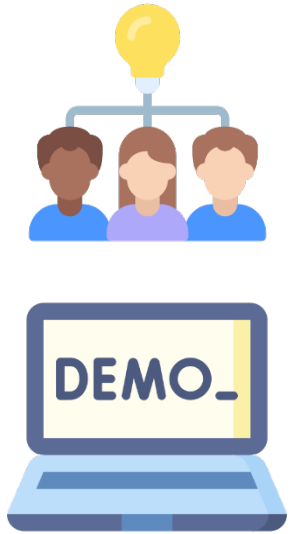
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

System Demo Q4-2024

12/12/2024

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

EUROPEAN MEDICINES AGENCY

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:
26 March 2025

Agenda

EUROPEAN MEDICINES AGENCY

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

Managing the Agency Value Stream

2 **New Fee Regulation (NFR)**
09:05 – 09:25

Product Lifecycle Management Value Stream

3 **Product Management Service (PMS)**
09:25 – 09:45

4 **Product User Interface (UI)**
09:45 – 10:15

5 **Electronic Product Information (ePI)**
10:15 – 10:45

10 min break

6 **Regulatory Procedure Management (RPM)**
10:55 – 11:25

7 **Electronic Application Form (eAF)**
11:25 – 11:40

8 **Union Product Database (UPD)**
11:40 – 11:55

9 **Closing remarks**
11:55

How to give feedback & ask questions

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2. check progress in achieving the goals of the system
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- Remains open until 19th December
- Please identify yourself
- Specific suggestions and feedback about your priorities

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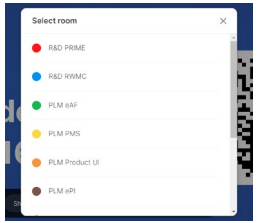

Step 2 – Choose/switch to the room for the right product

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
Manager: Hugo de Jong / Erik Gerritsen

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

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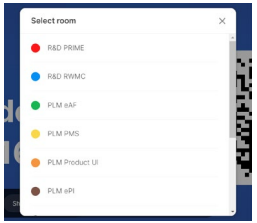

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Managing the Agency VS | New Fee Regulation (NFR)

Patrick Lopez Fernandez, *Product Team Support for NFR*

Miroslava Hladíková, *Data Scientist for Certificates Processing System*

NFR PI achievements Q4/2024

EUROPEAN MEDICINES AGENCY

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

PI ACHIEVEMENTS – Q4 2024

- Implemented the remaining system changes to Certificates and Parallel Distribution, in order to be in compliance with the New Fee Regulation requirements and to be ready for UATs
- Performed SATs and UATs for procedures to make sure that these fees are ready to deploy for the go-live.
- Designed and began implementing a Transition plan with all dev teams to make sure the fees transition from current to the new regulation according to the EC guidelines.
- Finalised and published the new NFR webpage, including fee Q&As and relevant regulatory documentation, to enable internal and external stakeholders to apply the New Fee Regulation effectively as of 1st January 2025.
- Conducted webinars, demos and disseminated informative materials, to ensure the readiness of internal and external stakeholders to adopt the new legislation, processes, and ways of working by 1st January 2025.

Q4 DEMO:

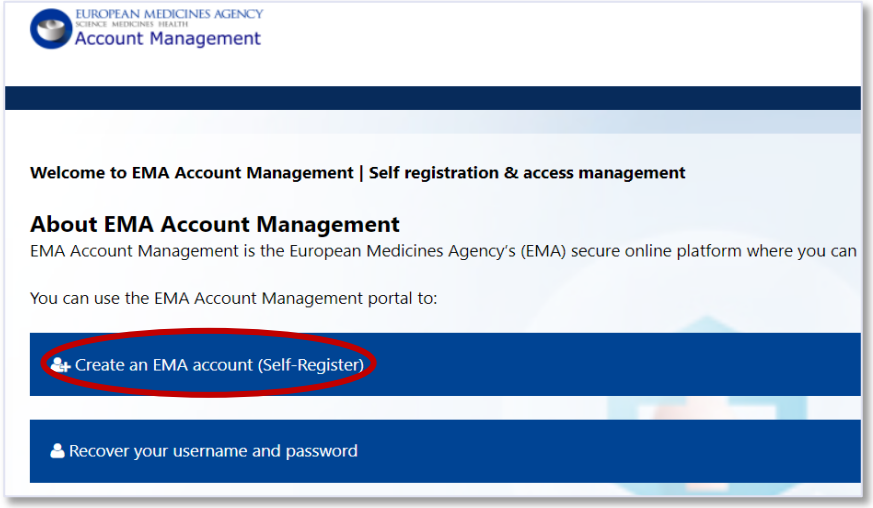
Certificates Processing System (CPS)

Register now on EMA Account Management to request certificates

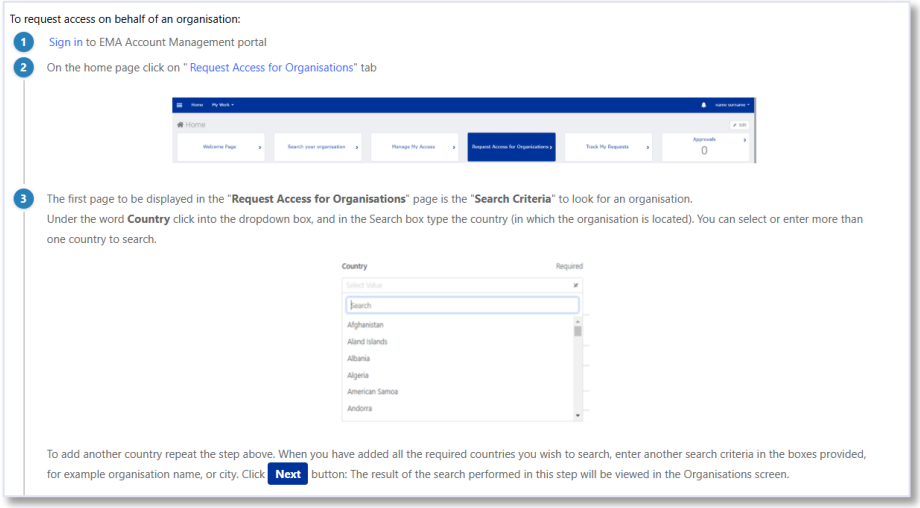
EUROPEAN MEDICINES AGENCY

MAHs/requesting companies must have a **valid EMA account** in order to **request *certificates*** from 1st January 2025, as the request will be sent via a **webform** as opposed to the currently used pdf form sent via email.

STEP 1 **To register**, please follow instructions here



STEP 2 **To request access for an organisation**, and to **request roles** please follow instructions here



Further details on the new webform have been provided by **email, and a notice** has been published on the Certification of medicinal products webpage. **A video tutorial** will be published on the same page in the next few weeks.

System Demo: let’s see it working!

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Certificates Processing System (CPS)

Updates to available regulatory guidance

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Documents are now available on EMA's website

Currently available documentation:

- Current Fee regulations
- Explanatory note
- Implementing rules

Documentation applicable starting from 1st January 2025:

- Regulation (EU) 2024/568
- Working arrangements
- Fee Q&As

Ad-hoc information for implementation and transition

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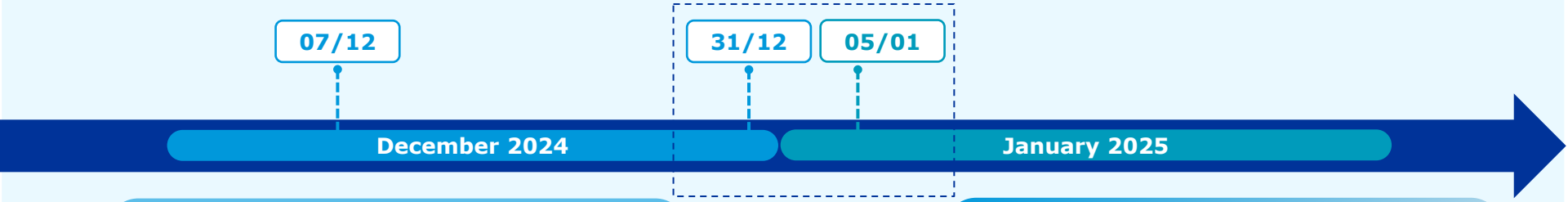
General transitional provisions:

- *Information about transitional provisions* between Council Regulation (EC) No 297/95 (current Fee Regulation) and Regulation (EU) 2024/568 (new Fee Regulation) for each procedure are included in Fee Q&As on EMA's website



Variations (Human & Vet):

- MAH are advised to **not submit** human and veterinary variations after **7/12/2024** and to **postpone submissions to after 1/1/2025**

Parallel Distribution and Certificates:

- Planned **system downtime** for the submission of *Parallel Distribution* procedures and *Certificates* between **31/12/2024 and 5/1/2025**

Please note, the Agency will be closed from 20 December to 5 January.

Industry and Network stakeholders' engagement opportunities

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

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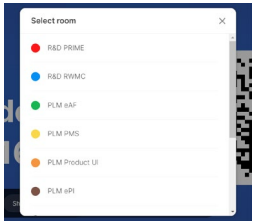

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PLM VS | Product Management Services

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

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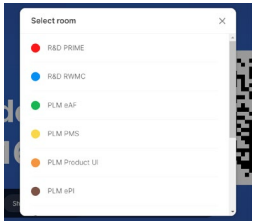

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Product Lifecycle Management Insights - Newsletter

EUROPEAN MEDICINES AGENCY

Want to keep up to date on EMA's development of PLM VS products?
Scan the QR code and subscribe to the quarterly PLM Newsletter, titled:

Product Lifecycle Management Insights
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Target Audience:
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slido # 9116064

PMS PI achievements Q3/2024

EUROPEAN MEDICINES AGENCY

Oct | Nov | Dec

PI ACHIEVEMENTS – Q4 2024

- **PMS API Production Go-Live for Human NCAs**
- Start implementation of new transfer process for NAPs
- **Change the business logic for grouping products from Luxemburg**
- Start the analysis of the public PMS API and upgrade FHIR to R5
- **Implementation of end-to-end process to consume data from Product UI**
- Support the implementation of the bulk update process in Product UI
- **Create the initial documentation for the write PMS API**
- Bug fixes during Q4
- EU IG Chapter 1, 2, 3, 5, 9 updates (release planned for 18/Dec)

Q4 DEMO:

- New business logic for grouping products from Luxemburg

slido # 9116064

Next PMS training sessions

Training session on PMS API read-only for NCAs

15 January 2025 (14:00 – 15:30 CET)

For NCAs only – register on EU-NTC

→ Provide NCAs support on using the PMS API in read-only mode.

New business logic for grouping products from Luxemburg

During the initial migration from XEVMPD to PMS, for LU products, the MA number was one of the grouping elements as explained in Chapter 7.
We were notified that different packages of the same medicinal product could have different MA numbers and that is why now, the new grouping element for LU products is the procedure number and not the MA number.

If your products for LU were incorrectly migrated to PMS due to this issue, please, send a dummy update to XEVMPD on the impacted EV Codes and the deltas will fix these products.

A dummy update could be the addition of a dot in the comment section of XEVMPD.

System Demo: let's see it working!

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EV code	Full presentation name	Package description	MA number	Procedure number	PMS ID
PRD1111	Talidat® chewable pastilles for heartburn, 500 mg	10 CHEWABLE TABLETS	11111	AT/H/1234/001	600001111
PRD2222	Talidat® chewable pastilles for heartburn, 500 mg	5 CHEWABLE TABLETS	22222	AT/H/1234/001	600002222
PRD3333	Talidat® chewable pastilles for heartburn, 500 mg	2 CHEWABLE TABLETS	3333	AT/H/1234/001	600003333

Submit a dummy update for PRD1111, PRD2222 and PRD3333 in XEVMPD.

EV code	Full presentation name	Package description	MA number	Procedure number	PMS ID
PRD1111	Talidat® chewable pastilles for heartburn, 500 mg	10 CHEWABLE TABLETS	11111	AT/H/1234/001	600001111
PRD2222	Talidat® chewable pastilles for heartburn, 500 mg	5 CHEWABLE TABLETS	22222	AT/H/1234/001	
PRD3333	Talidat® chewable pastilles for heartburn, 500 mg	2 CHEWABLE TABLETS	3333	AT/H/1234/001	

600002222 & 600003333 are nullified. PRDs from these products are moved to 600001111

If your products for LU were incorrectly migrated to PMS due to this issue, please, send a dummy update to XEVMPD on the impacted EV Codes and the deltas will fix these products.

A dummy update could be the addition of a dot in the comment section of XEVMPD.

PLM VS |Product User Interface (PUI)

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

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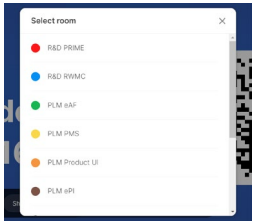

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Product UI PI achievements Q4/2024

EUROPEAN MEDICINES AGENCY

Oct Nov Dec

PI ACHIEVEMENTS – Q4 2024

- **Launch of internal and external beta PUI EDIT pages in UAT environment**
- Refinement and bug fixes of view pages ie. Orphan Drug Designation and Product composition pages
- Refinement and bug fixes of Dynamic and Public reports
- Implementation of EMA PUI Read-only role
- Improved performance of PUI EDIT pages
- PUI Navigation Guide for enrichment process (draft)

Q4 DEMO:

- End-to-end Minimum Viable Product Enrichment process in PUI
- My Workspace area (overview of change requests)

Next PUI training sessions

PMS PUI edit training webinar

28 January 2025 (10:00 – 12:00 CET)

For Industry users.

→ Provide PUI overview and guidance on how to use new PUI edit functionalities.

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

System Demo: let’s see it working!

PLM VS | Electronic Product Information (ePI)

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

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

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

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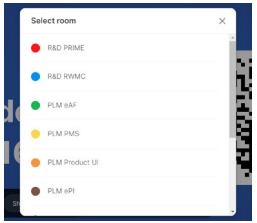

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ePI PI achievements Q4/2024

EUROPEAN MEDICINES AGENCY

October ***November*** ***December***

PI ACHIEVEMENTS – Q4 2024

- ePI **pilot report** to be published next week
- ePI **versioning advances**: ePI creation based on any status, publish will always unpublish previous published version, unpublish will allow option to republish previous
- **FHIR import testing** started with externally created ePIs
- **PMS linking developed:** ePI linked to PMS ID and PMS data carrier
- **Automated testing** suite expanded with export scenarios

Q4 DEMO:

- Pilot update
- ePI versioning
- PMS linking

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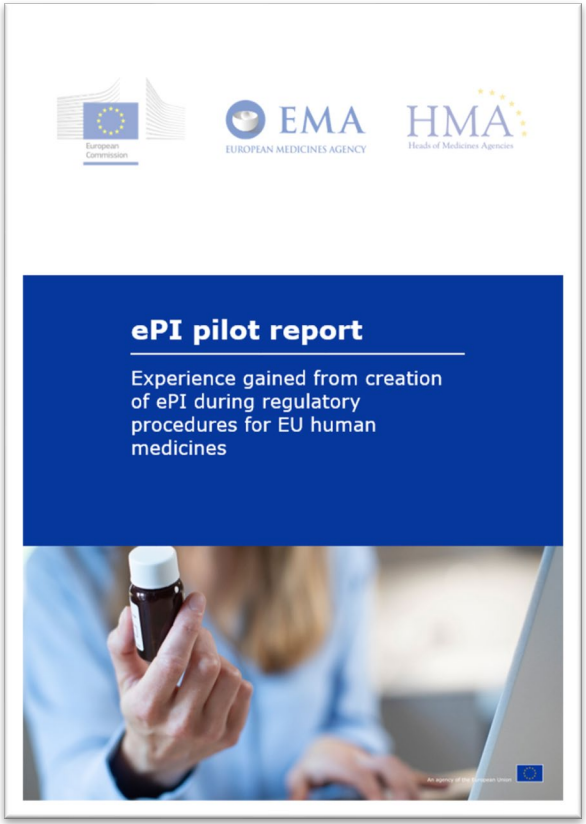

ePI report published next week

- KPI targets
- Recommendations for:
  - Guidance
  - Business processes
  - PLM portal
- Next steps

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System Demo: let’s see it working!

Q4 DEMO:

- ePI versioning
- PMS linking

PLM VS | Regulatory Procedure Management (IRIS)

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

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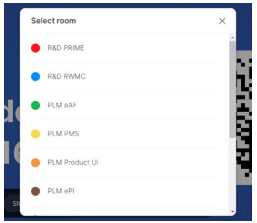

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RPM PI achievements Q3/2024

EUROPEAN MEDICINES AGENCY

October ***November*** ***December***

PI ACHIEVEMENTS – Q4 2024

- Implement prioritised User Acceptance Testing findings
- Address New Fee Regulation User Acceptance Testing findings
- Adapt integrations with other systems (esubmissions)
- Prepare for go live (1 Jan 2025): templates configuration, access roles
- Trainings, Change management activities & hypercare business support plan
- Non functional work (deployments, bug fixing)

Q4 DEMO:

- Overview of post-authorisation procedures in IRIS

slido # 9116064

Before 2025: Key actions for Industry users to prepare for the transition

EUROPEAN MEDICINES AGENCY

1 *ALL Marketing Authorisation Holders (MAHs) need to be registered in OMS*. Check section 4 of **IRIS guide to registration and RPIs** for more information.

2 ***Contact persons*** *for all registered MAHs in OMS have* ***EMA account*** *and the appropriate* ***IRIS Industry role****.*

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

Instructions are available in the **IRIS guide to registration and RPIs**.

3 ***CAP MAHs update product contact information****:*

Scenario 1

The product contact person remains unchanged, but linked to a generic mailbox - Update products currently list generic mailboxes with personal email addresses associated with responsible contact person.

How do you change the product contact email? Raise a ticket:

- In sub-section 'Service', select 'Identity and access management'
- In sub-section 'Service offering', select 'Eudra Common Directory – ECD'

Scenario 2

The product contact person changes - Submit the updated form using this template

How to submit the form?

- Human-use products: Contacting EMA: post-authorisation | European Medicines Agency (europa.eu)
- Veterinary-use products: Notifying EMA of changes to contact persons (veterinary medicines) | European Medicines Agency (europa.eu)

System Demo: let’s see it working!

PLM VS | Electronic Application Form (eAF)

Kristiina Puusaari, *Product Owner for eAF, EMA*

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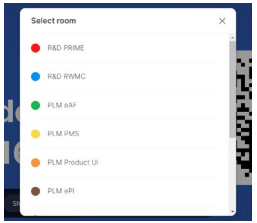


Step 2 – Choose/switch to the room for the right product

Step 3 - Choose Q&A or Polls as appropriate

Product Lifecycle Management Insights - Newsletter

EUROPEAN MEDICINES AGENCY

Want to keep up to date on EMA's development of PLM VS products?
Scan the QR code and subscribe to the quarterly PLM Newsletter, titled:

Product Lifecycle Management Insights
Developments in EMA digital capabilities to manage the authorisation and lifecycle of medicines

Target Audience:
→ Pharmaceutical companies for Human and Veterinary products

Scope:
→ News on the latest digital capabilities and upcoming events for:

- 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

eAF PI achievements Q4/2024

EUROPEAN MEDICINES AGENCY

Jul | Aug | Sep

PI ACHIEVEMENTS – Q4 2024

- **Released non-CAP data in eAF**
  - Training and Q&A sessions for non-CAP users held
  - All non-CAP MAHs/applicants invited to familiarise with the production system and provide consolidated feedback to EMA (via email)
- **Implementation of updates to reflect the amended variation regulation**
- **Implementation of most important non-CAP features to enable the use of the eAF for non-CAP procedures**
  - **Contact person MS multiselect**
  - Proof of Payment (will be delivered in January 2025)
- **Implementation of redesign for Present and Proposed section (partially delivered)**

Q4 DEMO:

- Non-CAPs in the eAF
- Variation regulation changes (super-grouping, mandatory WS)
- Contact person MS multiselection
- Present and Proposed

System Demo: let’s see it working!

PLM VS | Union Product Database (UPD)

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

What is this system demo for?

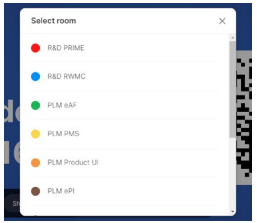
1. show system features developed over the past 3 months
2. check progress in achieving the goals of the system
3. obtain feedback from stakeholders to build the right solution

How can you interact with this system demo?

Option 1 – Slido Q&A
- Questions and answers are public
- You can upvote questions
- Top questions answered verbally, time allowing
- Questions & available answers published on event page

Option 2 – Slido short feedback poll
- **Not public**
- Remains open until 19th December
- Please identify yourself
- Specific suggestions and feedback about your priorities

Step 1 - Go to slido.com



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UPD PI achievements Q4/2024

EUROPEAN MEDICINES AGENCY

October | November | December

PI ACHIEVEMENTS – Q4 2024

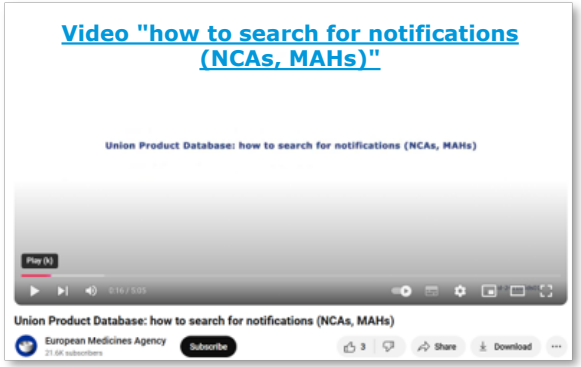
- The **replacement of non-current substances with SMS-proposed current substances is now an automatic process**, eliminating the need for individual replacements by NCAs.
- **MAHs are able to see all products under their portfolio based on location-id even when a technical merge of a location has occurred in OMS** due to the identification of duplicate addresses.
- **UPD UI menus have been updated** for alignment and compliance.
- **QPPV email** is now **mandatory** to be provided **during product creation and optional for update operations**.
- **MAH ability to provide the QPPV email** via UI has been **discontinued**.
- To prevent accidental nullification, **the 'nullify' button is disabled for MRP products created after SPC harmonisation procedure**.

POSTPONED TO 2025:

- **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

slido # 9116064

Additional achievements



[Video "how to search for notifications (NCAs, MAHs)"]

[Chapter 2 EU IG]

- Refresher webinar for national competent authorities some basic functionalities e.g. create product
- Refresher webinar for marketing authorisation holders on volume of sales submission
- Bite-sized video on searching for notifications
- Chapter 2 EU Implementation Guide revision
- Dissemination of actions based on Adoption Survey results

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Reminder of the Volume of Sales (VoS) submission process and deadline

Download
VoS file

Prepare
VoS file for submission

Validate
VoS file in validation environment

Submit
VoS file

Check
status of VoS submission

View
VoS recorded in UPD

Yearly deadlines for VoS data submission is the last day of February (for each preceding year)

Due date for the year 2024 is 28 February 2025

slido # 9116064

Volume of Sales (VoS) submission key messages

- VoS submission deadline is the **last day of February** for each preceding year
- **Plan your submission(s)** throughout the year
- **Errors or doubts?** Consult Chapter 7 of the Vet EU Implementation Guide
- **Data quality issues?** Contact the relevant competent authority

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Training sessions, recordings and available guidance materials

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Guides

- UPD registration guide *for UI and API users*
- UPD Implementation Guide – *new Chapter 2 published on 3 December*
- Guidance for NCAs *on email addresses configuration, updating packages and VNRA highlighting*
- Guidance for MAHs *on the calculation of dose factor, how to configure email addresses for UPD notifications*

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

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Closing

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

Next System Demo
26 March 2025