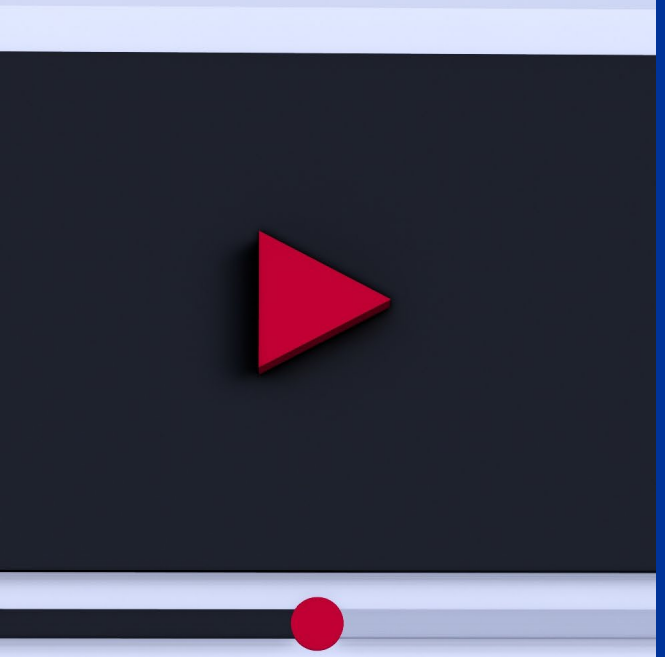
EMA
EUROPEAN MEDICINES AGENCY

System Demo 25Q2

Public System Demo

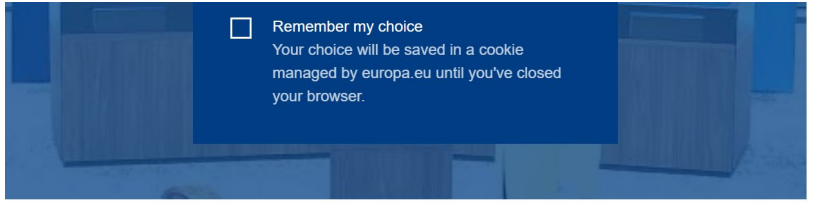
26 June 2025



Welcome & Introduction

Jean-Michel Becar, Head of EMA Portfolio Management Office

Housekeeping



To view the broadcast please ensure you meet the YouTube requirements .

To view the video in the highest quality, click on the 'Settings' symbol in the right-hand corner of the video player and select '720p' or a higher resolution.

To watch the video in full screen mode, click on the link 'Watch on Youtube' in the bottom left-hand corner of the video to watch it on YouTube.com.

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

Participants may be able to ask questions or share feedback via Slido, with the option of remaining anonymous*.

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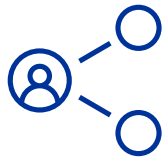
System demo at EMA



Agile teams showcase the features they have been working on in the last 3 months

Creates an opportunity to gain a **shared understanding** of the current **state of the products and solutions** on a regular cadence.

It provides an objective measure of **progress** towards the goal of the PI.

Creates a safe space for early identifications of defects or design flaws and for the generation of new ideas to improve over time.

Enables the attendees to provide **instant feedback** allowing the Agile teams to make **necessary adjustments** to the solutions they are building

Is recorded and published on the EMA **Corporate web site**

The next public system demo is

17 September 2025

Agenda

09:00	**Welcome / Introductions**
09:05-10:40	Product Lifecycle Management Value Stream (PLM VS)
09:05-09:30	Product Management Service (PMS)
09:30-09:55	Product user interface (PUI)
09:55-10:25	Electronic application form (eAF)
10:25-10:40	Electronic product information (ePI)
10:40	**Closing**

Give feedback & ask questions

Option 1 - Q&A

Questions and answers are public
You may unvote the questions
Top questions are answered verbally
Questions & available answers published on event page

Option 2 - Poll

Feedback shared only with product team
Stays open for comments till 3 July
Please identify yourself
Give the product team feedback and suggestions about your priorities

Join at
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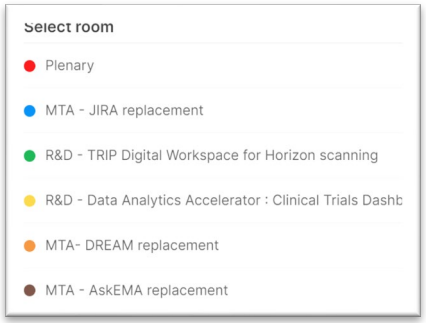

Step 2 – Choose/switch to the room for the right product

Step 3 - Choose Q&A or Polls as appropriate

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EMA 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

Research and Development

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

Product Lifecycle Management

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

Monitoring

Capabilities to monitor availability and safety of products

Technology Lifecycle Management and Information Security

Capabilities to manage information technology and security

EMA

PLM VS | Product Management Service (PMS)

Marcos Fernandez Gomez, PMS Product Owner

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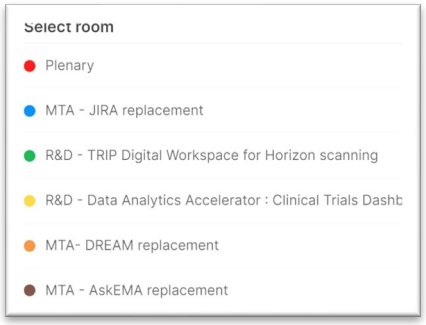

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PMS – Product Management Service

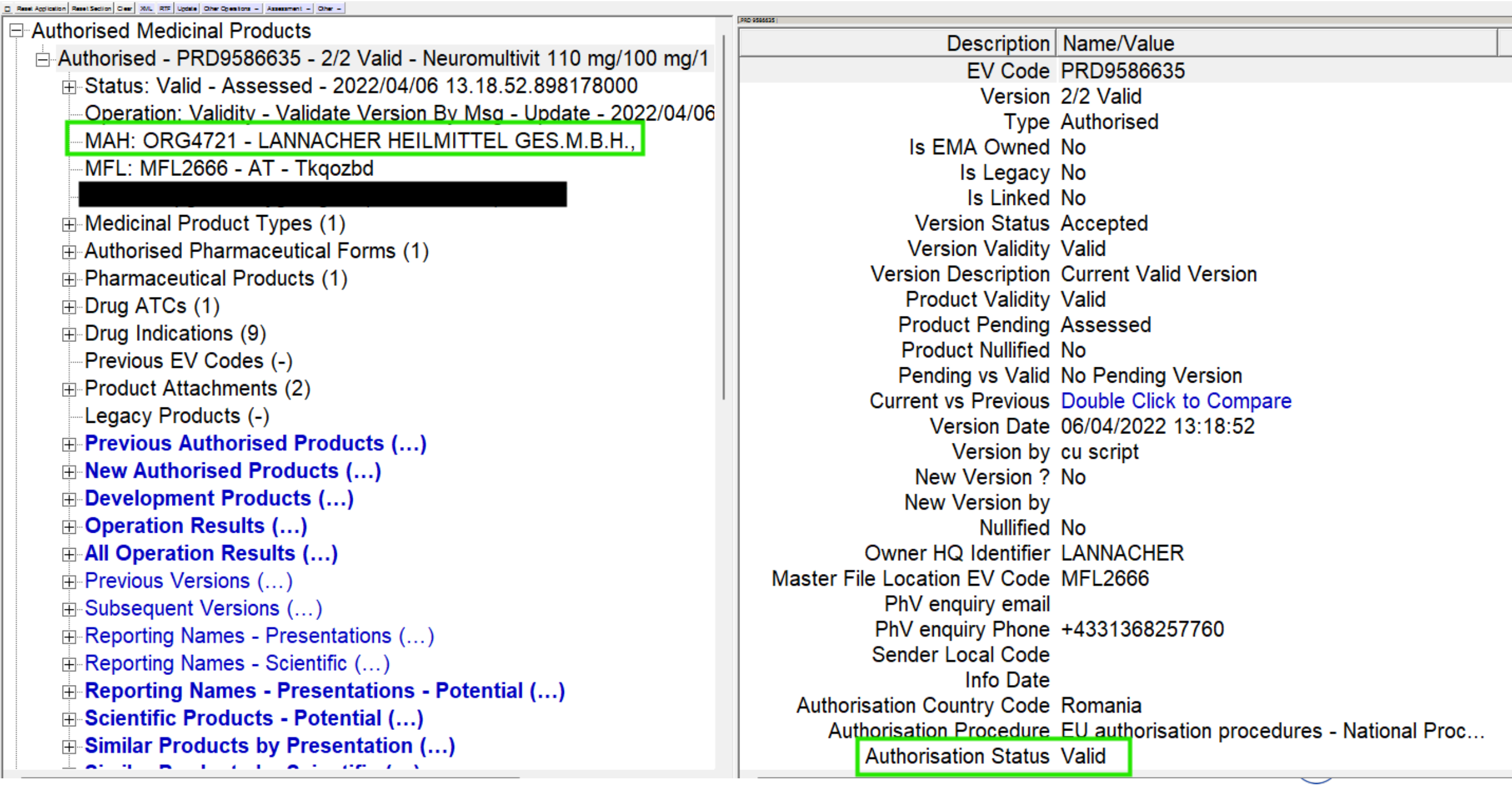
Committed objectives 25Q2	Demo
▪ **Design** the **public PMS API** so users can access public product data increasing the availability of medicinal product data for any interested party	–
▪ **Release** the new transfer process for non-CAPs so users can have access to accurate product data increasing the **accuracy of product data** that is going to be consumed by other systems	**YES**

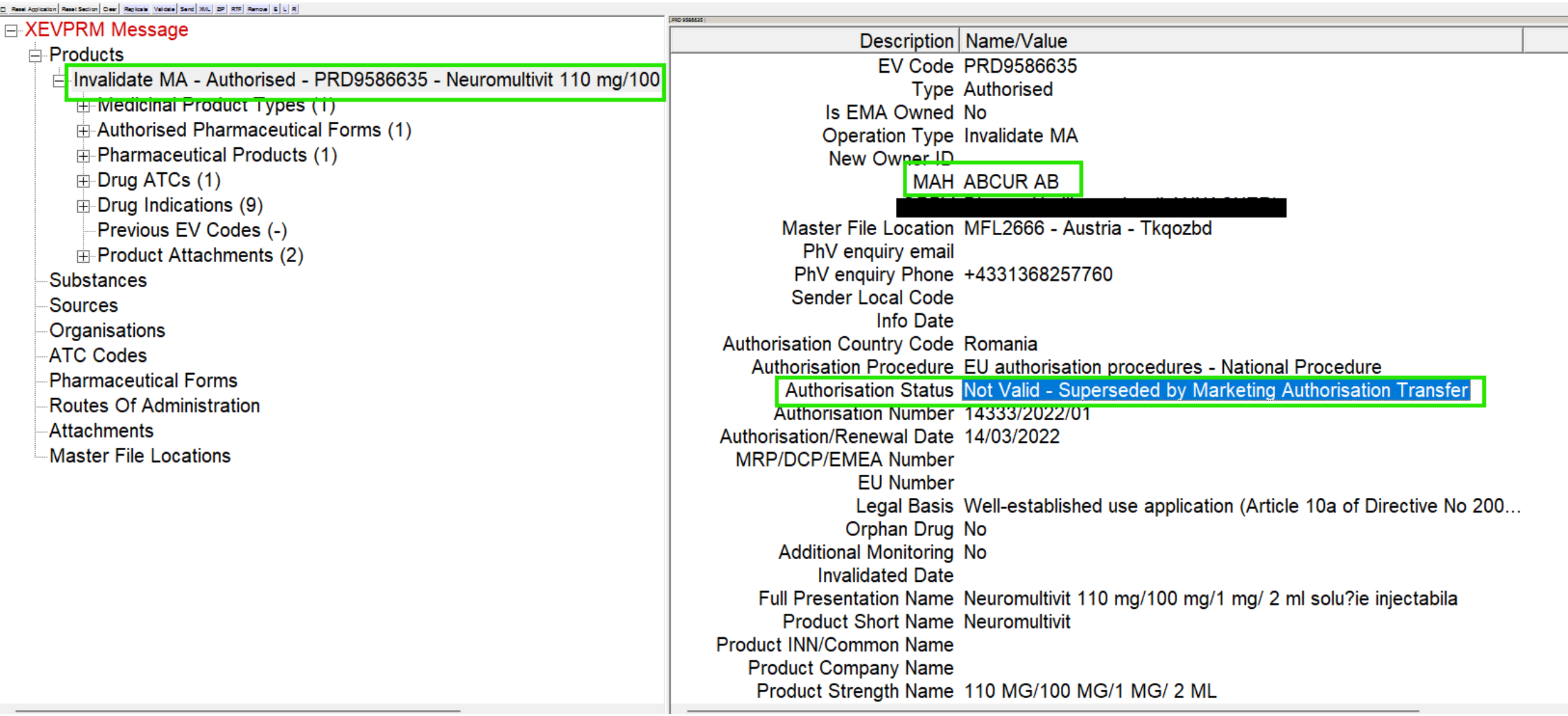
Former MAH

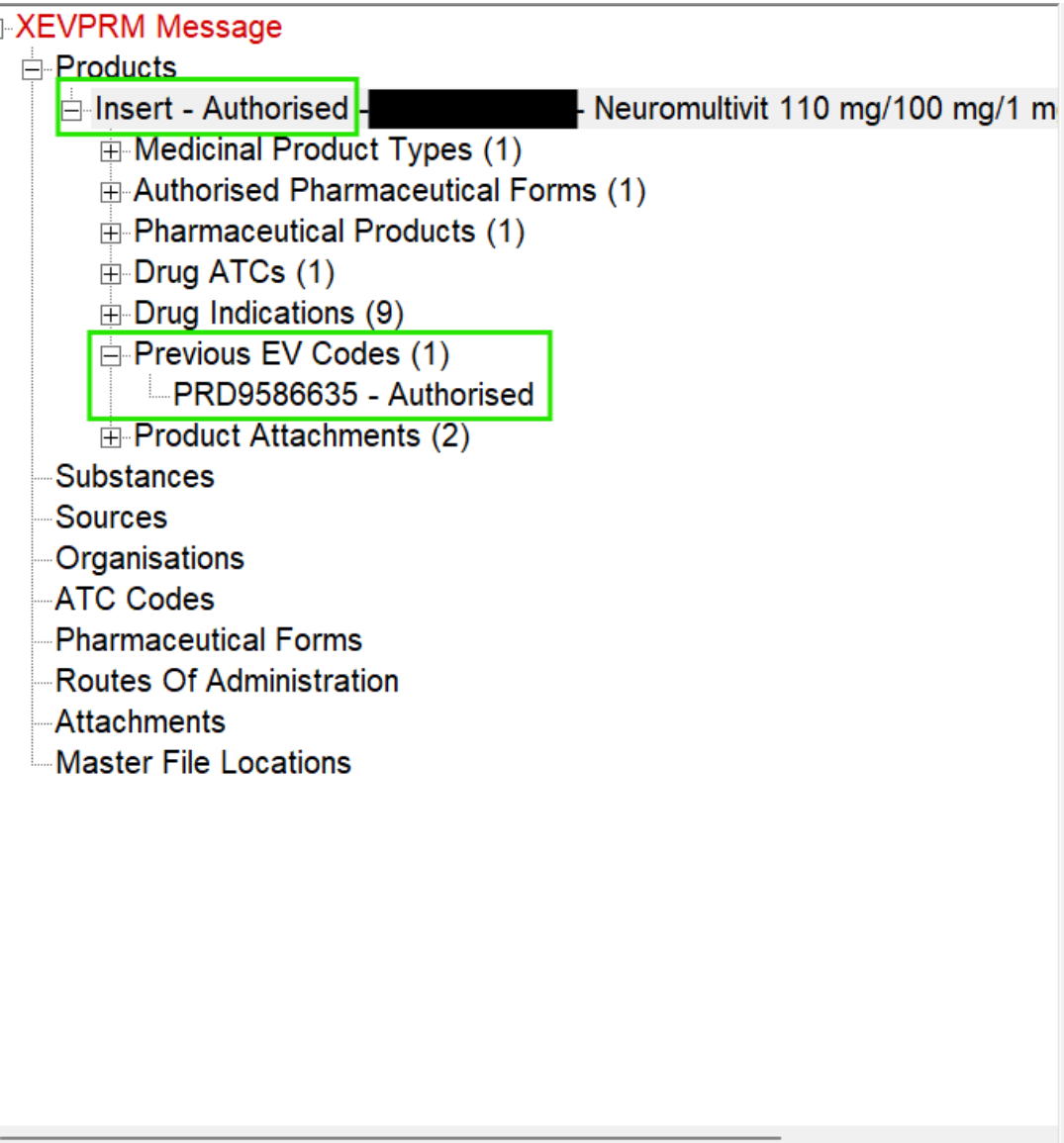
- Submission of an invalidation.
- New MAH should be indicated in the MAH's field.

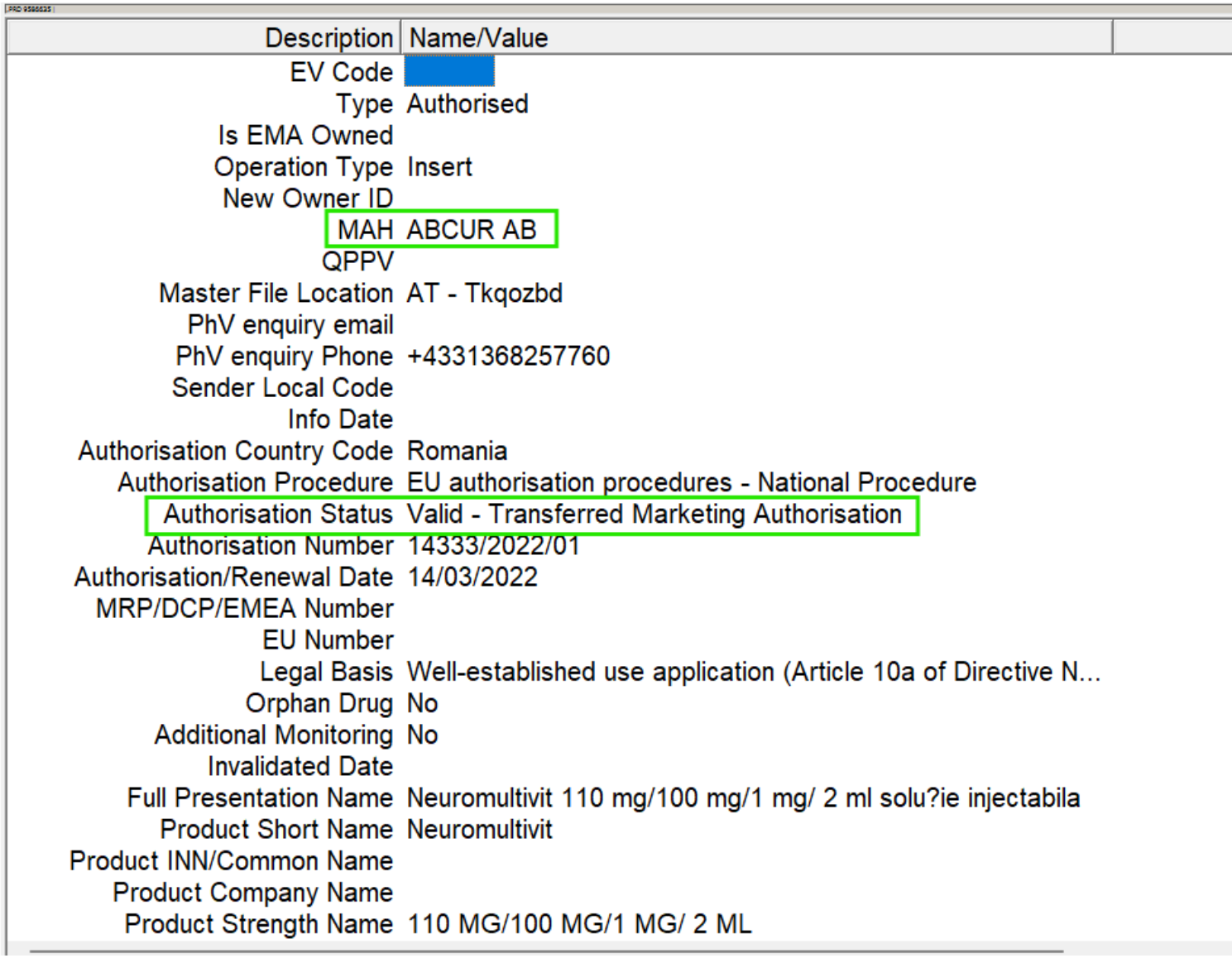
New MAH

- Submission of an insert.
- Former EV Code should be referred in the Previous EV Code field.









Former MAH		
Product A	EV Code 123	10, 20 and 50 tablets

New MAH			
			Previous EV Code
Product A	EV Code 456	10 tablets	EV Code 123
	EV Code 457	20 tablets	EV Code 123
	EV Code 458	50 tablets	EV Code 123

- Former MAH only submitted 1 EV Code for all pack sizes
- New MAH is submitting 1 EV Code per pack size

- Current approach was taking into account only the previous EV Code and new packages were not created.

- With this new approach, new packages are created when the new MAH submits the inserts.

- Data fix for the impacted transferred products will take place in Q3.

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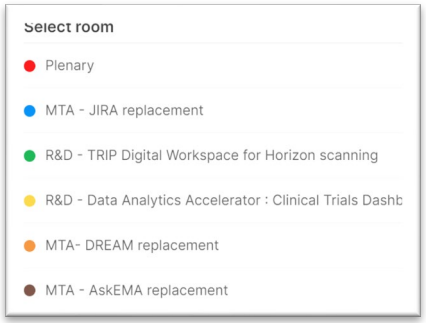

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PLM VS | Product User Interface (PUI)

Veronica Lipucci di Paola, PMS UI Product Owner

PMS UI and FHIR adapter

Committed objectives (PMS UI) 25Q2	Demo
▪ Release the **bulk update functionality** in UAT so testers can perform the external UAT in order to identify possible bugs or improvements on the implementation	**YES**
▪ Release the read-only industry role so **Industry can assign users** to access the PMS Data with an only-read role so **they can verify the data** submitted or migrated without the risk to modify any of the PMS fields	**YES**
▪ Create **two new BI reports** in the product UI so users can have access to additional PMS data through the Product UI in a structured way that will allow them to **validate** and verify the data migrated from other sources such as XEVMPD or SIAMED	**NO**

Committed objectives (FHIR adapter) 25Q2	Demo
▪ Improve the security in existing environments so users will be able to perform the UAT on the write API with a **proper security and access management in place**	**NO**
▪ Improve performance of the product-copy so users will see a **decrease of the time needed to load their products** during the enrichment process in the Product UI reducing the amount of time needed during the bulk update	**NO**
▪ Implement the conflict resolution during the submission of changes so users will see a **reduction on the amount of failed transactions** due to different versions between PMS API and IRIS so the **amount of tickets** or re-opened changes will be reduced	**NO**

PMS upcoming events

Q&A clinics on PMS

- **22 July 2025** (11:00 – 12:00 CEST): Event page
- **28 August 2025** (10:00 -11:00 CEST): Event page
- **18 September 2025** (10:00 – 11:00 CEST): Event page
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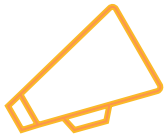

Quarterly system demo

Live broadcast on event page

17 September 2025
(from 9:00 CEST)

SPOR & XEVMPD status update webinars

Live broadcast on event page

- **9 July 2025** (10:00 – 12:30 CEST): Event page
- **8 October 2025** (10:00 – 12:30 CEST): Event page

PLM VS | electronic application form (eAF)

Kristiina Puusaari, eAF Product Owner

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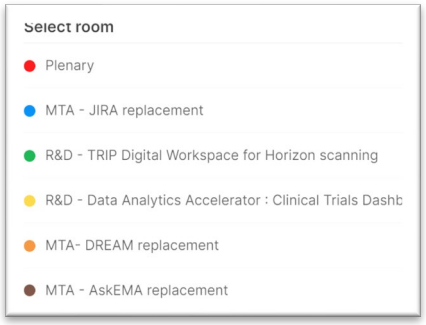

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eAF – Human Variations electronic Application Form

Committed objectives 25Q2	Demo
Implement the **new UX designs** (Part 1 i.e. non-functional updates only) across remaining pages so that the users will have **consistent user experience** that follows the **EMA design principles**	**YES**
Continue implementing general **performance improvements** so that the users have better user experience and they spend **less time** filling in the form – e.g. max 50 medicinal products can be selected at one time (repeatable)	**YES**
Allow the applicant to select an '**alternative company name**' from OMS so that they can reflect the desired organisation name in the MAH field to avoid rejections by regulators	**YES**
Update the MRP number field business rule so that the users get notified of the mandatory business rule timely	**YES**

Other deliverables and non-committed objectives 25Q2	Demo
4.a Orphan Medicinal Product information • Issues related to Orphan Medicinal Product information have been solved	**YES**
4.b Paediatric requirements • Issue related to Paediatric requirements section have been solved	**YES**
Other product types e.g. homeopathic medicines • The form can now be used for products authorised through other procedure types (national authorisation)	**YES**
Structured changes • The PLM Portal eAF is now connected to the PUI to enable the use of structured changes in the eAF (Not in production)	**YES**

Human variations eAF – Recommended use for all non-CAPs

- The PLM Portal web-based variation form is **in Recommended use for all non-CAP variations** since Monday 26th May 2025
- All **NCAs now accept** the web based eAF
- Issues, concerns, bugs should be reported via the **EMA ServiceNow tool** – please pay attention to the correct category
- If no major issues are experienced, we are planning to move to **strongly recommended use in late Q3**

Human variations eAF - statistics

2160 non-CAP applications
created in the PLM Portal since February 2025

2690 Centralised Procedure application forms received by EMA
since the go-live

Human variations eAF – Key steps and milestones

2022 – 2024

Nov 2022
Go-live of Human variations eAF supporting CAPs only

May 2024
Strongly recommended use of Human variations eAF for CAPs following PMS CAPs release

2025

Q1	Q2	Q3	Q4
Go-live of optional use of Human variations eAF supporting non-CAPs	Recommended use of Human variations eAF for non-CAPs	Strongly recommended use of Human variations eAF for non-CAPs, where applicable* (exact date TBD)	

Incremental release of the new UX design

Incremental release of new features, including maintenance and optimisation updates and performance improvements

Exploring structured changes in eAF

2026 and beyond (TBC)

UAT minus 2 months	UAT announcement *("Transition ready" form available)*
2 months after UAT	Confirmation of transition period start date *
2 months after confirmation	Start of transition period
6 months after transition start	Use of the Human variations web-form only

TBC

Analysis & development of web forms	Marketing Authorisation Applications, Veterinary variations, Renewals

TBC: To be confirmed, more precise information will be communicated in due time
Note: CAPs and NAPs data in PMS are sourced from EMA's internal database and XEVMPD

Acronyms

CAPs: Centrally Authorised Products
NAPs: Nationally Authorised Products
XEVMPD: eXtended EudraVigilance Medicinal Product Dictionary

Legend

Key milestone
Dev activities for Human variations eAF
Recurring activity

* on the condition that no major issues are identified

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Known Issues and Bugs

List of **known issues and bugs** is **continuously reviewed** and fixes are planned for each sprint.

Reminder

Please review the eAF **Release Notes** and **Navigation Guide** if you have issues. If you experience a known issue please consider if you need to raise a service desk ticket and carefully select the correct category in ServiceNow

PMS and IRIS dataverse dependencies – corrupted products and organisational data issues

1. Corrupted Products (*affecting CAPS and non-CAPs)*

A small number of corrupted products are still visible in the eAF causing errors when selected, and while a list of these products is unavailable, the PMS team is working on a fix and users should raise a service desk ticket if affected.

2. Duplicate Products (*affecting CAPS and non-CAPs)*

Some packaged medicinal products appear under two different medicinal products due to data errors from xEVMPD/PMS, causing eAF errors that block progress, users should report the issue via a service desk ticket. In most of these cases you may be asked to use the interactive PDF version instead.

3. Missing Products (*affecting only non-CAPs)*

Approximately 19,000 non-CAP medicinal products (mainly with combined dose forms) are missing from PMS due to data errors, making them unavailable in the PLM Portal eAF. In most of these cases you may be asked to use the interactive PDF version instead.

4. Organisational data issues (*affecting CAPS and non-CAPs)*

A known issue in the intermediate dataverse layer from where the Organisation data is fetched to the eAF is continuing to impact number of products/users/applications. A platform level review is ongoing to ensure that the issue can be solved without negatively affecting various different systems that feed from this data

Live Demo: UX/UI Updates

Live Demonstration

Upcoming eAF events

eAF training on web-based application form functionalities for non-CAPs –

1 July 2025 (10:00 – 11:30 CET) – Event web-page

Q&A Clinic on web-based application form functionalities for CAPs and non-CAPs

8 July 2025 (10:00 – 11:00 CET) – Event web-page

Additional training events will be planned and organised in the following two quarters of the year.

In Q3 a training will be prepared to address National Competent Authorities' (NCAs) doubts and uncertainties gathered through the survey exercise, performed between May and June 2025.

Relevant and detailed information will be shared in due time on the events registration and participation procedures.

PLM VS | electronic product information (ePI)

Elizabeth Scanlan, ePI Product Owner

ePI – electronic Product Information

Committed objectives 25Q2	Demo
▪ Perform UAT with external participants on FHIR import functionality at PLM portal	**Update**
▪ Implement new styling strategy with QRD stylesheet integrated into PLM portal ePI components	**Update** **Next SD**
▪ Enable versioning of the QRD template	**Next SD**

Electronic product information (ePI) – Q2 achievements

Key achievements:

FHIR import UAT

Currently testing:

1. **Prepare FHIR** files according to IG
2. **Create ePI** at the portal
3. **Validate** ePI FHIR files
4. Files that pass validation:
    - **Import** ePI FHIR files into PLM portal
5. Files that fail validation:
    - **Use validation report to fix** errors and re-try

FHIR

ePI Style Guide

- In future: **QRD** styles will be added using a **style sheet**
- **Guide** explains to applicants **what styles should be included in ePI** created by FHIR import or using the editor at the PLM portal

Reminder: Reflection paper for public consultation

- How can we realise the benefits of ePI and **deliver it into the hands of patients** across Europe?
- **Reflection paper open for public consultation** until end June

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ePI User Acceptance Testing

Thank you to our valuable testers!

Scope

- Import FHIR ePI created by UAT participant

Timelines

22 April – 19 May	20 May - 15 June	16 – 27 June	Next step
Call for interest	Confirm testers, **Role allocated**	**Testing**	***Triage***

No. Testers

20 organisations	Companies	Approx half of participants represent pharmaceutical companies
	Vendors	Approx half of participants represent vendors: participating independently or together with a company

Early findings

Validation	• Occasionally, ePI is not validated as the validation process timed-out; Easier local validation requested.
Portal	• Users easily creating ePI and navigating portal; Majority have successfully imported
Guidance	• Validation report could be easier to read and better named; Style guidance needed

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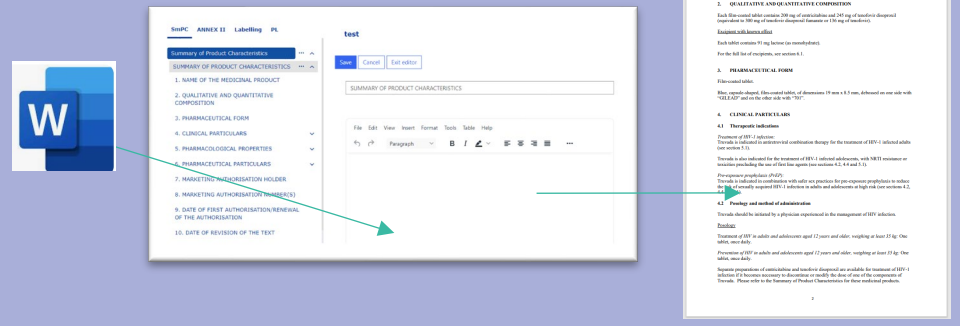
ePI Styling

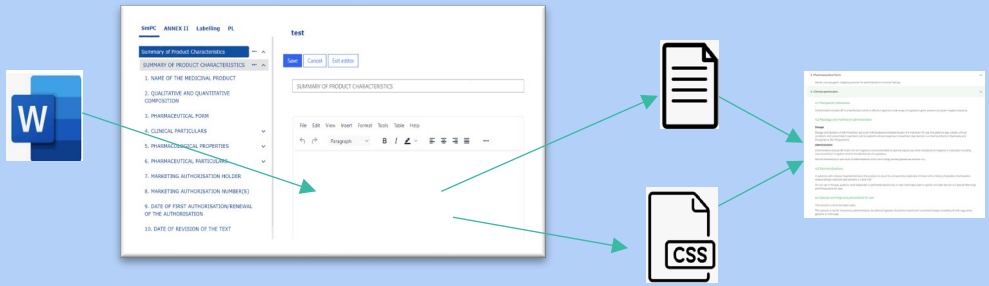
As is:

Copy paste from **Word** & **Keep** styling
All styling in-line in ePI FHIR



To be:

Copy paste from **Word** & **Lose** styling
Some styling in line, most styling **external in style sheet**



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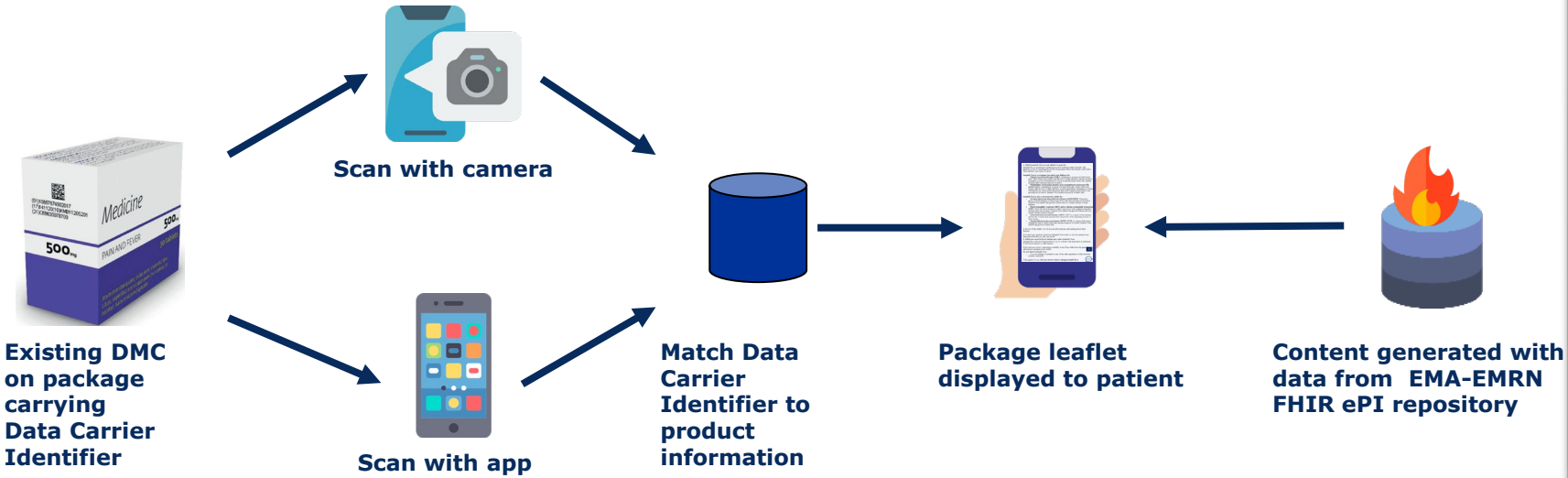
Digital format easily accessible to all patients



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 31 March 2025
2 EMA/95076/2025
3 European Medicines Agency

4 Reflection paper on linking to electronic product
5 information (ePI) from EU medicine packages
6 Draft

Start of public consultation	31 March 2025
End of consultation (deadline for comments)	30 June 2025

7 Comments should be provided using this EUSurvey form. For any technical issues with the form, please contact the EUSurvey Support.

8

Keywords	Electronic product information, ePI, summary of product characteristics, package leaflet, DataMatrix, data carrier identifier, patients, healthcare professionals

- ❑ Data matrix code (already on the box and used for anti-falsification) preferred to adding additional QR code
- ❑ Availability of EU wide solution is desirable in cross-industry collaboration
- ❑ Public consultation ends 30th June

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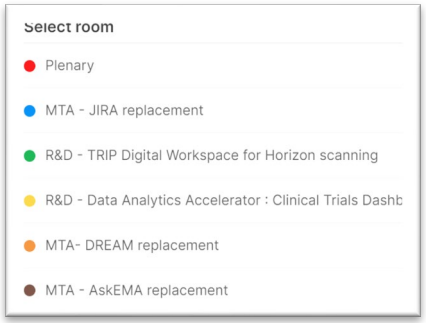

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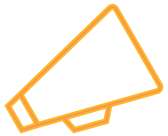

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