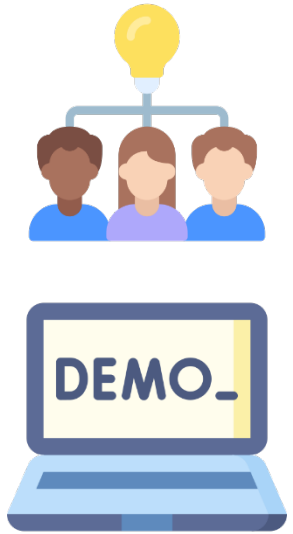
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

System Demo Q3-2024

18/09/2024

Public System Demo



Welcome/Introduction

***Jean-Michel Becar**, Head of Portfolio Management Office, EMA*

*Please note that **this session is being live streamed.***
It is being recorded** and **will be made available** through the **EMA Corporate Website

*At certain points throughout the meeting, participants will be able to 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.*

System Demo

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Is a major part of the **transparency goal** of the Agency's new governance: lean and agile.

Shows an integrated view on what has been built in the past 3 months (Planning Interval (PI)) .

Is an opportunity for the audience to **give instant feedback** to the Agency's development teams to build the right solution.

Is recorded and published on the EMA **Corporate website**.

Next System Demo:
12 December 2024

Agenda

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1 **Welcome/Introduction**
09:00 – 09:05
- ***Jean-Michel Becar,*** *Head of Portfolio Management Office, EMA*

Monitoring Value Stream

2 **European Shortages Monitoring Platform**
09:05 – 10:05

Technology Lifecycle Management and Information Security Value Stream

3 **EMA Account Management - Authentication to EMA systems using email address**
10:05 – 10:20

Managing the Agency Value Stream

4 **New Fee Regulation (NFR)**
10:20 – 10:40

10 min break

Product Lifecycle Management Value Stream

5 **Union Product Database (UPD)**
10:50 – 11:10

6 **Product Management Service (PMS)**
11:10 – 11:30

7 **Product User Interface (UI)**
11:30 – 11:50

10 min break

8 **Electronic Product Information (ePI)**
12:00 – 12:20

9 **Regulatory Procedure Management (RPM)**
12:10 – 12:50

10 **Electronic Application Form (eAF)**
12:50 – 13:10

11 **Closing remarks**
13:10

How to give feedback & ask questions

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1. show system features developed over the past 3 months
2. check progress in achieving the goals of the system
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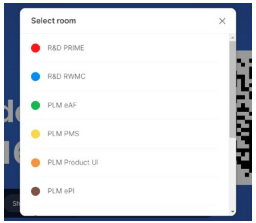

Step 2 – Choose/switch to the room for the right product

Step 3 - Choose Q&A or Polls as appropriate

Value Streams

EUROPEAN MEDICINES AGENCY

Managing the Agency

Capabilities to empower EMA staff and support the Network through modernisation and digitalisation of the Agency's systems, processes and ways of working, increasing efficiency, transparency and collaboration

Owner: Mireia Castillon/Ieva Lobaciute (ad interim)
Manager: Rob Hopping

Research and Development

Capabilities to support the development of new medicines and generation of scientific evidence

Owner: Steven Le Meur
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Monitoring

Capabilities to monitor availability and safety of products

Owner: Pedro Pina Ferreira
Manager: Pedro Oliveira

Technology Lifecycle Management and Information Security

Capabilities to manage information technology and security

Owner: Leonidas Tertipis
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Monitoring VS | European Shortages Monitoring Platform (ESMP)

Sofia Zastavnik, *Product Owner for ESMP, EMA*

Pieter Jan Desiere*, SME for ESMP, EMA*

Introduction: European Shortages Monitoring Platform (ESMP)

Sofia Zastavnik, *ESMP Product Owner*

The European Shortages Monitoring Platform (ESMP)

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Data collection

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

Analysis & Reporting

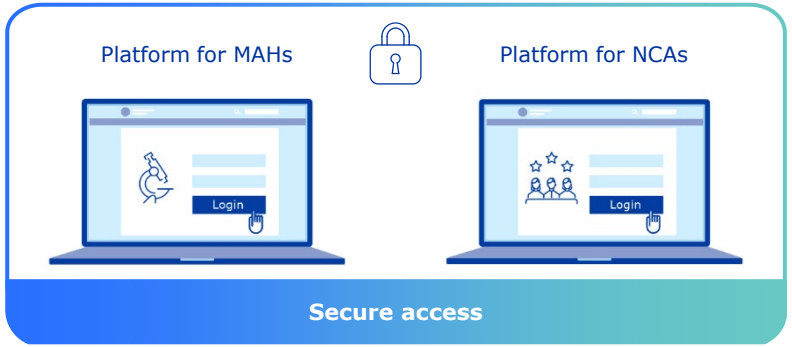
- Matching supply & demand
- Reporting findings and results
- Public reports

Shortages management

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

Data integration

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



Development timeline

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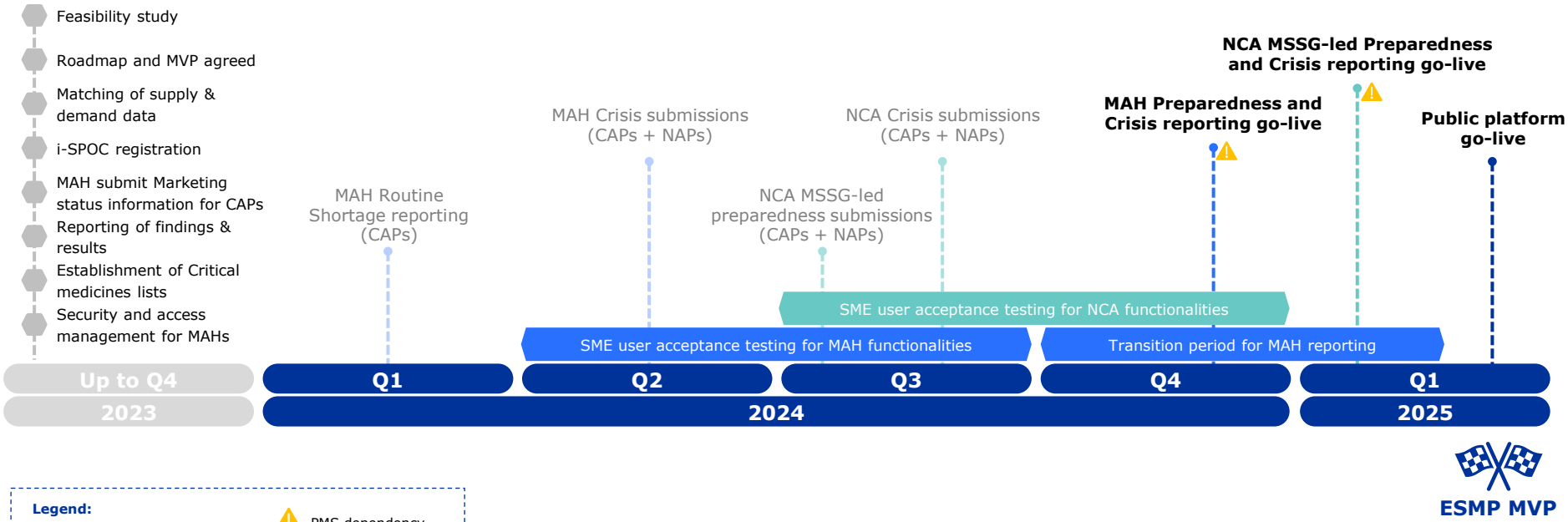

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High level progress diagram – incremental development

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Access Management

MAHs | NCAs | Public

Data collection

MAHs

Crisis / MSSG-led preparedness		Preparedness
User Interface	Alternative Therapies	User interface
Overview of critical medicines	Marketing status NAPs	Routine shortage reporting CAPs
Marketing status CAPs	Manufacturing details, production plan CAPs	
Availability of medicines	Production plan NAPs	

NCAs

Crisis	MSSG-led preparedness
User interface	User interface
Stock and supply (DEMO.)	National demand (DEMO.)
Patient estimation (DEMO.)	
Medicine usage	

Analysis & Reporting

- Match supply and demand
- EMA dashboards and reports
- NCA dashboards and reports
- Public webpage

Shortages Management

- iSPOC registration
- Maintain lists of critical products
- Case management of CAP shortages

Data Integration

PMS integration (CAPs) | RMS integration | PMS integration (NAPs) | Interoperability

Completed | Refactoring | In Progress | Not Started

PMS : Product Management Services
RMS : References Management Services

Recent publications and upcoming events

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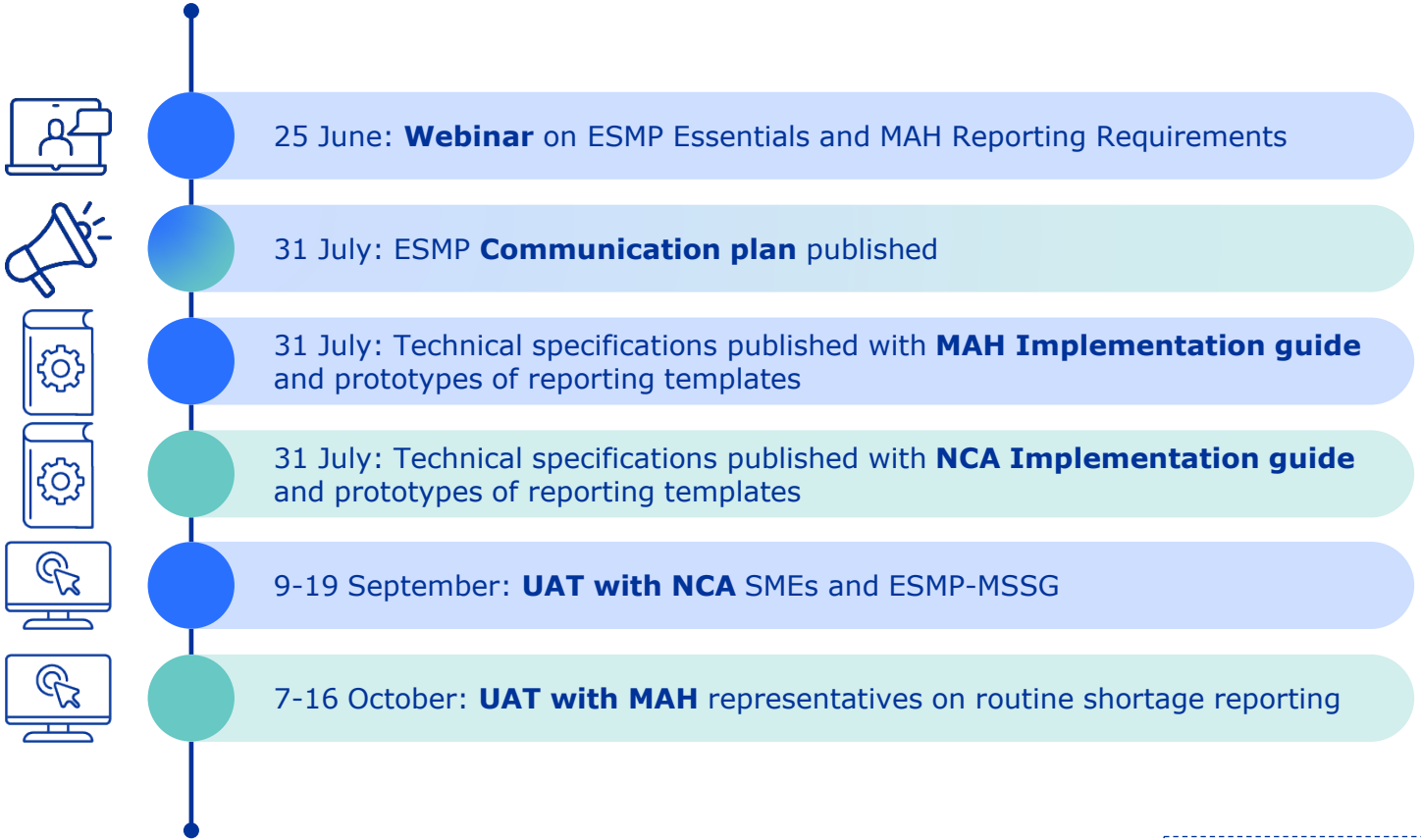

- 25 June: **Webinar** on ESMP Essentials and MAH Reporting Requirements
- 31 July: ESMP **Communication plan** published
- 31 July: Technical specifications published with **MAH Implementation guide** and prototypes of reporting templates
- 31 July: Technical specifications published with **NCA Implementation guide** and prototypes of reporting templates
- 9-19 September: **UAT with NCA** SMEs and ESMP-MSSG
- 7-16 October: **UAT with MAH** representatives on routine shortage reporting

Legend: MAH NCA EMA

ESMP features for NCAs:
national demand, stock and supply, patient estimation

NCA reporting instances to ESMP

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	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 exercise	EC recognition of a PHE/ME
Products in scope:	List of medicines to be monitored for MSSG-led crisis preparedness (CAPs and NAPs)	List of critical medicines for a public health emergency/major event (CAPs and NAPs)
Frequency of reporting:	Defined by the MSSG	Defined by the MSSG
Features in scope of System demo:	- National demand	- Stock and supply - Patient estimation

**Of note: reporting of critical medicines shortages will not be available in the ESMP minimum viable product (MVP) Post-MVP development pending budgeting decisions for 2025.*

PHE: public health emergency ME: major event

ESMP Homepage: dynamic display of submission checklists

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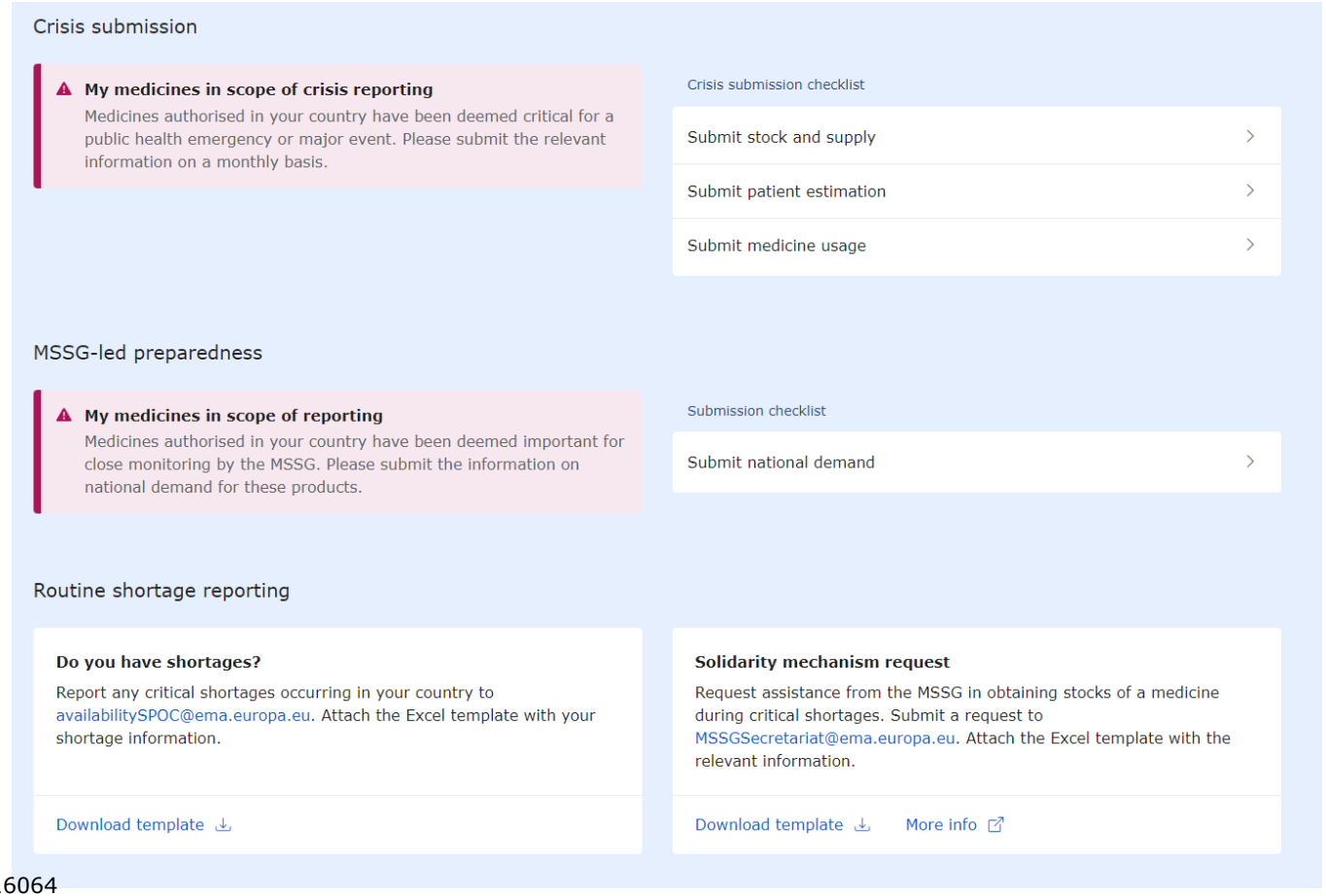

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Features: national demand

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Preparedness (PHE, ME)

MSSG-LED PREPAREDNESS

National demand

The national demand feature applies to **MSSG-led preparedness** reporting situations. For each medicinal product **in scope of close monitoring**, national competent authorities (NCAs) will be requested to report information about the **estimated number of units** of the medicinal product **needed to treat patients for a six months** forecast period.

Data elements: national demand

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● **Preparedness (PHE, ME)**

Product information *pre-populated from PMS*	*PMS ID (Medicinal product)*
	Full product name
	Short product name
	MAH
	Active substance
	Active substance strength
	Pharmaceutical form
	Units of presentation
Demand forecast	Month 1
	Month 2
	Month 3
	Month 4
	Month 5
	Month 6

System Demo: let’s see it working!

Features: stock and supply

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● **Crisis (PHE, ME)**

CRISIS SUBMISSIONS

› **Stock and supply**

Patient estimation

Medicines usage

The stock and supply feature is activated in crisis conditions.

In this eventuality, national competent authorities (NCAs) will be requested to report for each packaged medicinal **product in scope of crisis monitoring** details about **member state available stock**, reflecting stocks available in the supply chain of the MS at various levels (hospitals, pharmacies, and wholesale distributors). NCAs are also required to report information on the current and planned strategic reserve and planned minimum stock.

NCAs will also need to report **non-PHE/ME information** about **past consumption** and **volume of prescriptions**.

Data elements: crisis stock and supply

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● **Crisis (PHE, ME)**

Product information *pre-populated from PMS*	*PMS ID (Packaged medicinal product)*
	Full product name
	Short product name
	Marketing Authorisation Holder (MAH)
	Active substance
	Strength
	Pharmaceutical form
	Package size
	Packaging
MS available stock	Current hospital stock
	Current community pharmacy stock
	Current wholesale distributors stock
	Current strategic reserve
Planned minimum stock	Planned minimum stock

Planned strategic reserve	Month 1
	Month 2
	Month 3
	Month 4
	Month 5
	Month 6
Historical consumption (non-PHE/ME)	Month 1
	Month 2
	Month 3
	Month 4
	Month 5
	Month 6
Historical volume of prescriptions	Month 1
	Month 2
	Month 3
	Month 4
	Month 5
	Month 6

System Demo: let’s see it working!

Features: patient estimation

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Crisis (PHE, ME)

CRISIS SUBMISSIONS

Stock and supply

Patient estimation

Medicines usage

The patient estimation feature apply in crisis situations with the aim to collect details about the **estimated number of patients** to be **vaccinated**, **hospitalised** and **treated in the intensive care unit** (ICU).

Data elements: crisis Patient estimation

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● **Crisis (PHE, ME)**

Vaccination - estimated total number of patients	Month 1
	Month 2
	Month 3
	Month 4
	Month 5
	Month 6
	PHE/ME RMS ID
Hospital - estimated total number of hospitalised patient-days	Month 1
	Month 2
	Month 3
	Month 4
	Month 5
	Month 6
	PHE/ME RMS ID
ICU - estimated total number of ICU patient-days	Month 1
	Month 2
	Month 3
	Month 4
	Month 5
	Month 6
	PHE/ME RMS ID

System Demo: let’s see it working!

ESMP features for NCAs: Monitoring Country Tool (MCT) for monitoring of national supply & demand

Pieter-Jan Desiere, *ESMP Subject Matter Expert*

Monitoring Country Tool (MCT): Design goals

Show all NCA relevant national **supply and demand information** from **MAHs** and **NCAs** in a single platform

Individual MS visualisations to monitor PHE critical medicinal products by automated **aggregation, analysis and visualization**

Risk analysis to determine which medicinal products need focused attention

Comprehensive overviews to assist in **effective decision-making during crises** on a national level

Monitoring Country Tool (MCT): Spotlight features

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Analysis of supply and demand data of each medicine on increasingly granular aggregation levels

- Active substance(s) f.e propofol
- Active substance(s) - Pharmaceutical Dose Form
  f.e. propofol – Emulsion for injection/infusion
- Active substance(s) - Pharmaceutical Dose Form – Strength f.e. propofol – Emulsion for injection/infusion – 10 mg/ml

Automatic analysis of the supply and demand data to provide NCAs with relevant information in the **management of emergency situations**

Details on the medicinal product's **stock and supply** for each MAH

Monitoring Country Tool (MCT): Spotlight features

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Demand forecast: Readiness of the stock

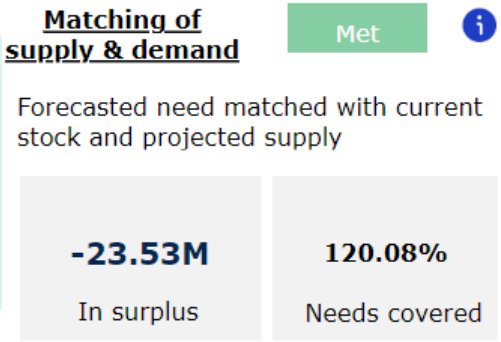
Units still needed (unmet demand) or in surplus (supply surplus) after matching:

- The Member State needs over the forecast period
- The available stock at MAH and Member State level

Supply and demand matching: Reliance on supply

Units still needed (unmet demand) or in surplus (supply surplus) after matching:

- The Member State needs over the forecast period
- The available stock at MAH and Member State level + forecasted supply



System Demo: let’s see it working!

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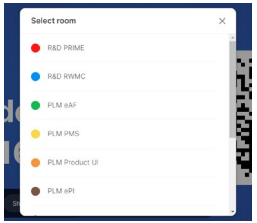

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EMA Account Management - Authentication to EMA systems using email address

Carlo De Vittoria, Product Owner for Identity and Access Management (IAM), EMA

Jhonny Oliveira, Platform Manager for IAM, EMA

18th of September 2024

Context

The EMA is working towards an **access management reshape** based on modern authentication capabilities like ***Bring Your Own Identity*** that can improve **security** and **usability** in line with the principles of the EMA Cloud and Security Strategy**.**

These features can be used only by applications relying on modern authentication protocols. Other **legacy EMA** applications will need to be refactored to consume these features: until that moment *different login mechanisms will live in parallel*.

Aim of this presentation is to give to an overview of upcoming changes and the path that EMA is following to adopt them.

IAM Team PI achievements Q3/2024

EUROPEAN MEDICINES AGENCY

Jul ***Aug*** ***Sep***

PI ACHIEVEMENTS – Q3 2024

- Start the switch to email authentication (federation of identities)
- Improve EMA Account Management features
- Support further EMA Agile Team for integration with IAM platforms
- Implementation of internal improvements
- Demos and change management activities

Q3 DEMO:

- Authentication to EMA systems using email address

AS-IS and TO-BE

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From EMA **username** and **password** …

… to **email** authentication with **federation** or **OTP**

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

Self service *forgot username* and *forgot password* are available to external users to recover their credentials.

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

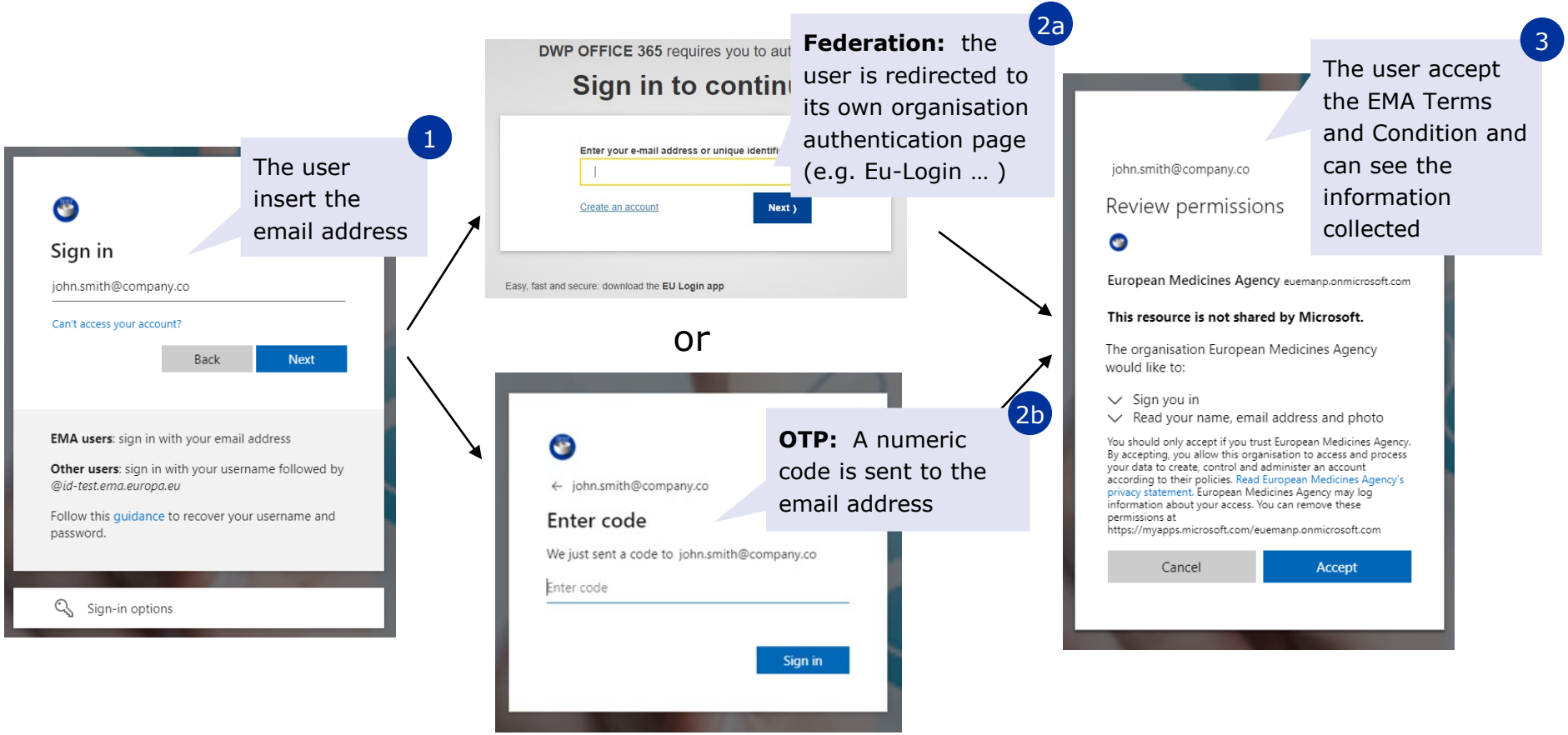
Federation: for users with an Azure AD Account in external tenant or a personal Microsoft account they will use their own password or defined method of authenticaiton.

One Time Passcode: all other users will receive a numerical one time code on the their email

Collaboration tools like Teams and SharePoint Online requires users to **switch accounts** and use incognito windows

Same account is used to switch between different tenants (EMA and home tenant)

How it looks like



Benefits and attention points

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For the Users

Users can no longer access EMA resources as soon as they leave their organisation, **no need to notify the EMA**

Users can login with a familiar experience, **no need** to remember **EMA username** and **password**

Seamless integration for **collaboration tools** like Teams and SharePoint Online

For the EMA

Automated cleansing of disabled accounts without the need of notification from organisations

No need to provide password reset features (and related **Service Desk calls deflection**)

User contact **data validation** at each login

Having the **correct email address** is vital

Access to **Webex** and **Confluence** requires 2 steps

Some **legacy applications** still requires username and password

Road to email authentication

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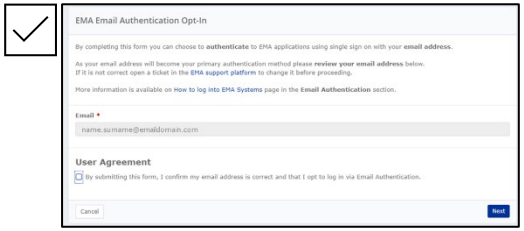
Current situation

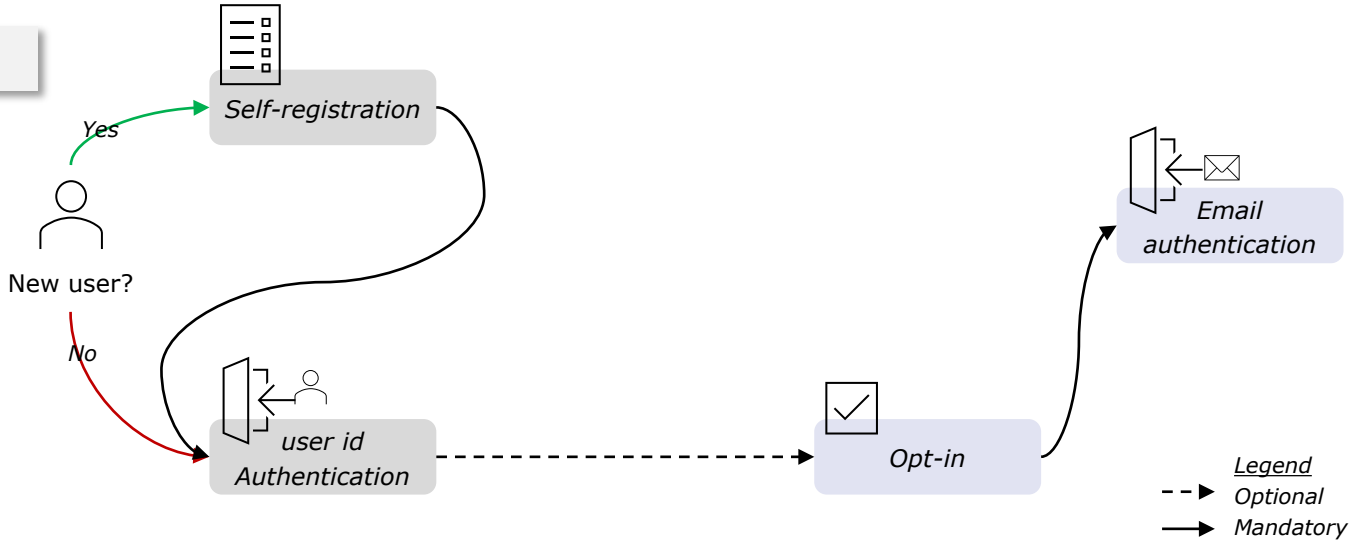


Dec 2023
Opt-In Mechanism

18 Sep 2024
Public System Demo

From December 2023 any user can Opt-In to the new authentication method:

- Around **120 users per month** requested to be converted for a total of over 1000 successfully logging in into more than 60 apps
- **Known issues**:
  - group email cannot be converted
  - Webex authentication requires 2 steps



Road to email authentication

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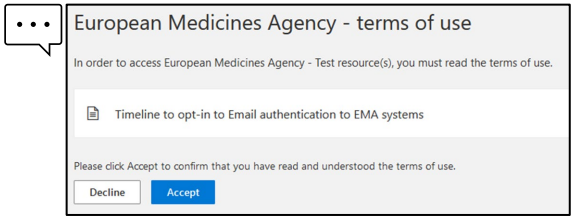
From 30th of September



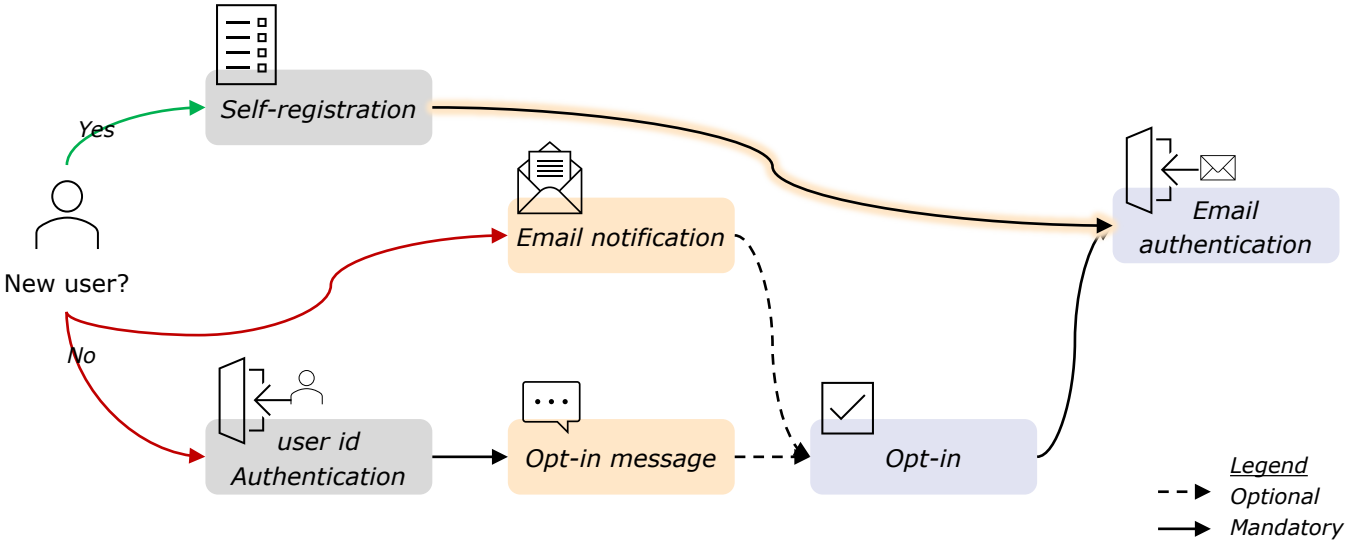
EAM What's new? Webinar

20 Sep 2024

30 Sep 2024

- **User prompt to switch authentication method**
- **Default method for all new registered users**

The **Next Steps** foresees the switch to the new authentication method for all new registered users in September 2024. At that time users not converted yet will be prompted to verify their email address and convert their account



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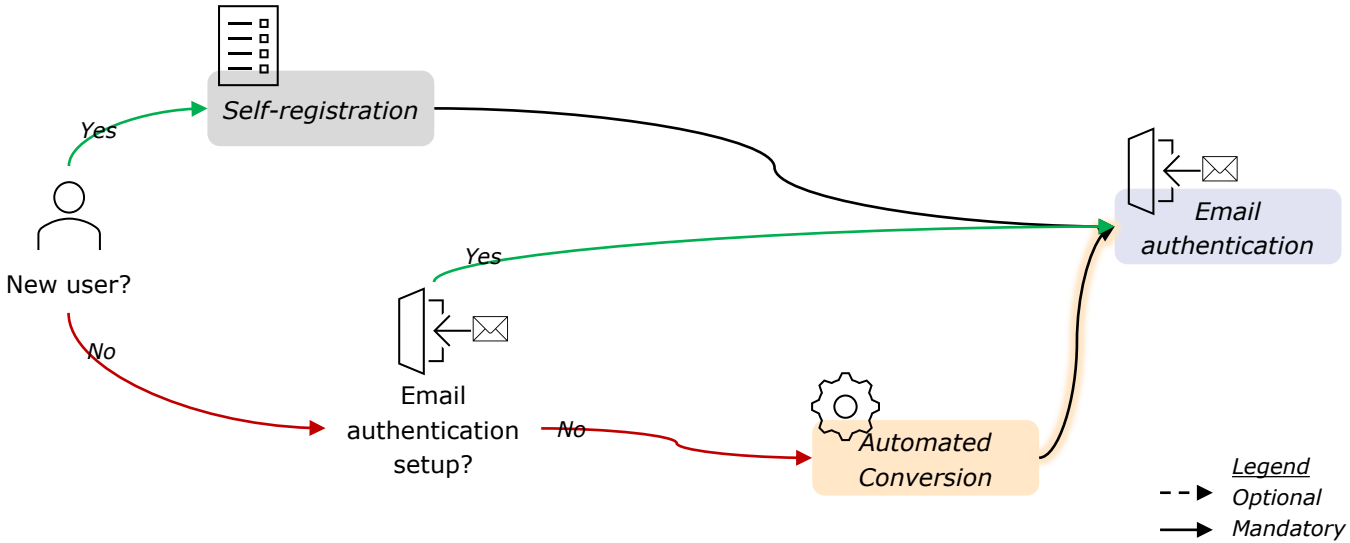
From January 2025

Jan 2025

Switch of all remaining users

In **January 2025** and based on the feedback received we foresee to convert all remaining users



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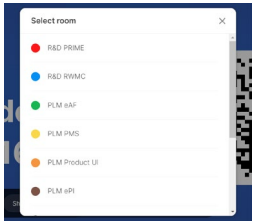

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Managing the Agency VS | New Fee Regulation

***Tarita Toufexi**, Product Owner for Regulatory Procedure Management for R&D, EMA*

***Anna Fiodorova**, Product Owner for Parallel distribution and Inspections for Monitoring, EMA*

NFR PI achievements Q3/2024

EUROPEAN MEDICINES AGENCY

Jul | Aug | Sep

PI ACHIEVEMENTS – Q3 2024

- Implemented priority 2 Parallel Distribution developments that are not dependent on other systems or integrations and were not part of the MVP. Those developments will allow the full functionality in IRIS.
- Implemented systems changes and end-to-end testing for Scientific Advice in order to comply with the New Fee Regulation requirements and to be ready for UATs.
- Performed end-to-end testing of Parallel Distribution, so that the fee creation process is ready for UAT in this quarter.
- Performed partial UAT, with support from CM team, on PD. This will reduce the number of UATs we have to perform in Q4 and will highlight potential issues earlier.
- Led and coordinated updates of relevant regulatory documentation to facilitate adoption of the New Fee Regulation among internal and external stakeholders.
- Prepared and provided trainings, webinars and presentation for internal and external stakeholders for all fee types that are ready for UAT. This will enable the stakeholders to apply the new ways of working both at the UAT sessions and at the go-live.

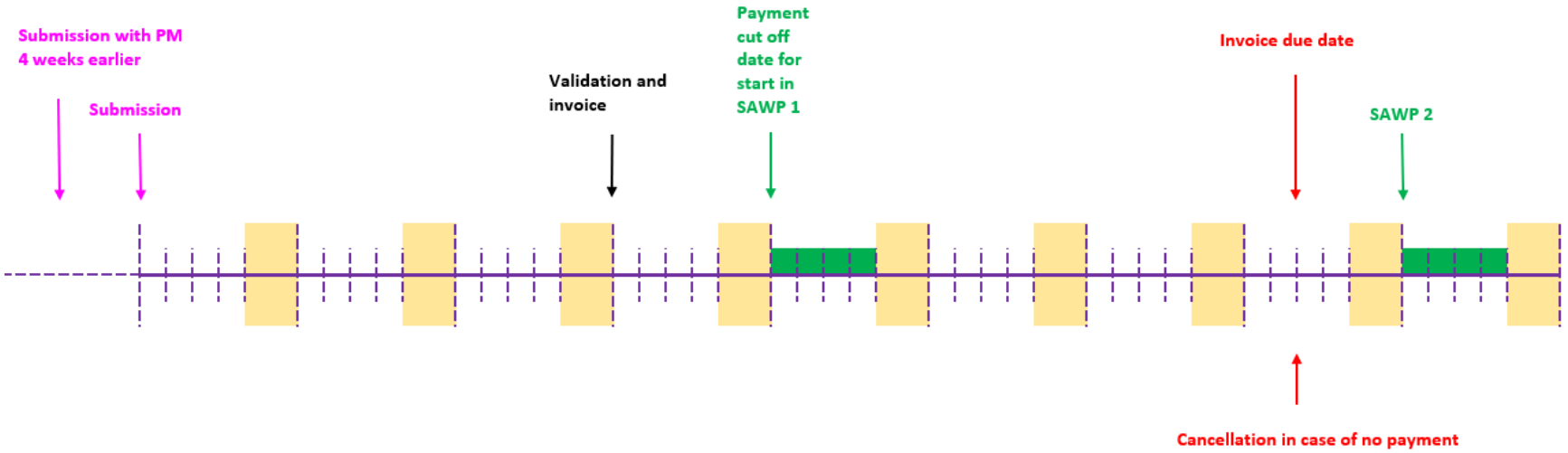
Q3 DEMO:

Prepayment process for

- Parallel Distribution
- Scientific Advice

slido # 9116064

Prepayment changes in Scientific Advice



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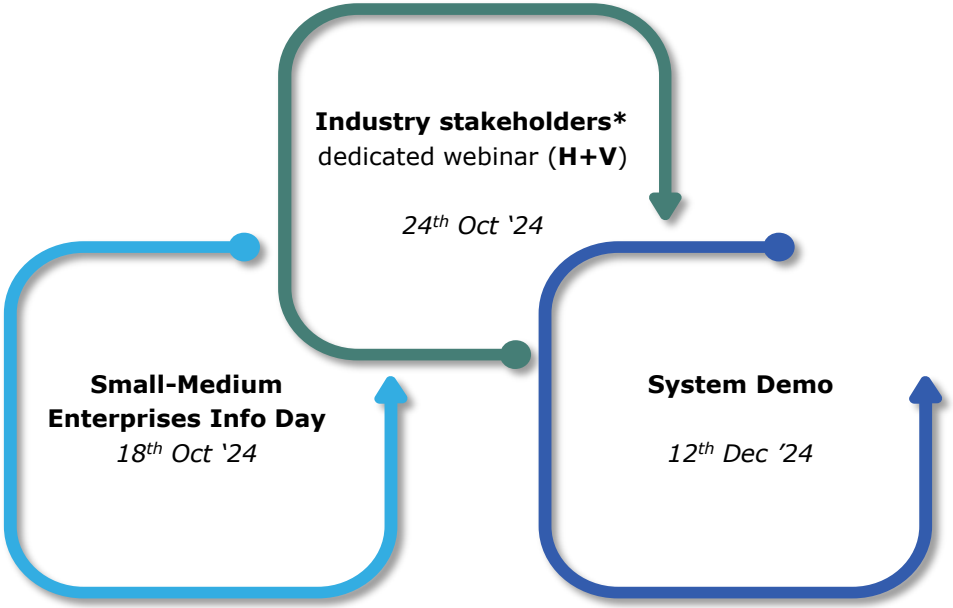
Industry and Network stakeholders' engagement opportunities



*Invitations will be sent out in the next few weeks, registration is already available at the following WebEx link.

Q&A For any questions, please email NFR@ema.europa.eu

Value Streams

Managing the Agency

Capabilities to empower EMA staff and support the Network through modernisation and digitalisation of the Agency's systems, processes and ways of working, increasing efficiency, transparency and collaboration

Owner: Mireia Castillon/Ieva Lobaciute (ad interim)
Manager: Rob Hopping

Research and Development

Capabilities to support the development of new medicines and generation of scientific evidence

Owner: Steven Le Meur
Manager: Erik Gerritsen/Hugo De Jong

Product Lifecycle Management

Capabilities to manage the authorisation and lifecycle of medicinal products and certain medical devices

Owner: Anne-Marie van Nederkassel
Manager: Ramona Zemache/Hannes Kulovits

Monitoring

Capabilities to monitor availability and safety of products

Owner: Pedro Pina Ferreira
Manager: Pedro Oliveira

Technology Lifecycle Management and Information Security

Capabilities to manage information technology and security

Owner: Leonidas Tertipis
Manager: Pedro Rodriguez/Christian Drescher

Product Lifecycle Management Insights - Newsletter

EUROPEAN MEDICINES AGENCY

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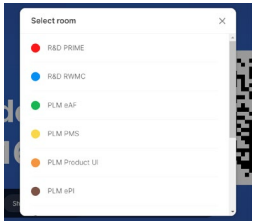

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Step 3 - Choose Q&A or Polls as appropriate

PLM VS | Union Product Database (UPD)

***Beyhan Mustafov**, Product Owner for UPD, EMA*

UPD PI achievements Q3/2024

EUROPEAN MEDICINES AGENCY

Jul | Aug | Sep

PI ACHIEVEMENTS – Q3 2024

- **Create MRP** (*Mutual Recognition Procedure*) **after SPC** (*Summary of Product Characteristics*) **harmonisation***
- **QPPV** (*Qualified Person for Pharmacovigilance*) **email address**
- **MAH** (*Marketing Authorisation Holders*) **read API** (*Application Programming Interface*) to full product data and **read API for the general public** to non-confidential product data*****
- **Export all search results**
- **Search by ATC vet code returns all products**
- **Web UI** (*User Interface*) **users - Upscaled 10x the number of VNRAs** (*Variations Not Requiring Assessment*) (allowed products/codes)*****
- Migration of all non-production environments to a single tenant i.e. **NEW UAT environment from 19 September**

**** due to be released on 3 October 2024***

Q3 DEMO:

DEMO

- **Create MRP after SPC harmonisation**

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Create MRP after SPC harmonisation – important notes

3 October - video tutorial available at Union Product Database

- **In case of ongoing VNRA(s) for these products it is not possible to proceed with the creation process.**
- **It is not possible to proceed with the creation process if two or more products from the same country are added**, either as RMS (Reference Member State) or CMSs (Concerned Member States).
- Extra caution is required when selecting the CMS product(s), because **after the creation** of the 'MRP after SPC harmonisation' **there is no option to remove nor to add other existing products**.
- **The RMS product and each CMS product(s) have the same common data**.
- **The Product identifier of the RMS product will be maintained and assigned to all CMSs' products**.
- **The Permanent identifiers are maintained**.
- **For existing packages**: the same package identifier from the RMS product will be kept even though some updates are done during the creation process.
- **For new packages**: a package identifier is generated and assigned to each package that has been created.
- **A new product version is assigned by the system** to each one of the products sharing the same product identifier.
- **All national data for the RMS/CMS products are maintained.**
- After the creation of the 'MRP after SPC harmonisation' all actions in UPD impacting these products will follow the same rules defined for MRP products, except 'product nullification'.

Provision of QPPV email addresses in UPD – extended deadline

EUROPEAN MEDICINES AGENCY

It has come to our attention that, **for a large number of decentralised (MRP/DCP/SR) products, submissions of QPPV email addresses were unsuccessful due to data quality issues**. An analysis of the affected products has identified the following attributes as the most common causes of blocked submissions:

- Legal status for the supply, both at product and package level.
- Substance (must have status *current*).
- Marketing authorisation number.
- Marketing authorisation date.
- Marketing authorisation status.
- Date of authorisation status change.

Consequently, **the deadline to submit QPPV email addresses in UPD has been extended to 31 October 2024**.

NCAs are kindly requested to prioritise and update any missing mandatory national data, focusing on the above-mentioned attributes to allow MAHs to resubmit the QPPV email addresses before 31 October.

Training sessions, recordings and available guidance materials

EUROPEAN MEDICINES AGENCY

Guides

- UPD Portal Guide to registration for UI and API users
- UPD Implementation Guide – *new Chapter 2 due on 3 October*
- NCA guides on email addresses configuration, updating packages and VNRA highlighting
- API specifications for MAHs - *due on 3 October*
- API specifications for General Public - *due on 3 October*

Release notes

- Periodically published on EMA's UPD webpage

Webinars and Trainings

- EMA's UPD webpage
- Video tutorials (divided by all users, NCAs and MAHs)

Q&A Documents

- UPD Q&As for Industry users
- UPD Q&As for Network users
- UPD Q&As about VoS

NEXT

- ***UPD webinar on API for veterinary industry*** *(17/10/2024 – Event page)*
- ***UPD refresher webinar for NCAs*** *(07/11/2024 – follow the Events page for further announcements)*
- ***UPD webinar on volume of sales submission*** *(05/12/2024 – follow the Events page for further announcements)*

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PLM VS | Product Management Services

***Marcos Fernandez**, Product Owner for PMS, EMA*

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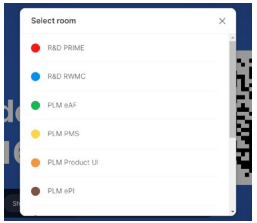

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PMS PI achievements Q3/2024

EUROPEAN MEDICINES AGENCY

Jul | Aug | Sep

PI ACHIEVEMENTS – Q3 2024

- **PMS API Production Go-Live for MAHs**
- Start implementation of capability to ingest MBOs and structured pack size data in PMS
- Analysis of public PMS API and upgrade of FHIR to R5
- **Re-use of IDs when moving packaged medicinal products (NAPs)**
- Analysis of the technical solution for the merge of packages in multilingual countries & CAPs in NO, IS and LI
- **Prepare access to PMS API for NCAs managing both H&V products**

Q3 DEMO:

- Re-use of IDs when moving packaged medicinal products among different medicinal products

slido # 9116064

Next PMS training sessions

EUROPEAN MEDICINES AGENCY

PMS NCA data mapping support service

19 September 2024 (10:00 – 11:30 CEST)

For NCAs only.

→ Provide NCAs support on the mapping exercise between PMS and their national databases.

Info session on PMS API for H&V NCAs

2 October 2024 (10:00 – 11:30 CEST)

For NCAs only.

→ Provide support on API use to NCAs managing both H&V products.

The events will take place on WebEx.
Details are published on EU-NTC platform.

System Demo: let's see it working!

EUROPEAN MEDICINES AGENCY

Re-use of IDs when moving packaged medicinal products among different medicinal products

As explained in Chapters 7 and 9 of the EU IG, specific XEVMPD data elements are used to group different EV codes under the same medicinal product in PMS.
Data quality issues in XEVMPD might lead to the generation of wrong medicinal products. By correcting the issues, the packages will be moved to the correct medicinal product keeping the original ID. This will help mapping exercises.

EV code	Full presentation name	Package description
PRD11168836	Aciclovir 200 mg comprimidos	705667 - 100 comprimidos
PRD11168837	Aciclovir 200 mg comprimido	705668 - 25 comprimidos

→

PMS ID	Full presentation name	Package ID
700000013709	Aciclovir 200 mg comprimidos	7624927
700000013714	Aciclovir 200 mg comprimido	7624928

EV code	Full presentation name	Package description
PRD11168836	Aciclovir 200 mg comprimidos	705667 - 100 comprimidos
PRD11168837	Aciclovir 200 mg comprimidos	705668 - 25 comprimidos

→

PMS ID	Full presentation name	Package ID
700000013709	Aciclovir 200 mg comprimido	7624927
		7624928

700000013714 is nullified in PMS as it has lost all its packaged medicinal products.

PLM VS |Product User Interface (PUI)

***Veronica Lipucci Di Paola**, Product Owner for PUI, EMA*

Product Lifecycle Management Insights - Newsletter

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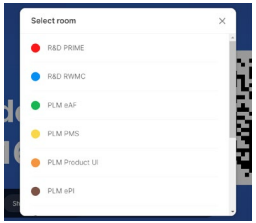

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Product UI PI achievements Q3/2024

EUROPEAN MEDICINES AGENCY

Jul *Aug* *Sep*

PI ACHIEVEMENTS – Q3 2024

- **Released non-CAP data in PMS PUI**
- **Released PUI EDIT pages in UAT environment**
- Extended public report dataset
- Improved performance of PUI EDIT pages

Q3 DEMO:

- 1st step of the enrichment process in PUI
- Non-CAPs data in PUI
- Extended dataset of Public Human Medicines Report

Next PUI training sessions

PMS PUI training webinar

16 October 2024 (10:00 – 11:00 CEST)

For both Industry & Network users.

→ Provide PUI overview and guidance to new PUI users after the completion of non-CAPs data load.

The event will take place on WebEx.
Details are published soon on EMA Website.

System Demo: let’s see it working!

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PLM VS | Electronic Product Information (ePI)

***Elizabeth Scanlan**, Product Owner for ePI, EMA*

***Evinn Drusys**, Network Product Owner for ePI, AEMPS*

ePI project supported by funding from the European Union EU4Health programme.

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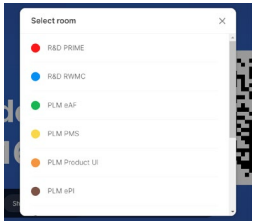

Step 2 – Choose/switch to the room for the right product

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ePI PI achievements Q3/2024

EUROPEAN MEDICINES AGENCY

July ***Aug*** ***Sept***

PI ACHIEVEMENTS – Q3 2024

- Closed ePI pilot
- Completed triage from UAT on portal functionality
- Developed FHIR upload functionality, including extraction, validation and import of FHIR ePI created by external systems
- Created automated regression testing suite

Q3 DEMO:

- Pilot update
- UAT results
- FHIR import: focus on validation

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ePI pilot completed

EUROPEAN MEDICINES AGENCY

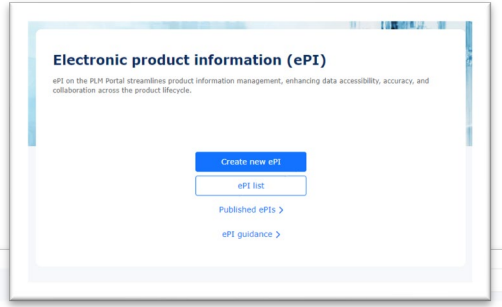
AEMPS: Spanish Medicines and Healthcare Products Agency
DKMA: Danish Medicine Agency
MEB: Medicines Evaluation Board (Netherlands Medicines Agency)
MPA: Swedish Medical Product Agency

23 Total Number of **ePIs published** in the Pilot

5 **CAP ePIs published**

18 **NAP/MRP/DCP ePIs published**

1 **Report in preparation on pilot outcomes**



EPI ID	Name of medicinal product	Procedure no.	Authorisation type	Reference MAH	Published on	Medicines regulatory agency	Country of authorisation
	for nebulisation		NAP	Ingelheim AB	04:09 PM	Products Agency	Sweden
EPI/23/1033	Voltaren Emulgel 1.16 %, Gel		NAP	GlaxoSmithKline Consumer Healthcare B.V.	26/01/2024 10:04 AM	Medicines Evaluation Board	Netherlands
EPI/23/1025	Efavirenz Aurovitas 600 mg comprimidos recubiertos con película EFG	NL/H/2950/001/IB/024	MRP/DCP	Aurovitas Spain S.A.	18/01/2024 03:54 PM	The Spanish Agency Of Medicines And Medical Devices	Spain
EPI/23/1028	ZOLADEX TRIMESTRAL 10,8 mg IMPLANTE EN JERINGA PRECARGADA	NA	NAP	Astrazeneca Farmaceutica Spain S.A.	22/12/2023 02:23 PM	The Spanish Agency Of Medicines And Medical Devices	Spain
EPI/23/1009	Brukinsa	EMEA/H/C/004978/II/0014	CAP	BeiGene Ireland Limited	24/11/2023 03:29 PM	European Medicines Agency	European Union
EPI/23/1016	Fluticasonpropionaat Teva 50 microgram, neusspray 50 microgram/dosis	RVG 33656	NAP	Teva Nederland B.V.	24/11/2023 09:53 AM	Medicines Evaluation Board	Netherlands
EPI/23/1022	Imatinib Teva	EMEA/H/C/002585/N/0053	CAP	Teva B.V.	07/11/2023 10:15 AM	European Medicines Agency	European Union
							Swedish

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ePI UAT triage complete

EUROPEAN MEDICINES AGENCY

PLM portal — ePI User Acceptance Testing: Thank you to our motivated and conscientious testers!

Scope

- ePI registration process in IAM and ePI registration guide
- ePI creation, management, approval, publication and ePI user guides

Timelines

10 – 21 June 2024
Testing

Completed
Triage

No. Testers

100 Testers	**50** Regulator testers	***21 NCAs:*** Austria, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Iceland, Ireland, Italy, Latvia, Netherlands, Norway, Poland, Slovakia, Slovenia, Spain, Sweden
	50 Industry testers	***6 Trade Organisations:*** Medicines for Europe, Vaccines Europe, AESGP, EFPIA, EUCOPE, EuropaBio

Findings

Outcomes

- 185 items in ADO, 230 other feedback items
- Triage: remove duplicates, update existing USs, 10 new bugs, 22 new USs

Completed/In progress

• Access issue from some users	Bug fixed
• Time taken by publishing action	Performance testing in progress
• Enhancements to optimize UI	Wireframes in preparation

System Demo: let’s see it working!

Q2 DEMO:

- Import FHIR: validation

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PLM VS | Regulatory Procedure Management (IRIS)

***Madalina Duta-Mare**, product owner for RPM (PLM), EMA*

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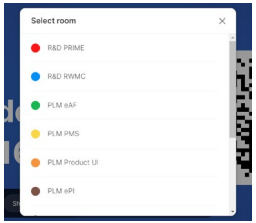

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RPM PI achievements Q3/2024

EUROPEAN MEDICINES AGENCY

Jul | Aug | Sep

PI ACHIEVEMENTS – Q3 2024

- Implement NFR requirements for variations and transfers of marketing authorisations (target architecture (SAP BTP))
- Implement post-authorisation measures
- Final customisations for new processes (Renewals, PSUR, PASS, Referral, Annual reassessment, Extension of MA)
- Adjust portals and Committees secretariat functionalities
- Deliver final customisations for PSUR
- Conduct UAT-related preparations, process and prioritise findings
- Demos and change management activities

Q3 DEMO:

- Overview of post-authorisation procedures in IRIS

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Reminder: Action required for Industry by the end of 2024

EUROPEAN MEDICINES AGENCY

1 *MAHs to be registered in OMS*

2 *MAHs products contact person for post-authorisation procedures to request EMA IRIS account **(CAP and NAP MAHs)***

How to request access? Via the EMA Account Management System for all affiliated roles.

Instructions are available in the IRIS guide to registration and RPIs. *It is crucial that all new submissions in IRIS created from CRM for PLM procedures reaches the correct portal contacts, under **individual** company email addresses. **Generic mailboxes are not supported for contact points.***

3 *Update product contact information*

MAHs for **CAPs** to submit an **updated form** to **change all product contacts to individual emails**. → Instructions to submit the form **here**

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PLM VS | Electronic Application Form (eAF)

Kristiina Puusaari, *Product Owner for eAF, EMA*

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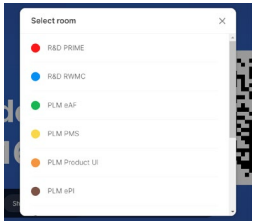
- Specific suggestions and feedback about your priorities

Step 1 - Go to slido.com



Step 2 – Choose/switch to the room for the right product

Step 3 - Choose Q&A or Polls as appropriate

eAF PI achievements Q3/2024

EUROPEAN MEDICINES AGENCY

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PI ACHIEVEMENTS – Q3 2024

- Continue implementing various performance improvements so that the use of the variation eAF can be expanded to NAP procedures e.g:
  - Performance improved production selection
- Progress on remaining non-CAP features to enable the use of the eAF for non-CAP procedures
  - e.g. pending products
- Implement fixes to most important issues relating to CAP features to allow further reinforce strongly recommended use for CAP variations
  - Product filters implemented
  - Add package improvements

Q3 DEMO:

- Updated product search (performance optimised search grid)
- Maintenance pop-up messages (saving products)
- Hotfix to filter out CAPs (Norway/Iceland/Liechtenstein products)
- Application form ID (e.g. VAR/24/1234) added in pdf export

System Demo: let’s see it working!

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- Product Management Service (PMS) data
- Union Product Database (UPD)
- electronic Applications Forms (eAF)
- Electronic Product Information (ePI)
- Regulatory Procedure Management (RPM) for IRIS
- Substance, Product, Organisation, Referentials (SPOR) services

Closing

***Jean-Michel Becar**, Head of Portfolio Management Office, EMA*

Next System Demo:
12 December 2024