact of making ESMP and EMVS **interoperable**.

## Scope of the analysis:

- Based on the **MSSG proposal** to explore the potential of MAH **supply data** included in the EMVS as a complementary source of information for the ESMP
- the **focus** included **datasets relevant to crises**, as well as broader data requirements to **support monitoring activities (as outlined in Regulation (EU) 2022/123)**. This approach ensured a comprehensive understanding on the potential use of the EMVS data in this context.

# ESMP data sets for MAH reporting

## Normal circumstances

EMA Ref	ESMP data element
<b>Product information</b>	
P1.1.2	Package PMS ID
P1.8	Country of authorisation
<b>Shortage information</b>	
S1.1	Shortage Status
S1.2	Shortage start date or expected start date
S1.3	Shortage end date or expected end date
S1.4	Point in supply chain at which disruption occurs
S1.5	Root cause of the shortage
S1.6.1	Countries in which manufacturing issues occur
S1.6.2	Countries in which increased demand occurs
S1.6.3	Countries in which distribution issues occur
S1.7	Root cause of the shortage - additional information
<b>Prevention and mitigation</b>	
S2.1	Shortage prevention and mitigation plans
S2.2	Shortage prevention and mitigation plans - ongoing and planned steps
<b>Impact assessment</b>	
S3.1	Affected population estimate
S3.2	Market share
S3.4	Shortage impact risk assessment
S3.5	Shortage impact risk assessment - additional information
<b>Alternative therapies</b>	
S4.1	Alternative therapies available?
S4.2	Alternative therapies
<b>Additional information</b>	
S5.1	Rapid Alert reference number
S5.2	Other authorities notified (e.g. other NCAs, EMA), including reference to Quality Defect report
S5.3	Reference to related pending regulatory action
S5.4	Required NCA actions, if any

5

ESMP/EMVS gap analysis report

## Crisis and MSSG-led preparedness

EMA Ref	ESMP data element
<b>Product information</b>	
P1.1.2	Package PMS ID
P1.8	Country of authorisation
<b>Marketing status details</b>	
P1.9	Marketing status
W1.1	Date of planned permanent withdrawal
W1.2	Planned withdrawal comment

EMA Ref	ESMP data element
<b>Product information</b>	
P1.1.2	Package PMS ID
P1.8	Country of authorisation
<b>Shortage information</b>	
S1.1	Shortage Status
S1.2	Shortage start date or expected start date
S1.3	Shortage end date or expected end date
S1.4	Point in supply chain at which disruption occurs
S1.5	Root cause of the shortage
S1.6.1	Countries in which manufacturing issues occur
S1.6.2	Countries in which increased demand occurs
S1.6.3	Countries in which distribution issues occur
S1.7	Root cause of the shortage - additional information
<b>Shortage prevention and mitigation plans</b>	
S2.1	Shortage prevention and mitigation plans
S2.2	Shortage prevention and mitigation plans - ongoing and planned steps
<b>Market share</b>	
S3.2	Market share
S3.3	Market share - additional information
<b>Sales volume</b>	
S6.1	Sales volume pre-PHE/ME
S6.2	Sales volume current
S.1.1 - S7.1.6	Sales volume forecast - Month 1 - Month 6
S7.2	Sales volume - additional information
<b>Supply forecast</b>	
S8.1.1 - S8.1.6	Supply forecast - Month 1 - Month 6
S8.2	Supply forecast - additional information
<b>Stock information</b>	
S9.1	Available stocks
S9.2	Desired safety stock
S9.3	Stocks - additional information

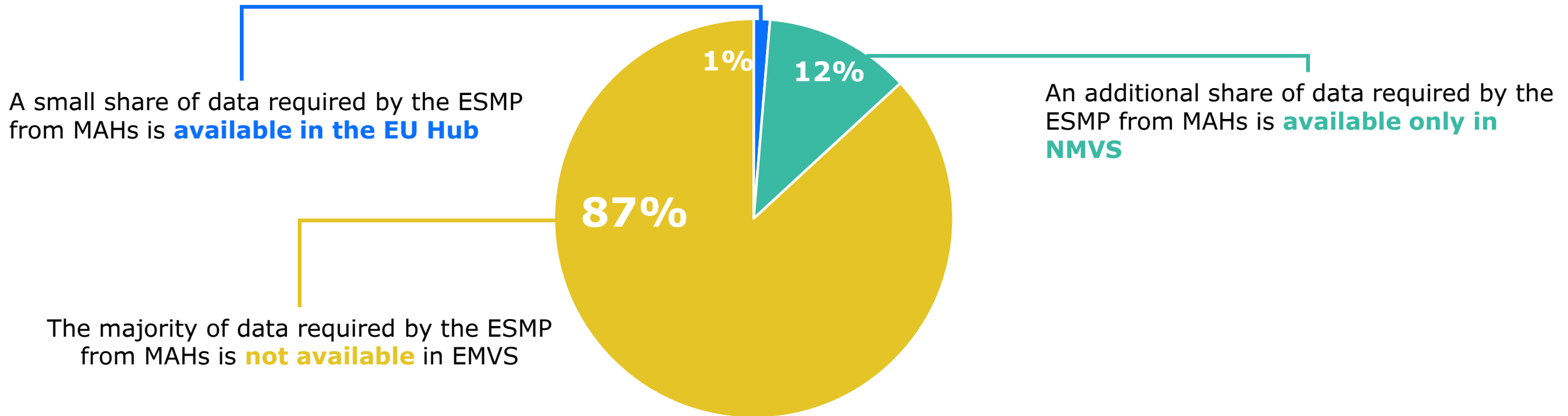
EMA Ref	ESMP data element
<b>Product information</b>	
P1.1.1	PMS ID
P1.3.1	Active substance SMS ID
<b>Representative product</b>	
X1.1	Representative product
<b>Organisation information</b>	
O1.1	Operation type ID
O1.3	ORG-ID (Manufacturer)
O1.5	LOC-ID (Manufacturer)
<b>Manufacturing details</b>	
M1.1	Manufacturing site status
M1.2	Is the site a contract manufacturer?
<b>Alternatives sites</b>	
M2.1	Alternative site LOC-ID
M2.2	Alternative site Country
<b>Production plan and capacity</b>	
M3.1	Unit of measurement
M3.2.1 - M3.2.6	Global Monthly Production plan - Month 1 - Month 6
M3.3	Global monthly production plan - additional information
M3.4	Average global monthly production output of previous year
M3.5	Peak global monthly production output of previous year

EMA Ref	ESMP data element
<b>Product information</b>	
P1.2.3	Invented name
P1.3.2	Active substance(s)
P1.6.2	Pharmaceutical form
<b>Alternative therapies</b>	
L1.1	Alternative therapies
L1.2	No alternatives



# Overall coverage of EMVS for ESMP data set

- EMVS cannot replace reporting to ESMP by MAHs.
- All datasets in the ESMP were compared against the data elements available in the EMVS. The analysis identified three categories:



EMVS-ESMP data element mapping with agreement with Industry and EMVO data experts

# Conclusions and recommendations (1/2)



- Data from EMVS cannot replace Industry reporting to ESMP
- While the scope of the MSSG request focused on supply, the **potential usefulness of dispensation data** was also discussed - this will need to be further **validated with the relevant stakeholders.**
- **A comparison of ESMP datasets with EMVS concluded that EMVS supply data alone is of limited use** as a complementary source of information to ESMP.

# Conclusions and recommendations (2/2)



- Nevertheless, the Agency sees a value in **proceeding with the EMVS integration**, therefore **recommending** the following **3 steps**:
  - 1) Product/package information in EMVS to be **mapped to PMS** - in progress and expected to be completed in February 2026
  - 2) Consumption of **EMVS supply data** by ESMP in Q2/Q3 2026
  - 3) Consumption of **EMVS aggregated data on dispensation** by the ESMP. Availability of this data:
    - Is key to realise the full value of the **EMVS supply data** (e.g. to accurately estimate stocks, market share by member state)
    - **Requires agreement to be reached** under EMVO governance, as it is currently only available in NMVS to the Member States, and **legal limitations** to be addressed

# Follow-up discussions

- Report presented at EMVO board in Feb 2026
- Follow-up meeting requested and held with GIRP Feb 2026
- Follow-up meeting requested and held with Affordable medicines Europe Feb 2026



# ESMP expansion: current scope overview

COMING  
NEXT



## Voluntary solidarity mechanism

Implementation of a data submission flow in the ESMP that will allow **Member States to flag critical national shortages of specific medicines**, enabling other Member States to indicate available stock that could **potentially be redistributed**.



## Critical shortage reporting

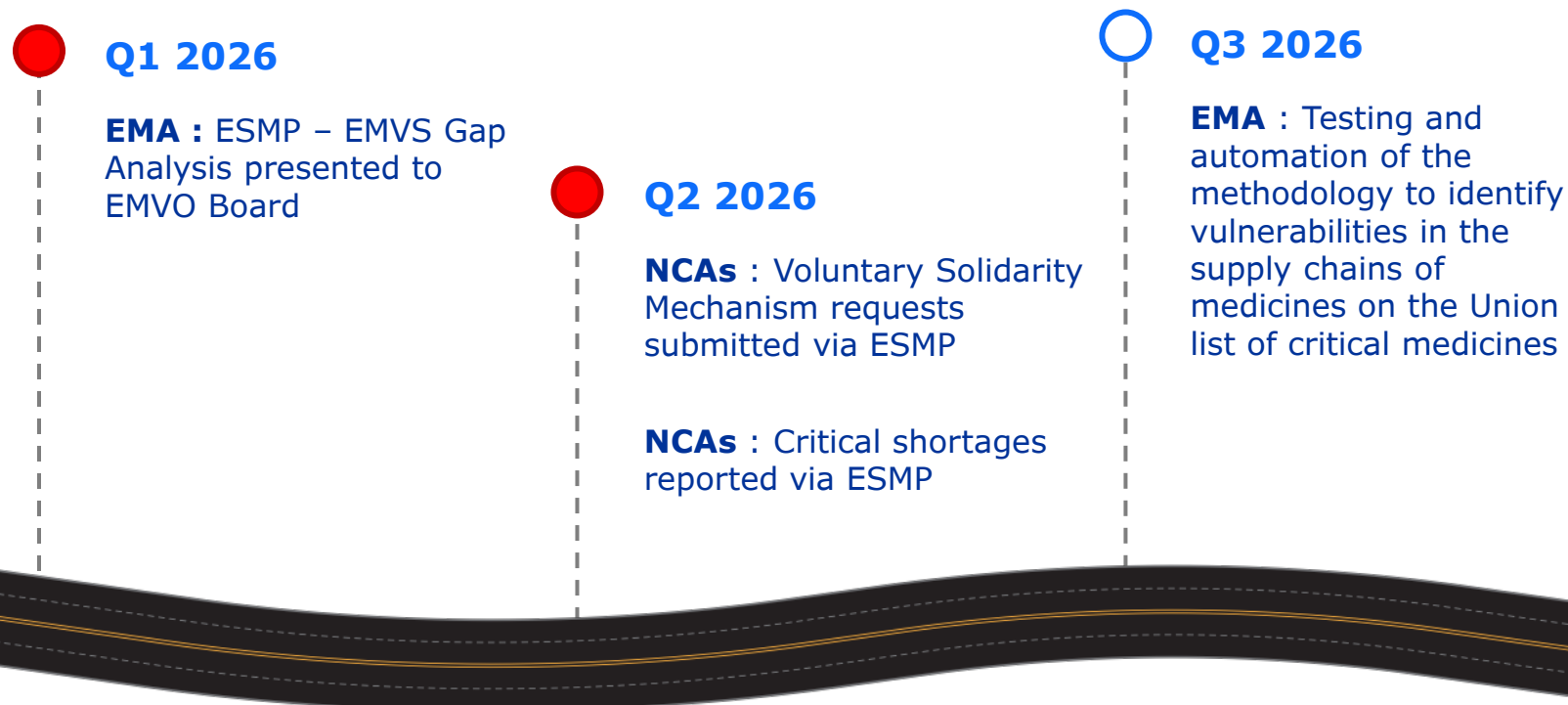
This feature builds on the current reporting of critical shortages by NCAs to EMA and streamlines the submission and management of critical shortage notifications.



## Testing of vulnerability assessment methodology

In line with upcoming pharmaceutical legislation reform, this feature will **support the MSSG in testing and automating a new methodology to identify vulnerabilities in the supply chains** of medicines on the Union list of critical medicines. It will allow step-by-step testing and provide initial large-scale analysis using defined indicators.

# Updates on European Shortages Monitoring Platform (ESMP) expansion



**Expected outcome:** Enhance shortage management capabilities, thereby strengthening the EU Network's ability to make faster and more accurate strategic decisions.



# ESMP developments on industry features

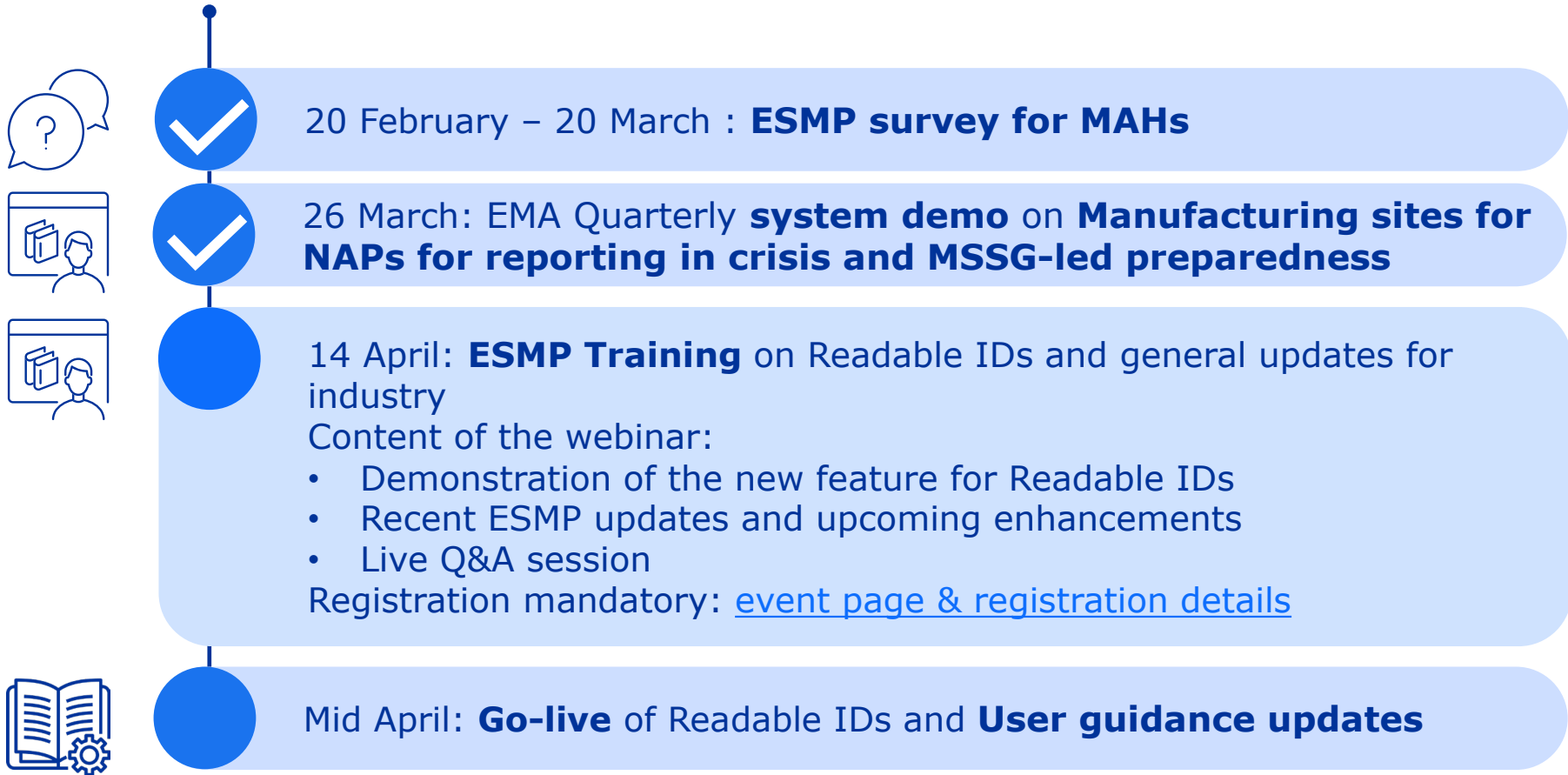
## Manufacturing information – addition of NAP sites

- Addition of **manufacturing sites of NAPs** in the **Manufacturing information** data submission flow for crisis/MSSG-led preparedness
- All manufacturing sites for NAPs are maintained exclusively in PMS
  - **MAHs should submit manufacturer data to PMS** by **June 2026** for NAPs (non-CAPs) on the [Union list of critical medicines](#) and by **December 2026** for all other non-CAPs. *Full deadline details [here](#)*
- Demonstrated during [System demo Q1 2026](#) on 26 March

## Readable IDs in ESMP submission templates

- To enhance user experience with RMS IDs and simplify data verification.
- For MAHs of CAPs in submission templates for **routine CAP shortage reporting**.
- For MAHs of non-CAPs and CAPs in submission templates for **MSSG-led preparedness reporting and crisis** reporting.
- This enhancement to the reporting process is a direct outcome of the feedback EMA received from ESMP users.

# Main recent and upcoming events



# Useful links and resources for MAHs



## [User guide](#)

Comprehensive **step-by-step guidance** to fulfil reporting requirements and data analysis.

Central **hub for information**, progress updates, guidance documents, timelines, **FAQs**, and more to keep you informed.



## [ESMP webpage](#)

All mentioned resources (and more) are published and linked on the dedicated ESMP webpage on the EMA corporate website.



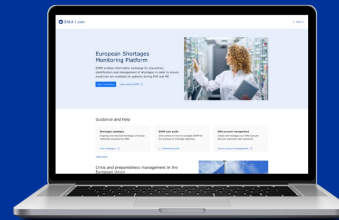
## [Implementation guide](#)

Detailed **technical specifications** and reporting data guidelines to ensure accurate submissions.

Structured **visual guides** to support you in following ESMP reporting processes.



## [Training recordings and video tutorials](#)



## [ESMP portal](#)

# Shortage root cause definition and descriptions

Presented by Siofradh McMahon on 31 March 2026

Supply and Availability of Medicines and Devices, Regulatory Science and Innovation Task Force (TRS-SAM)

# Harmonisation is key to interoperability

- EMA and member states have been working to harmonise shortage-related definitions and the implementation of them, including the root causes of shortages
  - Aim is to ensure coherence across EU/EEA and support future interoperability plans
- Following the work of the [CHESSMEN Joint Action](#), a harmonized list of shortage root causes and corresponding descriptions has been developed
  - Next step: Industry consultation for input on guidance
- Final version targeted for endorsement by MSSG in Q2 2026
- CHESSMEN work package 5 work will continue to develop this topic





EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Thank you

[siofradh.mcmahon@ema.europa.eu](mailto:siofradh.mcmahon@ema.europa.eu)

Follow us

