System Demo 26Q1

Public System Demo

26 March 2026

Welcome & Introduction

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

slido # 9116064

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Housekeeping

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

Participants may be able to ask questions or share feedback via Slido, with the option of remaining anonymous, If you choose to use Slido, you consent to the processing of your personal data as explained in the EMA Data Protection Notice for Webex (europa.eu).

To view the video in the highest quality, click on the settings symbol and select 720p or a higher resolution
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System demo at EMA
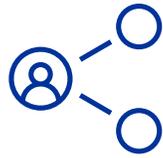
Agile teams showcase the features they have been working on in the last 3 months

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 and focus on **what is important.**

LLM
LARGE LANGUAGE MODELS

AI

01 01 001
01 01 01

25 June 2026

Is the next public system demo

Agenda

09:00	**Welcome / Introductions**
09:05 – 10:00	**Monitoring Value Stream (MON VS)**
	EudraGMDP
	European Shortages Monitoring Platform (ESMP)
10:00 – 10:20	**Research & Development Value Stream (R&D VS)**
	Clinical Trials Information System (CTIS) modernisation
10:20 – 10:30	Break
10:30 – 12:40	**Product Lifecycle Management Value Stream (PLM VS)**
	Union Product Database (UPD)
	Electronic product information (ePI)
	Electronic Common Technical Document version 4.0 (eCTD v4.0)
	Electronic application forms (eAF)
11:35 – 11:45	Break
	Product Management Service (PMS)
	Product user interface (PUI)
	Regulatory Procedure Management (RPM) for Product Lifecycle Management for IRIS
12:40	**Closing**

Give feedback & ask questions

Option 1 - Q&A
Questions and answers are public
You may upvote the questions
Top questions are answered verbally
Questions & available answers published
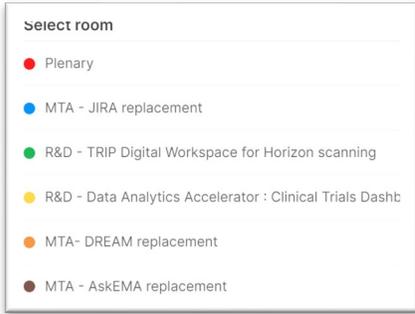on event page on EMA website

Option 2 - Poll
Feedback shared only with product team
Stays open for comments till 2 April
Please identify yourself
Give the product team feedback and
suggestions about your priorities

Join at
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Select room
- Plenary
- MTA - JIRA replacement
- R&D - TRIP Digital Workspace for Horizon scanning
- R&D - Data Analytics Accelerator : Clinical Trials Dashb
- MTA- DREAM replacement
- MTA - AskEMA replacement

Q&A   Polls

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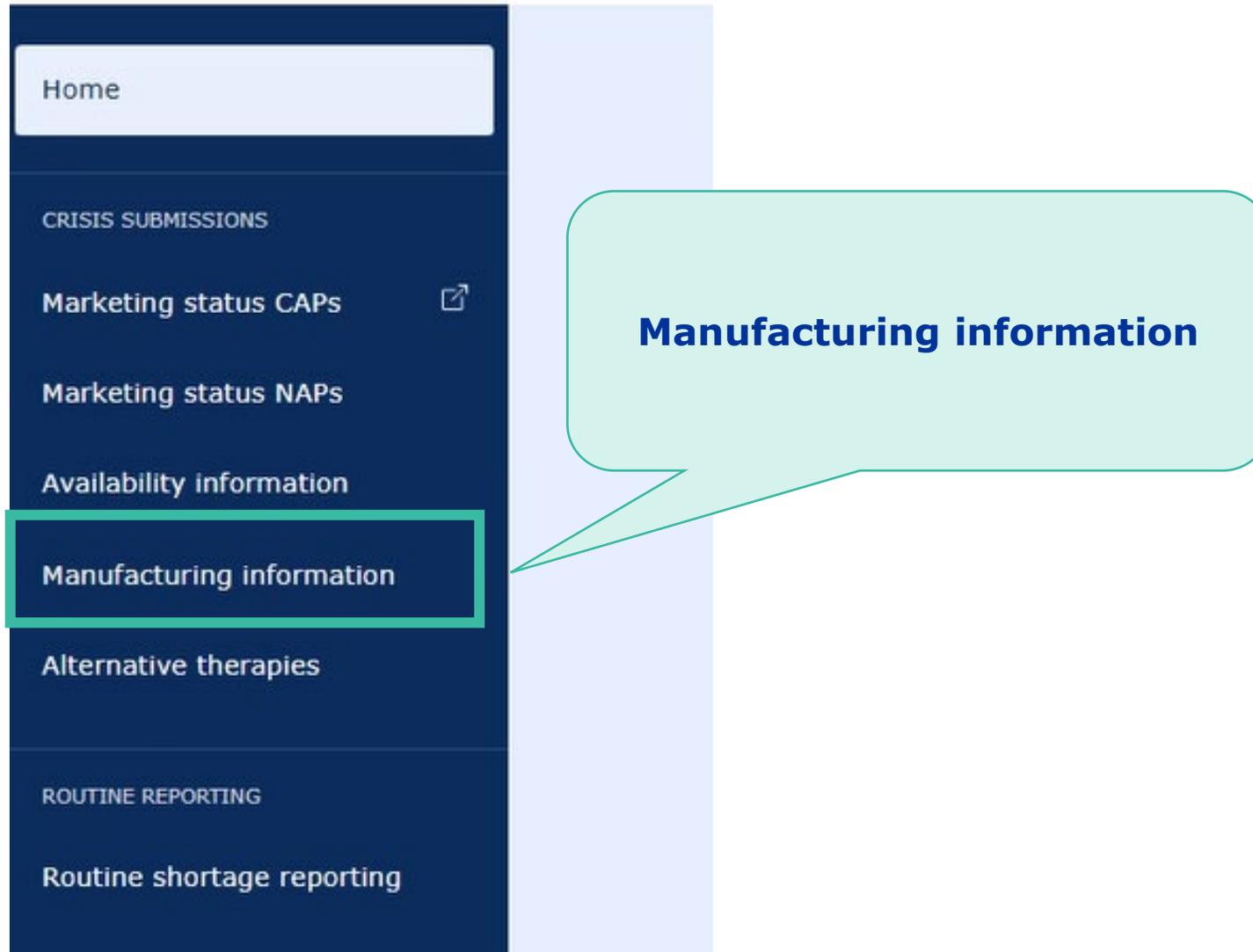
Step 3 - Choose Q&A or Polls as appropriate

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Template 2: Manufacturing information

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

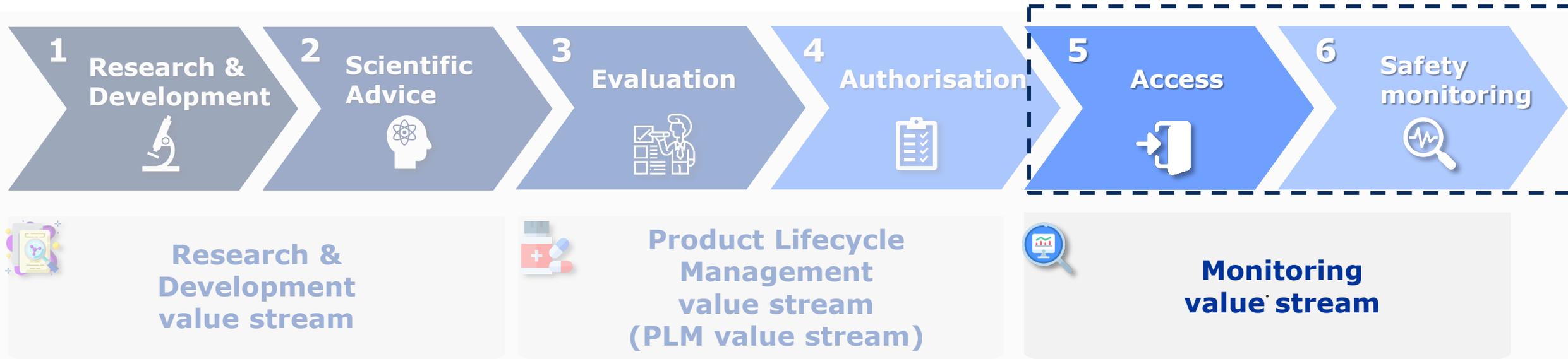## Technology Lifecycle Management and Information Security

Capabilities to manage information technology and security

Monitoring value stream (MON VS)

Empowering stakeholders with optimal data and tools to assess and monitor availability, safety and quality of medicines **to achieve higher standards of public and animal health protection in the EU**.

Lifecycle of a centrally authorised medicinal product

| 1 Research & Development | 2 Scientific Advice | 3 Evaluation | 4 Authorisation | 5 Access | 6 Safety monitoring |

Research & Development value stream

Product Lifecycle Management value stream (PLM value stream)

Monitoring value stream

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Monitoring VS |EudraGMDP

Public/private search and creation of Manufacturing/Importation Authorisation (MIA)

Ivana Radic, EudraGMDP Product Owner

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Overview of EudraGMDP

EudraGMDP is the **EU/EEA's official database** for GMP and GDP certificates and authorisation information. It supports regulators in submitting the legally required documents and enables stakeholders to search and access this data. The database was launched to the public in 2011 and includes:

- Manufacturing/ Importation Authorisations (**MIA**);

- Wholesale Distribution Authorisations (**WDA**);

- Good Manufacturing Practice (**GMP**) and Good Distribution Practice (**GDP**) certificates, or Non-Compliance Statements (**SNC**);

- Registrations of Active Pharmaceutical Ingredient manufacturers, importer and distributors (**APIreg**).

The **new platform** replaces outdated components, enhances public/private search, and refactors the core modules listed above (MIA, WDA, GMP/SNC, GDP/SNC, APIreg) to support consistent, reliable and efficient regulatory workflows.

Benefits of modernisation

Strengthened Strategic & Regulatory Readiness	Increased System Stability & Efficiency	Enhanced User Experience

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EudraGMDP modernisation roadmap

Date 25Q4
- Refactoring analysis start
- Operate and maintain legacy system

Date 26Q1
- Onboarding NPO, SMEs and dev team
- UX interviews
- MIA creation
- Public/Private searches

Date 26Q2
- GMP , GMP SNC
- APIreg

Date 26Q3
- UAT1 test strategy
- UAT1 start MIA & GMP
- API reg,WDA
- GDP, GDP SNC

Date 27Q1
- **MVP Go-live APIreg, WDA, GDP**
- 2nd epic: Addition of NPL functionalities
- Planning Module review
- Reporting/analytics needs

Date 26Q4
- UAT2 start all other modules
- **MVP Go-Live MIA & GMP**

Date 27Q3/Q4

Decommission of legacy EudraGMDP*

Date 2028

Operate and maintain new EudraGMDP

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EudraGMDP Demo Functionalities:

- Public search
- Private (restricted) search
- Manufacturing/Importation Authorisation (MIA) creation

Video Demonstration

Monitoring VS |European Shortages Monitoring Platform (ESMP)

Manufacturing information data submission in crisis/MSSG-led preparedness situations – inclusion of NAP manufacturing sites from PMS

Sofia Zastavnik, ESMP Product Owner

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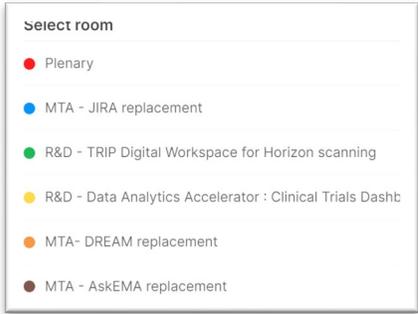Questions & available answers published
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ESMP

The ESMP is a harmonised, transparent, and collaborative IT platform for ensuring medicines are available when and where they are needed most.

- Designed to improve the **prevention**, **monitoring**, and **management** of medicines **shortages** across the EU/EEA

- It will centralise and automate **data collection on medicine shortages**, giving access to real-time and comprehensive information.
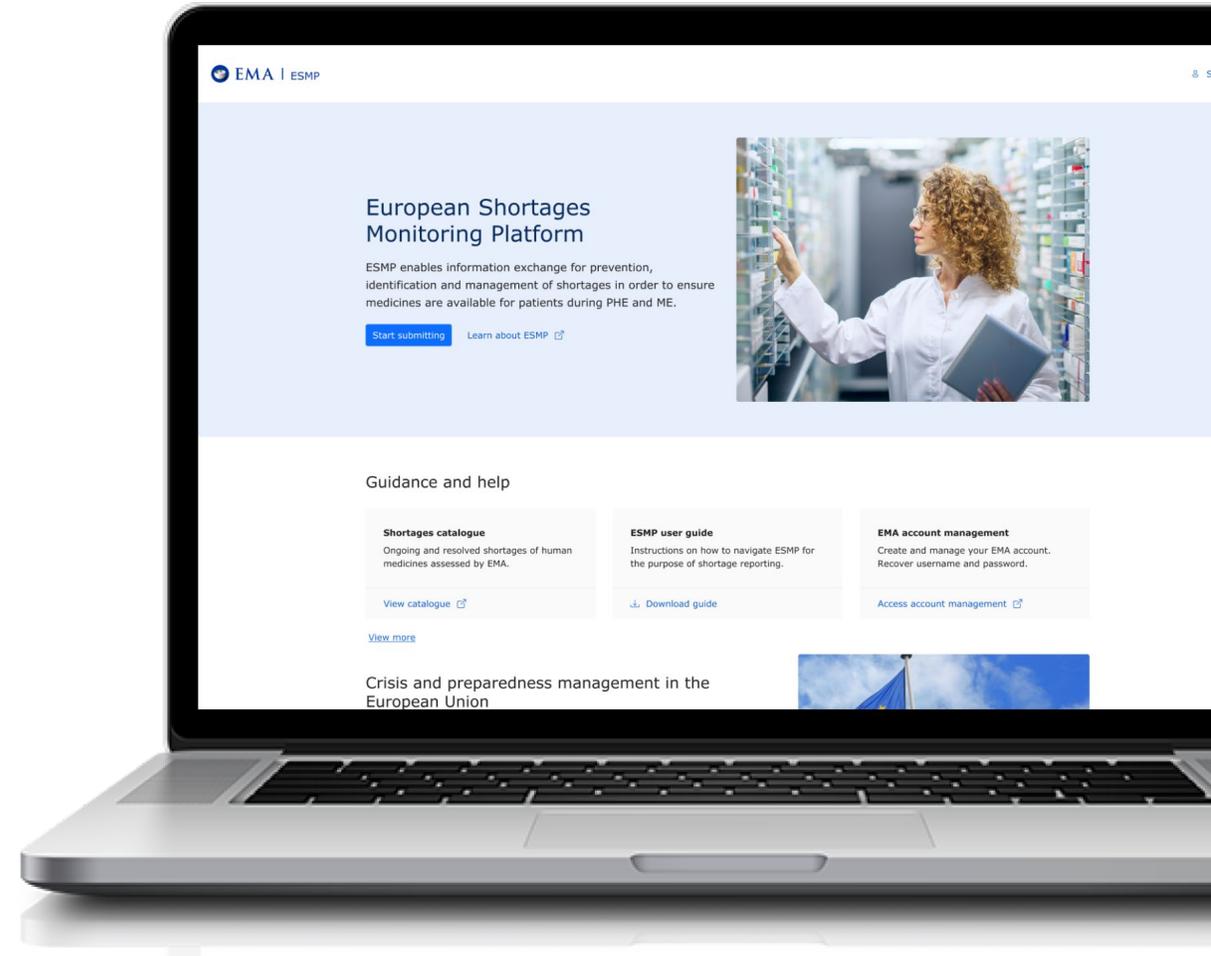
Insertion of manufacturing information: what is it?

WHO?
Marketing Authorisation Holders

WHEN?
In case of a crisis situation or MSSG-led preparedness action for CAPs and NAPs

WHAT?
The data submission pathway requires a set of information, **including manufacturing** details such as the production plan, capacity, and alternative sites.

WHAT'S NEW?

Manufacturing sites of **NAPs** stored in **PMS are automatically pre-populated in the ESMP submission template** for manufacturing information.

All manufacturing sites for NAPs are maintained exclusively in PMS.

Key deadlines for MAHs for manufacturer data submission to PMS:

- June 2026 for non-centrally authorised products (non-CAPs) featured on the Union list of critical medicines

- December 2026 for all other non-CAPs

- Check full details on data submission deadlines on PMS page on EMA corporate website

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What's new

Manufacturing data submission in **crisis or MSSG-led preparedness actions now includes retrieval of NAP manufacturing site information from PMS** to support EU-wide monitoring of medicine supply.

Q1 2025

Go-live of ESMP for crisis and MSSG-led preparedness reporting for CAPs and NAPs.

*Manufacturing data **for CAPs** imported from PMS*

Q1 2026

Addition of NAP manufacturing sites to previously released features.

*Manufacturing data for **BOTH CAPs and NAPs** imported from PMS*

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Manufacturing information

EMA | ESMP

My critical medicines

Marketing status CAPs

Marketing status NAPs

Availability information

❯ **Manufacturing information**

Alternative therapies

For medicinal products subject to crisis/MSSG-led preparedness monitoring through the ESMP MAHs need to report on **manufacturing methods** (own factory or subcontracted), **production plans** and **production capacity** (average and peak outputs) for the active substances and final dose form

To perform this data submission, MAHs will:
1) **Download a reporting template** pre-filled with the relevant CAP & NAP product information
   - **CAPs and NAPs will be listed** alongside their manufacturing sites for all stages of production (from data available in PMS)
2) **Compile and submit** relevant information
3) **Perform updates** to keep information current at a **frequency defined by the MSSG**

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Manufacturing information data submission

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

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

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Product information

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

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

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

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Product information

	PMS ID	Full product name	Active substance SMS ID	Active substance
	P1.1.1	P1.2.1	P1.3.1	P1.3.2
🔵	600000000555	Atenolol ESMP 25 mg tablet	100000089155	Atenolol
🔵	600000000555	Atenolol ESMP 25 mg tablet	100000089155	Atenolol
🟣	600001622030	Pantoprazol ESMP 40 mg - magensaftresistente Tabletten	100000092491	Pantoprazole
🟣	600001839370	Pantoprazol ESMP 20 mg - magensaftresistente Tabletten	100000092491	Pantoprazole

The table above has a title row spanning all columns: **Product information**

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Organisation information

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

- **For NAPs**, due to the absence of manufacturing information in PMS at the time of development, <u>two pre-populated operation types were implemented to represent the manufacturing of the active substance and the bulk product</u> (excluding packaging and labeling)

  - As MAHs are now inputting manufacturing details for NAPs in PMS, this information will be integrated into the ESMP *in upcoming iterations*

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

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

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Organisation information

- **For CAPs and NAPs**, manufacturing organisation information fields will be **pre-populated** from data inserted via the EMA's Product Management Services (PMS) and <u>they cannot be changed by updating the data in ESMP</u>
  - As MAHs are now inputting manufacturing details for NAPs in PMS -> please ensure the data in PMS is inserted and up-to-date
  - If there is still no manufacturing information in PMS at the time of ESMP data insertion, two pre-populated operation types will be shown to represent the manufacturing of the active substance and the bulk product (excluding packaging and labelling)

Organisation information	Operation type		**Production capacity**	Unit of measurement
	ORG-ID (Manufacturer)			Global monthly production plan – Months 1-6
	Manufacturer			Global monthly production plan – additional information
	LOC-ID (Manufacturer)			Average global monthly production output of previous year
	City (Manufacturer)			Peak global monthly production output of previous year
	Country (Manufacturer)			

Manufacturing organisation information: CAP/NAPs **with** manufacturing data inserted in PMS

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

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

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

Manufacturing organisation information: NAPs **without** manufacturing data inserted in PMS

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

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

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Manufacturing details

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

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

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

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Alternative sites

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

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

- **Alternative sites** collects information on manufacturing sites not currently listed in the marketing authorisation of the product in question, but could be used to partially or fully manufacture the active substance or finished product

- **Alternative site Location ID** of an alternative site refers to the identifier of the physical location of it as present in the EMA's Organisation Management Service (OMS), if the alternative site is registered in OMS. If it is not registered in OMS, it must be left blank

- **Alternative site country** must be entered using the standard country code format

- **Alternative site LOC-ID** or **Alternative site country** can be populated, but not both

- If applicable, **multiple values may be entered** for both fields

Manufacturing details and Alternative sites

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

Production capacity

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

	Active substance		*Unit of measurement*
Representative product	Representative product		
Organisation information	Operation type ID		*Global monthly production plan – Months 1-6*
	Operation type		
	ORG-ID (Manufacturer)	**Production capacity**	*Global monthly production plan – additional information*
	Manufacturer		
	LOC-ID (Manufacturer)		*Average global monthly production output of previous year*
	City (Manufacturer)		
	Country (Manufacturer)		*Peak global monthly production output of previous year*

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Production capacity

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

- • Values inserted depend on the "Operation type" inserted in "Organisation information"

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

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Representative product

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

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

- A **representative product** is a medicinal product whose manufacturing details, production plan, and capacity can be used as a reference for another product with an **identical manufacturing process** up to packaging and labeling, produced at the same sites, and following the same global production plan

- Using a representative product allows the MAH to **enter manufacturing information only once for** a group of products, reducing duplicate entries for equivalent products

Live Demonstration

Useful links and resources

User guide (MAHs)

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

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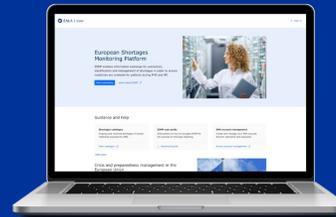
ESMP webpage

ESMP portal

Implementation guide (MAHs)

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

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

Training recordings and video tutorials

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

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Technology Lifecycle Management and Information Security

Capabilities to manage information technology and security

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Managing the medicinal product lifecycle

Integrating data and technology, the R&D value stream enables the development of medicines through efficient processes and generation of scientific evidence for the benefit of public and animal health in the EU.

Lifecycle of a medicinal product
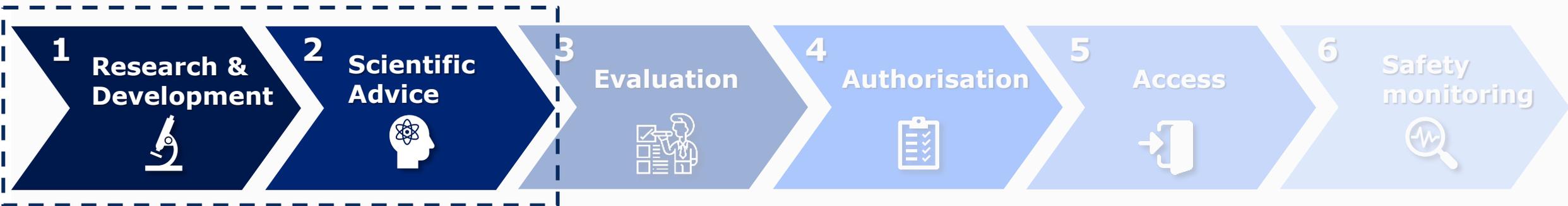
1 **Research & Development**

2 **Scientific Advice**

3 **Evaluation**

4 **Authorisation**

5 **Access**

6 **Safety monitoring**

Research & Development value stream

Product Lifecycle Management value stream (PLM value stream)

Monitoring value stream

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R&D VS | Clinical Trials Information System (CTIS) Modernisation

Annual safety report (ASR) submission

Ana Rodriguez, CTIS Product Owner

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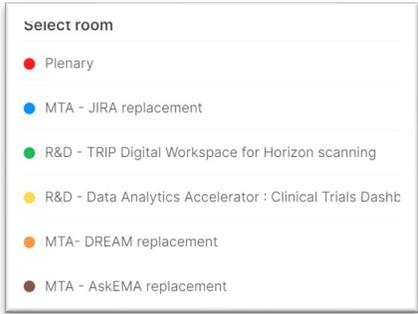on event page on EMA website

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CTIS Modernisation - New Safety Module

Committed objective 26Q1	Demo
Safety Module MVP – Fix critical and high bugs identified in **SaMS selection** Business Validation	NO
Safety Module MVP – Complete **ASR submission** implementation	YES
Safety Module MVP - Develop and Test **ASR assessment**	NO

Demonstration

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Capabilities to monitor availability and safety of products

Technology Lifecycle Management and Information Security

Capabilities to manage information technology and security

Lifecycle of a centrally authorised medicinal product

1 Research & Development

2 Scientific Advice

3 Evaluation

4 Authorisation

5 Access

6 Safety monitoring

Research & Development value stream

Product Lifecycle Management value stream (PLM value stream)

Monitoring value stream

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PLM VS | Union Product Database(UPD)

Saskia Schiemann, UPD Network Product Owner

Beyhan Mustafov, UPD Product Owner

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UPD – Union Product Database (1/2)

Committed objectives 26Q1	Demo
Release read-only Industry API for retrieving Volume of Sales data.	NO *Released on 16 March 2026*
Improve the NCA API for retrieving Volume of Sales data *(NCA API users can now apply authorisation country filter and have the product owner value in the retrieved Volume of Sales data).*	NO *Released on 16 March 2026*
Enhance the Public API by enabling members of the general public and organisations to retrieve product information (SPC, PL, Labelling) **documents and public assessment reports**.	NO *Released on 16 March 2026*
Enhance the NCA API for Variations Not Requiring Assessment by enabling pagination.	NO *Released on 16 March 2026*

UPD – Union Product Database (2/2)

Committed objectives 26Q1	Demo
Enhance data quality by enforcing the creation of new products in UPD via UI and API to be only under the EU Vet IG Chapter 2 rules.	NO *Released on 16 March 2026*
Enable product grouping information entered in UPD by a former MAH to reset, so the new MAH can provide their own value of product grouping in the system. *For info: MAH product grouping functionality enables users to combine safety information for similar EEA products (and similar non-EEA products via the third country product name submission) in the EVVet datawarehouse queries). In further simplifies and reduces the administrative burden for MAHs with the submission of Signals and Annual Statements in IRIS, as well as the submission of non-EEA sales data and third country product names within the UPD.*	NO *Released on 16 March 2026*
Enable NCA and MAH UI users to retrieve/export Volume of Sales data for whole search results.	**YES** *Released on 16 March 2026*
Refine the process of converting nationally authorised products to MRP after SPC harmonisation, to improve user experience and prevent costly datafixes.	**YES** *Released on 16 March 2026*

Classified as public by the European Medicines Agency

UPD – Q1 achievements

Highlights

- ✓ Numerous new and improved functionalities for API users (MAH, NCA and General Public).
- ✓ Increase UI user experience for retrieval of Volume of Sales data.
- ✓ NCA UI and API mandatory use of Vet EU IG Chapter 2 validation rules for new products creation.
- ✓ NCA UI and API users get details related to product data validation and associated pending VNRA within the product creation process for MRP after SPC harmonisation

Additional enhancements

- ✓ Only products with Authorisation status 'Valid', 'Pending' and 'Suspended' are included when MAH user selects 'Select all my non-CAPs products' in VNRA submissions related to QPPV and/or PSMF data.
- ✓ Migrated all (over 270.000) product information (SPC, PL, Labelling) documents and public assessment reports to a new storage, to improve the Public portal performance and enable these files to be retrieved via the Public API.

New/revised guidance and training materials

- ✓ Updated Vet EU IG Chapter 5, example payloads for API users, Swager pages for NCA, MAH and General Public API users.
- ✓ Three new video tutorials for NCA and MAH users.

Live Demo:

1 & 2 NCA and MAH UI users can retrieve volume of sales data for multiple products through 'Retrieve volume of sales' menu page

3. NCA UI users get details related to product data validation and associated pending VNRA within the product creation process for MRP after SPC harmonisation

Live Demonstration

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Useful materials

Guides

- [UPD registration guide](#) *for UI and API users*

- [UPD EU Implementation Guides](#)

- [Guidance for MAHs](#) *on the calculation of dose factor, how to configure email addresses for UPD notifications*

- **NEW** [Revised EU IG Chapter 5](#) and [zip file with example payloads for API users](#)

Release notes

- Periodically published on [EMA's UPD webpage](#)

Webinars and Trainings

- [EMA's UPD webpage](#)

- [Video tutorials](#)

  - **NEW** 1) How to **view and download volume of sales data - NCA user**.

  - **NEW** 2) How to **view and download volume of sales data - MAH user**.

  - **NEW** 2) How national products can be grouped under an **MRP at the end of SPC harmonisation procedure**

Q&A Documents

- [UPD Q&As for Network users](#)
- [UPD Q&As for Industry users](#)
- [UPD Q&As about VoS](#)

PLM VS | Electronic product information (ePI)

Elizabeth Scanlan, ePI Product Owner

Evinn Drusys, ePI Network Product Owner

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Q&A   Polls

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Achievements

UI optimisation: alignment with PLM portal

Process streamlining: approval–publication into one role and step

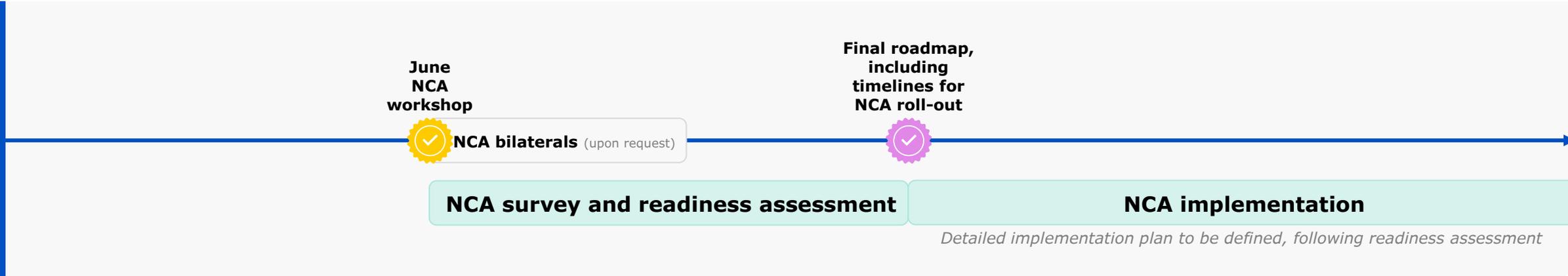**Refactoring & stabilisation**

ePI roadmap: adoption & publication

ePI implementation roadmap [DRAFT]

CAPs

	2026				2027		2028	
	Q1	Q2	Q3	Q4	H1	H2	H1	H2

Industry UAT (Milestone)

Go-live voluntary submission for vaccines (ATC code J07) (Go-live)

Go-live voluntary oncology products (ATC code L01, L04) (Go-live TBC)

Go-live voluntary all CAPs (Go-live TBC)

Features and guidance development

Hypercare

Transition period

Non - CAPs

June NCA workshop

NCA bilaterals (upon request)

Final roadmap, including timelines for NCA roll-out

NCA survey and readiness assessment

NCA implementation

Detailed implementation plan to be defined, following readiness assessment

Acronyms
CAP: Centrally Authorised Product
Non-CAP: Non-Centrally Authorised Product
HMA: Heads of Medicines Agencies
NCA: National Competent Authority
TBC: To be confirmed
ATC: Anatomical Therapeutic Chemical
UAT: User Acceptance Testing

Legend
Go-live
Milestone
Go-live TBC
Dev. activities
Annoucement

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Kick-off implementation

Initial implementation **will not interfere** with the assessment

Applicants will be requested to **author / upload ePI** at the **PLM portal** through an extra step in process (alongside current Word/PDF submission)

Future vision: ePI integrated in a fully digitalised assessment

Once a product's PI is available in electronic format, it will **remain electronic in all subsequent variations**

CAPs: Initial ePI implementation for **English**, with all languages optional – **fully multilingual at a later stage**

ePI implementation roadmap [DRAFT]

	2026				2027		2028	
	Q1	Q2	Q3	Q4	H1	H2	H1	H2

CAPs
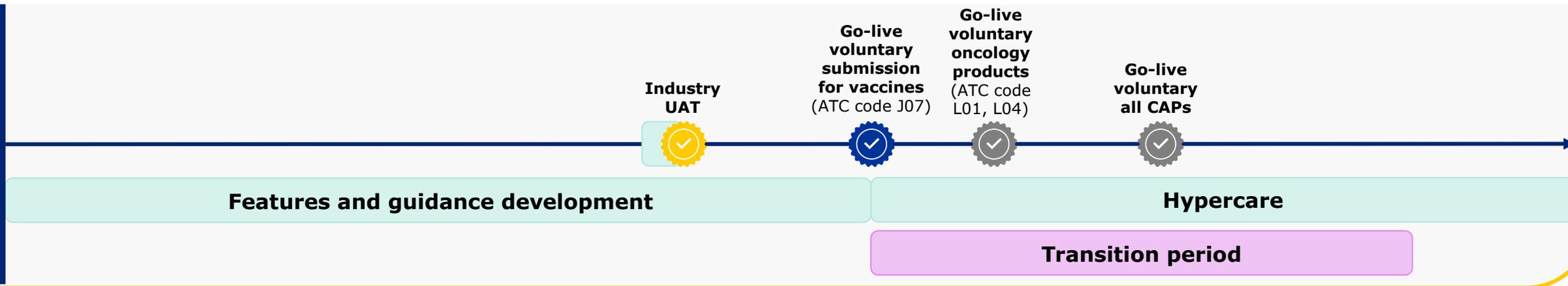
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Legend

Go-live
Milestone
Go-live TBC
Dev. activities
Announcement

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NCA implementation

ePI central **repository according to NPL (new pharmaceutical legislation)** – model tested during the pilot

NCAs implementation may require:

Each NCA to **do pre-implementation development work** to adapt national systems as well as **NCAs procedure** change management

Additional development may be needed by EMA/NCA to support full interoperability of each NCA

Joint EMA/HMA Road Map for implementation will support orderly, well managed & timely go live

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PLM VS |Electronic Common Technical Document version 4 (eCDT4)

Kristiina Puusaari, eCDT v4.0 Product Owner

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eCTD v4.0 – Q1 achievements

Optional use for CAPs new MAAs

- Go-live of **optional use** for **CAPs new MAAs** in eCTD v4.0 format from 22nd December 2025.

- Applicants are **invited** to **contact EMA prior** to any eCTD v4.0 format submission to ensure that the assessment teams are ready and so that enhanced support can be provided. **Test submissions are welcomed**

Technical pilot for CAPs new MAAs held

- **Automation** to support the next phases of the technical pilots implemented.

- Applicants and Vendors are **invited** to **resubmit test eCTD v4.0 CAP new MAAs** using the new 'test' channel

- Technical pilot for **Forward Compatibility** i.e. products with existing eCTD v3.2.2 lifecycle announced.

- Preparation for **non-CAPs new MAA** technical pilot ongoing.

Updated documentation published

- Updated validation criteria **published** (13th March 2026).

- EU IG being reviewed and updated to include updates from the practical guidance – preparation. The IG is currently being finalised for planned the publication before end of Q1 2026.

Process: Forward Compatibility CAPs (1/2)

> **Pre-requisite for participation**
>
> Have a Centrally Authorised Product (CAP) with an existing lifecycle you would like to submit the eCTD v4.0 sequences for.

Applicants step-by-step process

1	Contact the EMA via e-mail (eCTD4consultation@ema.europa.eu) to request 'test folder' to be added into your eSubmission Gateway account (syncplicity or B2B)
2	Provide the routing ID of your eSubmission Gateway (in the test account request)
3	Identify the UUID of the product(s) included in testing and provide to EMA with other relevant details (EMEA/H/C number, eCTD v4.0 sequence number(s), submission type(s), and unit(s) per sequence)
4	Create the delivery file for the current eCTD(s) v.3.2.2 in the production environment
5	Submit the v.3.2.2 submission sequences to the **test** environment
6	Ensure that you have received successful acknowledgment for the v.3.2.2 packages before proceeding
7	Submit technically valid eCTD v4.0 package(s) to the **test** environment

> **!** In case you do not have a Centrally Authorised Product but do wish to participate in the pilot, please contact us for specific instructions.

Process: Forward Compatibility CAPs (2/2)

EMA Responsibilities

Confirm applicant acceptance into the pilot

Add new 'test' environment to the applicant eSubmission Gateway account

Provide the Delivery File(s) for the eCTD v4.0 follow-up submission unit(s) to the applicant

Points for considerations

▸ It is **not mandatory** to include all previous eCTD sequences in the pilot. The applicant is responsible for deciding how many sequences to include.

▸ Test documents may be used in the follow-up eCTD v4.0 submission unit.

▸ If test documents are included, the scenario(s) must be clearly described in the cover letter.

EURSnext and eCTD v4.0 implementation roadmap

2025	2026				2027	
Dec	Q1	Q2	Q3	Q4	H1	H2

CAPs

- Release of the practical guidance and xml delivery file UI
- Release of the updated EU IG and Validation criteria
- Release of the updated EU IG and Validation criteria
- Go-live for optional use for CAPs forward compatibility *(subject to pilot outcome)*
- Release of the updated EU IG and Validation criteria
- Mandatory use for CAPs – **Date TBC**

Go-live for optional use for CAP new MAA

eCTD v4.0 Pilot on forward compatibility for CAPs (products with existing lifecycle)

Readiness check before CAPs mandatory use

Non - CAPs

- December - Go-live for optional use for non-CAP new MAA *(subject to Central Repository)*
- Q4 - Go-live for optional use for non-CAPs forward compatibility

Readiness check before non-CAPs optional use

eCTD v4.0 Pilot for non-CAPs new MAA

eCTD v4.0 Pilot on forward compatibility for non-CAPs

Technical Dev.

- Release of EURSnext 26.02
- Release of EURSnext 26.06
- Release of EURSnext 26.10

Acronyms

CAP: Centrally Authorised Product
Non-CAP: Non- Centrally Authorised Product
IG: Implementation Guide

TBC: To be confirmed
MAA: Marketing Authorisation Application
UI: User Interface

Legend

- Go-live
- Milestone
- Dev. activities
- TBC Go-live

EMA

PLM VS | Electronic application forms (eAF)

Kristiina Puusaari, eAF Epic Owner

EMA

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Human variations eAF - statistics

13 292 non-CAP applications created in the PLM Portal (as of March 2025)

8 533 Centralised Procedure application forms created since the go-live

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Human variations eAF – eAF List

The **eAF lists**
(all tabs: Draft, Deactivated, Completed and All) will retain the **sorting order** and the column visibility **until the local cache is deleted.**

The settings are **saved for each separate tab.**

Human variations eAF – **Super grouping for NAPs**

Domain *
Human use

Type of application
Single Regulatory Activity

☐ Including a line extension ⓘ
☐ Worksharing ⓘ
☑ Super-grouping ⓘ

Procedure type ⓘ
Variation Type IAIN

For the eAFs where:
- there are **1 or more products selected from the same country**, and
- **1 or more scopes of type IA/IAIN.**

The user can manually select the "**Super-grouping**" checkbox (to be used in case the health authority previously approved the use of "Super-grouping" for the specific scenario.

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Human variations eAF – **Counter**

In the product selection page, there is a **more complete counter** which details:
- products shown,
- products added,
- products selected in total

For example, if there were 4 products selected and the user adds a new one, the counter will show: 100 products shown, 1 added, 5 selected in total

Human variations eAF –
New variation classification

- *The revised Variations Regulation applies since 1 January 2025 for variation applications implemented and submitted to the European Medicines Agency (EMA) from 1 January 2025.*

- A single cut-off date for the entry into application (i.e., **15 January 2026**) is set out in the **final** version of the **Variations Guidelines**.

- [Guidance on the application of the revised variations framework | European Medicines Agency (EMA)](#) and [Heads of Medicines Agencies: Revised Variations Framework](#)

*All identified **missing conditions and documentation** were **corrected/added**. If you find other inconsistencies (e.g. different content/name for the details of a scope), please raise a Service Desk ticket with the RMS team ([Request RMS Service - Employee Center](#))*

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Known eAF 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, Navigation Guide and the Q&A document** 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.

Known PLM eAF issues

1. Performance issue for large applications

A known performance limitation in the PLM portal eAF prevents the creation of large applications (for scenarios covering around 200 products and more).

There are several activities planned for 2026 to improve the behaviour.

2. Medical Devices section

A known issue in the Medical Devices section requiring use of the interactive pdf eAF.

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Known Issues and Bugs – outside eAF

Known issues

1. PMS issues(*affecting CAPS and non-CAPs)*

The complete list of known PMS issues can be found in the following document: product-management-service-pms-frequently-asked-questions-faqs_en.pdf (page 16), with the expected resolution date. The issues range from "Duplicated products and packages " and "Duplicated entries" to "Truncated full product name".
Please consult the list and potential action for the MAHs before raising a ticket.

2. 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 systems that feed from this data.

Several workarounds were applied in eAF to address OMS synchronisation issues. Similar approach will be further analysed and implemented (contact person and proof of payment).

Human variations eAF – Q2 plan

- Implementation of the **Annual update** checkbox (and the 'Earliest implementation' date field)

- **Default-select** the "January 2026" version

- Continue the **Performance** improvements

- Changes in the **Procedural information** (MAH contact details, Contact person)

Human variations eAF –
Mandatory use for CAPs to be announced

- **Mandatory use** for **CAPs only** (in case there are no technical issues (e.g. Product Data, OMS integration, Medical Devices) will be announced in the upcoming days

- Information and details on how to flag that an **issue** preventing the creation of the PLM eAF will be shared

- Planned date of entering into force: **1st of September 2026**

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Human and Veterinary Marketing Authorisation Application (MAA) eAFs update

Updates to address **structural limitations** in the **MAA eAFs**; on high level, the updates aim to **improve** both the **quality and usability of regulatory data**.

- **Alignment with ISO IDMP**, enabling structured and interoperable product data across EU regulatory systems.
- **Improved representation** of complex medicinal products, including multiple pharmaceutical forms, strengths or manufactured components.
- Clear distinction between product concepts, such as **pharmaceutical form**, **manufactured dose form** and **administrable dose form**.
- More structured and consistent data capture, **replacing free-text fields with controlled terminology.**
- Improved traceability of manufacturing activities; **linking medicinal products, manufacturers and site-specific steps**.
- Clearer product composition, through **structured mapping between ingredients and manufactured items**.

Timeline

The updated versions will be made available during **Q2** allowing **sufficient transition** time for network and industry to adapt systems and processes before the forms enter into force.
Note: **Vet MAA eAF** contains large number of **additional changes** requested by Vet business.

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New interactive pdf eAFs

New pdf eAFs are being analysed and developed to enable **automated case creation** and more efficient processing of these types of applications;

- **Plasma Master File Certification** (PMF) – new interactive pdf eAF to be launched in **Q2**

- Consultation procedure for changes made to an **ancillary medicinal substance incorporated in a medical device** - new interactive pdf eAF being analysed in Q2

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PLM VS | Product Management Service (PMS)

Marcos Fernandez Gomez, PMS Co-Product Owner

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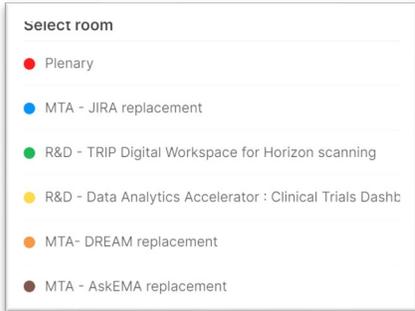Questions & available answers published
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💬 Q&A   ▮▮▮ Polls

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PMS – Product Management Service

Committed objectives 26Q1	Demo
Design the plan to upgrade the PMS API to FHIR R5 -- Achieved	NO
Conduct external UAT on the public PMS API -- Achieved	NO
Release the MVP of the public PMS API in the Production environment -- In progress	NO
Cleanse duplicated packages and product -- In progress	NO

PMS – Product Management Service

PMS Q&A Clinics every month

1-hour sessions where the PMS team is available to **answer your questions** regarding the Product Management Service (PMS) User Interface (PUI) and the Application Programming Interface (API)

PMS FAQ document

- Review the **FAQ document** in the PLM portal as this document contains a direct **record of frequently asked questions**, as well as an overview of **known issues,** including current status and progress update

- The majority of questions raised during the Q&A clinics are covered in the FAQ document

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PLM VS | Product user interface (PUI)

Veronica Lipucci Di Paola, PMS UI Co-Product Owner

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Product UI

Committed objectives (PMS UI) 25Q2	Demo
▪ Implement UX/UI enhancements and critical bug fixes so that MAHs experience an improved interface and interaction with the Product UI functionalities, incl. the optimisation of guide pages and news article section.	YES
▪ Complete the analysis of the data fields and business rules required for pending product creation and authorised medicinal products handling in the Product UI thereby enabling product creation workflows and accurate and compliant product data management and supporting future SIAMED and XEVMPD decommission and initial MAA form creation.	NO
▪ Start design and implement the end-to-end user journey for the creation of pending products in the Product UI (implementation of business rules is excluded) so that MAHs have a clear and intuitive process to create/manage pending products.	NO

Upcoming events

Q&A clinics on PMS PUI and API

- **14 April 2026** (15:00 – 16:00 CEST): Event page

- **12 May 2026** (15:00 – 16:00 CEST): Event page

Q&A Clinics on SOR

- **14 April 2026** (11:00 – 12:00 CEST): Event page

- **12 May 2026** (11:00 – 12:00 CEST): Event page

Q&A Clinics on XEVMPD

- **12 March 2026** (15:00 – 16:00 CET): Event page

- **16 April 2026** (15:00 – 16:00 CEST): Event page

- **13 May 2026** (15:00 – 16:00 CEST): Event page

SPOR & XEVMPD status update webinar

Registration open

13 April 2026 (10:00 – 12:30 CEST): *registration available on event page on EMA website*

PMS Info-Day

9 June 2026 (09:00 – 13:00 CEST):

Live broadcast on EMA's YouTube channel

More information on event page on EMA website

Live Demonstration

PLM VS | Regulatory Procedure Management (RPM) for Product Lifecycle Management on IRIS

Madalina Duta-Mare, RPM for PLM Product Owner

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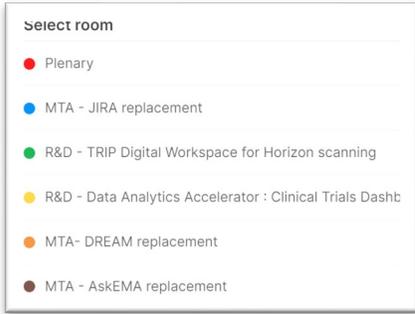on event page on EMA website

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Regulatory Procedure Management (RPM)

Achievements and ongoing objectives	Demo
Finalise core accelerated assessment capabilities to achieve functional go-live readiness	**YES**
Finalise development of a unified Transfer & Withdrawal process type by merging and upgrading the existing R&D process types to support PRE and enable Transfer and Withdrawal of multiple entitlements, simplifying the applicant experience and reducing maintenance effort (in progress)	NO
Analyse and conduct the data migration from SIAMED to support roll-out of pre-submission processes, ensuring complete understanding of data scope, dependencies, and required migration approach. (in progress)	NO
Implement a solution to enable industry users to manage product contact information for H&V CAPs via IRIS portal	**YES**
Implement improvements to MAA process	NO
Implement automations for case and product record creation for H/V MAA (in progress)	NO
Implement improvements to existing Post-Authorisation processes in IRIS	NO
Initiate development of a solution for the IRIS implementation of MRL process for veterinary products to support the decommissioning of SIAMED (in progress)	NO

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Live Demonstration

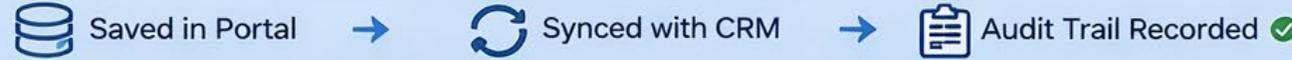# User Journey: authorisation product contact management

Live Demonstration

EMA

MAA Requirement – IRIS Account

> ⚠ • All designated contacts involved in Marketing Authorisation Applications (MAA) must hold an **active IRIS account** correctly associated to their organisation.
>
> • Please **review and update contact details** to ensure all relevant individuals are properly registered in IRIS.

How to register in IRIS?

1. Create an **EMA account** via **EMA Account Management Portal**

2. Login to the **OMS portal** with your EMA account credentials and create a change request to register or update your organisation

3. Login to the **EMA Account Management Portal** and request necessary role and affiliation

4. After notification that your IRIS user access role has been approved, go to **IRIS website** and click **"Sign In"**

EMA

LLM
LARGE LANGUAGE MODELS

AI

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Is the next public system demo