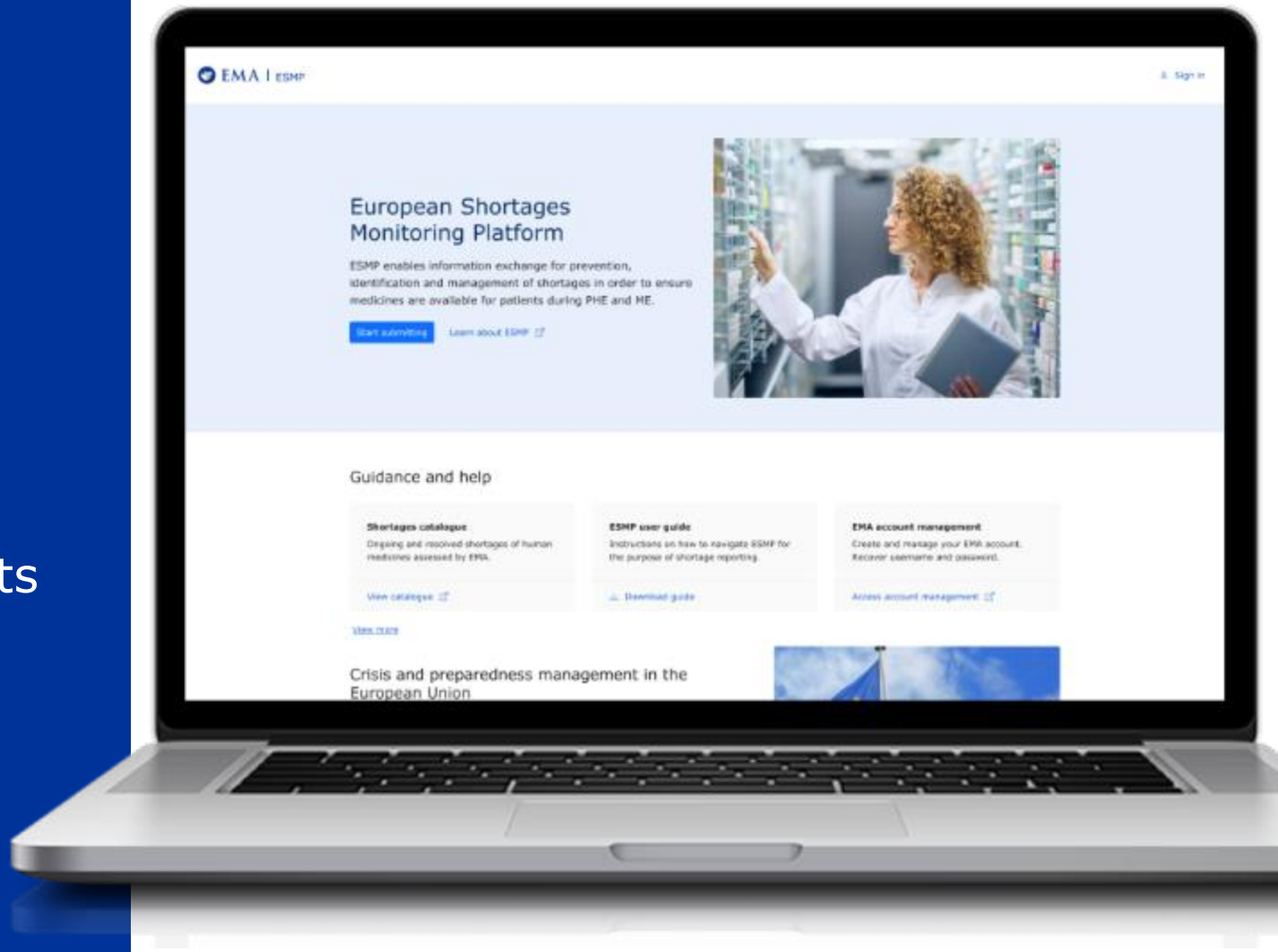
EMA
EUROPEAN MEDICINES AGENCY

European Shortages Monitoring Platform (ESMP)

Training session on routine shortage reporting for Marketing Authorisation Holders of Centrally Authorised Products



20 November 2024, 10:00 – 12:00 CET

Housekeeping

*Please note that **this session is being recorded** and **will be made available** through **EMA corporate website** and **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.*

Agenda

- **Welcome and opening of the training session**, Pedro Pina Ferreira
- **Benefits of efficient shortage management in the EU**, Mónica Dias
- **Overview of the European Shortages Monitoring Platform (ESMP)**, Sofia Zastavnik
- **ESMP user access management**, João Costa
- **Routine shortage reporting functionalities**, Sofia Zastavnik
- **Q&A** through Slido
- **Closing remarks**, Pedro Pina Ferreira

1

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 routine shortage reporting of centrally authorised products.

UNDERSTAND THE IMPORTANCE OF CONSISTENT REPORTING

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

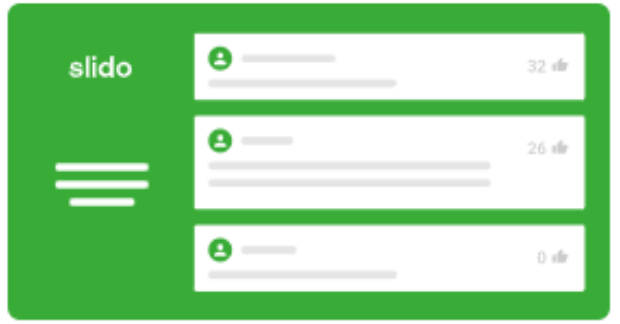
COLLECT FEEDBACK & CLARIFY QUESTIONS

Clarify any questions to ensure your full readiness for the platform go-live.

Send your questions via Slido

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

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

2

Benefits of efficient shortage management in the EU/EEA

Mónica Dias

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)

Regulatory authorities - within and outside Europe - are increasingly **working together** to prevent shortages and to limit their impact whenever they occur

The joint **HMA/EMA Task Force on the Availability of Authorised Medicines** for Human and Veterinary Use (TF-AAM) provides **strategic support** to tackle disruptions in medicine supply and ensure availability

Regulation 2022/123 equipped the EMA to address medicines shortages through **enhanced coordination**, **proactive monitoring**, and **preventive measures**; the ongoing Reform of the EU pharmaceutical legislation and the European Commission Communication on addressing medicine shortages in the EU/EEA further reinforce and expand EMA's role in shortage management and security of supply

A practical example: antibiotics (1/3)

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

Indication: Treatment of bacterial infections, including respiratory infections.

Root cause: Reduced production combined with increased incidence of respiratory infections during the autumn/winter season.

Key actions:

- Launch of dedicated SPOC WP subgroup to investigate shortage causes and extent of situation
- Engagement with MAHs to agree on possible mitigation measures
- Cooperation with EU institutions, international regulators, trade associations, HCPs and patients
- Sharing best practices (incl. toolkit on mitigating measures)
- Regulatory flexibilities
- MAH presentations to MSSG
- Public communication, shortages catalogue

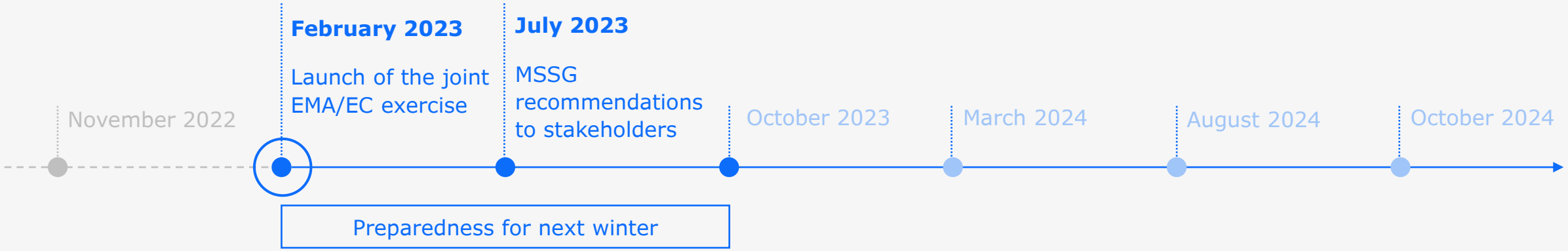
Antibiotics exercise: matching of supply and demand to prepare for winter 2023/2024

A practical example: antibiotics (2/3)

MSSG-led preparedness for winter 2023-2024

Matching of supply and demand to identify whether shortages could be expected

Understand if EU-level actions need to be undertaken to ensure sufficient supply for European patients



A practical example: antibiotics (3/3)

Outcome:

Reactive → Proactive approach

EU/EEA is better prepared to prevent or mitigate shortages of antibiotics:

- EU/EEA moved from critical shortages in **most** countries in 2022-2023 to critical shortages in a **handful** EU/EEA countries in 2023-2024
- To a **stable situation** at the start of autumn-winter 2024-2025 which will continue to be monitored

EMA is continuously gathering up to date information on supply and shortages from industry and from NCAs.

There are a number of tools at hand that can be used if any critical shortages occur this winter.

A practical example: GLP-1 RAs

Situation: Global shortage of most compounds in class.

Indication: Treatment of diabetes and obesity.

Root cause: Increase in demand mixed with constraints in supply leading to shortages.

Key actions:

EMA and the SPOC WP are in close contact with **companies** to gain **overview of the market situation** and map **current and anticipated shortages**.

EMA **coordination of stock redistribution** amongst EU/EEA member states to avoid immediate patient-level stock-outs.

Communication at EU and national level, including letters to healthcare professionals, shortage catalogue entries, and responses to public queries.

Assessment and granting of regulatory flexibilities to industry, if appropriate.

Action is ongoing and aligned via MSSG recommendations and the multistakeholder workshop (1 July 2024).

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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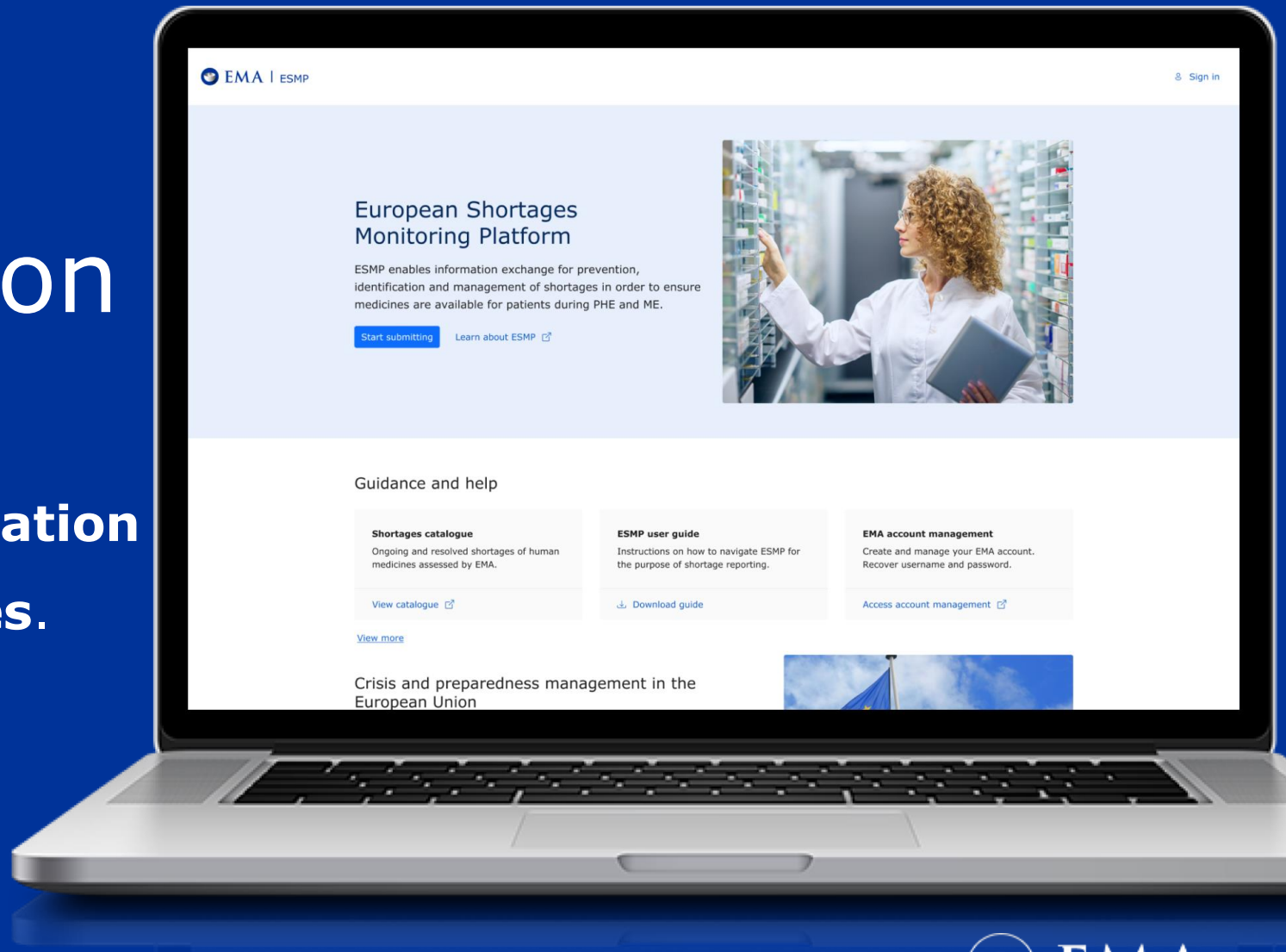
Overview of the European Shortages Monitoring Platform (ESMP)

Sofia Zastavnik

ESMP aims to enable information exchange

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



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

ESMP overview

PREVENTION | **MONITORING** | **MANAGEMENT**

Data collection

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

Analysis & reporting

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

Case management

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

Data integration

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

Platform for MAHs

Platform for NCAs

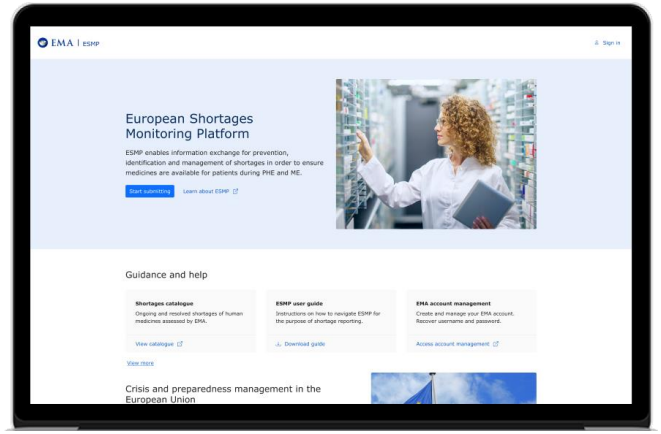
Secure access

Platform for general public

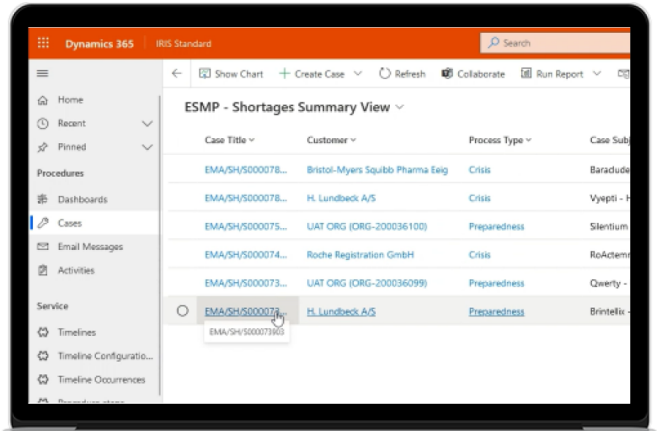
Open access

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

ESMP components



Data collection



Case management

Analysis & reporting

Data integration

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 exercise	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

Release timeline

November 2024

Go-live for Industry Routine shortage reporting for CAPs

February 2025

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

After February 2025

Improvements and expansion

Transition period: Routine shortage reporting for MAHs

28 November 2024

MAHs should report only **new shortage cases** through the ESMP.
Ongoing shortages already reported to EMA should not be resubmitted through ESMP.

2 February 2025

All new shortages for CAPs must be reported **exclusively through ESMP**.
After this date, EMA will no longer accept new shortage reports via previous channels.

Between November 2024 and February 2025

During this period, MAHs may provide information on routine shortage reporting either through ESMP, or through existing channels (e.g., via email). This flexibility allows MAHs time to familiarise themselves with ESMP and ensure a smooth transition.

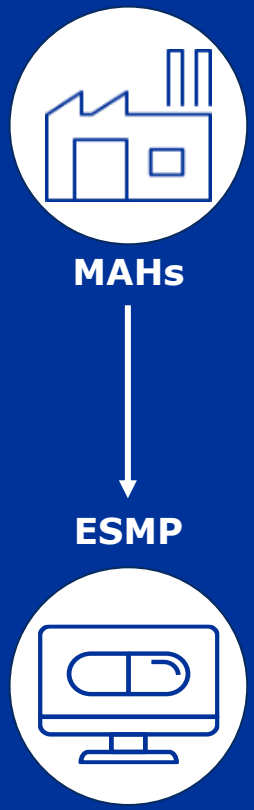
National reporting requirements remain unchanged and should be followed alongside ESMP reporting.

Routine shortage reporting in normal circumstances

Routine shortage reporting

Monitoring of actual or potential shortages that can lead to a public health emergency or major event

Available in:	● **Normal circumstances**
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
Reporting requirements:	Shortage information, prevention and mitigation plans, impact assessment, potential alternative therapies, other relevant data



4

ESMP user access management

João Costa

ESMP role profiles overview

- From an **access management** point of view, you can **engage with ESMP** via **2 different role profiles**:

ESMP administrator(s)
Handle the approval/rejection of ESMP access role requests

Learning objectives:

- **create/activate** your **EMA account**
- **role** to be requested to act as such
- **request** the ESMP **administrator role**
- **approve/reject** access roles **requests**

ESMP user(s)
Access the ESMP Report data

Learning objectives:

- **create/activate** your **EMA account**
- **role** to be requested to act as such
- **request** the ESMP **user role**
- **access the ESMP**

Pre-requisites to engage with ESMP

- To be a **ESMP Administrator** or **ESMP User**, you are required to have:
  - an active EMA user account (external e-mail address)
  - an **admin** and/or a **user role** assigned to that account
  - signed proof of authority *(only for administrators)*

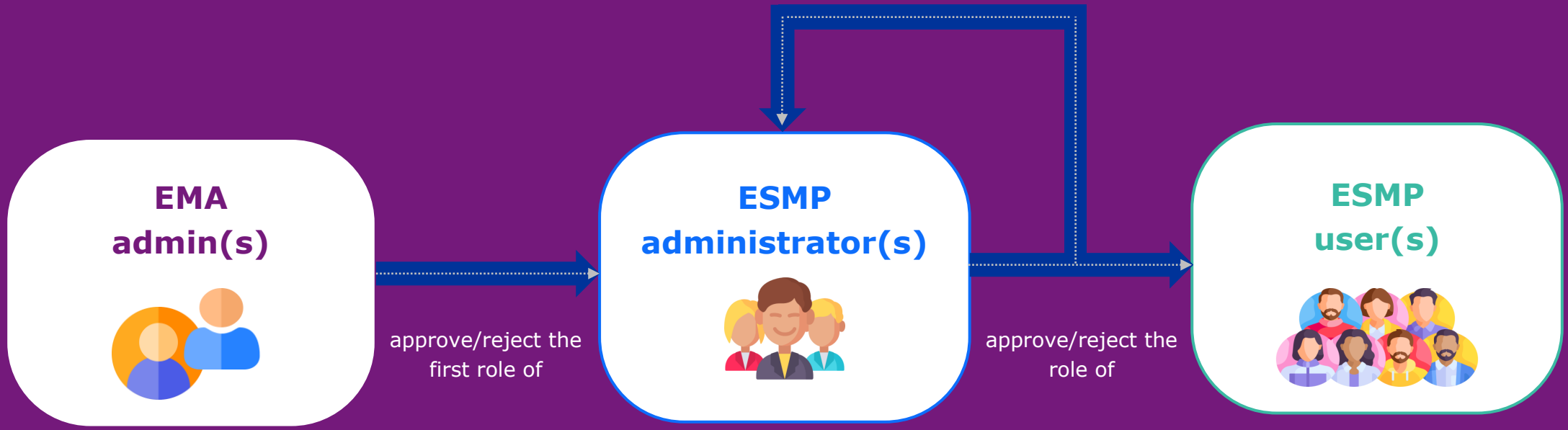
    - If you already have an active EMA user account, please log in to the EMA Account Management portal
    - If you do **not** yet have an active EMA user account, you need to self-register with EMA as a new "user"

Note that the organisation on whose behalf you will be acting must be listed in the EMA's Organisation Management Service (OMS)

More information

- European Shortages Monitoring Platform (ESMP) **User guide** for marketing authorisation holders

ESMP access management approval workflow



The ESMP Industry Admin role

ESMP administrator(s)

- Users with the **ESMP Industry Admin** role can handle the users' access management for the organisation(s) to which they have an affiliation
- Your organisation must **nominate** at least one person who will be responsible for approving and revoking ESMP access role requests from users within that same organisation
  - The approval of the first administrator:
    - is validated by the EMA and can take up to 2 working days
    - requires to attach a *proof of authority*
  - Once approved by the EMA, administrators can also approve/reject other administrator requests

Your organisation may already have an **External Organisation Administrator** who can manage access role requests not only for ESMP but also for other EMA-run systems within your organisation/country.

More information on this webpage.

The ESMP Industry User role

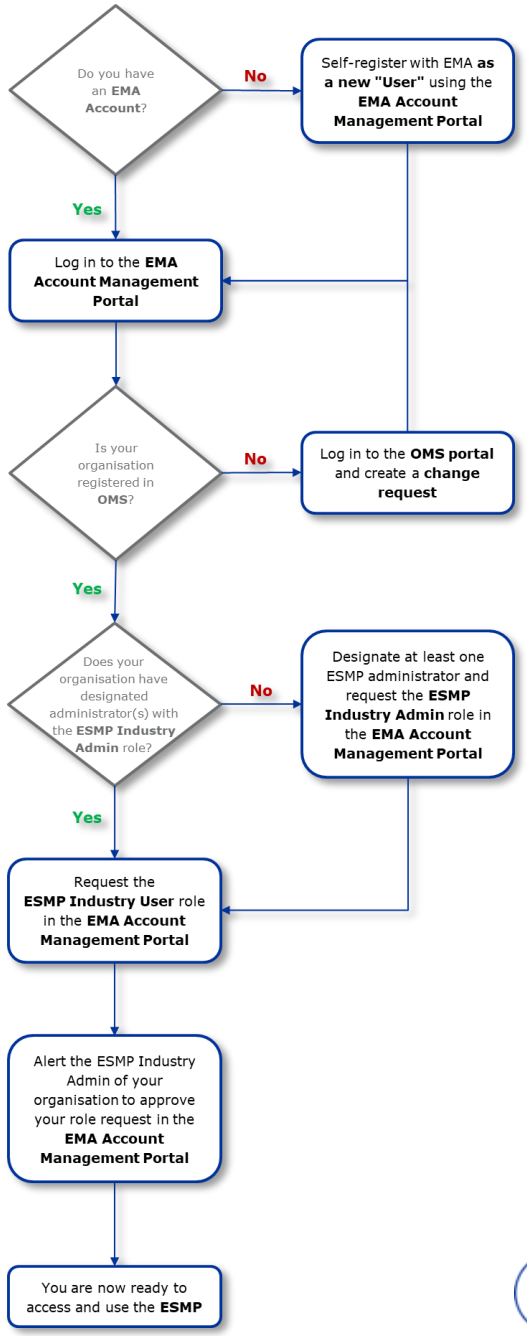
ESMP user(s)

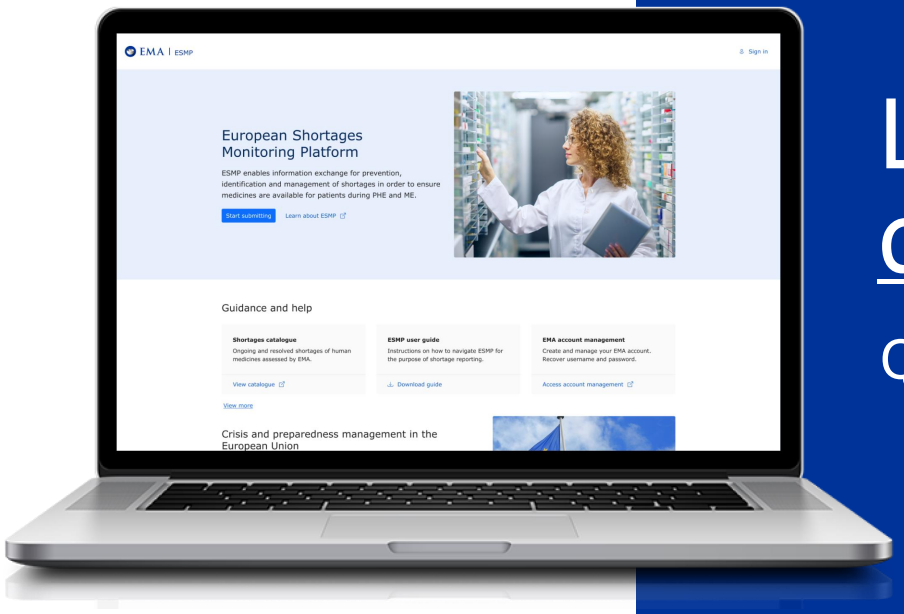
Users with the **ESMP Industry User** role can access ESMP and perform any operation within the ESMP

- This includes:
  - downloading a pre-filled template file,
  - submitting data,
  - checking your submission status and history
- ESMP Industry User role requests are approved/rejected by approved ESMP Industry Admins
- User roles are associated to organisation(s)
  - User roles are assigned to single users and are granted at organisation level – not at product level

The ESMP Industry Admin role does **NOT** by itself provide access to the ESMP. Any user who intends to access and perform operations in the ESMP must request the **ESMP Industry User** role

Overall process to follow to be granted access to the ESMP





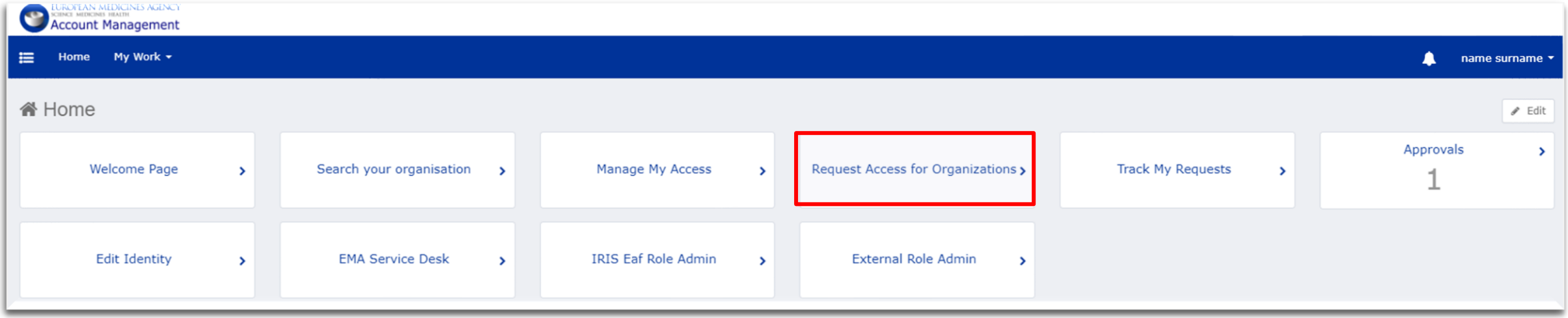
Let's see how it works: demo*

Quick guide through access roles requests

*Recording: timestamp 39:50
https://www.youtube.com/watch?v=A8q9KRYujKo&t=2390s

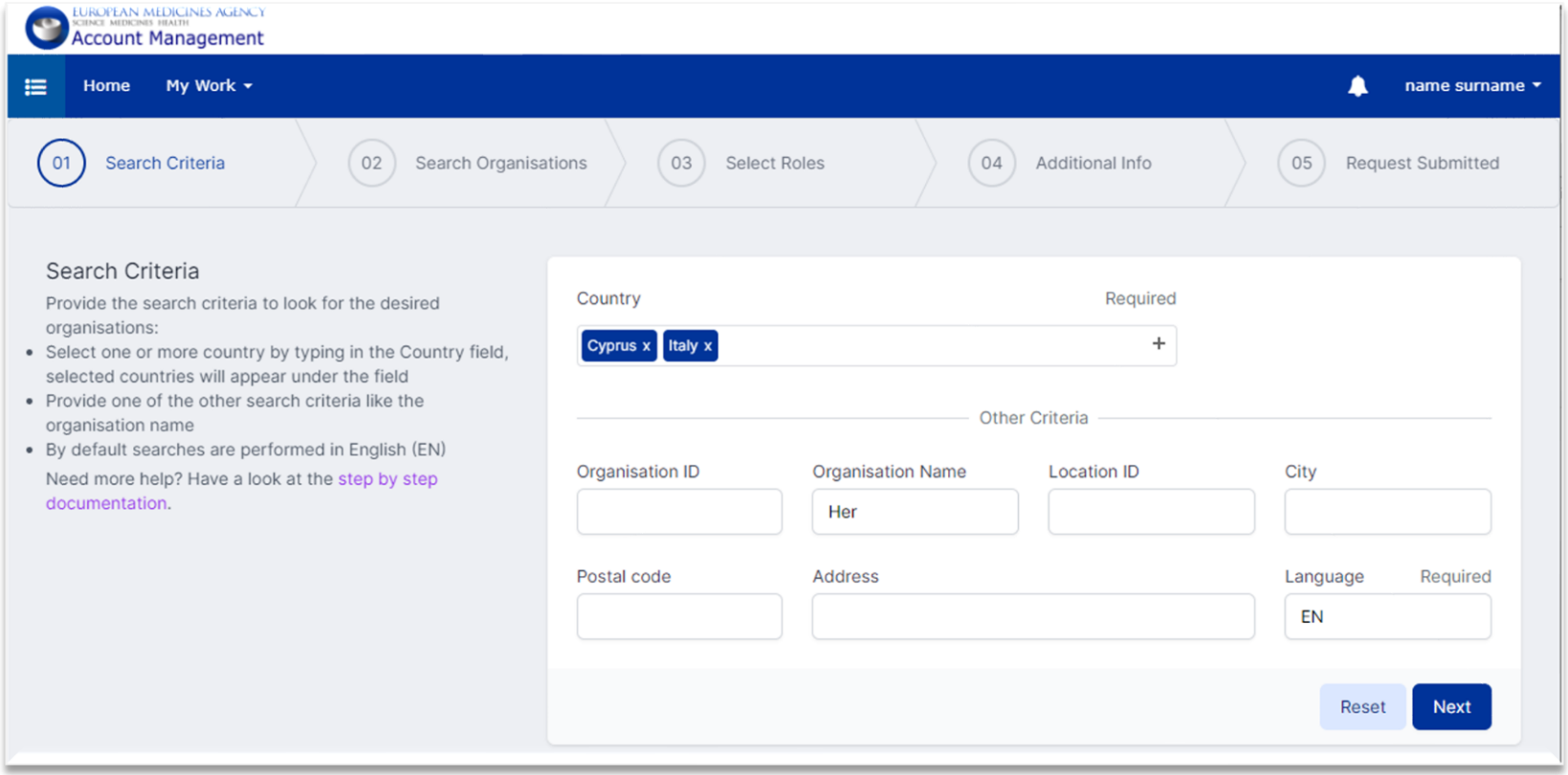
Requesting ESMP roles

The **EMA Account Management portal** (https://register.ema.europa.eu) is the EMA secure online platform where you can request and manage access to EMA applications.
EMA Account Management portal > Login > 'Request Access for Organisations'



Requesting ESMP roles

01 Search Criteria (Add at least one Country and one Other Criteria) > ‘Next’

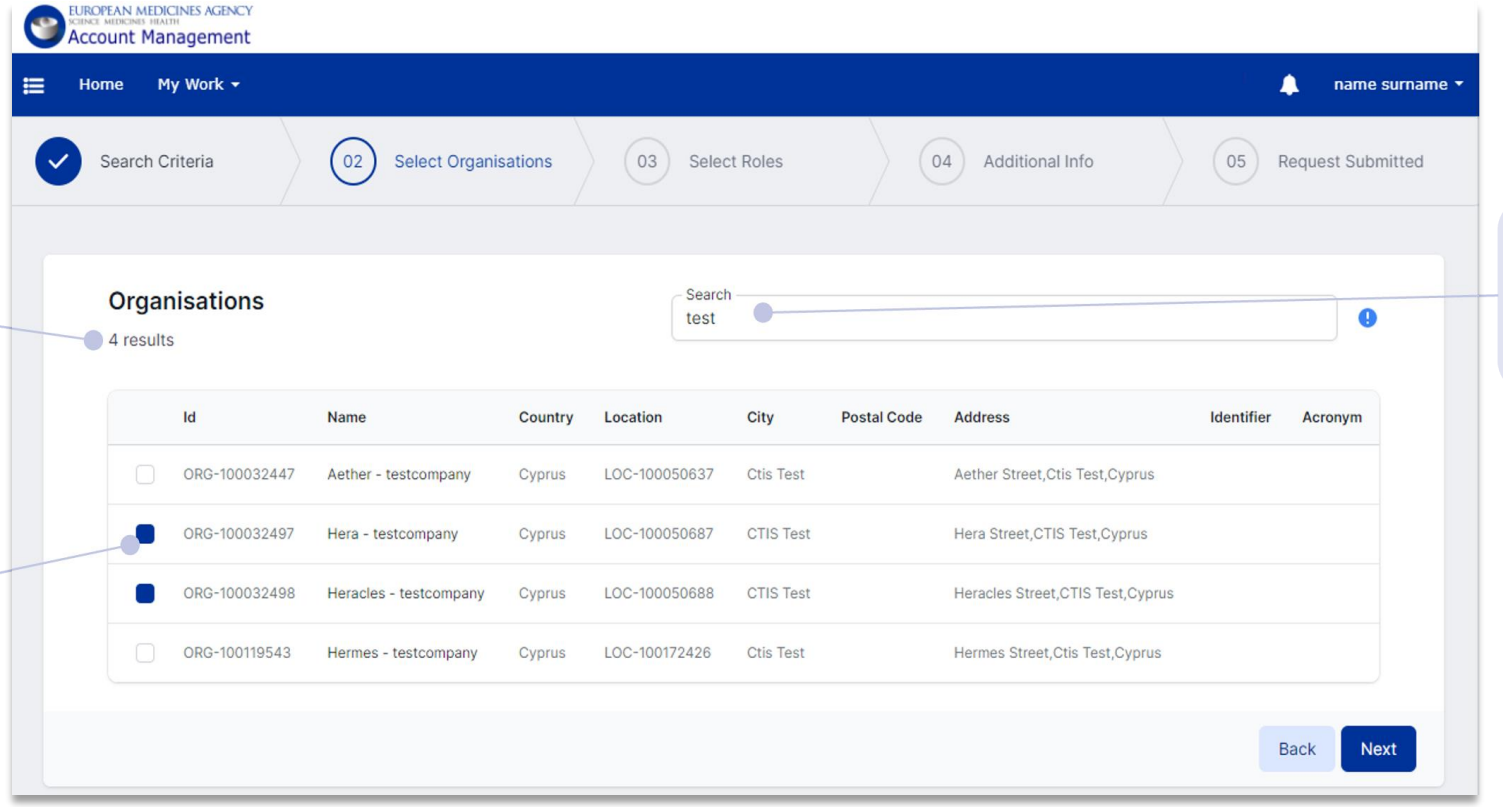


Requesting ESMP roles

02 Select Organisations (Tick-mark the organisation(s) you wish to request access) > ‘Next’

Up to **200 results** are shown, narrow down your research if you hit this limit

Use the **checkbox** close to each organisation to select them.



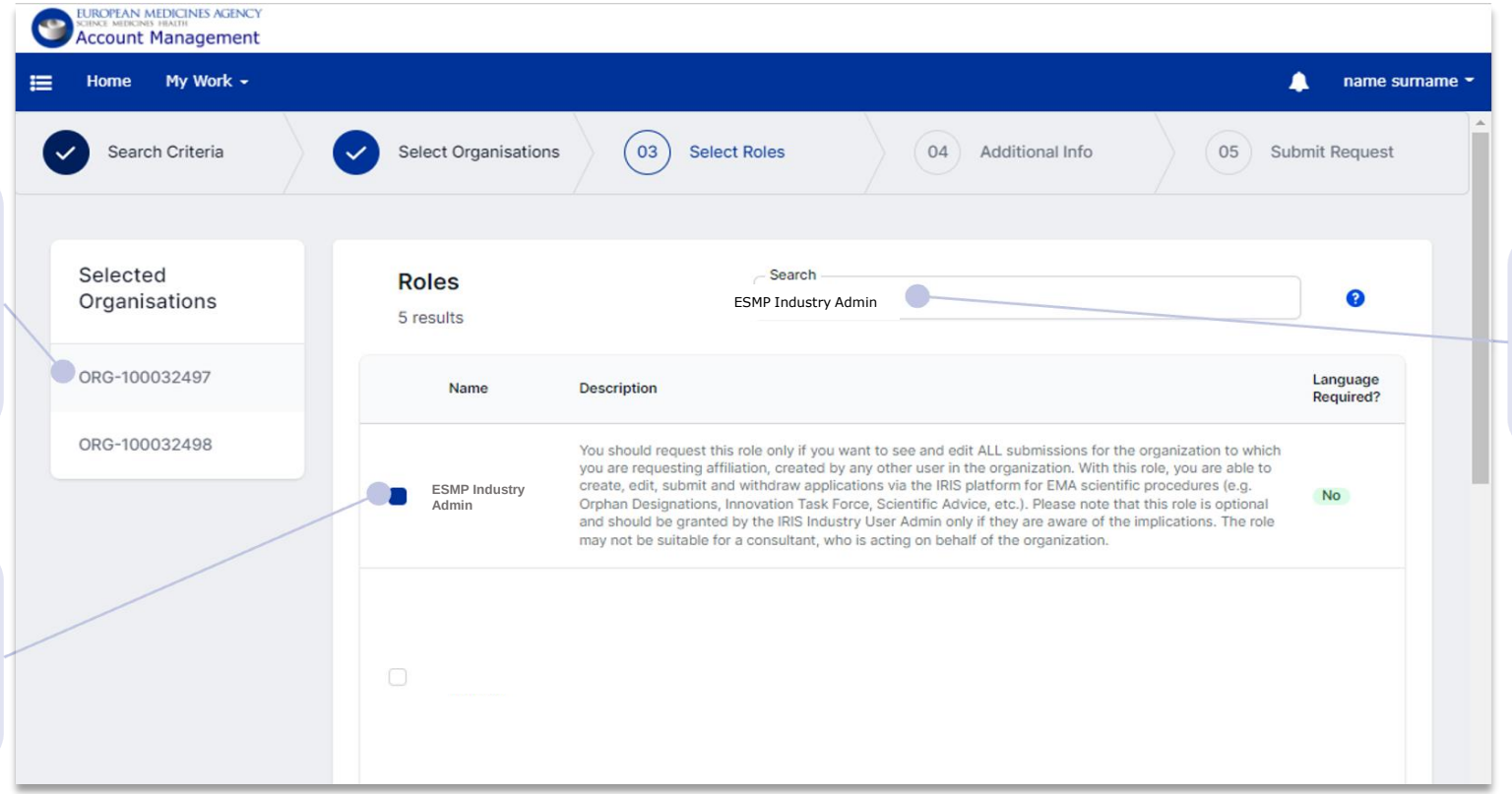
Use the Search field to restrict further your search

Requesting ESMP roles

03 Select Roles (Tick-mark the roles(s) you wish to request an access) > ‘Next’

Selected **organisations** are shown here.
The **selected roles** will be requested **for all displayed organisations**

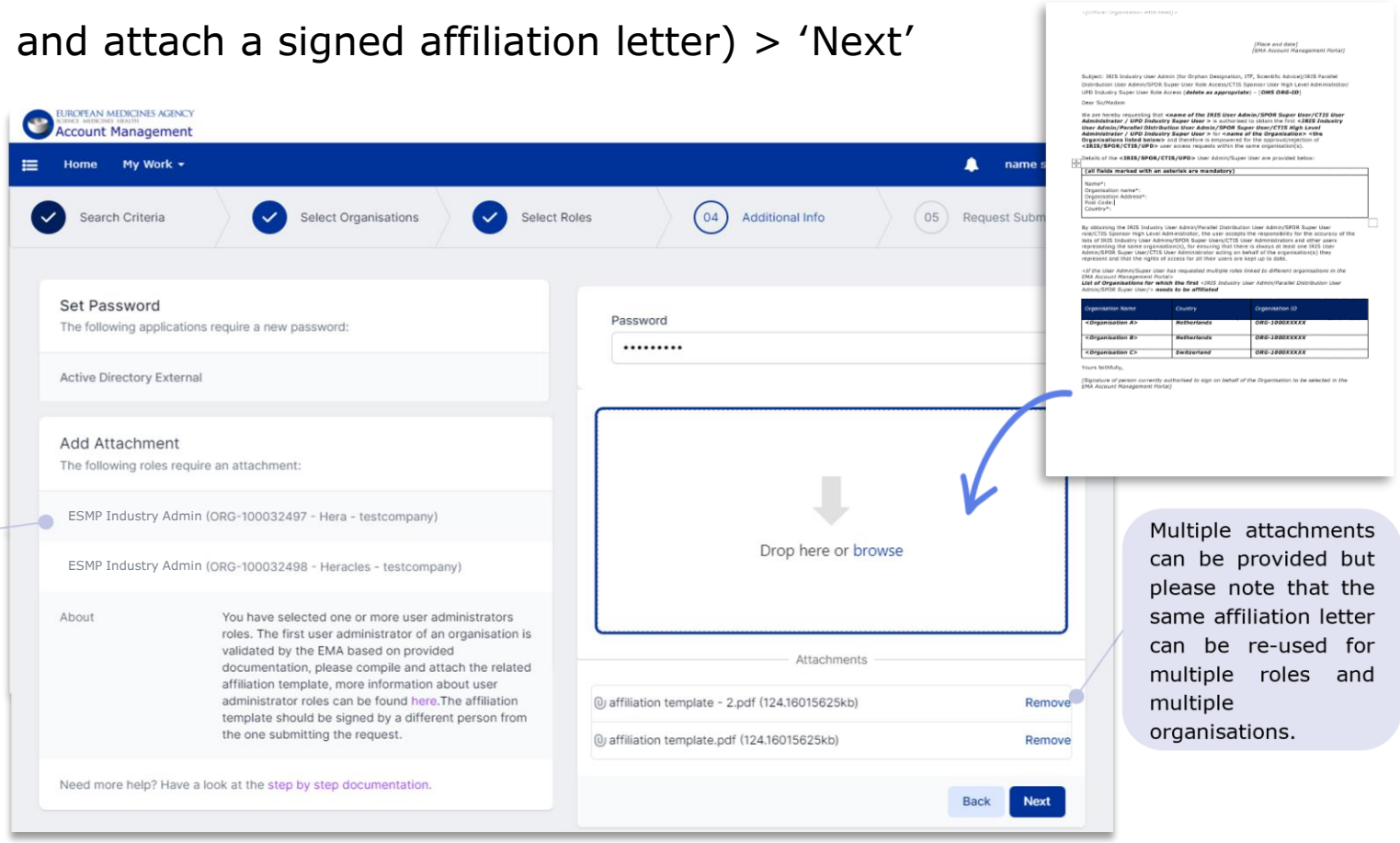
Use the **checkbox** close to each role to select them.



Use the **Search** field to look for desired roles

Requesting ESMP roles *(only for administrators)*

04 Additional Info (Fill in and attach a signed affiliation letter) > 'Next'

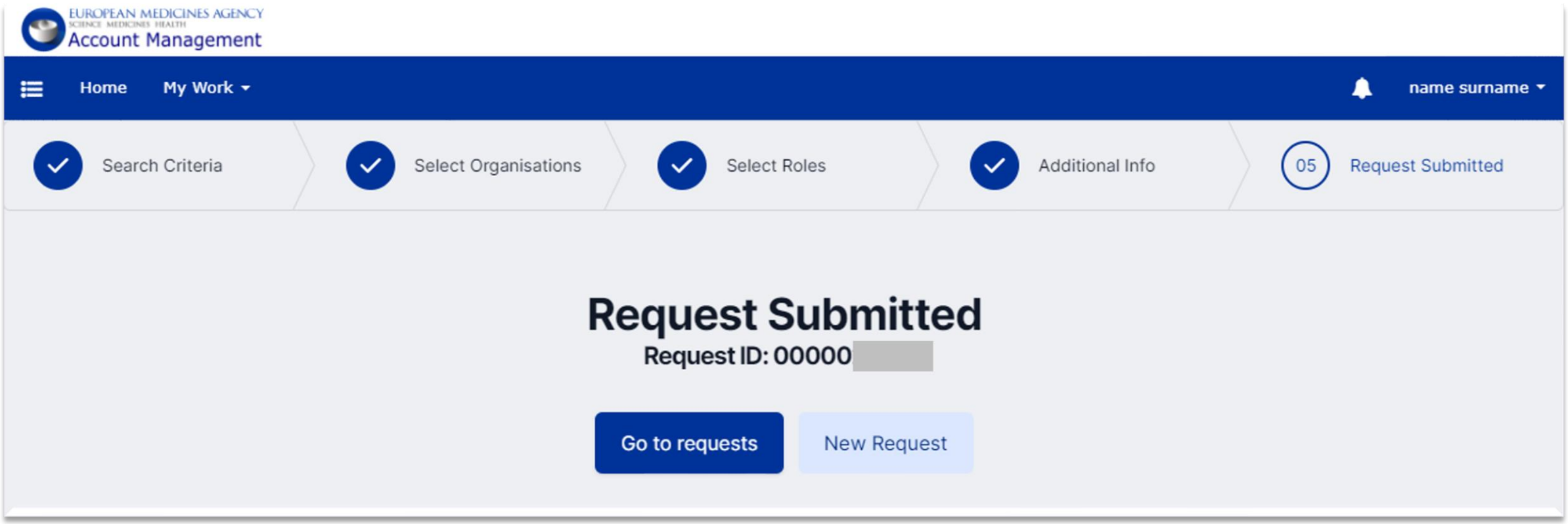


The role requiring additional information is displayed in the righthand panel

Multiple attachments can be provided but please note that the same affiliation letter can be re-used for multiple roles and multiple organisations.

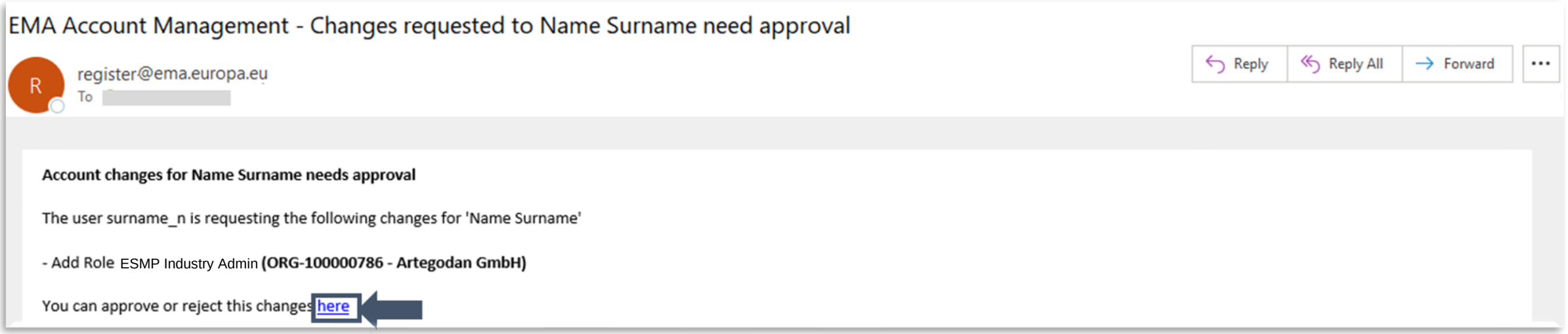
Requesting ESMP roles

05 Request Submitted (Window confirming that the request has been submitted)



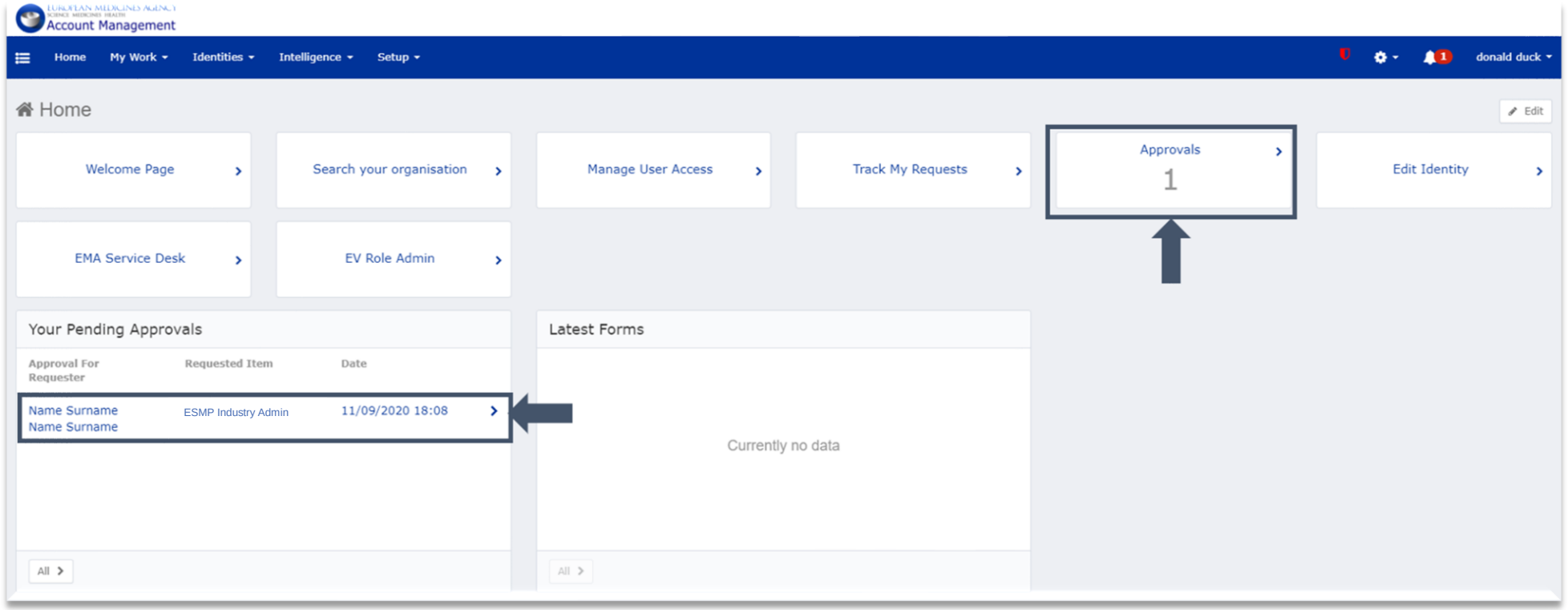
Approving access roles requests *(only for administrators)*

As an administrator, you receive an email every time a new access role request has been submitted. Click on the link you have received in the email to process it.



Approving access roles requests *(only for administrators)*

Alternatively, log into the **EMA Account Management portal**. The request will appear in “Your Pending Approvals” and “Approvals” tabs



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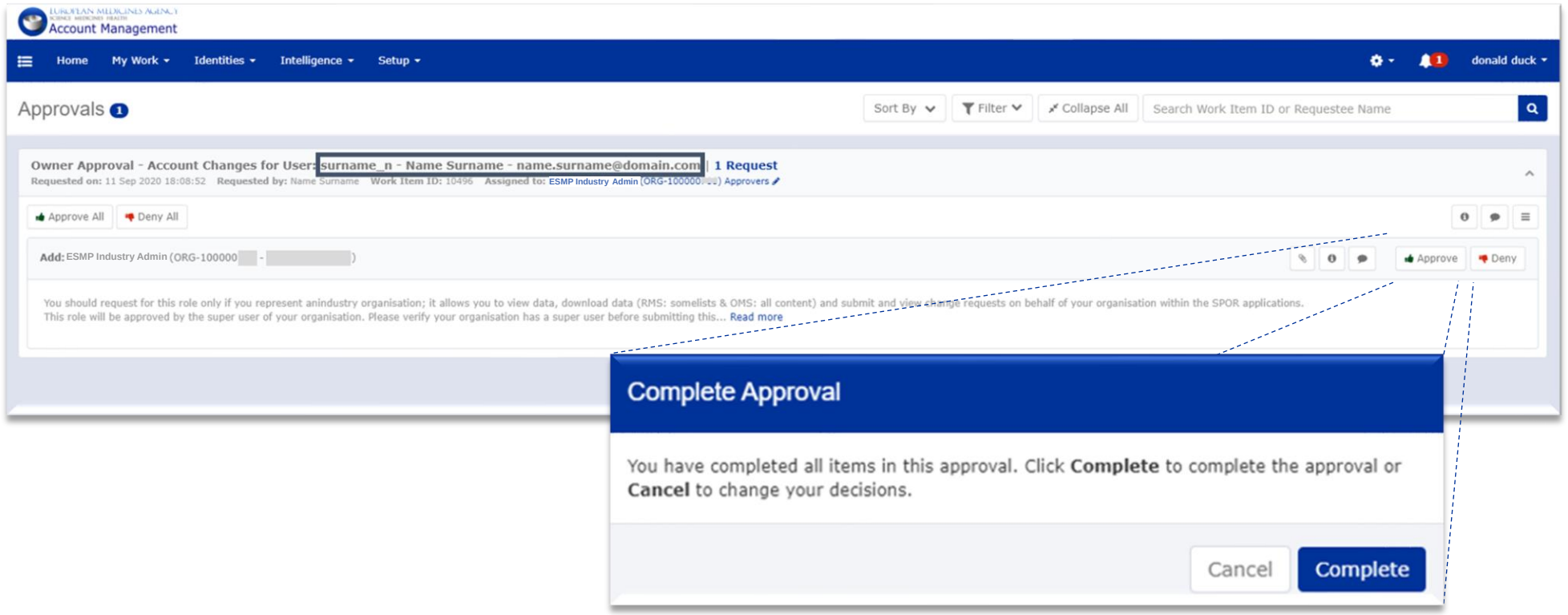
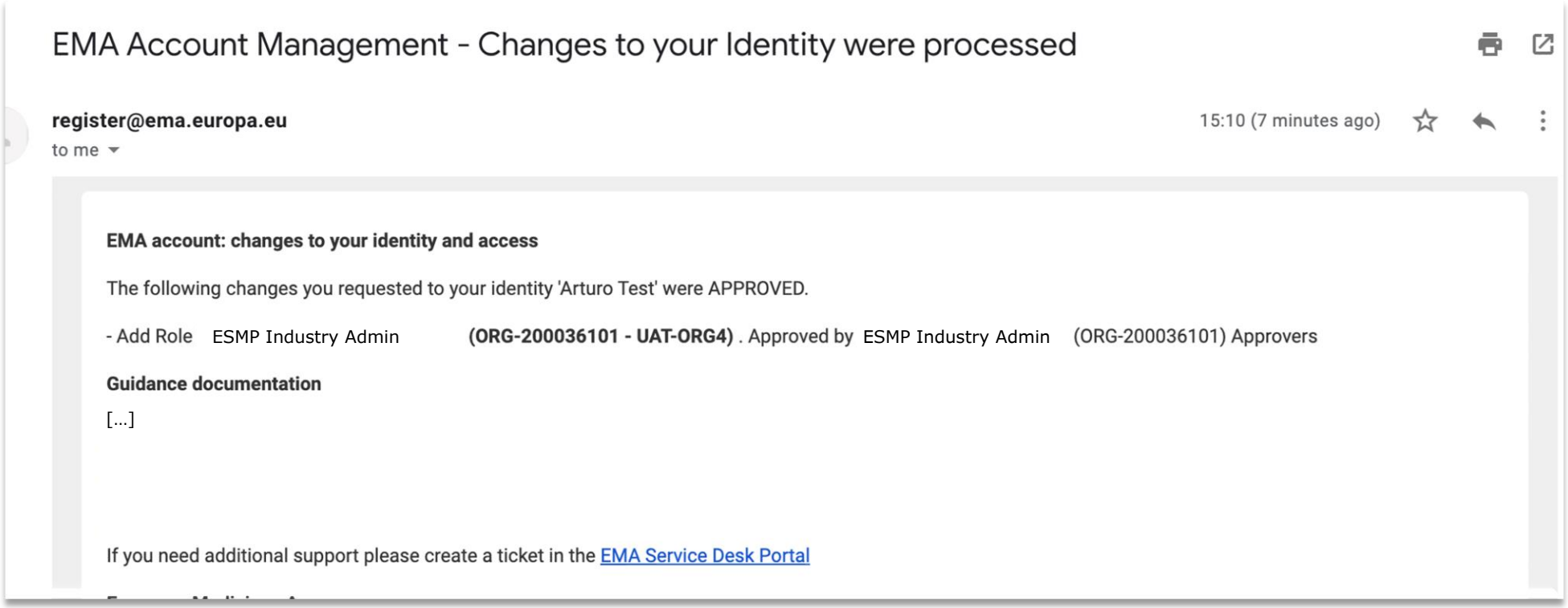


Approving access roles requests *(only for administrators)*

Users receive a confirmation email coming from register@ema.europa.eu as soon as an access role request is approved/rejected.



EMA Account Management - Changes to your Identity were processed

register@ema.europa.eu 15:10 (7 minutes ago)

to me

EMA account: changes to your identity and access

The following changes you requested to your identity 'Arturo Test' were APPROVED.

- Add Role ESMP Industry Admin **(ORG-200036101 - UAT-ORG4)** . Approved by ESMP Industry Admin (ORG-200036101) Approvers

Guidance documentation

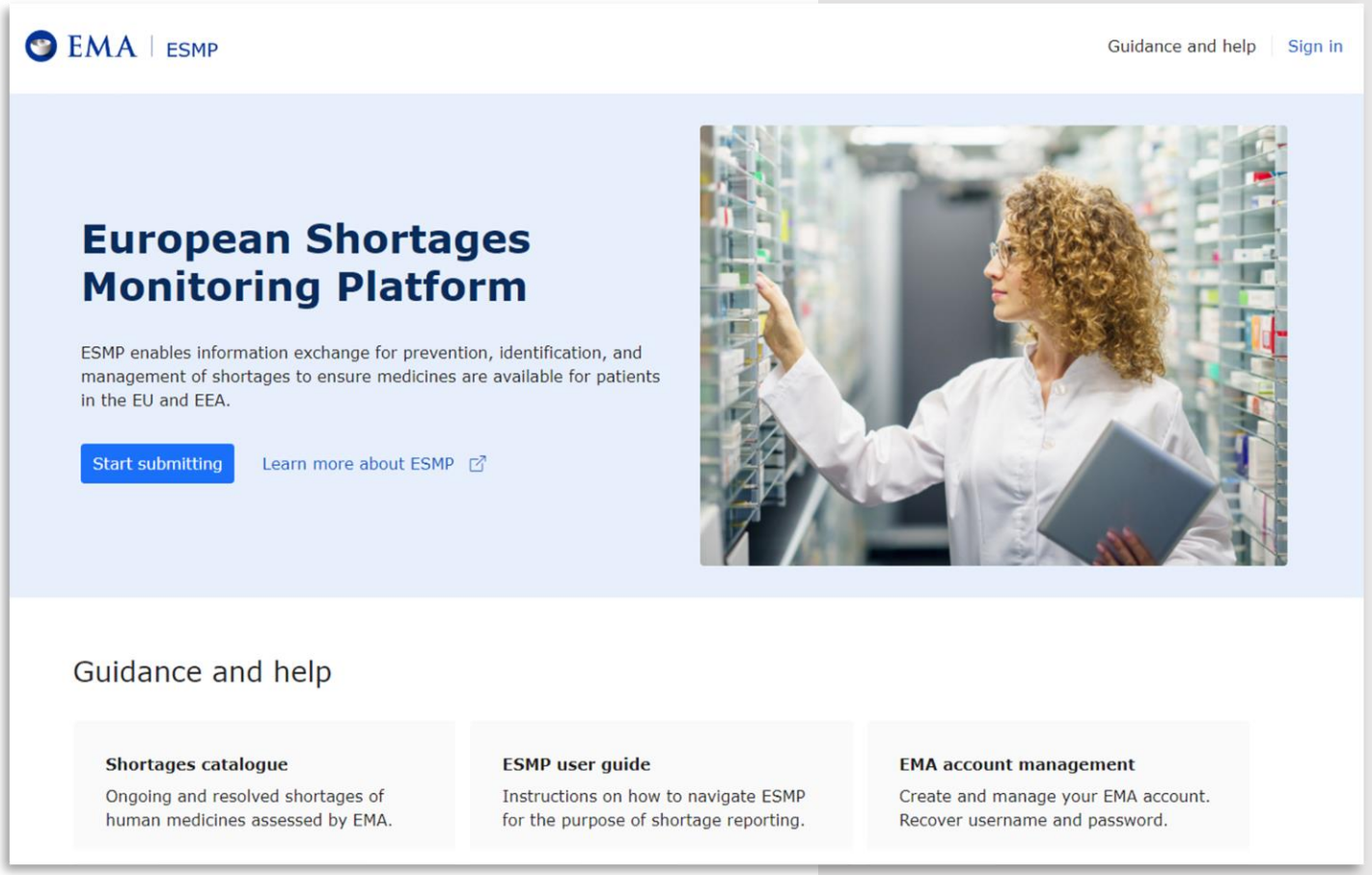
[...]

If you need additional support please create a ticket in the EMA Service Desk Portal

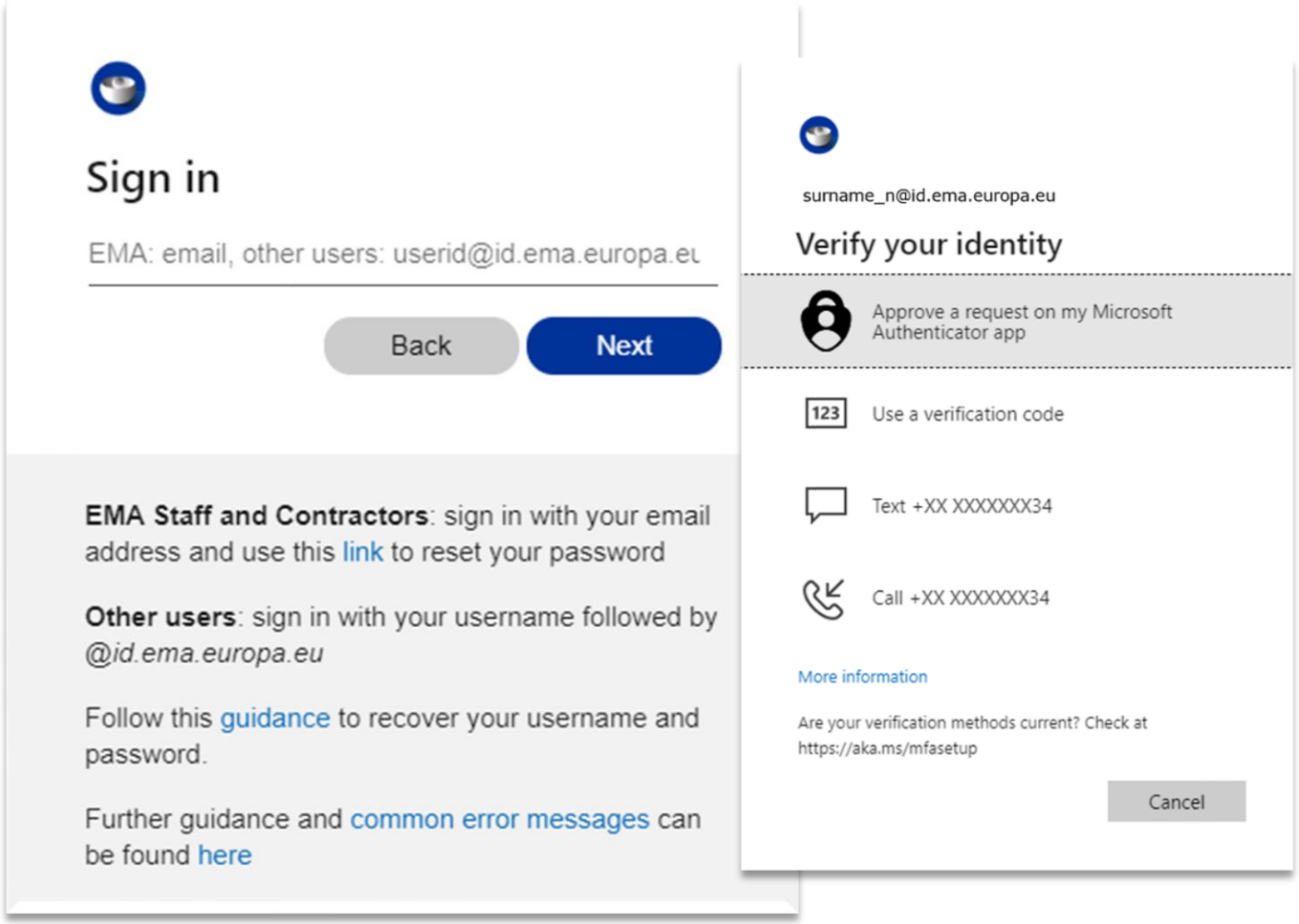
Signing in to the ESMP

ESMP URL:

https://www.esmp.ema.europa.eu/



Signing in to the ESMP



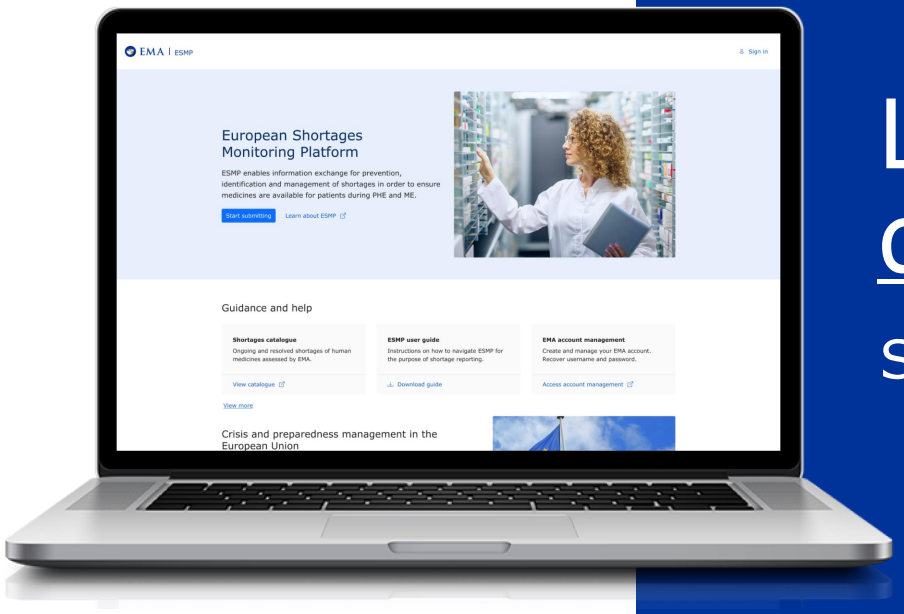
Please note that:

You must sign in with your username followed by @id.ema.europa.eu: *username*@id.ema.europa.eu

The password is the same as in https://register.ema.europa.eu

Multifactor authentication is required:

- You can use the **Microsoft Authentication app** or **SMS**



Let's see how it works: demo*

Signing in to the ESMP

*Recording: timestamp 48:16
https://www.youtube.com/live/A8q9KRYujKo?t=2896s

5

Routine shortage reporting functionalities

Sofia Zastavnik

Routine shortage reporting of CAPs

During normal circumstances, MAHs of CAPs for human use are required to routinely report information on potential or actual shortages of medicinal products to EMA through the ESMP.

To perform routine shortage submissions, MAHs will:

1. *Select relevant products under your product portfolio*
2. *Download a reporting template pre-filled with the relevant product information*
3. *Compile, upload, and submit relevant information*
4. *Perform updates to keep information current*
5. *Update a previous submission when a shortage is resolved*

Disclaimer

- All the information on shortages displayed is fictional and made for the purpose of this training.

Preliminary requirements

Marketing status of all CAPs must be inserted correctly and kept up-to-date within the IRIS platform

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

- If the information on the marketing status of CAPs is not populated or not up-to-date in IRIS, please perform the necessary changes in IRIS

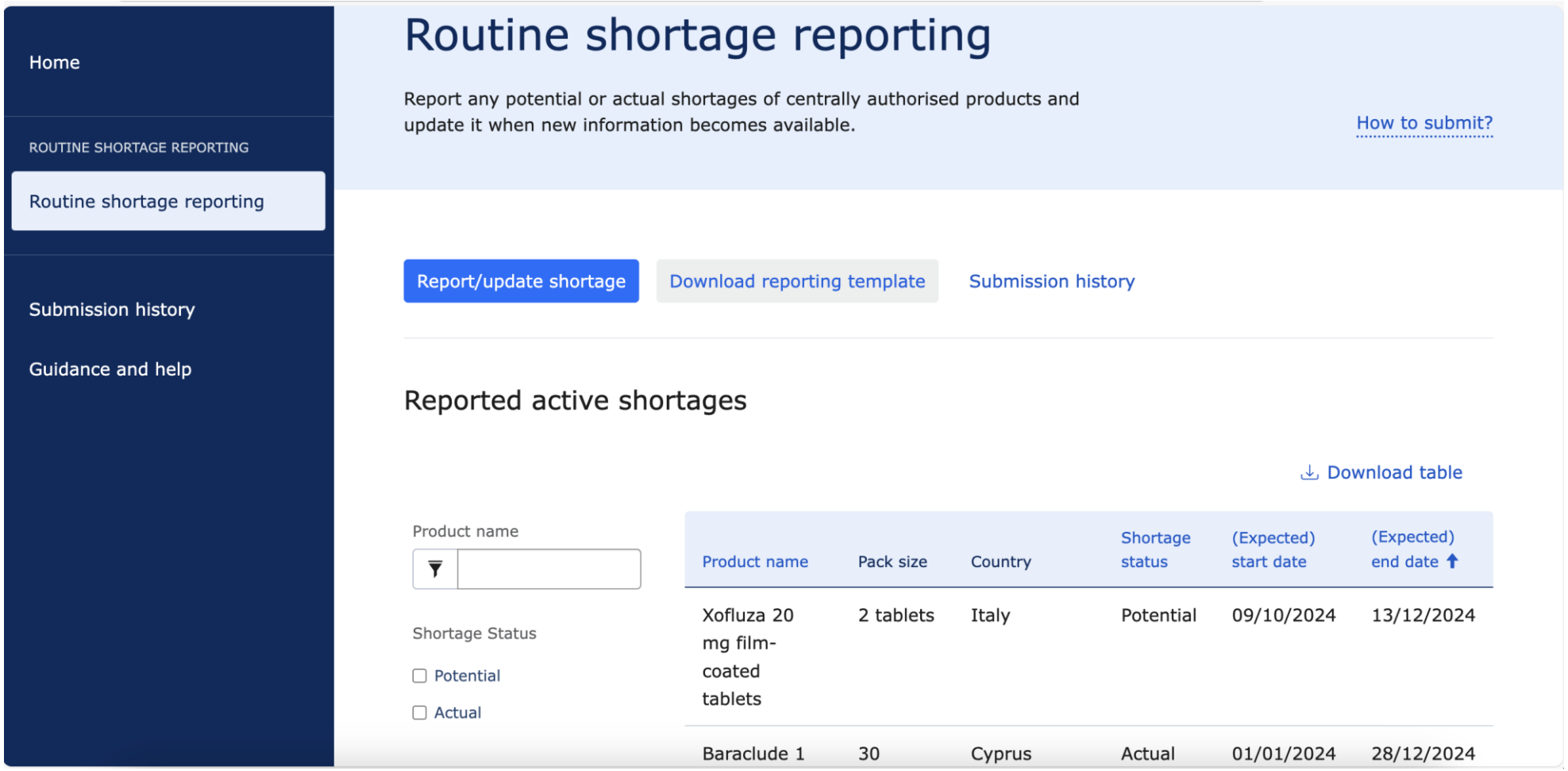
Please refer to:

IRIS

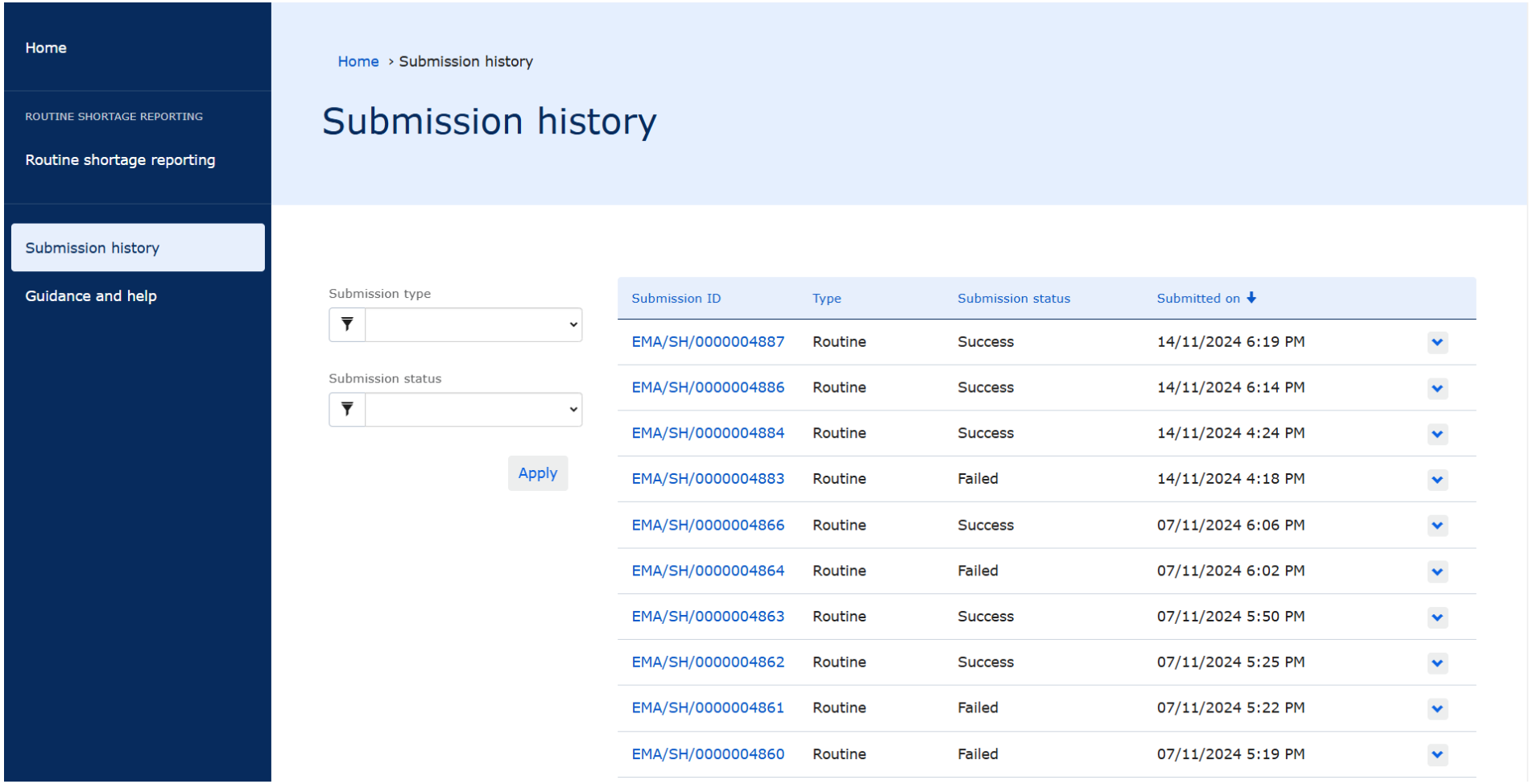
IRIS guide for applicants

Notifying a change of marketing status

How to navigate the platform



How to navigate the platform



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 data entries, demonstrating how to populate the template accurately for varying shortage details and marketing statuses.

Highlight country-specific reporting needs, showing the importance of tailored data submission based on each country’s marketing and shortage status.

Guide best practices to showcase common issues to avoid and steps to ensure accurate reporting across multiple regions.

Scenario example: Esempin 500 mg

Product Esempin 500 mg has varying availability across the EU/EEA countries, requiring a tailored reporting approach.

Country	Marketing status	Shortage status
 Germany (DE)	Marketed	No shortage
 Italy (IT)	Marketed	Active shortage
 Spain (ES)	Temporarily unavailable	Potential shortage
All other EU/EEA countries	Not marketed	Not applicable

The timelines and root causes for the actual (IT) and potential (ES) shortages differ and are multi-factored (manufacturing, quality, and commercial reasons in for IT and distribution reasons for ES), as well as proposed prevention and mitigation actions, the shortage impact, availability of alternative therapies and other important information. Throughout time, the shortage dates for IT change and the shortage will be updated and later on resolved.

Demo 1: Select relevant products and download reporting template

1. *Select relevant products under your product portfolio*
2. *Download a reporting template pre-filled with the relevant product information*
3. *Compile, upload, and submit relevant information*
4. *Perform updates to keep information current*
5. *Update a previous submission when a shortage is resolved*

Downloading the reporting template: Esempin 500 mg

Product Esempin 500 mg has varying marketing statuses across the EU/EEA countries.

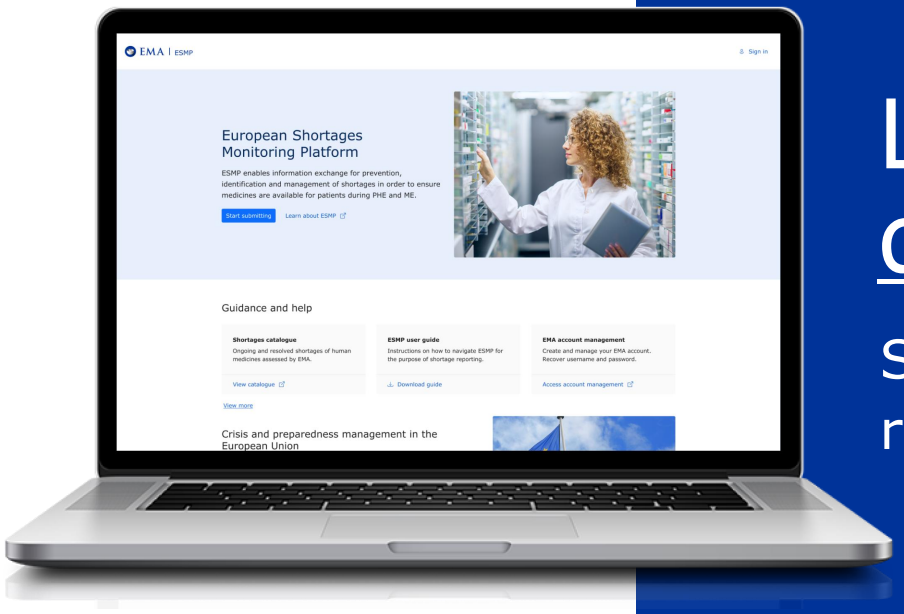
Country	Marketing status	Product available for reporting in the ESMP
Germany (DE)	Marketed	Yes
Italy (IT)	Marketed	Yes
Spain (ES)	Temporarily unavailable	Yes
All other EU/EEA countries	Not marketed	No

Downloading the reporting template: Esempin 500 mg

Product Esempin 500 mg has varying marketing statuses across the EU/EEA countries.

Country	Marketing status	Product available for reporting in the ESMP
Germany (DE)	Marketed	Yes
Italy (IT)	Marketed	Yes
Spain (ES)	Temporarily unavailable	Yes
All other EU/EEA countries	Not marketed	No

- Only products listed as "**Marketed**" or "**Temporarily Unavailable**" in IRIS will be retrieved from IRIS and pre-populated in ESMP templates. Products listed as "Not Marketed", "Never Marketed", or missing marketing status information in IRIS, will not appear in the ESMP submission templates.
- If information is outdated or incorrect, **update it directly in IRIS**. Changes will automatically be reflected in ESMP.



Let's see how it works: demo*

Select relevant products and download reporting template

*Recording: timestamp 1:01:19
https://www.youtube.com/watch?v=A8q9KRYujKo&t=3679s

Data elements for shortage reporting

Product information *(pre-populated from PMS and IRIS)*	*PMS ID (Packaged medicinal product)*
	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 increased demand occurs
	Countries in which distribution issues occur
	Additional information on the root cause of the shortage
Prevention and mitigation plans	Shortage prevention and mitigation plans
	Shortage prevention and mitigation plans – ongoing and planned steps
Impact assessment	Affected population estimate
	Market share
	Shortage impact risk assessment
	Shortage impact risk assessment – additional information
Potential alternatives therapies	Alternatives available (yes/no)
	Alternative therapies
Additional information	Rapid alert reference number
	Other authorities notified (e.g., other NCAs, EMA), including reference to Quality Defect report
	Reference to related pending regulatory action
	Required NCA actions, if any

Demo 2: Data compilation, template overview and submission

1. *Select relevant products under your product portfolio*
2. *Download a reporting template pre-filled with the relevant product information*
3. *Compile, upload, and submit relevant information*
4. *Perform updates to keep information current*
5. *Update a previous submission when a shortage is resolved*

Product information

Product information *(pre-populated from PMS and IRIS)*	*PMS ID (Packaged medicinal product)*
	Full product name
	Short product name
	Active substance
	Strength
	Pharmaceutical form
	Pack size
	Packaging
	PCID
	Country of authorisation
	Marketing status
	Additional information on the root cause of the shortage

Prevention and mitigation plans	Shortage prevention and mitigation plans
	Shortage prevention and mitigation plans – ongoing and planned steps
Impact assessment	Affected population estimate
	Market share
	Shortage impact risk assessment
	Shortage impact risk assessment – additional information
Potential	Alternatives available (yes/no)
	Required NCA actions, if any

PMS ID (Packaged medicinal product)	Full product name	Short product name	Active substance	Strength	Pharmaceutical form	Pack size	Packaging	PCID	Country of authorisation	Marketing status

Product information

Product information *(pre-populated from PMS and IRIS)*	*PMS ID (Packaged medicinal product)*
	Full product name
	Short product name
	Active substance
	Strength
	Pharmaceutical form
	Pack size
	Packaging
	PCID
	Country of authorisation
	Marketing status
	Shortage status
	Countries in which increased demand occurs
	Countries in which distribution issues occur
	Additional information on the root cause of the shortage

Prevention and mitigation plans	Shortage prevention and mitigation plans
	Shortage prevention and mitigation plans – ongoing and planned steps
Impact assessment	Affected population estimate
	Market share
	Shortage impact risk assessment
	Shortage impact risk assessment – additional information
Potential	Alternatives available (yes/no)
information	Reference to related pending regulatory action
	Required NCA actions, if any

- Product information fields will be pre-populated from data inserted via the EMA's Product Management Services (PMS) and IRIS systems
- The PCID field will be empty

Product information

Product information					
PMS ID	Full product name	Short product name	Active substance	Strength	Pharmaceutical form
P1.1.1	P1.2.1	P1.2.2	P1.3.2	P1.4	P1.6.2
uat-pp-pmsid-0001	Esempin 500 mg - Film-coated tablet	Esempin	Paracetamol	500 MG	Film-coated tablet
uat-pp-pmsid-0001	Esempin 500 mg - Film-coated tablet	Esempin	Paracetamol	500 MG	Film-coated tablet
uat-pp-pmsid-0001	Esempin 500 mg - Film-coated tablet	Esempin	Paracetamol	500 MG	Film-coated tablet

Product information				
Pack size	Packaging	PCID	Country of authorisation	Marketing status
P1.7.2	P1.7.3	P1.7.1	P1.8	P1.9
100 tablets	Blister		DE	Marketed
100 tablets	Blister		IT	Marketed
100 tablets	Blister		ES	Temporarily unavailable

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 increased demand occurs	Countries in which distribution issues occur	Root cause of the shortage - additional information

	Packaging	assessment
	PCID	Shortage impact risk assessment
	Country of authorisation	Shortage impact risk assessment – additional information
	Marketing status	
Shortage information	Shortage status	**Potential alternatives therapies**
	Shortage start date or expected start date	Alternatives available (yes/no)
	Shortage end date or expected end date	Alternative therapies
	Point in supply chain at which disruption occurs	
	Root cause of the shortage	**Additional information**
	Countries in which manufacturing issues occur	Rapid alert reference number
	Countries in which increased demand occurs	Other authorities notified (e.g., other NCAs, EMA), including reference to Quality Defect report
	Countries in which distribution issues occur	Reference to related pending regulatory action
	Additional information on the root cause of the shortage	Required NCA actions, if any

Shortage 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 RMS values with semicolons (";") with no additional spaces

	PMS ID (Packaged medicinal product)
	Full product name
	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 increased demand occurs
	Countries in which distribution issues occur
	Additional information on the root cause of the shortage

Prevention and	Shortage prevention and mitigation plans
Potential alternatives therapies	Alternatives available (yes/no)
	Alternative therapies
Additional information	Rapid alert reference number
	Other authorities notified (e.g., other NCAs, EMA), including reference to Quality Defect report
	Reference to related pending regulatory action
	Required NCA actions, if any

Shortage information

	PMS ID (Packaged medicinal product)
	Full product name
	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 increased demand occurs
	Countries in which distribution issues occur
	Additional information on the root cause of the shortage

- Refer to the **ESMP Implementation guide for MAHs** for technical specifications on how to populate the data fields


EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 November 2024
European Medicines Agency

European Shortages Monitoring Platform (ESMP) Implementation Guide for Marketing Authorisation Holders

Version 1.1

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact Telephone +31 (0)88 781 6000 An agency of the European Union

ESMP Implementation guide: example

Tag	Explanation
ID	S1.5
Name	Root cause of the shortage
Description	Primary reason(s) for the shortage. If applicable, multiple values may be entered.
Example	200000028683;200000028684
Conformance	Conditional
Data type	String

Validation rule	• If the Shortage status is reported as "No Shortage":
	  ○ Must not be filled in (to be left empty)
	• If the Shortage status is reported as "Actual", "Potential" or "Resolved":
	  ○ Must be filled in (mandatory)
	  ○ Must be the RMS term ID of a term in the RMS list "Shortage root cause" with list ID "200000028648". Consult possible values in the Annex 1 – RMS ID list Shortage root cause
	  ○ Multiple values must be separated by a ";"
	  ○ Must not contain duplicate values

Destination reference	MAH Routine shortage reporting template / column P

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Shortage root cause

RMS list 200000028648 | https://spor.ema.europa.eu/rmswi/#/lists/200000028648/terms

Identifier	Term name
200000028689	Manufacturing issues - Manufacturing issues preventing production/release
200000028690	Manufacturing issues - Restrictions on people
200000028691	Manufacturing issues - GMP non - compliance
200000028692	Manufacturing issues - Capacity issues
200000028694	Quality issues - Suspected defective product preventing release of batches to the market
200000028695	Quality issues - Suspected defective product requiring batch recall
200000028697	Regulatory issues - Marketing authorisation restricted/suspended
200000028698	Regulatory issues - Regulatory approval delay
200000028700	Unexpected increased demand - Consumer driven stockpiling
200000028701	Unexpected increased demand - Member State driven stockpiling
200000028702	Unexpected increased demand - Changes in prescribing behaviour
200000028703	Unexpected increased demand - Change in use (off label or through changes in MA)
200000028704	Unexpected increased demand - Increased demand due to unavailability from other MAHs
200000028706	Distribution issues - Air transport
200000028707	Distribution issues - Sea transport
200000028708	Distribution issues - Land transport
200000028709	Distribution issues - Export restrictions
200000028710	Distribution issues - Import restrictions
200000028712	Commercial reasons - Pricing and reimbursements
200000028713	Commercial reasons - Insolvency
200000028714	Commercial reasons - Prioritisation of other markets
200000028715	Commercial reasons - Business strategy (other)
200000043380	Other

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				
Actual	15/01/2025	30/04/2025	200000028585;200000028587	200000028692;200000028695;200000028697;200000028715
Potential	01/12/2024	01/01/2025	200000028592	200000028707

Shortage information			
Countries in which manufacturing issues occur	Countries in which increased demand occurs	Countries in which distribution issues occur	Additional information on the root cause of the shortage
S1.6.1	S1.6.2	S1.6.3	S1.7
BE			Impurity found in stability sample for one bulk batch, product recall; reduced production capacity; pending variation procedure for second manufacturing site; reallocation of available products to other markets/countries
		CN;CO	Adverse weather conditions

Shortage information

Shortage status	Shortage start date / expected start date		Point in supply chain at which disruption occurs	Root cause of the shortage
S1.1	S1.2		S1.4	S1.5
No shortage				
Actual	15/01/2025	30/04/2025	200000028585;200000028587	200000028692;200000028695;200000028697;200000028715
Potential	01/12/2		200000028592	200000028707

Primary packaging; Supply of raw materials, excipients, packaging components

Distribution of released products

Shortage information

Countries in which manufacturing issues occur	Countries in which increased demand occurs	Countries in which distribution issues occur	Additional information on the root cause of the shortage
S1.6.1	S1.6.2	S1.6.3	S1.7
BE			Impurity found in stability sample for one bulk batch, product recall; reduced production capacity; pending variation procedure for second manufacturing site; reallocation of available products to other markets/countries
		CN;CO	Adverse weather conditions

Shortage information

Shortage information

Shortage status	Shortage start dat… expected start da…		…hain at … occurs	Root cause of the shortage
S1.1	S1.2			S1.5
No shortage				
Actual	15/01/2025		…0000028587	200000028692;200000028695;200000028697;200000028715
Potential	01/12/2024	01/01/2025	200000028592	200000028707

Manufacturing issues - Capacity issues; Quality issues - Suspected defective product requiring batch recall; Regulatory issues - Marketing authorisation restricted/suspended; Commercial reasons - Business strategy (other)

Distribution issues - Sea transport

Shortage inform…

Countries in which manufacturing issues occur	Countries in which increased demand occurs	Countries in which distribution issues occur	Additional information on the root cause of the shortage
S1.6.1	S1.6.2	S1.6.3	S1.7
BE			Impurity found in stability sample for one bulk batch, product recall; reduced production capacity; pending variation procedure for second manufacturing site; reallocation of available products to other markets/countries
		CN;CO	Adverse weather conditions

Prevention and mitigation plans

Product information *(pre-populated from PMS and IRIS)*	*PMS ID (Packaged medicinal product)*
	Full product name
	Short product name
	Active substance
	Strength
	Pharmaceutical form
	Pack size
	Packaging
	PCID
Shortage information	Countries in which distribution issues occur
	Additional information on the root cause of the shortage

Prevention and mitigation plans	Shortage prevention and mitigation plans
	Shortage prevention and mitigation plans – ongoing and planned steps
Impact assessment	Affected population estimate
	Market share
	Shortage impact risk assessment
	Shortage impact risk assessment – additional
	NCAs, EMA), report
	ory action
	Required NCA actions, if any

Shortage prevention and mitigation plans	Shortage prevention and mitigation plans - ongoing and planned steps

Prevention and mitigation plans

Product information *(pre-populated from PMS and IRIS)*	*PMS ID (Packaged medicinal product)*
	Full product name
	Short product name
	Active substance
	Strength
	Pharmaceutical form
	Pack size
	Packaging
	PCID
	Additional information on the root cause of the shortage

Prevention and mitigation plans	Shortage prevention and mitigation plans
	Shortage prevention and mitigation plans – ongoing and planned steps
Impact assessment	Affected population estimate
	Market share
	Shortage impact risk assessment
	Required NCA actions, if any

- **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 technical specifications on how to compile data fields

Prevention and mitigation plans

Prevention and mitigation plans	
Shortage prevention and mitigation plans	Shortage prevention and mitigation plans - ongoing and planned steps
S2.1	S2.2
200000028634;200000028635;200000028633;	Manufacturing of finished product commissioned to alternative manufacturer;Batch testing taking place at alternative testing site;
200000028644;200000028646;200000028637	Transport temporarily via air transport; Re-allocation of German labelled stocks to ES to be explored

Prevention and mitigation plans

Prevention	
Shortage prevention and mitigation plans	and planned steps
S2.1	
200000028634;200000028635;200000028633;	Manufacturing of finished product commissioned to alternative manufacturer;Batch testing taking place at alternative testing site;
200000028644;200000028646;200000028637	Transport temporarily via air transport; Re-allocation of German labelled stocks to ES to be explored

Alternative finished product manufacturer; Alternative batch control site; Alternative active substance manufacturer

Change mode of transportation; Prioritisation of supplies to critical customers; Supply of product in foreign language labelling

Impact assessment

Product information *(pre-populated from PMS and IRIS)*	*PMS ID (Packaged medicinal product)*
	Full product name
	Short product name
	Active substance
	Strength
	Pharmaceutical form
	Pack size
	Packaging
	PCID
	Country of authorisation
	Marketing status
Prevention and mitigation plans	Shortage prevention and mitigation plans
	Shortage prevention and mitigation plans – ongoing and planned steps
Impact assessment	Affected population estimate
	Market share
	Shortage impact risk assessment
	Shortage impact risk assessment – additional information

Affected population estimate	Market share	Shortage impact risk assessment	Shortage impact risk assessment - additional information

Shortage information

Impact assessment

Product information *(pre-populated from PMS and IRIS)*	*PMS ID (Packaged medicinal product)*
	Full product name
	Short product name
	Active substance
	Strength
	Pharmaceutical form
	Pack size
	Packaging
	PCID
	Country of authorisation
	Marketing status
	Shortage status
	Additional information on the root cause of the shortage
Prevention and mitigation plans	Shortage prevention and mitigation plans
	Shortage prevention and mitigation plans – ongoing and planned steps
Impact assessment	Affected population estimate
	Market share
	Shortage impact risk assessment
	Shortage impact risk assessment – additional information
Potential	Alternatives available (yes/no)
	Required NCA actions, if any

- For shortage impact risk assessment:
  - Use numerical codes from the EMA's Referentials Management Services (**RMS**) to ensure **standard identifiers**
  - Separate multiple RMS values with semicolons (";") with no additional spaces
- Refer to the **ESMP Implementation guide for MAHs** for technical specifications on how to compile data fields

Impact assessment

Impact assessment			
Affected population estimate	Market share	Shortage impact risk assessment	Shortage impact risk assessment - additional information
S3.1	S3.2	S3.4	S3.5
967500	59	200000033601	Risk level medium due to limited alternatives available and consistent market share
2500500	100	200000033600	High due to high market share and no marketed alternatives

Impact assessment

Impact assessment			
Affected population estimate	Market share	Shortage impact risk assessment	Shortage impact risk assessment - additional information
S3.1	S3.2	S3.4	S3.5
967500	59	200000033601	Risk level medium due to limited alternatives available and consistent market share
2500500	100	200000033600	High due to high market share and no marketed alternatives

Medium

High

Potential alternative therapies

Product information *(pre-populat from PMS ar*	*PMS ID (Packaged medicinal product)*	**Prevention and**	Shortage prevention and mitigation plans
	Full product name		
	Marketing status		
Shortage information	Shortage status	**Potential alternatives therapies**	Alternatives available (yes/no)
	Shortage start date or expected start date		Alternative therapies
	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	**Additional information**	Rapid alert reference number
	Countries in which increased demand occurs		Other authorities notified (e.g., other NCAs, EMA), including reference to Quality Defect report
	Countries in which distribution issues occur		Reference to related pending regulatory action
	Additional information on the root cause of the shortage		Required NCA actions, if any

Alternative therapies available?	Alternative therapies

Potential alternative therapies

Alternative therapies available?	Alternative therapies

Potential alternatives therapies	Alternatives available (yes/no)
	Alternative therapies

- Refer to the **ESMP Implementation guide for MAHs** for technical specifications on how to compile data fields

Potential alternative therapies

Alternative therapies	
Alternative therapies available?	Alternative therapies
S4.1	S4.2
Yes	Esempin 250 mg – film-coated tablets;ibuprofen
No	

Additional information

Rapid alert reference number	Other authorities notified (e.g. other NCAs, EMA), including reference to Quality Defect report	Reference to related pending regulatory action	Required NCA actions, if any

Additional information

	PMS ID (Packaged medicinal product)
	Full product name
	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 increased demand occurs
	Countries in which distribution issues occur
	Additional information on the root cause of the shortage
Prevention and	Shortage prevention and mitigation plans
Potential alternatives therapies	Alternatives available (yes/no)
	Alternative therapies
Additional information	Rapid alert reference number
	Other authorities notified (e.g., other NCAs, EMA), including reference to Quality Defect report
	Reference to related pending regulatory action
	Required NCA actions, if any

- Free text fields
- Refer to the **ESMP Implementation guide for MAHs** for technical specifications on how to compile data fields

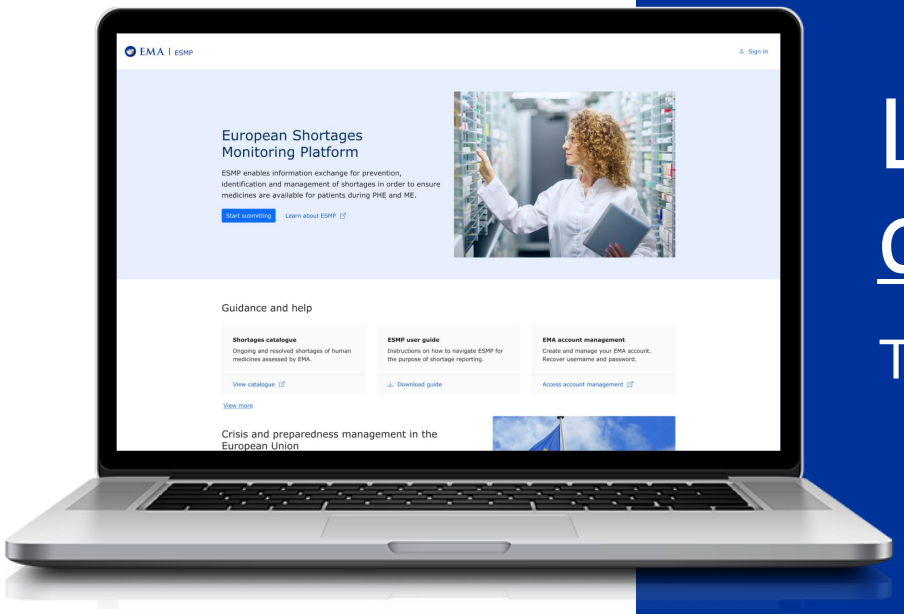
Additional information

Additional information			
Rapid alert reference number	Other authorities notified (e.g. other NCAs, EMA), including reference to Quality Defect report	Reference to related pending regulatory action	Required NCA actions, if any
S5.1	S5.2	S5.3	S5.4
ES/II/2019/05/02	AIFA, European Medicines Agency; Reference: QDYYYY - 123	EMA/H/IB/999919	Possibly acceleration of related pending regulatory procedure
	AEMPS, EMA	Does not apply	Investigate possible import of alternative therapies; Explore potential regulatory flexibilities to address the shortage, (e.g. possible labelling exemption)

Additional information

Additional information			
Rapid alert reference number	Other authorities notified (e.g. other NCAs, EMA), including reference to Quality Defect report	Reference to related pending regulatory action	Required NCA actions, if any
S5.1	S5.2	S5.3	S5.4
ES/II/2019/05/02	AIFA, European Medicines Agency; Reference: QDYYYY - 123	EMA/H/IB/999919	Possibly acceleration of related pending regulatory procedure
	AEMPS, EMA	Does not apply	Investigate possible import of alternative therapies; Explore potential regulatory flexibilities to address the shortage, (e.g. possible labelling exemption)

Reference relates to the Quality Defect report



Let’s see how it works: demo*

Template overview and submission

*Recording: timestamp 1:17:09
https://www.youtube.com/watch?v=A8q9KRYujKo&t=4629s

Demo 3: How to perform an update

1. *Select relevant products under your product portfolio*
2. *Download a reporting template pre-filled with the relevant product information*
3. *Compile, upload, and submit relevant information*
4. *Perform updates to keep information current*
5. *Update a previous submission when a shortage is resolved*

Shortage information - old

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				
Actual	15/01/2025	30/04/2025	200000028585;200000028587	200000028692;200000028695;200000028697;200000028715
Potential	01/12/2024	01/01/2025	200000028592	200000028707

Shortage information			
Countries in which manufacturing issues occur	Countries in which increased demand occurs	Countries in which distribution issues occur	Additional information on the root cause of the shortage
S1.6.1	S1.6.2	S1.6.3	S1.7
BE			Impurity found in stability sample for one bulk batch, product recall; reduced production capacity; pending variation procedure for second manufacturing site; reallocation of available products to other markets/countries
		CN;CO	Adverse weather conditions

Shortage information - new

Shortage information

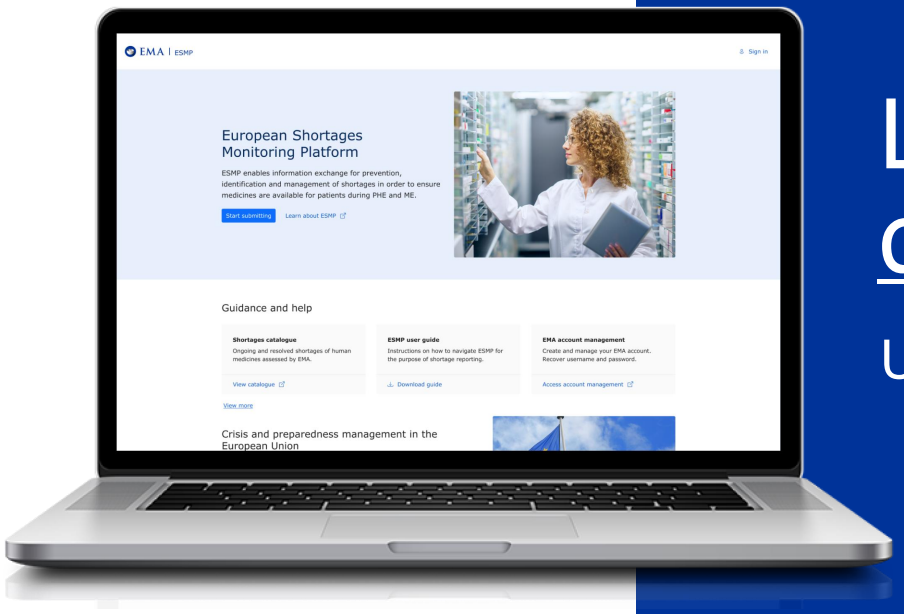
Shortage status	Shortage start date or expected start date	Shortage end date or expected end date	Point in supply chain at which disruption occurs	Root cause of the shortage
	S1.2	S1.3	S1.4	S1.5
No shortage				
Actual	**06/01/2025**	**24/12/2025**	200000028585;200000028587	200000028692;200000028695;200000028697;200000028715
Potential	01/12/2024	01/01/2025	200000028592	200000028707

New expected shortage start date

New expected shortage end date

Shortage information

Countries in which manufacturing issues occur	Countries in which increased demand occurs	Countries in which distribution issues occur	Additional information on the root cause of the shortage
S1.6.1	S1.6.2	S1.6.3	S1.7
BE			Impurity found in stability sample for one bulk batch, product recall; reduced production capacity; pending variation procedure for second manufacturing site; reallocation of available products to other markets/countries
		CN;CO	Adverse weather conditions



Let's see how it works: demo*

Update a previous submission

*Recording: timestamp 1:21:13
https://www.youtube.com/watch?v=A8q9KRYujKo&t=4873s

Demo 4: How to update a report as resolved

1. *Select relevant products under your product portfolio*
2. *Download a reporting template pre-filled with the relevant product information*
3. *Compile, upload, and submit relevant information*
4. *Perform updates to keep information current*
5. *Update a previous submission when a shortage is resolved*

Shortage information - old

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				
Actual	06/01/2025	24/12/2025	200000028585;200000028587	200000028692;200000028695;200000028697;200000028715
Potential	01/12/2024	01/01/2025	200000028592	200000028707

Shortage information			
Countries in which manufacturing issues occur	Countries in which increased demand occurs	Countries in which distribution issues occur	Additional information on the root cause of the shortage
S1.6.1	S1.6.2	S1.6.3	S1.7
BE			Impurity found in stability sample for one bulk batch, product recall; reduced production capacity; pending variation procedure for second manufacturing site; reallocation of available products to other markets/countries
		CN;CO	Adverse weather conditions

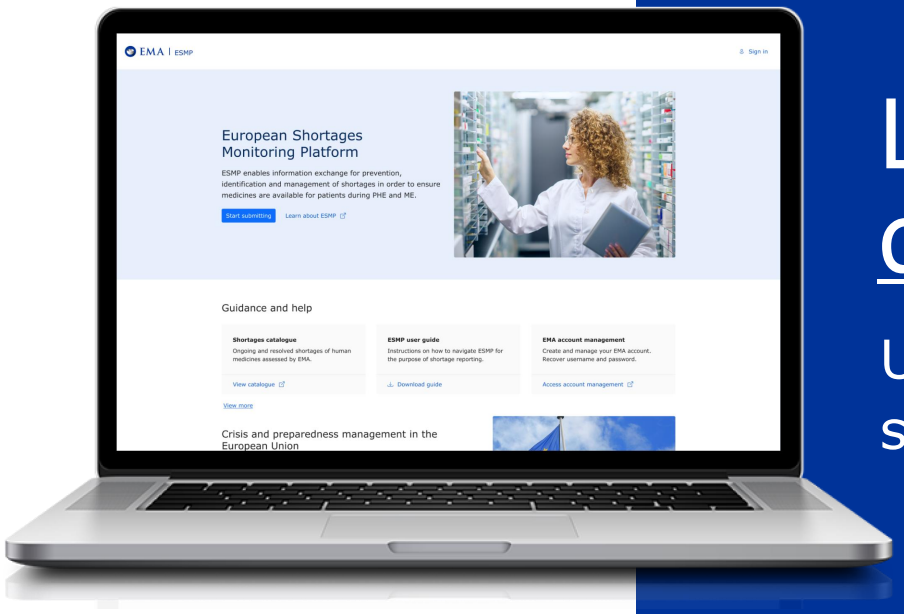
Shortage information - new

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				
Resolved	06/01/2025	24/12/2025	200000028585;200000028587	200000028692;200000028695;200000028697;200000028715
Resolved	01/12/2024	01/01/2025	200000028592	200000028707

New shortage status

Shortage information			
Countries in which manufacturing issues occur	Countries in which increased demand occurs	Countries in which distribution issues occur	Additional information on the root cause of the shortage
S1.6.1			
BE			one bulk batch, product pending variation procedure for second manufacturing site; reallocation of available products to other markets/countries
		CN;CO	Adverse weather conditions

- The information in the other columns must be populated when the shortage status is changed to resolved
- The information in other fields can be updated to reflect the latest information



Let's see how it works: demo*

Update a previous submission when a shortage is resolved

*Recording: timestamp 1:25:06
https://www.youtube.com/watch?v=A8q9KRYujKo&t=5106s

Validation errors when submitting a file - example

Failed

Some fields in the submitted file require your attention
Please review the validation results below.

Submission Type	Upload date and time	Submission ID
Routine	07/11/2024 5:13 PM	EMA/SH/0000004859

Filename	Upload status
esmp-shortage-20241107-1642_I	Failed

Download validation results

Position	Formatted Message
[O4]	Value for 'Point in supply chain at which disruption occurs' is required
[P4]	Value for 'Root cause of the shortage' is required
[U4]	Value for 'Shortage prevention and mitigation plans' is required

Completed!

1. *Select relevant products under your product portfolio*
2. *Download a reporting template pre-filled with the relevant product information*
3. *Compile, upload, and submit relevant information*
4. *Perform updates to keep information current*
5. *Update a previous submission when a shortage is resolved*

Tips and tricks (1/2)

1. Upload only **one file at a time** - the system will only process the last file if multiple are selected
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 **Marketing status must be "Marketed" or "Temporarily Unavailable" in IRIS for CAPs** before submitting information in ESMP

For **CAPs marketing status changes, make updates in IRIS** rather than ESMP - changes 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)**

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 date formats, ID formats, and codes

INTERNAL COORDINATION

- Use version-controlled files to prevent multiple or outdated submissions
- Update submissions as shortage situations evolve to reflect the latest information

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

Useful resources

User guide

Comprehensive **step-by-step guidance** to fulfill routine shortage reporting requirements for CAPs.

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

Where can you find everything you need?

Implementation guide

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

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

ESMP webpage

Training recording and video tutorials

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

7

Closing remarks

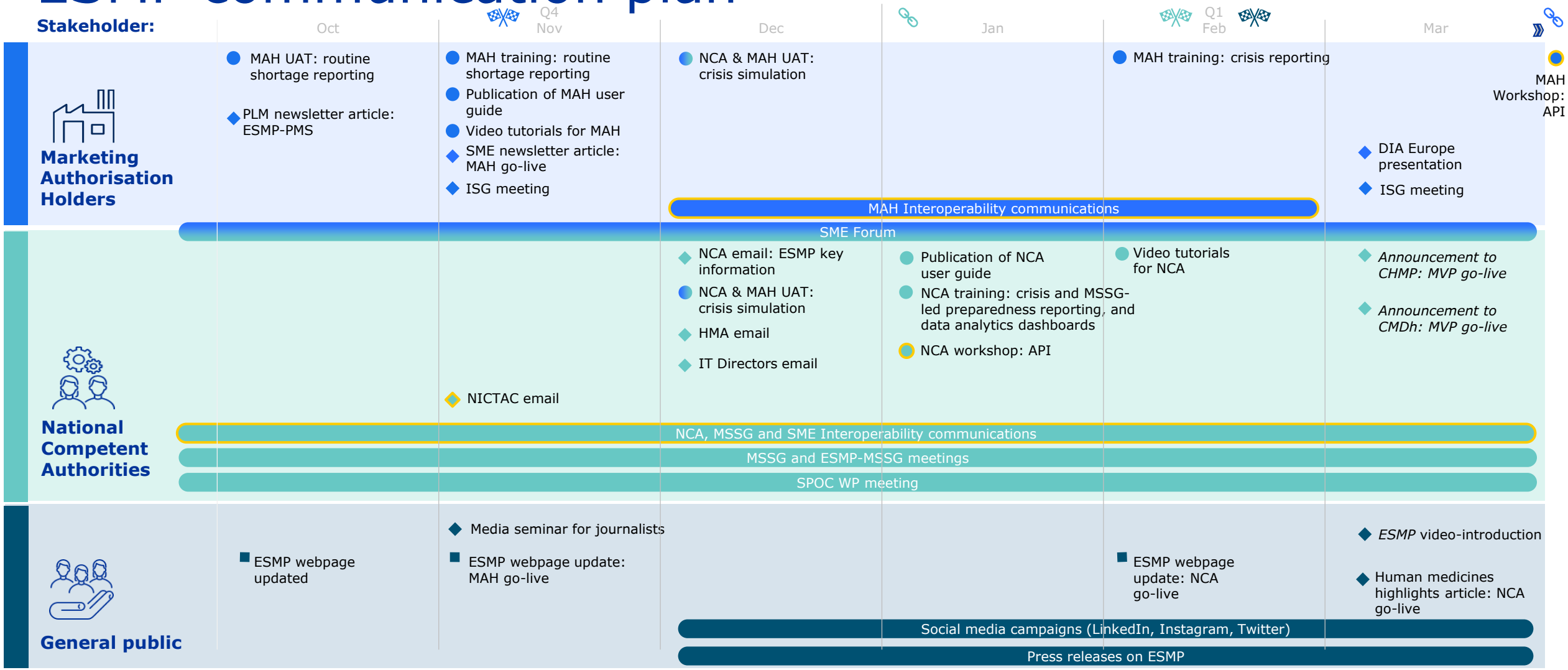
Pedro Pina Ferreira

Wrap up

Thank you for your participation! Today we covered:

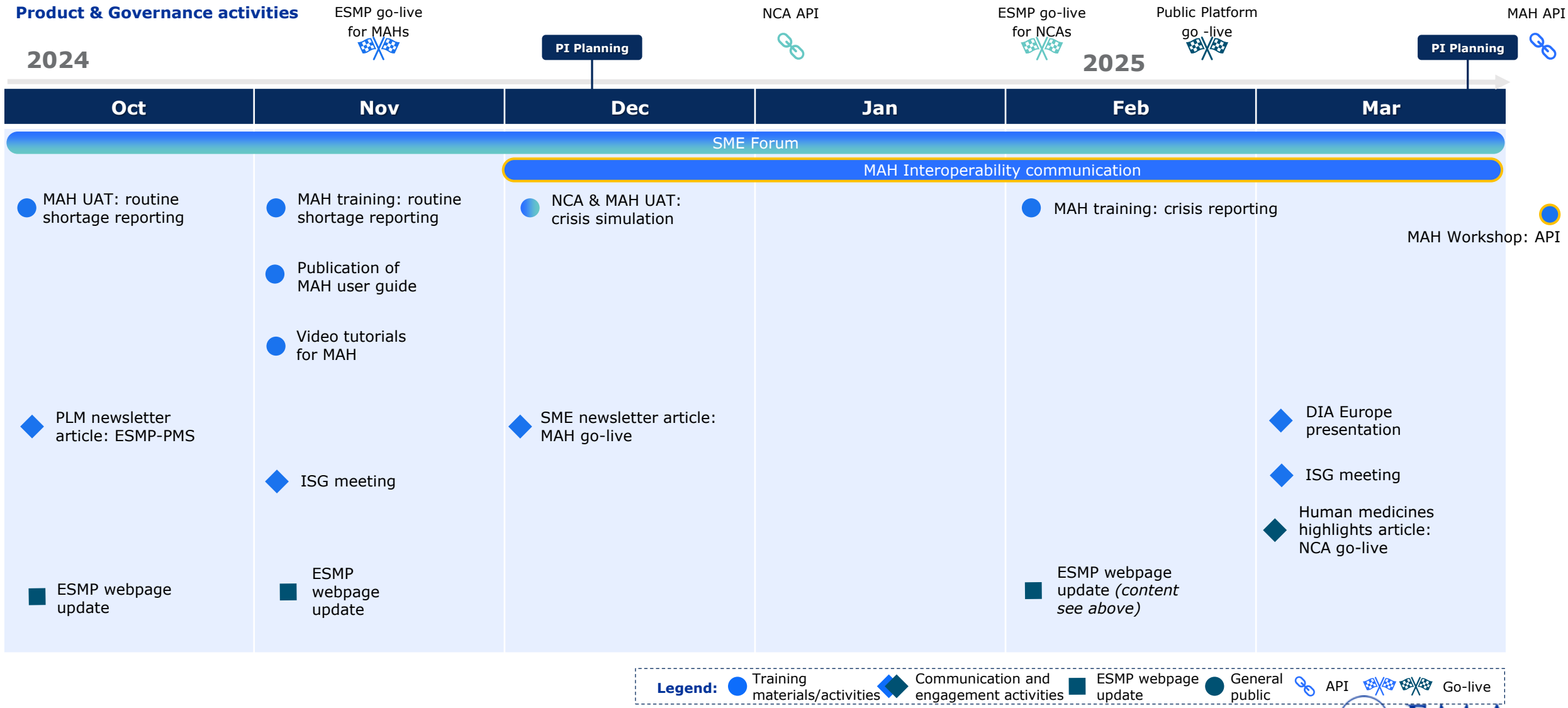
1. *Benefits of efficient shortage management in the EU and how this minimises the public health impact and enhances medicine availability*
2. *The ESMP's goals, structure, and the role it plays in monitoring medicine shortages*
3. *Steps for obtaining and managing access roles within ESMP for secure and streamlined reporting*
4. *Detailed walk-through of reporting processes, template usage, and submission examples to ensure accurate data entry*
5. *Real knowledge sharing for efficient management of shortages in the EU and effective impact on public health*

ESMP communication plan



Please note: the presented timings may be subject to change. Specific dates will be confirmed closer to each deadline. Yellow initiatives are related to ESMP Interoperability.

ESMP communication plan: focus on MAHs



Please note: the presented timings may be subject to change. Specific dates will be confirmed closer to each deadline. Yellow initiatives are related to ESMP Interoperability.

Main upcoming events

Legend: MAH NCA General public

**A dedicated training will be provided by EMA closer to the go-live date*

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-RSR** 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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