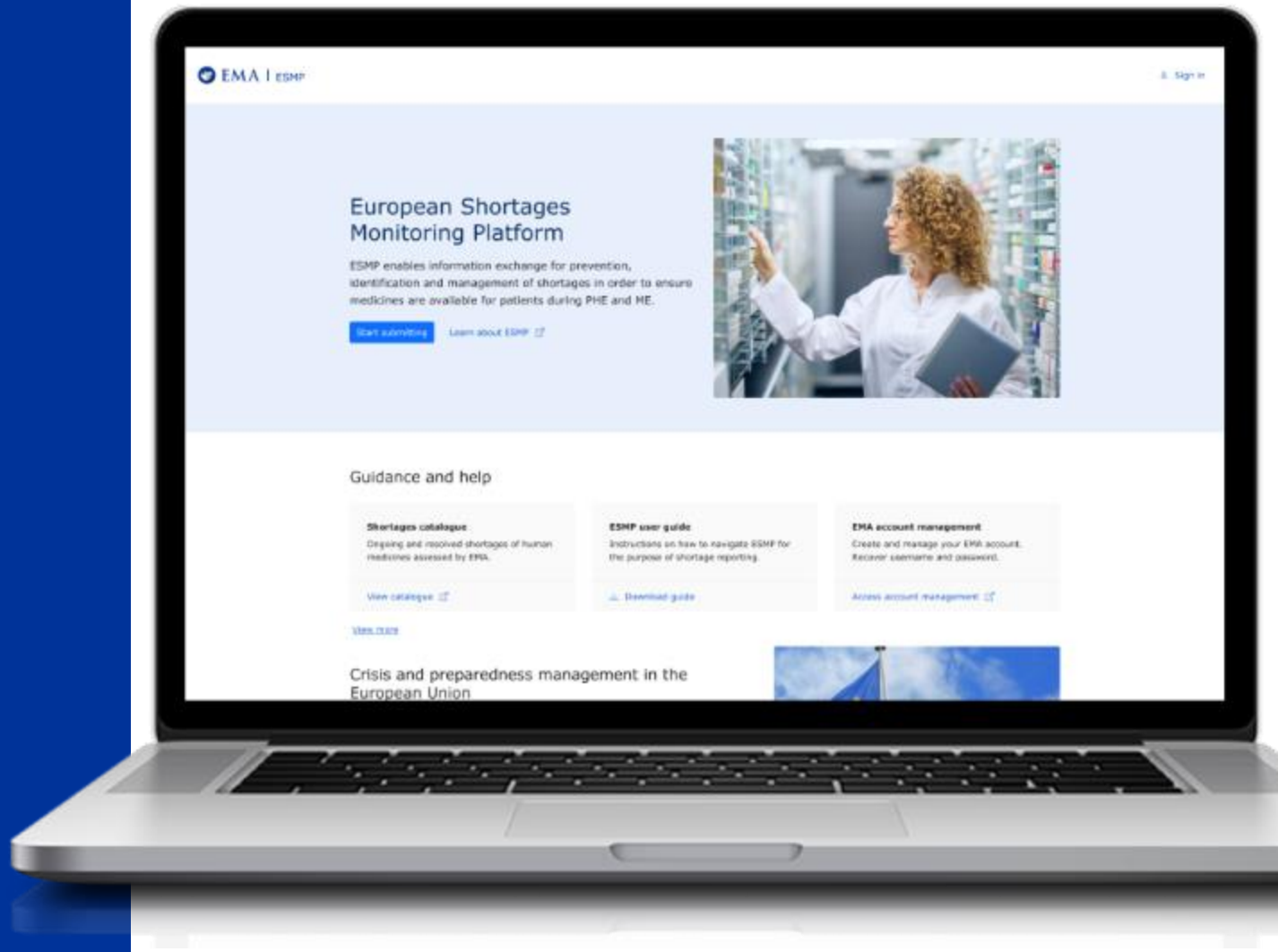
EMA
EUROPEAN MEDICINES AGENCY

European Shortages Monitoring Platform (ESMP)

Training on crisis and MSSG-led preparedness reporting for marketing authorisation holders (MAHs)



19 February 2025, 10:00 – 12:30 CET

Housekeeping

*Please note that **this session is broadcast live on EMA's YouTube channel and is being recorded** and **will be made available** through **EMA's corporate website (on the event page)** and **EMA's YouTube channel***

*Participants can ask questions or give their input via the audience interaction tool **Slido***

*Interaction via Slido is voluntary, and you may opt to remain anonymous. If you chose to use Slido, **you consent to the processing of your personal data** as explained in the EMA Data Privacy Statement for Slido**

**https://www.ema.europa.eu/en/documents/other/european-medicines-agencys-privacy-statement-use-audience-interaction-tool-slido_en.pdf*

Agenda

- **Welcome and opening of the training session**, Pedro Pina Ferreira
- **Overview of reporting instances**, Mónica Dias
- **Overview of the European Shortages Monitoring Platform (ESMP)**, Sofia Zastavnik
- **Updates to access management**, Pietro Patti
- **Reporting functionalities**, Sofia Zastavnik
- **Interoperability**, Pedro Oliveira and Christophe Pée
- **Q&A** through Slido, moderated by Stephanie Marschler
- **Closing remarks**, Pedro Pina Ferreira

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Welcome and opening of the training session

Pedro Pina Ferreira

Goals and objectives

DEEPEN YOUR KNOWLEDGE ABOUT THE PLATFORM

Learn how to access and navigate ESMP, with step-by-step guidance on reporting process for crisis and MSSG-led preparedness.

UNDERSTAND THE IMPORTANCE OF CONSISTENT REPORTING

Discover the critical role of accurate and timely reporting in preventing, mitigating and managing shortages across the EU/EEA and explore how ESMP simplifies this process.

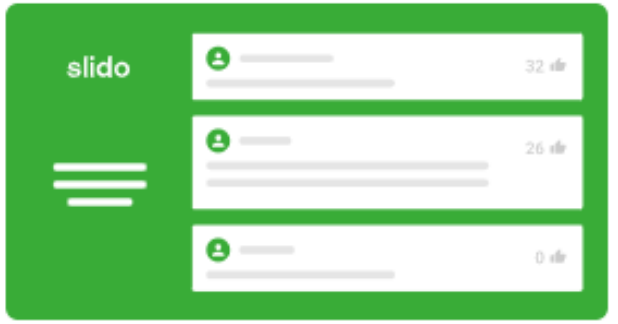
COLLECT FEEDBACK & CLARIFY QUESTIONS

Clarify any questions to ensure your full readiness to use ESMP for the covered reporting instances.

Send your questions via Slido

1. Join via the QR code or on www.slido.com with the session code #ESMP-MAH

2. Send or upvote the questions you want to hear answered



3. Questions will be shown on the screen and answered live in the Q&A session and compiled in the FAQ document on the ESMP webpage

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Overview of reporting instances

Mónica Dias

For questions: www.slido.com Code: #ESMP-MAH

Shortages management in the EU/EEA

Improving the availability of medicines authorised in the EU/EEA is a key priority for the **European Medicines Regulatory Network** (EMRN)

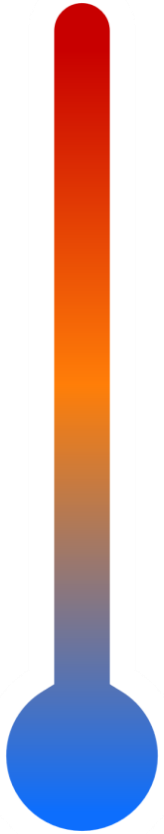
Availability and Supply of medicines is a key topic in the EMANS (European medicines agencies network strategy) for 2028. Theme 5 outlines two goals:

- Strengthen the availability of medicines to protect public and animal health
- Reinforce the oversight and protection of the supply chain and increase inspector capacity

Regulation 2022/123 equipped the EMA to address medicines shortages through **enhanced coordination**, **proactive monitoring**, and **preventive measures**;

Ongoing Reform of the EU pharmaceutical legislation and the European Commission **Communication** on addressing medicine shortages in the EU/EEA further reinforces and extends EMA's role in shortage management and consequently the **expansion of the ESMP**

Overview of medicines' lists



	List	What its purpose	When has it been used
Crisis	List of critical medicines for a public health emergency/major event	• Drawn up for a crisis • Listing medicines needed for a specific PHE/ME • Helping closely monitor supply and demand of medicinal products in scope	• COVID-19 • mPox
Preparedness	List of medicines to be monitored for MSSG-led crisis preparedness	• Drawn up for crisis preparedness • Listing medicines needed for managing a particular event • Helping closely monitor supply and demand of medicinal products in scope	• Antibiotics
Normal	Union list of critical medicines	• Identify vulnerabilities in supply chain of critical medicines • Ensure security of supply and availability of critical medicines at all times	• Launched in 2023 • Updated in 2024

MAH reporting instances to ESMP

	Routine shortage reporting	MSSG-led preparedness	Crisis
Available in:	Normal circumstances	Preparedness (PHE, ME)	Crisis (PHE, ME)
Purpose:	Early reporting of shortages to allow for efficient shortage prevention, management and mitigation	Specifically driven by the MSSG to address events that might lead to a PHE/ME	Focused on immediate actions to handle and mitigate the impact of ongoing or imminent crises, such as a PHE or ME
Submission trigger:	Potential or actual shortage of a marketing authorisation holders' product	MSSG announcement of preparedness action	EC recognition of a PHE/ME
Products in scope:	All centrally authorised products (CAPs) for human use	List of medicines to be monitored for MSSG-led crisis preparedness (CAPs and NAPs) for human use	List of critical medicines for a public health emergency/ major event (CAPs and NAPs) for human use
Frequency of reporting:	As required, updated when new relevant information is available	Defined by the MSSG	Defined by the MSSG

PHE: public health emergency ME: major event

MAH reporting in normal circumstances

	Routine shortage reporting
Available in:	● **Normal circumstances**
Purpose:	Early reporting of shortages to allow for efficient shortage prevention, management and mitigation
Submission trigger:	Potential or actual shortage of a marketing authorisation holders' product
Products in scope:	All centrally authorised products (CAPs) for human use
Frequency of reporting:	As required, updated when new relevant information is available

- Under normal circumstances, marketing authorisation holders (MAHs) must report any **actual or potential shortage** of centrally authorised products **to the EMA via the ESMP** as part of routine shortage reporting*
- For more information, the following resources are available on the EMA website (among others):
  - Medicine shortages and availability issues
  - Detecting and reporting medicine shortages

*national reporting requirements remain applicable

*For more information, please refer to the **training session on routine shortage reporting** held on 20 November 2024, available on the EMA event page*

MAH reporting in a crisis situation or MSSG-led preparedness action

- The purpose of this training refers to reporting via ESMP during a public health emergency/major event, or during an MSSG-led preparedness action
- For marketing authorisation holders (MAHs), reporting in these instances follows the **same process**

	MSSG-led preparedness	Crisis
Available in:	**Preparedness (PHE, ME)**	**Crisis (PHE, ME)**
Purpose:	Specifically driven by the MSSG to address events that might lead to a PHE/ME	Focused on immediate actions to handle and mitigate the impact of ongoing or imminent crises, such as a PHE or ME
Submission trigger:	MSSG announcement of preparedness action	EC recognition of a PHE/ME
Products in scope:	List of medicines to be monitored for MSSG-led crisis preparedness (CAPs and NAPs) for human use	List of critical medicines for a public health emergency/ major event (CAPs and NAPs) for human use
Frequency of reporting:	Defined by the MSSG	Defined by the MSSG

Reporting in a crisis situation or MSSG-led preparedness action: communication process

1. A Public Health Emergency (PHE) or a Major Event (ME) is **recognised** or the MSSG activates **a preparedness action**
2. The MSSG adopts a **list of critical medicines** relevant to the PHE or ME or identifies medicines to be monitored under MSSG-led preparedness action
3. The EMA's MSSG **defines the reporting frequency** for MAHs
4. The EMA **notifies MAHs of medicines in scope** and requests reporting
5. MAHs **submit information via ESMP** at the specified frequency
6. The MSSG **announces the end of the activities,** based on termination of a PHE or confirmation that the ME or preparedness action have been sufficiently addressed
7. The EMA **notifies MAHs** that reporting via ESMP is no longer required

MSSG-led preparedness in action: antibiotics

- **Situation:** Global shortage of amoxicillin and amoxicillin/clavulanic acid in autumn/winter 2022/23.

Launch of the SPOC WP subgroup to assess root causes of the shortage and impact

Sharing of **best practices** by MSs (i.e., MSSG toolkit) to mitigate critical shortages

Collaboration with MAHs, NCAs, EU institutions, international regulators, HCPs and patients

Public communication, shortages catalogue

- Amoxicillin (+- clavulanic acid) supply chain
- Additional supplies to Member States
- Flexibilities to product packaging requirements (use of products in foreign languages)
- Accelerated certificate assessments to increase manufacturing of API
- Faster regulatory assessments

Reactive → Proactive approach

MSSG-led preparedness: matching of supply and demand for a set of antibiotics to prepare for winter 2023/2024

1) Identify whether shortages could be expected in winter 2023/2024
2) Understand if EU-level actions need to be undertaken to ensure sufficient supply for European patients

MSSG **recommendations** to stakeholders.

Early risk identification enabled **proactive planning** by MAHs and NCAs.

Increased **cooperation** with industry (incl. SPOC WP and MSSG discussions with MAHs) and monitoring by HCPs and patients

Social media campaign

Benefits of establishing the ESMP

PREVENTION OF SHORTAGES

- More accurate, complete, and faster information on shortages
- Efficiency in monitoring supply and demand
- Central repository that allows early detection and prevention of medicine shortages

EU/EEA-WIDE APPROACH

- Working towards harmonised reporting standards across the EU/EEA
- Increased EU/EEA coordination for faster actions to prevent and mitigate shortages

TRANSPARENCY & COLLABORATION

- Easier collaboration among different actors through a centralised platform
- Data analytics capabilities to match supply with demand, offering valuable insights for collaboration

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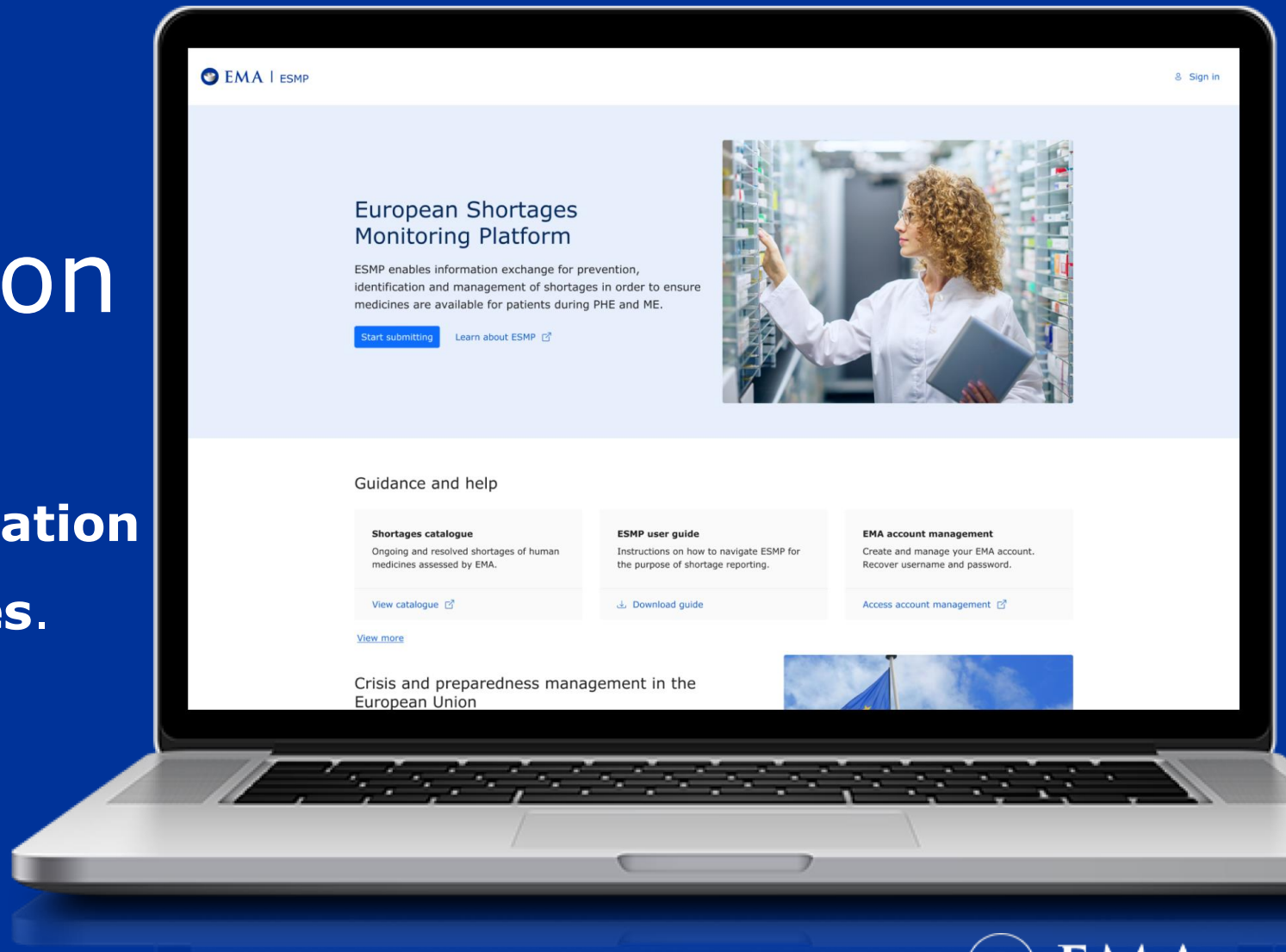
Overview of the European Shortages Monitoring Platform (ESMP)

Sofia Zastavnik

ESMP aims to enable information exchange

for better **prevention, identification and management of shortages**.



 For questions: www.slido.com Code: #ESMP-MAH

ESMP overview

PREVENTION

Data collection

- Shortage information
- Supply and demand of medicines
- i-SPOC Registration

MONITORING

Analysis & reporting

- Matching supply & demand
- Reporting findings and results
- Public reports

Case management

- Maintain critical medicinal product lists
- Evaluate and manage medicines shortages

MANAGEMENT

Data integration

- EMA data management (SPOR*, IAM**, IRIS integration)
- Interoperability with NCA and Industry systems

Platform for MAHs

Platform for NCAs

Secure access

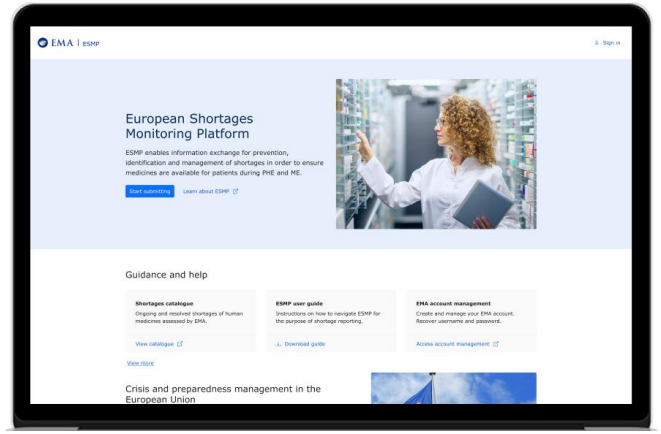
Platform for general public

Open access

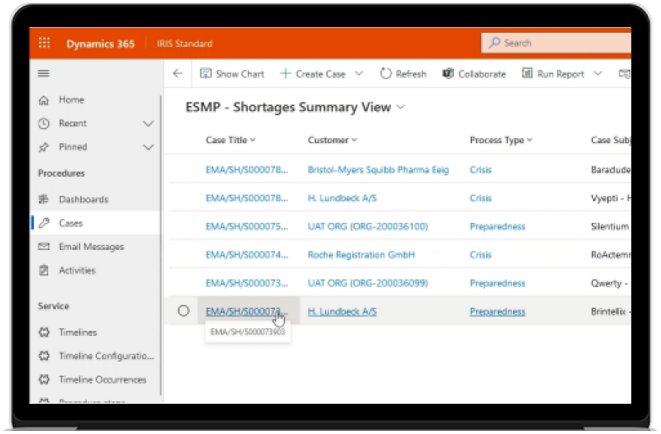
*SPOR: substance, product, organisation, referentials management system
**IAM: identity access management system

EMA

ESMP components



Data collection



Case management

Analysis & reporting

Data integration

Release timeline

28 November 2024

Go-live for Industry Routine shortage reporting for CAPs

29 January 2025

Go-live for Industry and Regulators' Crisis and MSSG-led preparedness reporting

After February 2025

Maintenance and improvements

4

Updates to access management

Pietro Patti

Access management: what's new regarding ESMP

What stays the same

- **Have an active EMA account**: It is required to self-register with EMA as a new "user" to activate EMA user account (see information on the EMA Account Management portal)
- **MAH registration in OMS**: The MAH on whose behalf you will be acting needs to be registered in the EMA's Organisation Management Service (OMS)
- **Access role request:** once the EMA account is activated and the MAH is registered in OMS, It is required to request access role for specific EMA applications. So, to access ESMP to roles are:
  - *ESMP Industry Admin* (to handle users' access management for an MAH)
  - *ESMP Industry User* (to access and perform operations in ESMP)
- Multi Factor Authentication (MFA) is always required.

What's new

- **The sign-in experience**: External users' login with their email (e.g. name@company.co) with automated federation or a One Time Passcode (OTP).
- **No separate credentials**: there is no longer the need to remember and maintain a username and password
- **Other info**: for other changes to the EMA's Account Management portal, please refer to the event held about it - EMA Account Management, what's new? | European Medicines Agency (EMA)

Previously covered information

- On 20 November 2024, during a **training session on routine shortage reporting** for marketing authorisation holders of centrally authorised products, the following topics on **access management were covered in detail:**
  - ESMP role profiles (i.e., ESMP user and ESMP admin roles)
  - Pre-requisites to ensure access to ESMP
  - Processes for requesting and approving role profiles

More information

- ESMP **User guide** for marketing authorisation holders
- ESMP training session on routine shortage reporting for marketing authorisation holders of centrally authorised products (CAPs)

*For more information, please refer to the **training session on routine shortage reporting** held on 20 November 2024, available on the EMA event page*

New Sign in - email address authentication

From EMA username and password

Currently external users' login with userid@id.ema.europa.eu and a password managed by EMA

External users recover their credentials by using the self-service "Forgot username" and "Forgot password" options

… to email authentication with federation or OTP

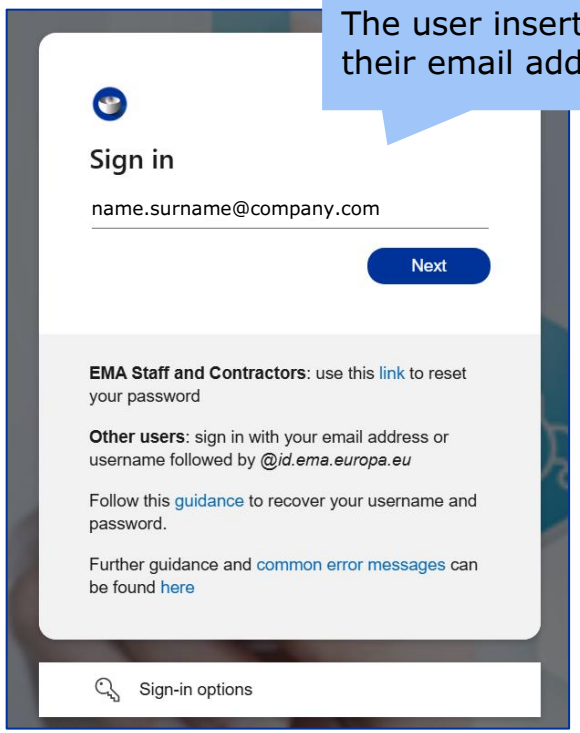
External users' login with **their email** (e.g. name@company.co) with automated federation or a One Time Passcode (OTP)

Federation: for users with an Azure AD Account, they will use their own password or defined method of authentication.
One Time Passcode: all other users will receive a numerical one-time code on their email

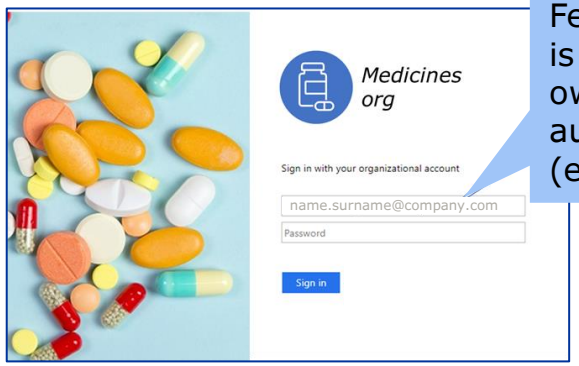
Take into consideration

- The steps related to the activation of an EMA account, organisation registration and user role requests are still required (refer to November 2024 training and ESMP user guide for MAHs, section *2.1 How to create an EMA account*)
- MFA is still required
- Users can opt-in to email authentication in EMA Account Management by following the detailed instructions (link to EMA Account Management)

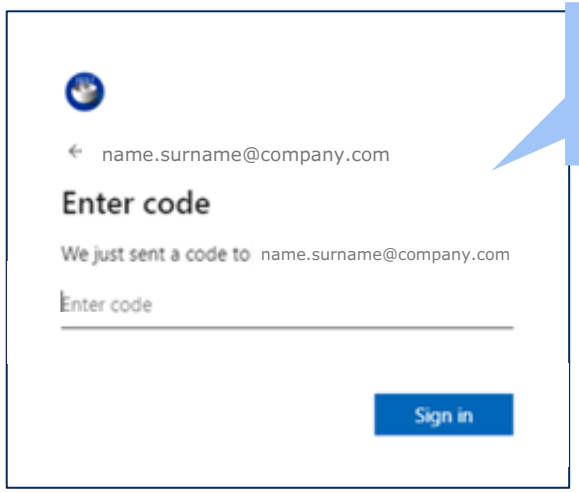
Secure access to ESMP via email address authentication



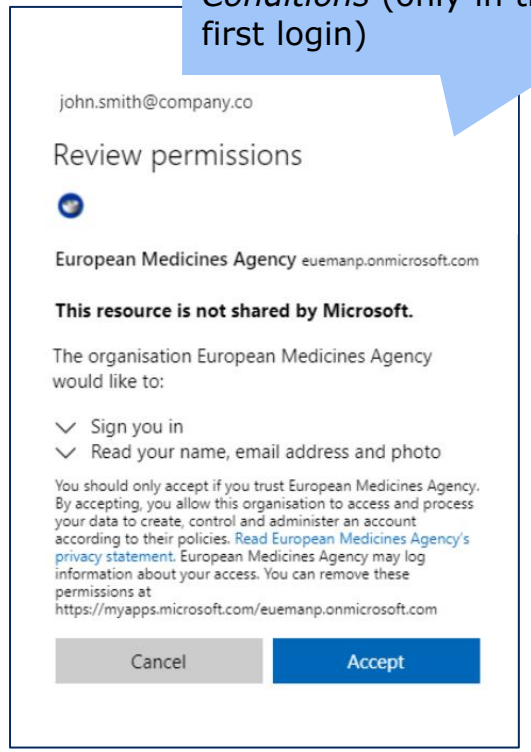
1 The user inserts their email address



2a Federation: the user is redirected to their own organisation authentication page (e.g. Eu-Login …)



2b OTP: A numeric code is sent to the user's email address



3 The user accepts the *EMA Terms and Conditions* (only in the first login)

5

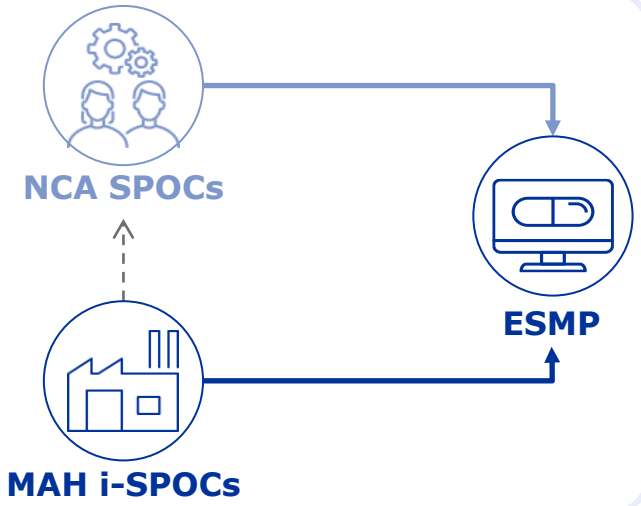
Reporting functionalities

Sofia Zastavnik

Data collection: Industry submissions

Data collection

- Shortage information
- Supply and demand of medicines
- i-SPOC Registration



In **normal circumstances**, MAHs will report shortages of centrally authorised products.

- **Shortage information**
- **Shortage prevention and mitigation plans**
- **Shortage impact assessment**
- **Alternative therapies**

Submissions are triggered by a potential or actual shortage and MAHs need to keep the entries up-to-date, including the latest information.

In a **crisis situation** or **MSSG-led preparedness action**, MAHs submit data on nationally and centrally authorised products in scope of a critical medicines list for a particular public health emergency, major event, or preparedness action.

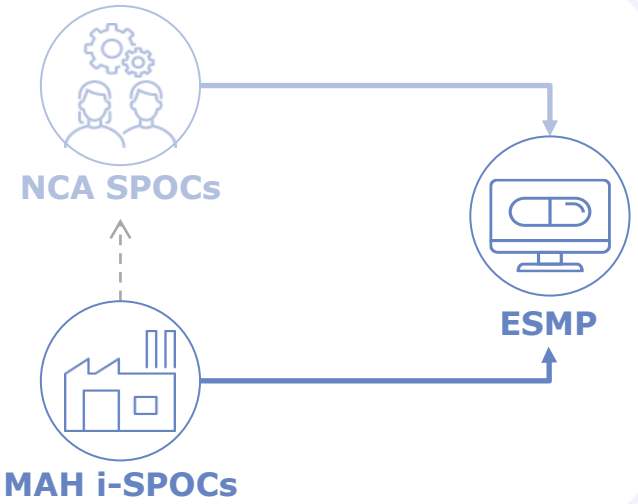
- **Shortage information**
- **Shortage prevention and mitigation plans**
- **Marketing status**
- **Market share, sales volume** and **sales forecast, stocks**
- **Manufacturing information** including production plan, capacity and alternative sites
- **Alternative therapies**

Submissions are triggered by an MSSG announcement and frequency of reporting is defined by the MSSG.

Data collection: Industry submissions

- i-SPOC Registration

The scope of this training refers to data submissions from MAHs in case of a crisis situation or MSSG-led preparedness action.



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- **Alternative therapies**

Submissions are triggered by an MSSG announcement and frequency of reporting is defined by the MSSG.

MAH reporting in a crisis situation or MSSG-led preparedness action

- For MAHs, reporting during a crisis or during an MSSG-led preparedness action follows the **same reporting process**
- The following section will outline the **step-by-step reporting processes** and the **required data elements** to be submitted via ESMP

	MSSG-led preparedness	Crisis
Available in:	**Preparedness (PHE, ME)**	**Crisis (PHE, ME)**
Purpose:	Specifically driven by the MSSG to address events that might lead to a PHE/ME	Focused on immediate actions to handle and mitigate the impact of ongoing or imminent crises, such as a PHE or ME
Submission trigger:	MSSG announcement of preparedness action	EC recognition of a PHE/ME
Products in scope:	List of medicines to be monitored for MSSG-led crisis preparedness (CAPs and NAPs) for human use	List of critical medicines for a public health emergency/ major event (CAPs and NAPs) for human use
Frequency of reporting:	Defined by the MSSG	Defined by the MSSG

Overview of the reporting process

Phase 1: activation and notification

- MSSG **activates a preparedness action** or a **PHE or ME is recognised**, triggering reporting
- EMA's MSSG **defines the reporting frequency** to ensure consistent updates from MAHs
- **EMA notifies MAHs** with products in scope, instructing them to begin reporting via ESMP

Phase 2: data review

- MAHs log into ESMP to **view the list of medicines** assigned for their reporting
- MAHs **review the marketing status of centrally authorised products** (CAPs) and update information if needed

Phase 3: data input

- MAHs **insert marketing status for nationally authorised products** (NAPs) if applicable
- MAHs **submit availability and manufacturing information** at the defined reporting frequency set by MSSG
- MAHs **submit information on alternative therapies** via a webform and keep it up-to-date

Overview of the reporting process: data input

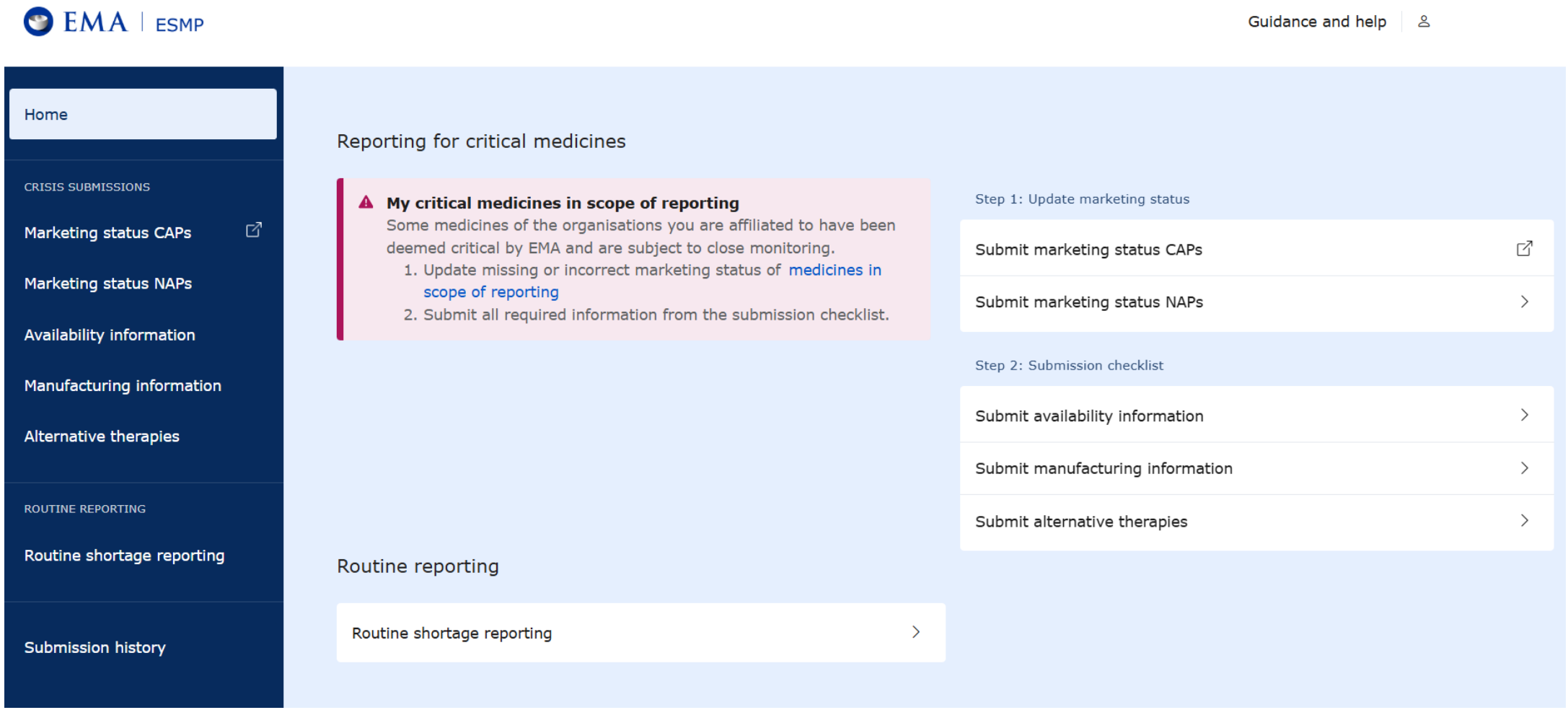
Phase 3: data input

- MAHs **insert marketing status for nationally authorised products** (NAPs) if applicable
- MAHs **submit availability and manufacturing information** at the defined reporting frequency set by MSSG
- MAHs **submit information on alternative therapies** via a webform and keep it up-to-date

To perform submissions, MAHs will:

1. *Download the pre-filled reporting templates or open the relevant web form directly in ESMP*
2. *Compile, upload, and submit relevant information*
3. *Submit updates according to frequency defined by MSSG, if applicable*

How to navigate the platform: overview



How to navigate the platform: steps to follow

1

Step 1: Update marketing status

Submit marketing status CAPs

Submit marketing status NAPs

- Reporting templates will be pre-filled with critical products and require correct information on the marketing status. To ensure complete reporting, verify that marketing status information is up to date.
  - For CAPs, submit or update marketing status in IRIS
  - For NAPs, submit marketing status information via the dedicated template in ESMP

2

Step 2: Submission checklist

Submit availability information

Submit manufacturing information

Submit alternative therapies

- You will report data in three different data flows, to cover different reporting requirements:
  - Template 1: availability information
  - Template 2: manufacturing information
  - Webform: alternative medicines

How to navigate the platform: submission history

Submission history

Submission type

Submission status

Apply

Submission ID	Type	Submission status	Submitted on
EMA/SH/0000005844	Marketing status NAPs	Success	13/02/2025 4:44 PM
EMA/SH/0000005839	Marketing status NAPs	Failed	13/02/2025 2:47 PM
EMA/SH/0000005838	Availability information	Failed	13/02/2025 2:46 PM
EMA/SH/0000005837	Manufacturing information	Success	13/02/2025 2:45 PM
EMA/SH/0000005823	Availability information	Failed	12/02/2025 5:59 PM
EMA/SH/0000005822	Availability information	Failed	12/02/2025 5:53 PM

Example

Guidance and resources

All information covered in this session is included in guidance materials publicly available through the ESMP webpage.

- Routine Shortage Reporting (RSR) training (presentation & video): step-by-step **instructions & demo** for access management & RSR
- User guide: **step-by-step instructions** on how to navigate and report through the ESMP for industry users
- Implementation guide: data **reporting guidelines** to ensure submissions pass validation checks
- Template prototypes: to familiarise with **reporting templates' format** and content, even if no reporting requirements are currently activated
- FAQs: **frequently asked questions** by both marketing authorisation holders and national competent authorities

Implementation guide: example

3.3.2. Marketing status details

The "marketing status details" section is intended to gather information about whether a particular product is placed on the market, and if applicable, the date of planned permanent withdrawal and any related information.

Data elements for Marketing status details		
Marketing status	Date of planned permanent withdrawal	Planned withdrawal comment
P1.9	W1.1	W1.2

Please consult the box and tables below for further details about each data element and relative conformance.

Tag	Explanation
ID	P1.9
Name	Marketing status
Description	Marketing status indicating whether a product is placed on the market.
Example	100000072083
Conformance	Mandatory
Data type	String
Validation rule	Must be the RMS term ID of a term in the RMS list "Marketing status" with list ID "100000072052". Consult possible values in the Annex 1 – RMS list Marketing status
Destination reference	Marketing status for NAPs template / column K

Example

Training scenario example

To enhance understanding and provide hands-on guidance, we will use a fictional scenario example throughout this training.

The scenario will:

Illustrate key points for data entry, demonstrating how to populate the templates accurately.

Guide best practices to showcase common issues to avoid and steps to ensure accurate reporting across different templates and granularities of data entry.

Disclaimer

- All the information used in the demonstrations displayed is fictional and made for the purpose of this training.

Scenario description

EU-wide critical shortages of **Rivastagmine, Pantropazole and Amoxicillin oral medicinal products** caused MSSG to adopt and publish a list of medicines for close monitoring and start the **MSSG-led preparedness** action.

MSSG requests the monitoring to begin from **1st of March 2025** and the forecast period is from **March to August 2025**.

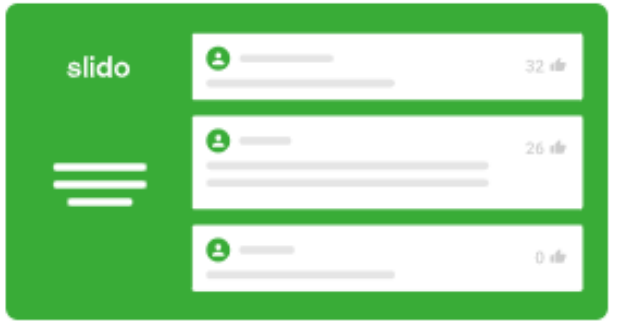
As the **MAH ESMP Pharma**, we have the following NAP and CAP medicinal products in our portfolio that are included in the list of medicines for close monitoring:

- Rivastigmine ESMP 4.5 mg, 112 hard capsules (CAP – authorised in all EU/EEA MS)
- Pantoprazol ESMP 20 mg and 40 mg gastro-resistant tablets, pack of 28 tablets (NAP – authorised in Austria)
- Daelvax 250 mg/5 ml, amoxicillin, powder for oral suspension, 60 ml and 100 ml bottle (NAP – authorised in Romania)

Send your questions via Slido

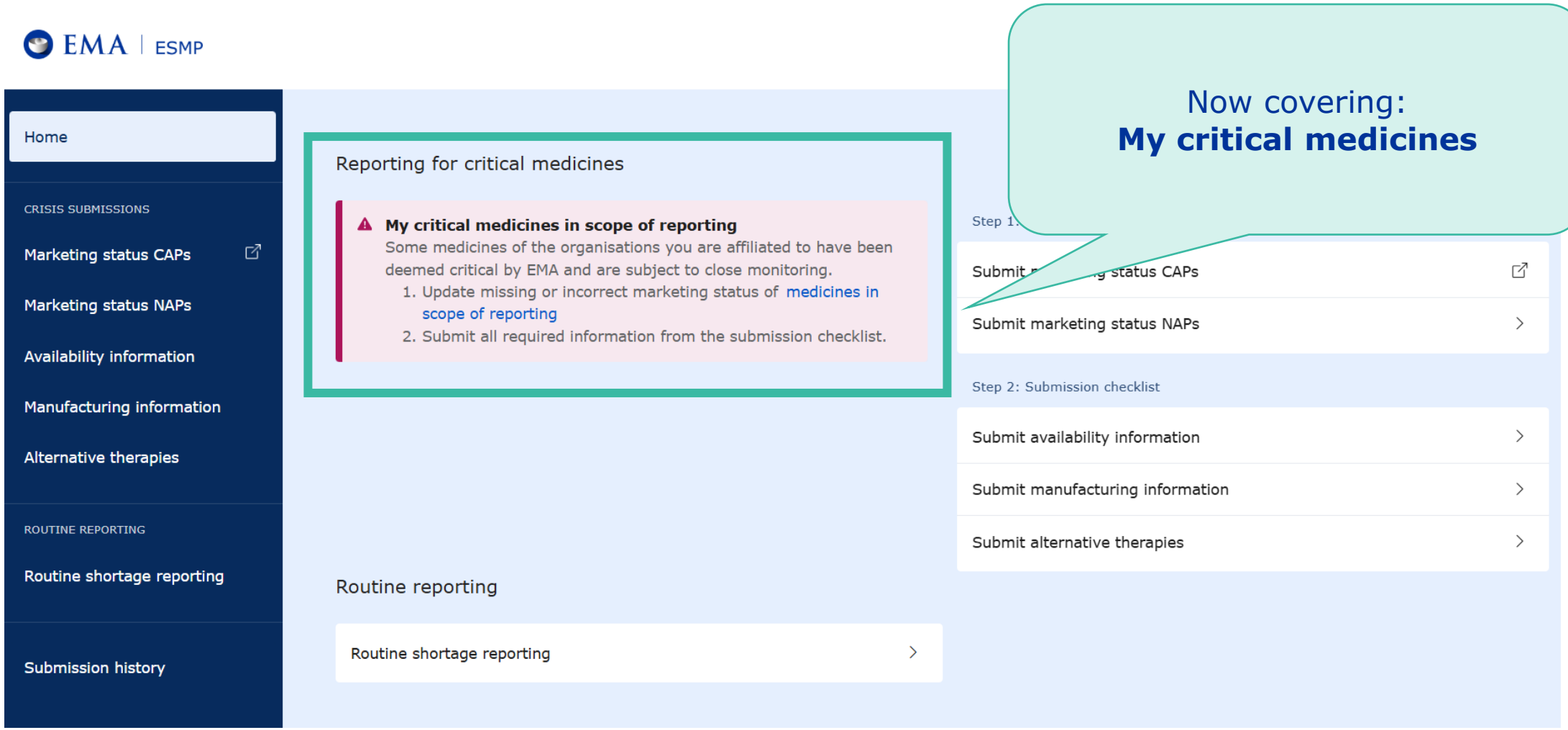
1. Join via the QR code or on www.slido.com with the session code #ESMP-MAH

2. Send or upvote the questions you want to hear answered



3. Questions will be shown on the screen and answered live in the Q&A session and compiled in the FAQ document on the ESMP webpage

Step 0: view your critical medicines

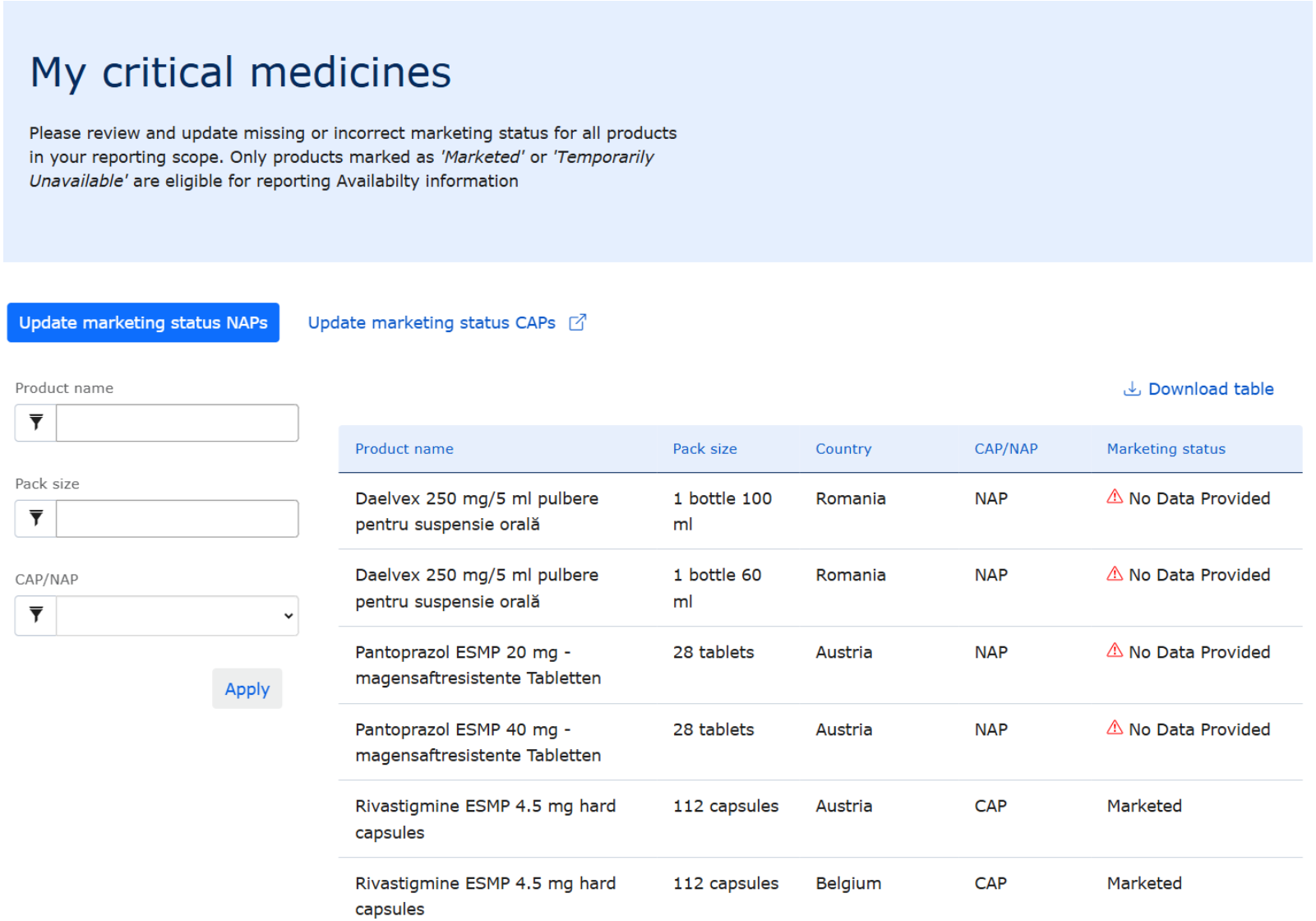


My critical medicines

- You can view all the **medicines under your product portfolio** that have been **marked as critical** for a particular crisis or MSSG-led preparedness action

- This page also shows the related marketing status information of your products in scope of reporting requirements for a given crisis or MSSG-led preparedness action

My critical medicines



My critical medicines

Please review and update missing or incorrect marketing status for all products in your reporting scope. Only products marked as *'Marketed'* or *'Temporarily Unavailable'* are eligible for reporting Availabilty information

Update marketing status NAPs

Update marketing status CAPs

Product name

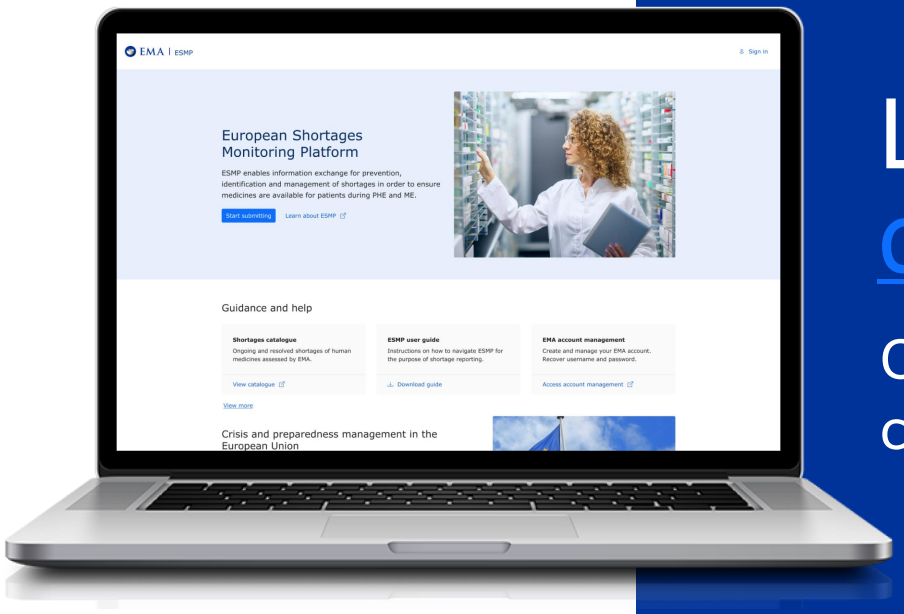
Pack size

CAP/NAP

Apply

Download table

Product name	Pack size	Country	CAP/NAP	Marketing status
Daelvex 250 mg/5 ml pulbere pentru suspensie orală	1 bottle 100 ml	Romania	NAP	No Data Provided
Daelvex 250 mg/5 ml pulbere pentru suspensie orală	1 bottle 60 ml	Romania	NAP	No Data Provided
Pantoprazol ESMP 20 mg - magensaftresistente Tabletten	28 tablets	Austria	NAP	No Data Provided
Pantoprazol ESMP 40 mg - magensaftresistente Tabletten	28 tablets	Austria	NAP	No Data Provided
Rivastigmine ESMP 4.5 mg hard capsules	112 capsules	Austria	CAP	Marketed
Rivastigmine ESMP 4.5 mg hard capsules	112 capsules	Belgium	CAP	Marketed



Let's see how it works: demo*

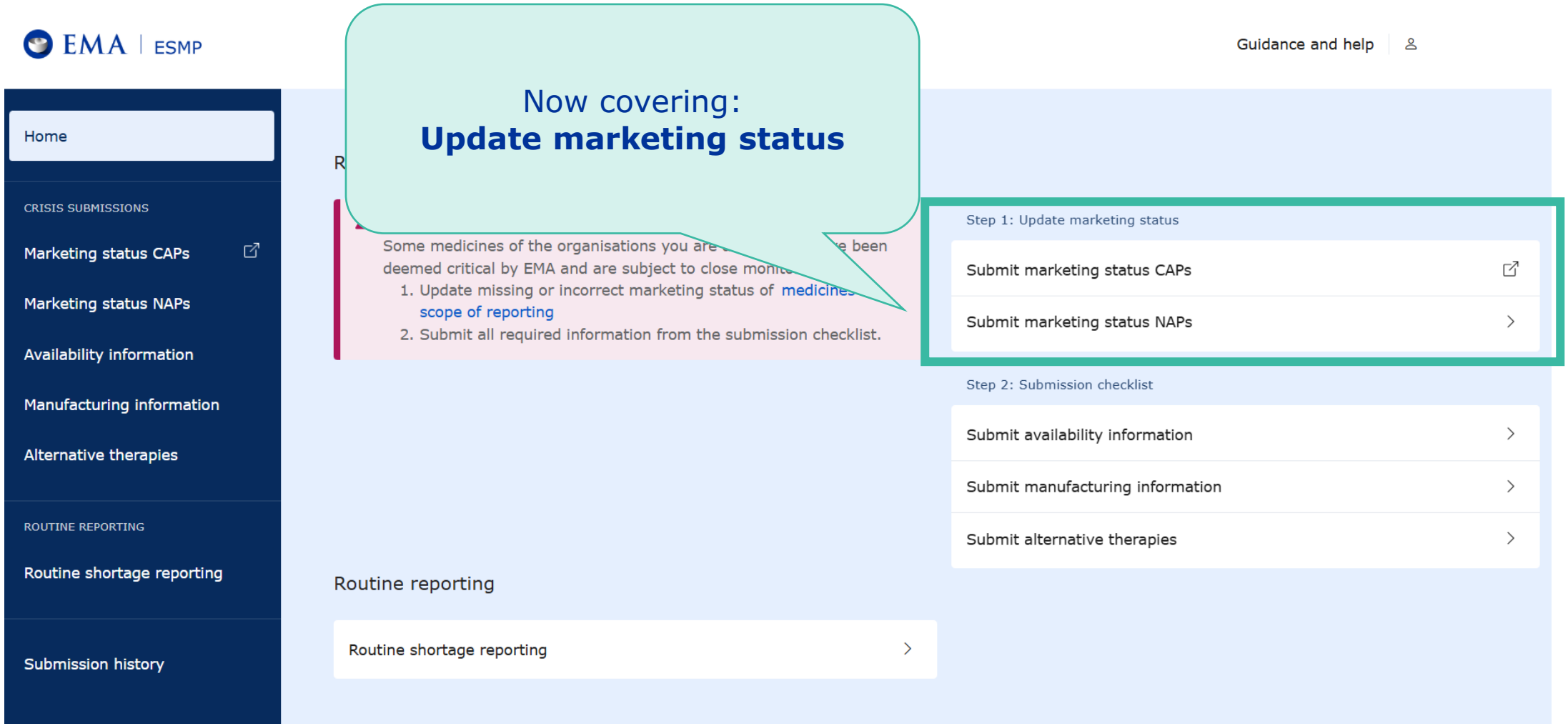
Overview of the homepage and the "My critical medicines" page

*Consult the demo in the training recording, accessible at this link:

https://www.youtube.com/watch?v=nvGR5k9ehg8&t=3031s

(timestamp 50:31)

Step 1: update marketing status

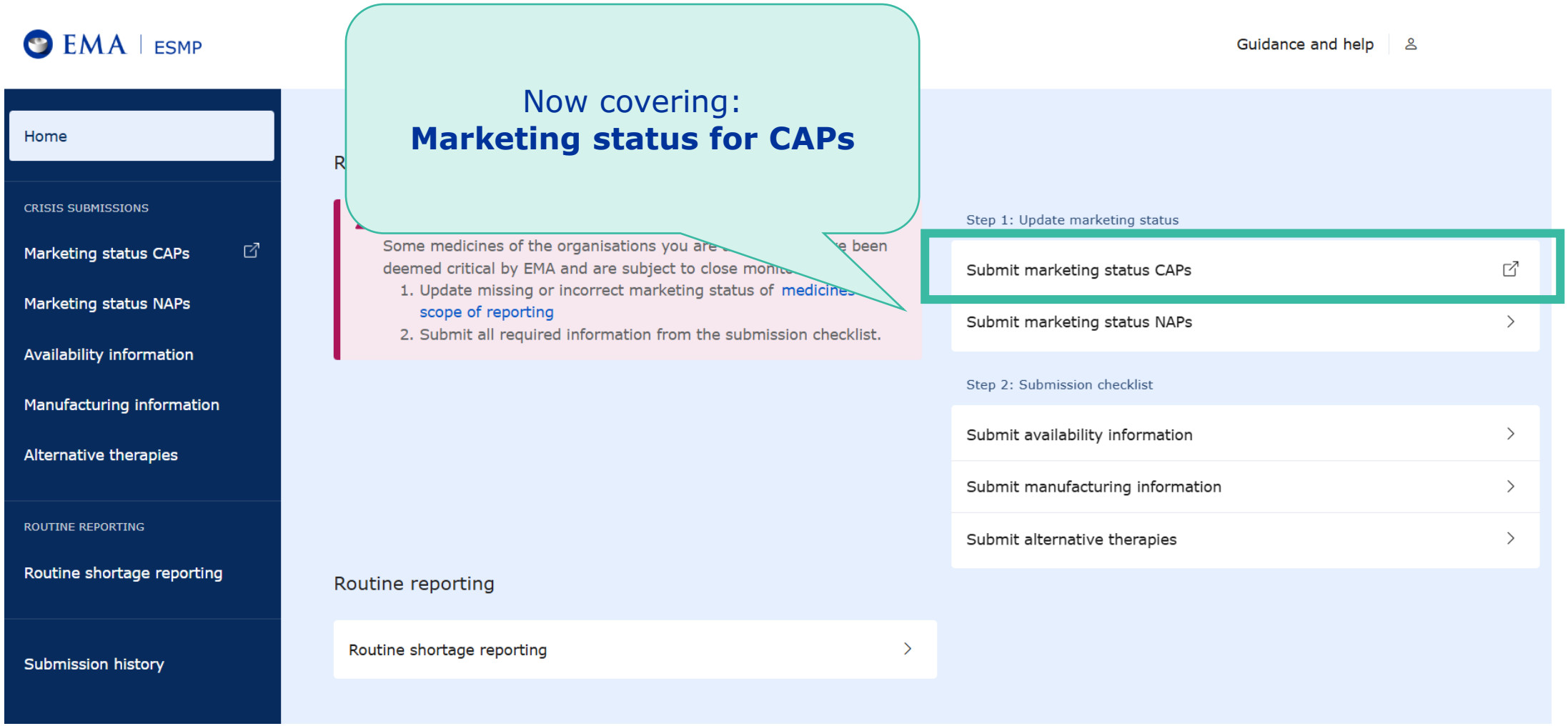


Reporting information on marketing status (MS) to EMA

MS of centrally authorised products (CAPs)	MS of nationally authorised products (NAPs)
Always required as a standard legal obligation	**Required only for critical products** during a crisis or MSSG-led preparedness action
Reported and kept up to date via **IRIS** at all times	Reported via **ESMP** while reporting requirements are active for a given crisis or MSSG-led preparedness action

Only products (both CAPs and NAPs) marked as «Marketed» or «Temporarily unavailable» will be eligible for reporting Availability information via ESMP

Marketing status for CAPs

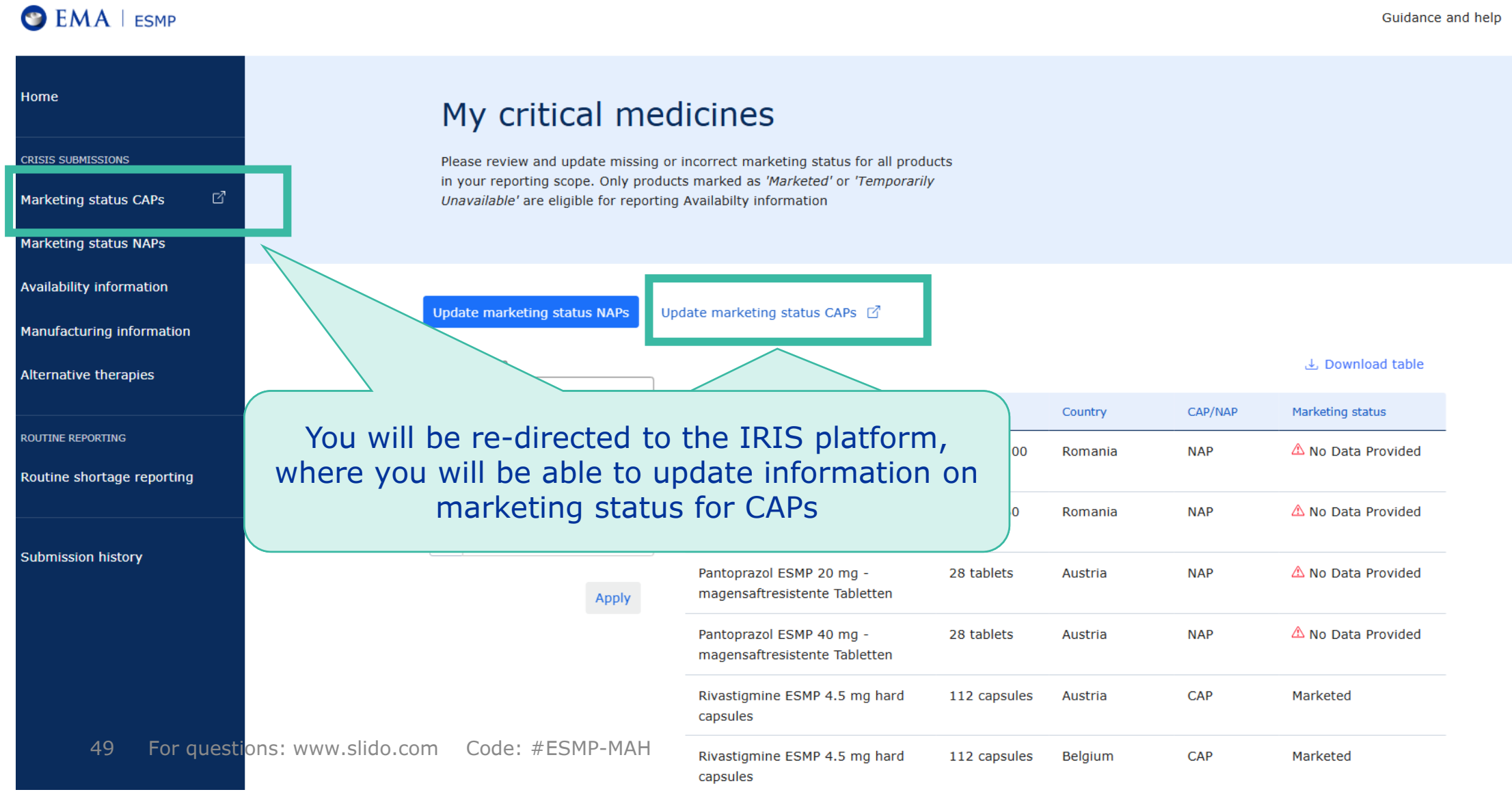


Marketing status for CAPs

- You will be able to **view** the marketing status of your products that fall within the reporting requirements of a specific crisis or MSSG-led preparedness action
- Marketing status of all CAPs must be inserted correctly and kept up-to-date within the IRIS platform
- Only products marked as «Marketed» or «Temporarily unavailable» will be eligible for reporting Availability information via ESMP

Product marketing status **in IRIS**	Product available for reporting Availability information in ESMP
Marketed	Yes
Temporarily unavailable	Yes
Not marketed	No
Never marketed	No
No data provided	No

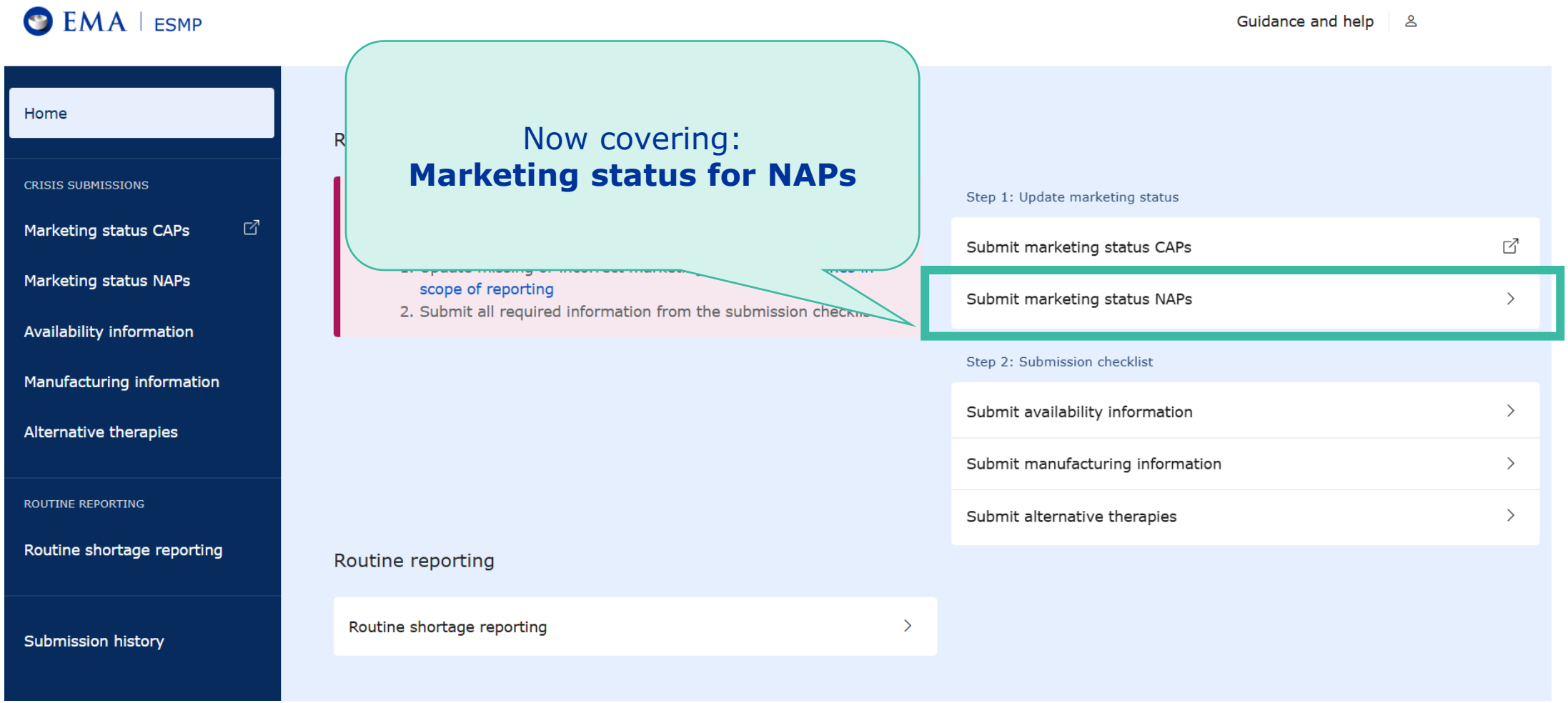
Marketing status for CAPs



You will be re-directed to the IRIS platform, where you will be able to update information on marketing status for CAPs

For questions: www.slido.com Code: #ESMP-MAH

Marketing status for NAPs



Marketing status for NAPs

- You will be able to **insert** the marketing status of your NAP products that fall within the reporting requirements of a specific crisis or MSSG-led preparedness action
- Marketing status of NAPs marked as critical during a crisis or MSSG-led preparedness action must be submitted and kept up to date via ESMP
- Only products marked as «Marketed» or «Temporarily unavailable» will be eligible for reporting Availability information via ESMP

Product marketing status **in ESMP**	Product available for reporting Availability information in ESMP
Marketed	Yes
Temporarily unavailable	Yes
Not marketed	No
Never marketed	No
No data provided	No

Marketing status for NAPs

Product information *(pre-populated from PMS)*	*Package PMS ID*
	Full product name
	Short product name
	Active substance
	Strength
	Pharmaceutical form
	Pack size
	Packaging
	PCID
	Country of authorisation
Marketing status details	Marketing status
	Date of planned permanent withdrawal
	Planned withdrawal comment

Product information

Product information *(pre-populated from PMS)*	*Package PMS ID*
	Full product name
	Short product name
	Active substance
	Strength
	Pharmaceutical form
	Pack size
	Packaging
	PCID
	Country of authorisation
Marketing status details	Marketing status
	Date of planned permanent withdrawal
	Planned withdrawal comment

- Product information fields will be **pre-populated** from data inserted via the EMA's Product Management Services (PMS) and they cannot be changed by updating the data in ESMP

Marketing status details

Product information *(pre-populated from PMS)*	*Package PMS ID*
	Full product name
	Short product name
	Active substance
	Strength
	Pharmaceutical form
	Pack size
	Packaging
	PCID
	Country of authorisation
Marketing status details	Marketing status
	Date of planned permanent withdrawal
	Planned withdrawal comment

- Marketing status data for NAPs must be kept **up to date** via ESMP
- Marketing status must be entered at **packaged medicinal product level** to ensure accurate reporting

Legend: Pantoprazol ESMP 40 mg; Pantoprazol ESMP 20 mg; Daelvax

Product information

Product information				
PMS ID	Full product name	Short product name	Active substance	Strength
P1.1.1	P1.2.1	P1.2.2	P1.3.2	P1.4
31113478	Pantoprazol ESMP 20 mg - magensaftresistente Tabletten	Pantoprazol ESMP 20 mg - magensaftresistente Tabletten	Pantoprazole	20 MG
31113135	Pantoprazol ESMP 40 mg - magensaftresistente Tabletten	Pantoprazol ESMP 40 mg - magensaftresistente Tabletten	Pantoprazole	40 MG
31415929	Daelvax 250 mg/5 ml pulbere pentru suspensie orală	Daelvax	Amoxicillin	250 MG/5 ML
31415930	Daelvax 250 mg/5 ml pulbere pentru suspensie orală	Daelvax	Amoxicillin	250 MG/5 ML

Product information				
Pharmaceutical form	Pack size	Packaging	PCID	Country of authorisation
P1.6.2	P1.7.2	P1.7.3	P1.7.1	P1.8
Gastro-resistant tablet	28 tablets	Blister		AT
Gastro-resistant tablet	28 tablets	Blister		AT
Powder for oral suspension	1 bottle 60 ml	Bottle		RO
Powder for oral suspension	1 bottle 100 ml	Bottle		RO

Legend: Pantoprazol ESMP 40 mg; Pantoprazol ESMP 20 mg; Daelvax

Marketing status details

				Marketing status details		
	Pack size	Country of authorisation	…	Marketing status	Date of planned permanent withdrawal	Planned withdrawal comment
	P1.7.2	P1.8	…	P1.9	W1.1	W1.2
●	28 tablets	AT	…	230000000000		
●	28 tablets	AT	…	100000072083	05/04/2026	Withdrawal due to commercial reasons
●	1 bottle 60 ml	RO	…	100000072083		
●	1 bottle 100 ml	RO	…	100000072074		

Legend: Pantoprazol ESMP 40 mg | Pantoprazol ESMP 20 mg | Daelvax

Marketing status details

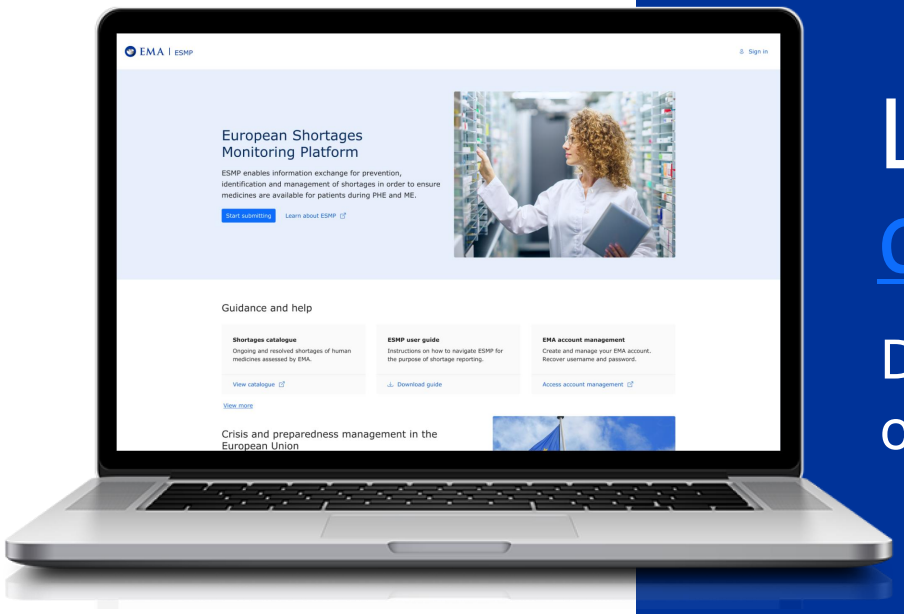
				Marketing status details		
	Pack size	Country of authorisation	…	Marketing status	Date of planned permanent withdrawal	Planned withdrawal comment
	P1.7.2	P1.8	…	P1.9	W1.1	W1.2
●	28 tablets	AT	…	230000000000		
●	28 tablets	AT	…	100000072083	05/04/2026	Withdrawal due to commercial reasons
●	1 bottle 60 ml	RO	…	100000072083		
●	1 bottle 100 ml	RO	…	100000072074		

Temporarily unavailable

Marketed

Not marketed

- Refer to Annex 1 of the **ESMP Implementation guide for MAHs** for **RMS lists and terms**



Let's see how it works: demo*

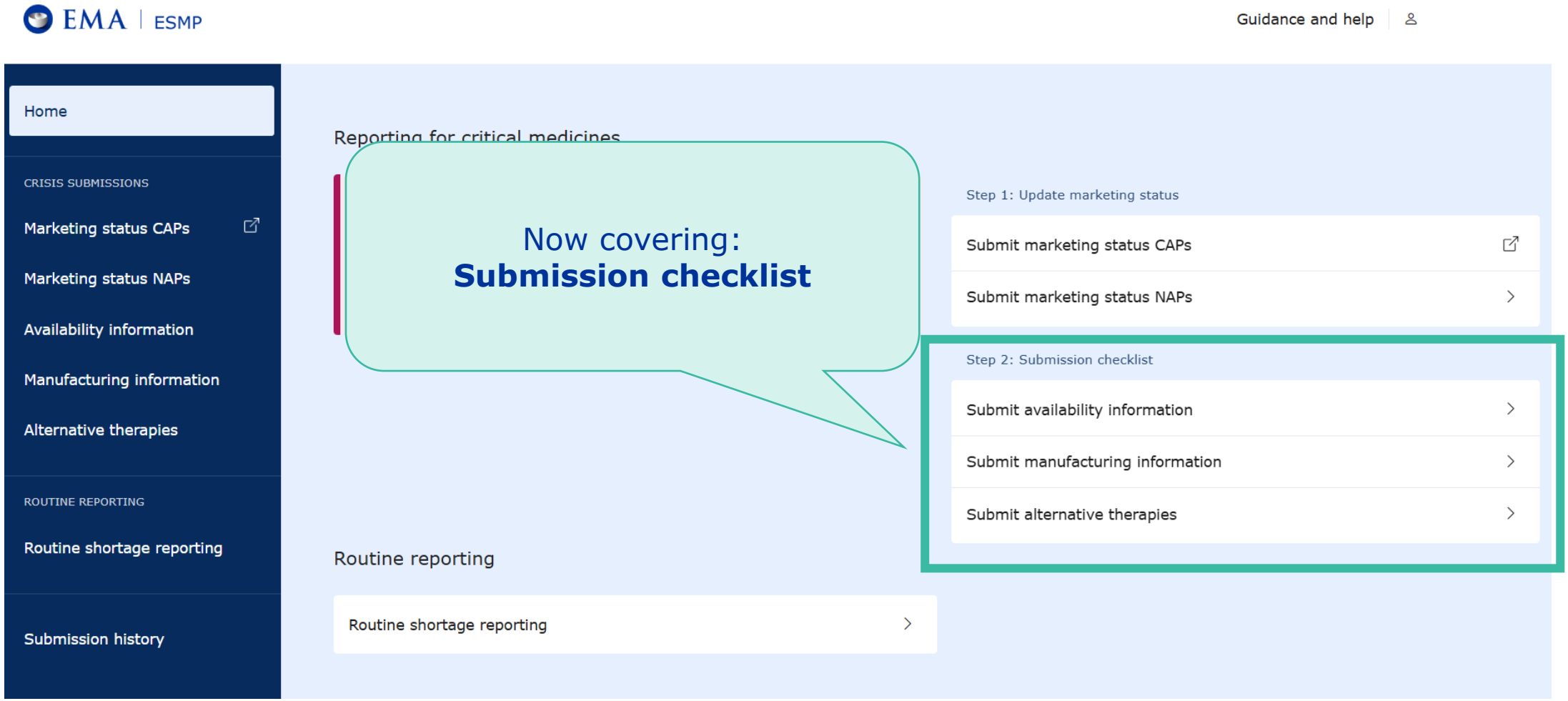
Download, compile, and upload the template of Marketing status for NAPs

*Consult the demo in the training recording, accessible at this link:

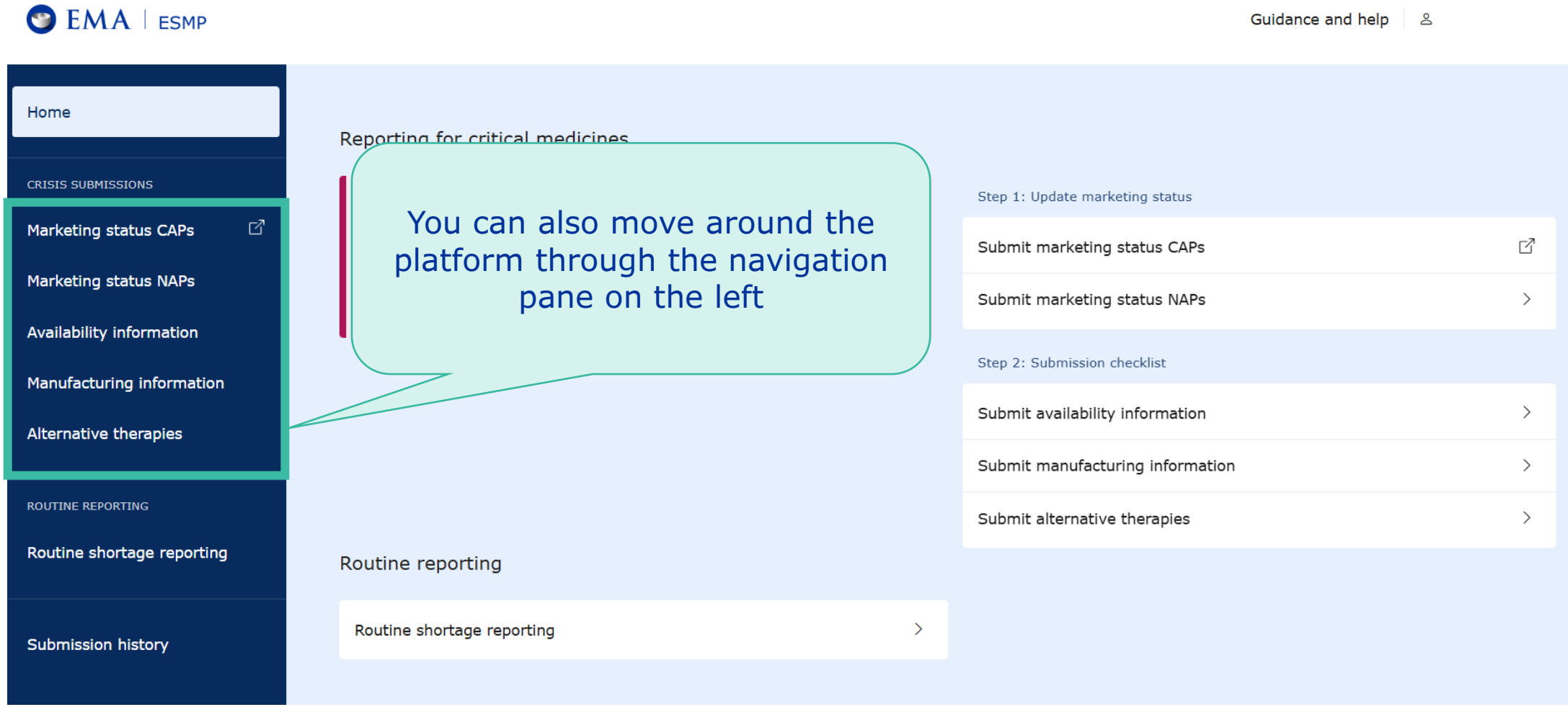
https://www.youtube.com/watch?v=nvGR5k9ehg8&t=3537s

(timestamp 58:57)

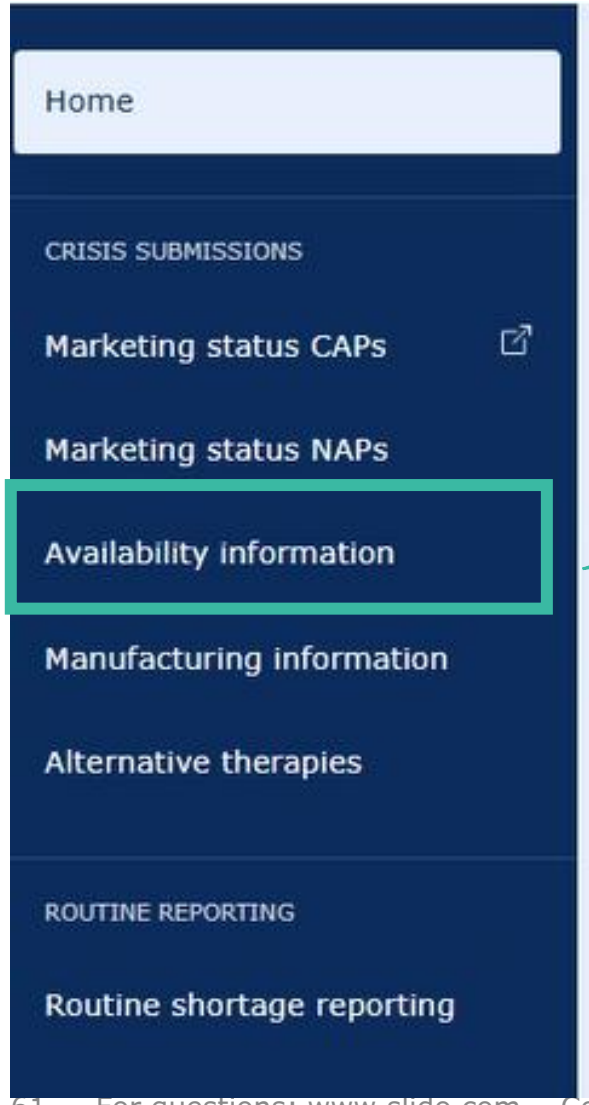
Step 2: start submitting



Step 2: start submitting



Template 1: Availability information



Now covering:
Availability information

Reporting process

Step 1: download template

- **Retrieve the reporting template** from ESMP
- The template will include all products in scope and the latest version of any previously inserted data, if available

Step 2: populate template

- **Enter the required information** for each product
- **Ensure accuracy and completeness** before proceeding

Step 3: upload to ESMP

- **Submit the completed template** back into the ESMP
- **Confirm successful upload** and review for any errors or required corrections

Template 1: Availability information

Product information *(pre-populated from PMS, marketing status from IRIS and ESMP)*	*Package PMS ID*
	Full product name
	Short product name
	Active substance
	Strength
	Pharmaceutical form
	Pack size
	Packaging
	PCID
	Country of authorisation
	Marketing status
Shortage information	*Shortage status*
	Shortage start date or expected start date
	Shortage end date or expected end date
	Point in supply chain at which disruption occurs
	Root cause of the shortage
	Countries in which manufacturing issues occur
	Countries in which distribution issues occur
	Root cause of the shortage - additional information

Shortage prevention and mitigation plans	*Shortage prevention and mitigation plans*
	Ongoing and planned steps
Market share	*Market share*
	Additional information
Sales volume and forecast	*Sales volume pre-PHE/ME*
	Sales volume current
	Forecast - Months 1-6
	Forecast - Additional information
Supply forecast	*Months 1-6*
	Additional information
Stock information	*Available stocks*
	Desired safety stock
	Stocks – additional information

Product information (1/2)

Product information *(pre-populated from PMS, marketing status from IRIS and ESMP)*	*Package PMS ID*
	Full product name
	Short product name
	Active substance
	Strength
	Pharmaceutical form
	Pack size
	Packaging
	PCID
	Country of authorisation
	Marketing status

Shortage prevention and mitigation plans	*Shortage prevention and mitigation plans*
	Ongoing and planned steps
Market share	*Market share*
	Additional information
Sales volume and forecast	*Sales volume pre-PHE/ME*
	Sales volume current
	Forecast - Months 1-6

- Product information fields will be **pre-populated** from data inserted via the EMA's Product Management Services (PMS) and they cannot be changed by updating the data in ESMP
- Marketing status information fields will be **pre-populated** from data inserted via the **IRIS (for CAPs)** or in the **dedicated ESMP template (for NAPs)** and they cannot be changed by updating this data in Availability information submission flow

Product information (2/2)

Product information *(pre-populated from PMS, marketing status from IRIS and ESMP)*	*Package PMS ID*
	Full product name
	Short product name
	Active substance
	Strength
	Pharmaceutical form
	Pack size
	Packaging
	PCID
	Country of authorisation
	Marketing status

Shortage prevention and mitigation plans	*Shortage prevention and mitigation plans*
	Ongoing and planned steps
Market share	*Market share*
	Additional information
Sales volume and forecast	*Sales volume pre-PHE/ME*
	Sales volume current
	Forecast - Months 1-6

- Only products listed as "**Marketed**" or "**Temporarily unavailable**" in IRIS (for CAPs) or in ESMP (for NAPs) will be retrieved and pre-populated in this template. Products listed as "Not marketed", "Never marketed", or with missing marketing status information will not appear in the Availability information submission templates
- If Marketing status information is incorrect, **update it directly in IRIS** (for CAPs) **or in the dedicated ESMP template** (for NAPs). Changes will automatically be reflected in the Availability template the next time it's downloaded

Legend: Pantoprazol ESMP 40 mg; Pantoprazol ESMP 20 mg; Daelvax; Rivastigmine ESMP

Product information

Product information

Package PMS ID	Full product name	Short product name	Active substance	Strength	Pharmaceutical form
P1.1.2	P1.2.1	P1.2.2	P1.3.2	P1.4	P1.6.2
31113135	Pantoprazol ESMP 40 mg - magensaftresistente Tabletten	Pantoprazol ESMP 40 mg - magensaftresistente Tabletten	Pantoprazole	40 MG	Gastro-resistant tablet
31113478	Pantoprazol ESMP 20 mg - magensaftresistente Tabletten	Pantoprazol ESMP 20 mg - magensaftresistente Tabletten	Pantoprazole	20 MG	Gastro-resistant tablet
31415929	Daelvax 250 mg/5 ml pulbere pentru suspensie orală	Daelvax	Amoxicillin	250 MG/5 ML	Powder for oral suspension
73387	Rivastigmine ESMP 4.5 mg hard capsules	Rivastigmine ESMP	Rivastigmine	4.5 MG	Capsule, hard

Product information

Pack size	Packaging	PCID	Country of authorisation	Marketing status
P1.7.2	P1.7.3	P1.7.1	P1.8	P1.9
28 tablets	Blister		AT	Marketed
28 tablets	Blister		AT	Temporarily unavailable
1 bottle 60 ml	Bottle		RO	Marketed
112 capsules	Blister		SK	Marketed

Shortage information

	Package PMS ID
	Full product name
	Country of authorisation
	Marketing status
Shortage information	*Shortage status*
	Shortage start date or expected start date
	Shortage end date or expected end date
	Point in supply chain at which disruption occurs
	Root cause of the shortage
	Countries in which manufacturing issues occur
	Countries in which distribution issues occur
	Root cause of the shortage - additional information

Shortage prevention and	*Shortage prevention and mitigation plans*
Sales volume and forecast	*Forecast - Months 1-6*
	Forecast - Additional information
Supply forecast	*Months 1-6*
	Additional information
Stock information	*Available stocks*
	Desired safety stock
	Stocks – additional information

- Date formats should be inserted as DD/MM/YYYY
- Use numerical codes from the EMA's Referentials Management Services (**RMS**) to ensure **standard identifiers**, where applicable
- Separate multiple values with semicolons (";") with no additional spaces
- Refer to the **ESMP Implementation guide for MAHs** for specifications on how to compile data fields to ensure they pass validations

Legend: Pantoprazol ESMP 40 mg; Pantoprazol ESMP 20 mg; Daelvax; Rivastigmine ESMP

Shortage information

Shortage information

Shortage status	Shortage start date or expected start date	Shortage end date or expected end date	Point in supply chain at which disruption occurs	Root cause of the shortage
S1.1	S1.2	S1.3	S1.4	S1.5
No shortage				
No shortage				
No shortage				
Actual	26/11/2024	08/03/2025	200000028591; 200000028592	200000028710

Importation; Distribution of released products

Distribution issues - Import restrictions

Shortage information

Countries in which manufacturing issues occur	Countries in which increased demand occurs	Countries in which distribution issues occur	Root cause of the shortage - additional information
S1.6.1	S1.6.2	S1.6.3	S1.7
		BE	Customs investigation ongoing

Shortage prevention and mitigation plans

Product information *(pre-populated from PMS)*	*Package PMS ID*
	Full product name
	Short product name
	Active substance
	Strength
	Pharmaceutical form
	Pack size
	Packaging
	PCID
	Country of authorisation
	Information

Shortage prevention and mitigation plans	*Shortage prevention and mitigation plans*
	Ongoing and planned steps
Market share	*Market share*
	Additional information
Sales volume	*Sales volume pre-PHE/ME*
	Sales volume current

- **Please note**: these fields do not require MAHs to submit the SPMP templates recently published by EMA, but if MAHs choose to submit the filled SPMP templates to EMA they can mention it in the free text field here as well
- Use numerical codes from the EMA's Referentials Management Services (**RMS**) to ensure **standard identifiers**, where applicable
- Separate multiple RMS values with semicolons (";") with no additional spaces
- Refer to the **ESMP Implementation guide for MAHs** for specifications on how to compile data fields to ensure they pass validations

Shortage prevention and mitigation plans: possible values

- Refer to Annex 1 of the **ESMP Implementation guide for MAHs** for **RMS lists and terms**

RMS list 200000028617 | https://spor.ema.europa.eu/rmswi/#/lists/200000028617/terms

Identifier	Term name
200000028633	Alternative active substance manufacturer
200000028634	Alternative finished product manufacturer
200000028635	Alternative batch control site
200000028636	Alternative batch release site
200000028637	Supply of product in foreign language labelling
200000028638	Supply of alternative unauthorised product
200000028639	Release of product with minor quality defects
200000028640	Increase production capacity of current site(s)
200000028641	Supply of other presentation(s) of the same product
200000028642	Use of exceptional change management process (ECMP)
200000028643	Resolve manufacturing or quality issue(s)
200000028644	Change mode of transportation
200000028645	Expedited shipment and shipment under quarantine
200000028646	Prioritisation of supplies to critical customers
200000029652	Alternative sources of raw/starting materials
200000028647	Other

Market share

Product information *(pre-populated from PMS)*	*Package PMS ID*
	Full product name
	Short product name
	Active substance
	Strength
	Pharmaceutical form
	Pack size
	Packaging
	PCID
	Country of authorisation
	Countries in which distribution issues occur
	Root cause of the shortage - additional information

Shortage prevention and mitigation plans	*Shortage prevention and mitigation plans*
	Ongoing and planned steps
Market share	*Market share*
	Additional information
Sales volume	*Sales volume pre-PHE/ME*
	Sales volume current
Stock information	*Desired safety stock*
	Stocks – additional information

- The latest year-to-date (YTD) market share data at pack level must be provided as a whole number between 0 and 100
- Market share data should address **both hospital and non-hospital** markets
- Refer to the **ESMP Implementation guide for MAHs** for specifications on how to compile data fields to ensure they pass validations

For questions: www.slido.com Code: #ESMP-MAH

Legend: Pantoprazol ESMP 40 mg | Pantoprazol ESMP 20 mg | Daelvax | Rivastigmine ESMP

Shortage prevention and mitigation plans and Market share

Shortage prevention and mitigation plans

Shortage prevention and mitigation plans	Shortage prevention and mitigation plans - ongoing and planned steps
S2.1	S2.2
200000028646	Investigation of mitigation strategies ongoing

Prioritisation of supplies to critical customers

Market share

Market share	Market share - additional information
S3.2	S3.3
28	Data represents snapshot from 01.01.2024
38	Data represents snapshot from 01.01.2024
22	Extract from 05.01.2025
45	

Disclaimer: all the information used in the demonstrations displayed is fictional and made for the purpose of this training.

Sales volume and forecast

Product information *(pre-populated from PMS)*	*Package PMS ID*
	Full product name
	Short product name
	Active substance
	Strength
	Pharmaceutical form
	Pack size
	Packaging
	PCID
	Country of authorisation
	Marketing status
	Shortage status
	Shortage start date or expected start date

Shortage prevention and mitigation plans	*Shortage prevention and mitigation plans*
	Ongoing and planned steps
Market share	*Market share*
	Additional information
Sales volume and forecast	*Sales volume pre-PHE/ME*
	Sales volume current
	Forecast - Months 1-6
	Forecast - Additional information

- **Sales volume pre-PHE/ME** should reflect the **full-year average of monthly packs** sold in a specific member state before the PHE/ME in scope
- **Sales volume current** should reflect the amount of **packs sold in the last 4 weeks** in a specific member state
- **Sales volume forecast** should indicate the **expected number of packs** to be sold in a specific member state during the forecasting period
- All data should be submitted at **packaged medicinal product level**

Supply forecast

- **Supply forecast** collects data on the expected availability of packs sold in a specific member state for a forecasting period of six months
- It should reflect the number of packs anticipated to enter the market, considering production schedules, stock levels, and distribution plans

	Package PMS ID
	Full product name
	Country of authorisation
	Marketing status
Shortage information	*Shortage status*
	Shortage start date or expected start date
	Shortage end date or expected end date
	Point in supply chain at which disruption occurs
	Root cause of the shortage
	Countries in which manufacturing issues occur
	Countries in which distribution issues occur
	Root cause of the shortage - additional information

Shortage prevention and	*Shortage prevention and mitigation plans*
Sales volume and forecast	*Forecast - Months 1-6*
	Forecast - Additional information
Supply forecast	*Months 1-6*
	Additional information
Stock information	*Available stocks*
	Desired safety stock
	Stocks – additional information

Legend: Pantoprazol ESMP 40 mg; Pantoprazol ESMP 20 mg; Daelvax; Rivastigmine ESMP

Sales volume and forecast and Supply forecast

Sales volume and forecast

Sales volume pre-PHE/ME	Sales volume current	Sales volume forecast - Month 1	Sales volume forecast - Month 2	Sales volume forecast - Month 3	Sales volume forecast - Month 4	Sales volume forecast - Month 5	Sales volume forecast - Month 6	Sales volume - additional information
S6.1	S6.2	S7.1.1	S7.1.2	S7.1.3	S7.1.4	S7.1.5	S7.1.6	S7.2
84	57	16	13	17	0	32	0	Decreased demand foreseen
129	90	5	19	7	0	20	0	
130	72	5,8	17	0	24	0	0	
180	62	51	28	0	23	4	20	

Supply forecast

Supply forecast - Month 1	Supply forecast - Month 2	Supply forecast - Month 3	Supply forecast - Month 4	Supply forecast - Month 5	Supply forecast - Month 6	Supply forecast - additional information
S8.1.1	S8.1.2	S8.1.3	S8.1.4	S8.1.5	S8.1.6	S8.2
0	85	64	97	0	103	
140	118	132	149	137	0	
116	0	0	87	167	0	Supply forecast currently not certain due to manufacturing incident
213	198	210	196	209	223	

Disclaimer: all the information used in the demonstrations displayed is fictional and made for the purpose of this training.

Stock information

	Package PMS ID
	Full product name
	Country of authorisation
	Marketing status
Shortage information	*Shortage status*
	Shortage start date or expected start date
	Shortage end date or expected end date
	Point in supply chain at which disruption occurs
	Root cause of the shortage
	Countries in which manufacturing issues occur
	Countries in which distribution issues occur
	Root cause of the shortage - additional information

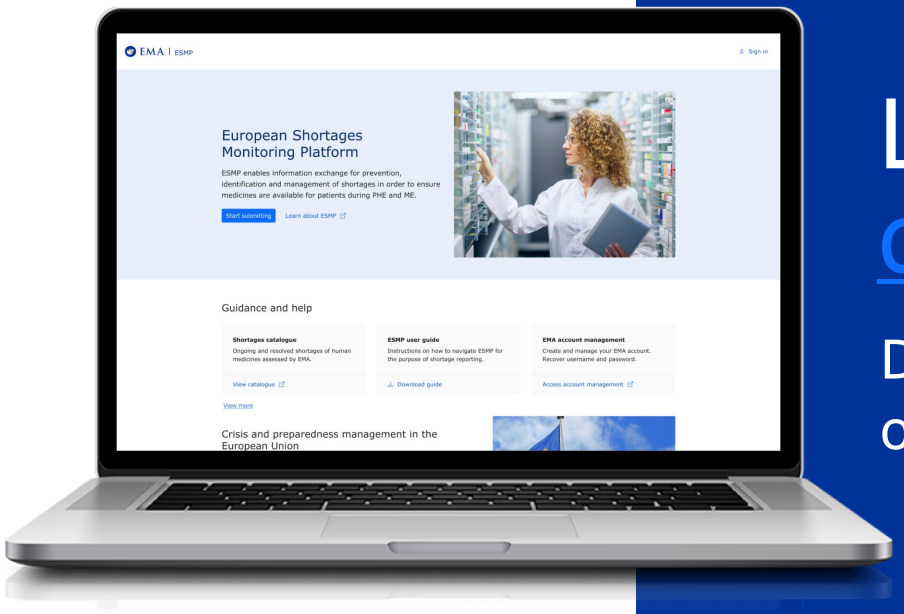
Shortage prevention and	*Shortage prevention and mitigation plans*
Sales volume and forecast	*Forecast - Months 1-6*
	Forecast - Additional information
Supply forecast	*Months 1-6*
	Additional information
Stock information	*Available stocks*
	Desired safety stock
	Stocks – additional information

- **Available stock** collects data on the **number of packs physically available** and owned by the MAH at the time of submission, intended for distribution to a specific member state
- **Desired safety stock** collects data on the **number of packs maintained as a buffer** by the MAH to manage demand fluctuations and ensure continuous supply to patients in a specific member state

For questions: www.slido.com Code: #ESMP-MAH

Stock information

Stock information		
Available stocks	Desired safety stock	Stocks - additional information
S9.1	S9.2	S9.3
206	68	
480	160	
188	62	
0	0	Low stock expected in second half of the year due to possible spikes in demand



Let's see how it works: demo*

Download, compile, and upload the template of Availability information

*Consult the demo in the training recording, accessible at this link:

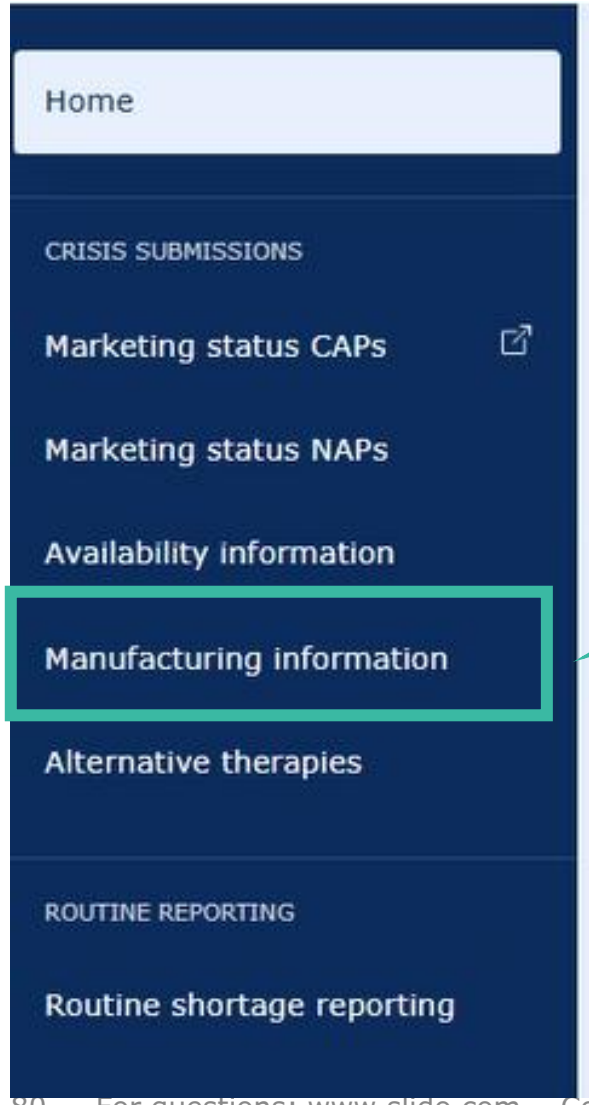
https://www.youtube.com/watch?v=nvGR5k9ehg8&t=4475s

(timestamp 1:14:35)

Coffee break

We're back in 5’

Template 2: Manufacturing information



Now covering:
Manufacturing information

Template 2: Manufacturing information

Product information *(pre-populated from PMS)*	*PMS ID*
	Full product name
	Active substance SMS ID
	Active substance
Representative product	Representative product
Organisation information *(pre-populated from PMS)*	Operation type ID
	Operation type
	ORG-ID (Manufacturer)
	Manufacturer
	LOC-ID (Manufacturer)
	City (Manufacturer)
	Country (Manufacturer)

Manufacturing details	Manufacturing site status
	Is the site a contract manufacturer
Alternatives sites	Alternative site LOC-ID
	Alternative site Country
Production capacity	*Unit of measurement*
	Global monthly production plan – Months 1-6
	Global monthly production plan – additional information
	Average global monthly production output of previous year
	Peak global monthly production output of previous year

Product information

Product information *(pre-populated from PMS)*	*PMS ID*
	Full product name
	Active substance SMS ID
	Active substance
Representative product	Representative product
	Operation type ID
	City (Manufacturer)
	Country (Manufacturer)

Manufacturing details	Manufacturing site status
	Is the site a contract manufacturer
Alternatives sites	Alternative site LOC-ID
	Alternative site Country
	previous year
	Peak global monthly production output of previous year

- Product information fields will be **pre-populated** from data inserted via the EMA's Product Management Services (PMS) and they cannot be changed by updating the data in ESMP
- Manufacturing data to be submitted at medicinal product level (not package)

Legend: Pantoprazol ESMP 40 mg; Pantoprazol ESMP 20 mg; Rivastigmine ESMP

Product information

Product information			
PMS ID	Full product name	Active substance SMS ID	Active substance
P1.1.1	P1.2.1	P1.3.1	P1.3.2
600000000844	Rivastigmine ESMP 4.5 mg hard capsules	100000089185	Rivastigmine
600000000844	Rivastigmine ESMP 4.5 mg hard capsules	100000089185	Rivastigmine
600001622030	Pantoprazol ESMP 40 mg - magensaftresistente Tabletten	100000092491	Pantoprazole
600001839370	Pantoprazol ESMP 20 mg - magensaftresistente Tabletten	100000092491	Pantoprazole

Organisation information

- **For CAPs**, organisation information fields will be **pre-populated** from data inserted via the EMA's Product Management Services (PMS) and they cannot be changed by updating the data in ESMP
- **For NAPs**, due to the absence of manufacturing information in PMS at the time of development, two pre-populated operation types were implemented to represent the manufacturing of the active substance and the bulk product (excluding packaging and labeling)
  - As MAHs are now inputting manufacturing details for NAPs in PMS, this information will be integrated into the ESMP in upcoming iterations

Organisation information	Operation type ID
	Operation type
	ORG-ID (Manufacturer)
	Manufacturer
	LOC-ID (Manufacturer)
	City (Manufacturer)
	Country (Manufacturer)

Production capacity	*Unit of measurement*
	Global monthly production plan – Months 1-6
	Global monthly production plan – additional information
	Average global monthly production output of previous year
	Peak global monthly production output of previous year

Organisation information: CAPs

Organisation information			
Operation type ID	Operation type	ORG-ID (Manufacturer)	Manufacturer
O1.1	O1.2	O1.3	O1.4
100000160453	Manufacturing of active substance intermediate	ORG-459	ESMP Laboratories Limited
100000160463	Primary packaging	ORG-464	ESMP Medical
100000160413	Processing operations for the medicinal product	ORG-466	ESMP Laboratories Limited IE
100000160467	Manufacturing of active substance	ORG-483	ESMP Integrated Services

Organisation information		
LOC-ID (Manufacturer)	City (Manufacturer)	Country (Manufacturer)
O1.5	O1.6	O1.7
LOC-126	Bern	Switzerland
LOC-131	New Delhi	India
LOC-133	Singapore	Singapore
LOC-153	Stockholm	Sweden

Legend: Pantoprazol ESMP 40 mg; Pantoprazol ESMP 20 mg

Organisation information: NAPs

Organisation information			
Operation type ID	Operation type	ORG-ID (Manufacturer)	Manufacturer
O1.1	O1.2	O1.3	O1.4
100000160467	Manufacturer of active substance		
100000160413	Processing operations for the medicinal product		
100000160467	Manufacturer of active substance		
100000160413	Processing operations for the medicinal product		

Organisation information		
LOC-ID (Manufacturer)	City (Manufacturer)	Country (Manufacturer)
O1.5	O1.6	O1.7

Manufacturing details

Product information *(pre-populated from PMS)*	*PMS ID*
	Full product name
	Active substance SMS ID
	Active substance
Representative product	Representative product
	Operation type ID
	City (Manufacturer)
	Country (Manufacturer)

Manufacturing details	Manufacturing site status
	Is the site a contract manufacturer
Alternatives sites	Alternative site LOC-ID
	Alternative site Country
	previous year
	Peak global monthly production output of previous year

- **Manufacturing details** collects data on whether the manufacturing sites currently in use and if the site is owned by the MAH or operated by a contract manufacturer
- The manufacturing site status of the can be either “Active” or “Backup”

Alternative sites

Product information *(pre-populated from PMS)*	*PMS ID*
	Full product name
	Active substance SMS ID
	Active substance
Representative product	Representative product
	Operation type ID

Manufacturing details	Manufacturing site status
	Is the site a contract manufacturer
Alternatives sites	Alternative site LOC-ID
	Alternative site country

- **Alternative sites** collects information on manufacturing sites not currently listed in the marketing authorisation of the product in question, but could be used to partially or fully manufacture the active substance or finished product
- **Location ID** of an alternative site refers to the identifier of the physical location of it as present in the EMA's Organisation Management Service (OMS), if the alternative site is registered in OMS. If it is not registered in OMS, it must be left blank
- **Alternative site country** must be entered using the standard country code format
- **Alternative site LOC-ID** or **Alternative site country** can be populated, but not both
- If applicable, **multiple values may be entered** for both fields

Legend: Pantoprazol ESMP 20 mg; Rivastigmine ESMP

Manufacturing details and Alternative sites

Manufacturing details		Alternative sites	
Manufacturing site status	Is the site a contract manufacturer?	Alternative site LOC-ID	Alternative site Country
M1.1	M1.2	M2.1	M2.2
Backup	Yes		
Active	No	LOC-123	
Active	No		
Active	No		CN

Production capacity

- **Production capacity** collects data on the global production plan, including future production estimates and the baseline and peak production outputs from the previous year for both active pharmaceutical ingredients (APIs) and the manufactured item (in bulk without packaging and labeling)

	Active substance
Representative product	Representative product
Organisation information	Operation type ID
	Operation type
	ORG-ID (Manufacturer)
	Manufacturer
	LOC-ID (Manufacturer)
	City (Manufacturer)
	Country (Manufacturer)

Production capacity	*Unit of measurement*
	Global monthly production plan – Months 1-6
	Global monthly production plan – additional information
	Average global monthly production output of previous year
	Peak global monthly production output of previous year

Production capacity

Production capacity							
Unit of measurement	Global monthly production plan					Average global monthly production output of previous year	Peak global monthly production output of previous year
	Month 1	Month 2	Month n	Month 6	Additional information		
M3.1	M3.2.1	M3.2.2	M3.2.5	M3.2.6	M3.3	M3.4	M3.5
kg	600000	400000	…	900000		222500	900000
units	1000	4000	…	400000		2400000	9000000
<empty>							

- Values inserted depend on the “Operation type” inserted in “Organisation information”

Operation type	Unit of measurement	Production plan and past outputs refers to
Manufacturer of active substance	kg	*Quantities of active substane*
Processing operations for the medicinal product	units	*Production of finished product w/o packaging and labelling*
<all other>	<empty>	

Representative product

Product information *(pre-populated from PMS)*	*PMS ID*
	Full product name
	Active substance SMS ID
	Active substance
Representative product	Representative product
	Operation type ID

Manufacturing details	Manufacturing site status
	Is the site a contract manufacturer
Alternatives sites	Alternative site LOC-ID
	Alternative site Country

- A **representative product** is a medicinal product whose manufacturing details, production plan, and capacity can be used as a reference for another product with an **identical manufacturing process** up to packaging and labeling, produced at the same sites, and following the same global production plan
- Using a representative product allows the MAH to **enter manufacturing information only once for** a group of products, reducing duplicate entries for equivalent products

Representative product

Product information								
PMS ID	Full product name	…	Representative product	Operation type	…		Global monthly production plan – month 1	…
P1.1.1	P1.2.1	…	X1.1	O1.2	…	M3.1	P1.3.2	…
600001839370	Pantoprazol ESMP **20** mg - magensaftresistente Tabletten	…		Manufacturer of active substance	…	kg	600000	…
600001839370	Pantoprazol ESMP **20** mg - magensaftresistente Tabletten	…		Processing operations for the medicinal product	…	units	1000	…
600001622030	Pantoprazol ESMP **40** mg - magensaftresistente Tabletten	…		Manufacturer of active substance	…	kg		…
600001622030	Pantoprazol ESMP **40** mg - magensaftresistente Tabletten	…		Processing operations for the medicinal product	…	units	900000	…

Representative product

Product information								
PMS ID	Full product name	…	Representative product	Operation type	…	…	Global monthly	…
P1.1.1	P1.2.1	…	X1.1	O1.2	…	…3.1	P1.3.2	…
600001839370	Pantoprazol ESMP **20** mg - magensaftresistente Tabletten	…		Manufacturer of active substance	…	kg	600000	…
600001839370	Pantoprazol ESMP **20** mg - magensaftresistente Tabletten	…		Processing operations for the medicinal product	…	units	1000	…
600001622030	Pantoprazol ESMP **40** mg - magensaftresistente Tabletten	…		Manufacturer of active substance	…	kg		…
600001622030	Pantoprazol ESMP **40** mg - magensaftresistente Tabletten	…		Processing operations for the medicinal product	…	…nits	900000	…

Same active substance manufacturer

Same active substance manufacturer

Representative product

Product information								
PMS ID	Full product name	…	Representative product	Operation type	…	…	Global monthly	…
P1.1.1	P1.2.1	…	X1.1	O1.2	…	…3.1	P1.3.2	…
600001839370	Pantoprazol ESMP **20** mg - magensaftresistente Tabletten	…		Manufacturer of active substance	…	kg	600000	…
600001839370	Pantoprazol ESMP **20** mg - magensaftresistente Tabletten	…		Processing operations for the medicinal product	…	units	1000	…
600001622030	Pantoprazol ESMP **40** mg - magensaftresistente Tabletten	…	**600001839370**	Manufacturer of active substance	…	kg		…
600001622030	Pantoprazol ESMP **40** mg - magensaftresistente Tabletten	…		Processing operations for the medicinal product	…	…nits	900000	…

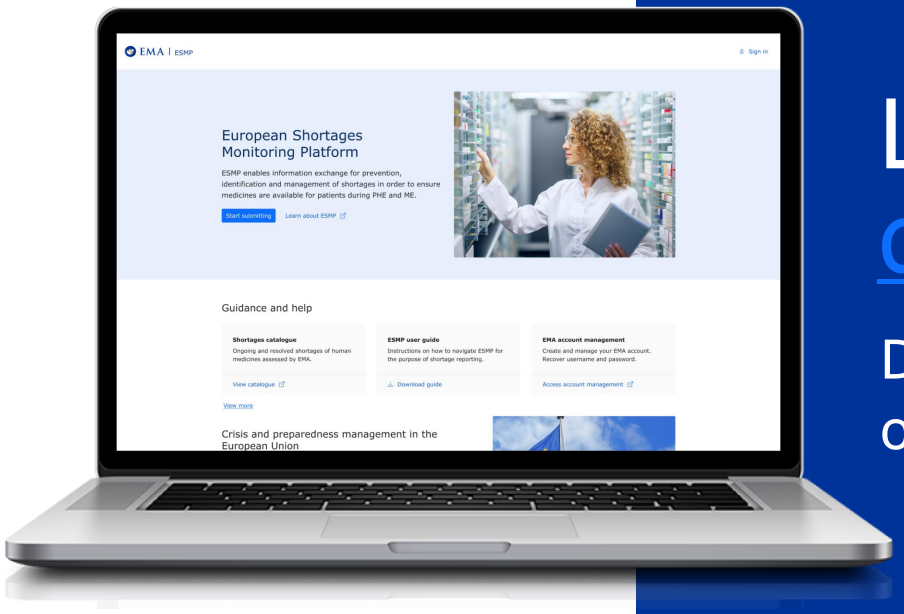
Same active substance manufacturer

Same active substance manufacturer

Representative product

Product information								
PMS ID	Full product name	…	Representative product	Operation type	…		Global monthly production plan – month 1	…
P1.1.1	P1.2.1	…	X1.1	O1.2	…	M3.1	P1.3.2	…
600001839370	Pantoprazol ESMP **20** mg - magensaftresistente Tabletten	…		Manufacturer of active substance	…	kg	600000	…
600001839370	Pantoprazol ESMP **20** mg - magensaftresistente Tabletten	…		Processing operations for the medicinal product	…	units	1000	…
600001622030	Pantoprazol ESMP **40** mg - magensaftresistente Tabletten	…	**600001839370**	Manufacturer of active substance	…	kg	**<empty>**	…
600001622030	Pantoprazol ESMP **40** mg - magensaftresistente Tabletten	…		Processing operations for the medicinal product	…	units	[illegible]0	…

No data to be inserted other than representative prod



Let's see how it works: demo*

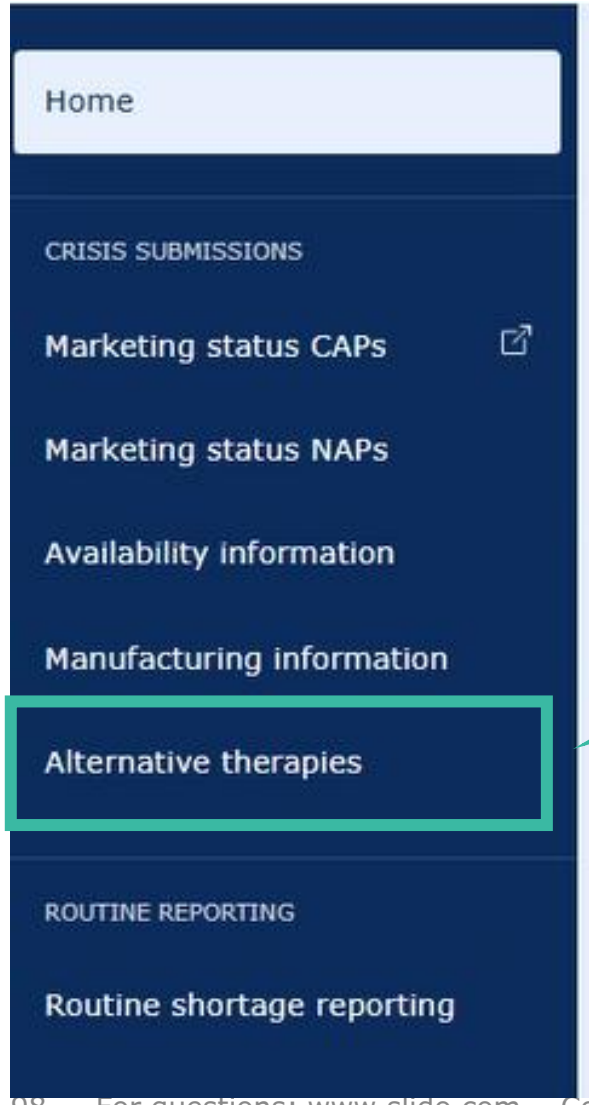
Download, compile, and upload the template of Manufacturing information

*Consult the demo in the training recording, accessible at this link:

https://www.youtube.com/watch?v=nvGR5k9ehg8&t=6238s

(timestamp 1:43:58)

Webform: Alternative therapies



Now covering:
Alternative therapies

Webform: Alternative therapies

Product information *(pre-populated from PMS)*	*Invented name*
	Active substance(s)
	Pharmaceutical form
Alternative therapies	Alternative therapies
	No alternatives

- ESMP will generate a **webform** which will be **tailored to your affiliation** and include the specific products in scope of reporting requirements for a particular crisis or MSSG-led preparedness action
- The webform will be **pre-populated** with product information from PMS
  - CAP products are grouped by invented name, active substance(s) and pharmaceutical form
  - NAP products are grouped by active substance(s) and pharmaceutical form

Alternative therapies

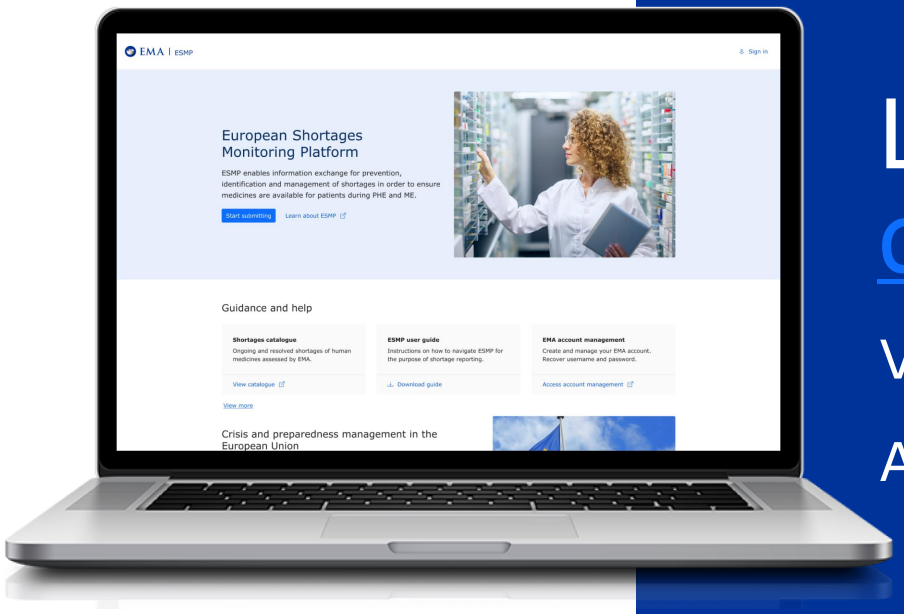
Product information		
Invented Name	Active Substance(s)	Pharmaceutical form
P1.2.3	P1.3.2	P1.6.2
	Pantoprazole	Gastro-resistant tablet
	Amoxicillin	Powder for oral suspension
Rivastigmine ESMP	Rivastigmine	Capsule, hard

Alternative therapies	
Alternative therapies	No alternatives
L1.1	L1.2

Alternative therapies

Product information		
Invented Name	Active Substance(s)	Pharmaceutical form
P1.2.3	P1.3.2	P1.6.2
	Pantoprazole	Gastro-resistant tablet
	Amoxicillin	Powder for oral suspension
Rivastigmine ESMP	Rivastigmine	Capsule, hard

Alternative therapies	
Alternative therapies	No alternatives
L1.1	L1.2
[Omeprazole], [Omeprazole magnesium]	
[Clavulanic acid, Amoxocillin]	
	X



Let's see how it works: demo*

View and compile the webform for

Alternative therapies

*Consult the demo in the training recording, accessible at this link: https://www.youtube.com/watch?v=nvGR5k9ehg8&t=6955s

(timestamp 1:55:55)

Best practices for accurate reporting

ENSURE ACCURATE DATA ENTRY

- Review pre-populated information to avoid discrepancies
- Make sure all mandatory fields are completed
- Double-check fields before submission, especially RMS IDs

INTERNAL COORDINATION

- Use version-controlled files to prevent multiple or outdated submissions
- Update submissions as per MSSG-defined frequency

VALIDATE RESULTS

- Check "Submission History" to confirm successful uploads and monitor any errors
- Download validation results for detailed error messages to easily identify and correct issues

Tips and tricks (1/2)

1. Upload only **one file at a time**
2. When inserting dates, **use DD/MM/YYYY format** and add an apostrophe before the date (e.g. '12/05/2025) to avoid Excel formatting issues
3. For fields with **RMS identifiers** (12-digit IDs), change **Excel cell format to "Text" to display numbers** correctly instead of scientific notation (2E+11). It is a **best practice to select all cells in Excel templates and change format to "Text"** to avoid formatting issues.
4. **Do not modify the order of columns or add new columns** in the template files
5. **Only data in the first worksheet will be processed** - do not create additional worksheets
6. When entering **multiple values in one field, separate them with semicolons** (e.g. 200000028683;200000028684)

Tips and tricks (2/2)

7 **Only products with the marketing status "Marketed" or "Temporarily unavailable" will be included in the template for** submitting Availability information in ESMP

→ For **CAPs marketing status changes, make updates in IRIS**, not in ESMP – changes in IRIS will **sync to ESMP** within approximately 15 minutes

8 **Do not change pre-populated product information fields as changes in ESMP will not transfer to source systems (SPOR and IRIS)**

Preliminary requirements

1. Ensure that the **insertion of data of the organisations' package and manufacturer information in PMS** has been **completed**
   - → Consult the PLM Portal – PMS guidance and Union list of critical medicines: Support implementation of standardised product information
   - → Deadline extension to insert pack sizes until **31 May 2025**!

2. Ensure your organisation has their **industry single point of contact (i-SPOC)** registered through EMA's IRIS platform and **ensure that the i-SPOC contact details are up to date**
   - → Refer to the industry single point of contact (i-SPOC) for supply and availability section on EMA's website
   - → mandatory for all marketing authorisation holders the EU/EEA, in line with Regulation (EU) 2022/123
   - → EMA uses the i-SPOC contact list for **rapid, two-way communication with MAHs**, e.g., to **notify MAHs with products in scope of reporting** in crises and MSSG-led preparedness actions

Support

- **For ESMP questions/ issues:**
  - **ESMP section of the EMA Service Desk portal (Service Now)** → report issues related to accessing the ESMP, seeing unexpected data, uploading data or the system performance
    - Report an issue with ESMP to create a ticket for the issue you are experiencing
    - Request information about ESMP to create a ticket for the question you have

  Depending on the issue or question, select one of the **different service offerings**:
  - ESMP MAH routine CAP shortage reporting
  - ESMP MAH Crisis/MSSG-led preparedness submissions
  - ESMP other (topics covering multiple aspects and/or general nature)

  ⚠ *Please provide a clear description of the issue and provide screenshots or the generated PDF as attachment as these can help to solve the query a lot faster.*

- **For other questions/ issues**:
  - **EMA Service Desk** for technical questions on the use of the portal and for reporting faults
  - **EMA account management portal** for access, account, and registration requests
  - **Ask EMA** for general questions not related to a specific submission/procedure

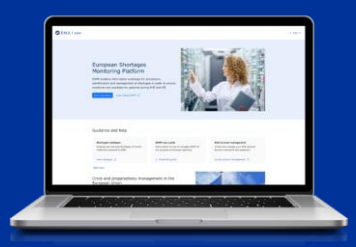
Useful links and resources

User guide (MAHs)

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

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

ESMP webpage



ESMP portal

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

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

5

Interoperability

Christophe Pée and Pedro Oliveira

ESMP and interoperability, legal background REGULATION (EU) 2022/123

- **Recital (20)** - In order to facilitate the coordination role of the Agency, the **interoperability of data** with existing Member States' IT platforms for monitoring shortages and other systems, as appropriate, is essential to allow the sharing of relevant information with the ESMP, which should be managed by the Agency.

- **Article 1 – Subject Matter:**

  setting up an **interoperable** information technology (IT) platform at Union level to monitor and report on shortages of medicinal products;

- **Article 9(1)** - Working methods and provision of information on medicinal products:

  (c) develop streamlined IT monitoring and reporting systems, in coordination with the relevant national competent authorities, that facilitate **interoperability** with other existing IT systems and IT systems under development until the ESMP is fully functional, **on the basis of data fields that are harmonised across Member States**;

- **Article 13(6)** - Working methods and provision of information on medicinal products:

  (e) ensure that data is **interoperable** between the ESMP, Member States' IT systems and other relevant IT systems …;

- **Article 20(a)** IT tools and data, and **Article 36(3)(d)** Reporting and review

Datasets and their prioritisation for API

MAH	NCA	

• Product information
• Shortage information
• Prevention & mitigation
• Market share & sales volume, forecast
• Supply forecast & stock information
• Manufacturing sites, alternative sites
• Production capacity & planning
• Alternative substances
 	
& MSSG-led Preparedness (2)
	• MS Need
	  • Historical consumption
	  • Planned minimum stock
	  • PHE patient need (vaccinations, ICU, pre-hospitalisation, hospitalisation) (3)
	• MS Available stock
	  • Hospital stocks
	  • Community pharmacy stocks
	  • Wholesale distributor stocks
	  • MS strategic reserve
	• Planned strategic reserve
		Crisis

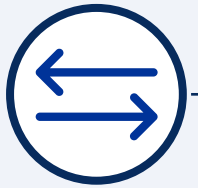
• Product information • Shortage information • Prevention & Mitigation • Shortage impact assessment • Alternative therapies • Additional information (1)	• Estimated MS Need • MS Available stock • MS strategic reserve MSSG-led Preparedness (1)	Preparedness
	• Marketing status • Shortage details • Alternative therapies • Further actions NCA shortage reporting	Preparedness

Technical options

FHIR

Data transfer

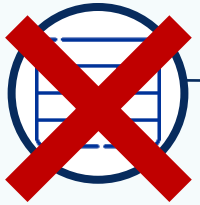
AGREED



Hypertext transfer protocol BASED

GATEWAY-LIKE (AS2/AS4)

Formats



TABULAR

STRUCTURAL

AGREED

JSON

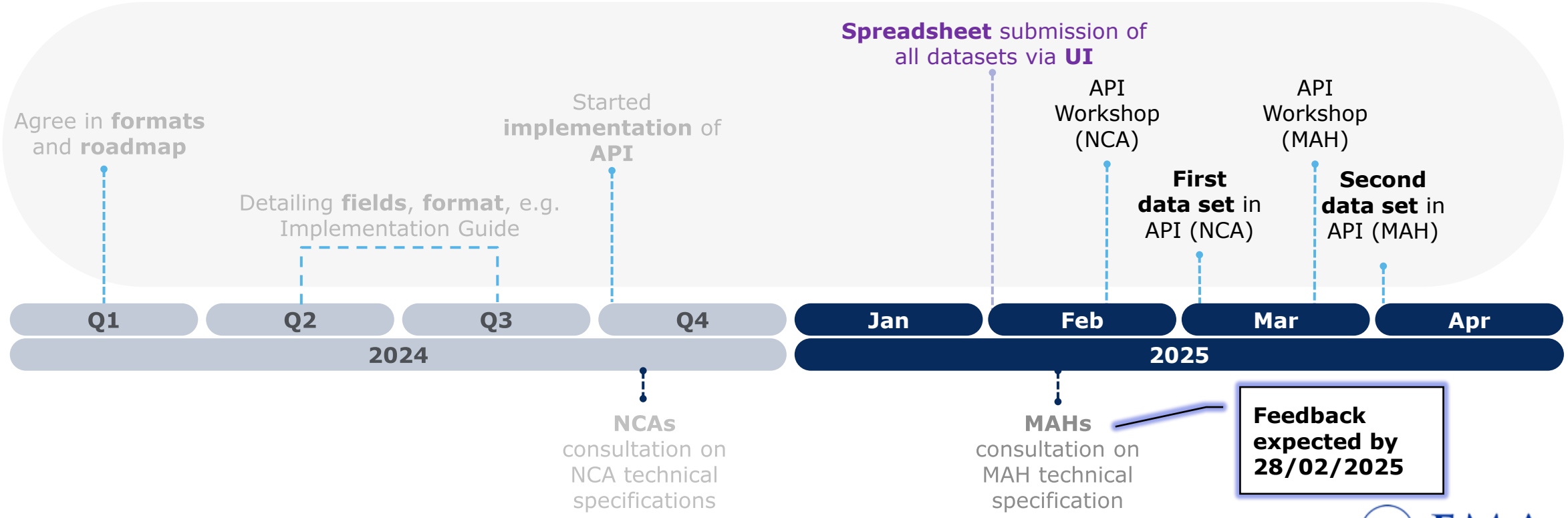
High-level functional components

- The implementation makes use of existing components of ESMP;
- **RESTful-like** approach;
- Use of ***simple* API** and data specifications;
- Use of **JSON** as exchange format;
- **Validation rules** are the **same as per the spreadsheet** + JSON format specific rules and transformation;
- **API** is a different route and format to express the **same as with the spreadsheet** upload through Web UI.

Timeline

Options for submission to the ESMP

- **Machine-to-machine (API)** (only limited datasets, from end of Q1)
- **Spreadsheet via UI** (small exceptions via web form: alternative therapies)



 For questions: www.slido.com Code: #ESMP-MAH

Q&A

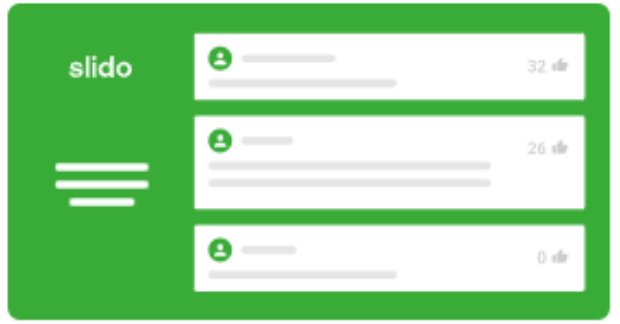
30’

Moderated by Stephanie Marschler

Send your questions via Slido

1. Join via the QR code or on www.slido.com with the session code #ESMP-MAH

2. Send or upvote the questions you want to hear answered



3. Questions will be shown on the screen and answered live in the Q&A session and compiled in the FAQ document on the ESMP webpage

7

Closing remarks

Pedro Pina Ferreira

Wrap up

Thank you for your participation! Today we covered:

1. *Benefits of crises and MSSG-led preparedness reporting and how this minimises the public health impact and enhances medicine availability*
2. *Detailed walk-through of reporting processes and templates during a crisis or MSSG-led preparedness action*
3. *The ESMP's structure and the reporting scenarios where MAHs are required to engage with the platform, includes two different ways to submit data (User Interface and Machine-to-Machine (API))*
4. *Overview of interoperability status, including the current state, progress made, and future plans*

ESMP communication plan

Stakeholder	Jan	Feb	Mar
Marketing authorisation holders	● Publication of complete MAH user guide ♦ Go-live email communications ♦ PLM newsletter article ♦ Change adoption survey	● MAH training: crisis reporting ● MAH training: Q&A clinics	♦ ISG meeting ♦ DIA Europe presentation ♦ SME newsletter article
	Interoperability communications		
	NCA and MAH SME Forum		
National competent authorities	● Publication of NCA user guide ● NCA training: reporting and data analytics dashboards ♦ Go-live email communications	● NCA API workshop ♦ Go-live announcement to EMA Committees	● NCA training: Q&A clinics ♦ Quarterly email to IT Directors ♦ Change adoption survey
	NCA, MSSG, and SME interoperability communications		
	MSSG and ESMP-MSSG meetings		
	SPOC WP meetings		
General public	♦ Go-live press release ♦ Social media posts on EMA channels	♦ Human Medicines Highlights newsletter article	
	ESMP webpage updates		

Please note: the presented timings may be subject to change. Specific dates will be confirmed closer to each deadline.

Legend: ● Training activities ♦ Communication and engagement activities Functionality release

Main recent and upcoming events

Your feedback matters

- Please spare **a few minutes to complete the feedback survey** in Slido, sharing your feedback on today's event.
- **Your input will guide us in tailoring next sessions** to better meet your needs and preferences.
- **Join Slido.com** using this code **#ESMP-MAH** or scan the above QR code

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Thank you

More information: ESMP webpage | ESMP Essentials webinar | ESMP RSR MAH training

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