EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Product Management Service Info Day

16 April 2024

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Welcome

Chairs:
Peter Arlett, Chair of EMA Data Board *and Head of Data Analytics and Methods Task Force*
Emmanuel Cormier, ESMP Business Sponsor *and Head of Regulatory Science and Innovation Task Force*

Housekeeping notes

This session is taking place at **EMA building** and is also being **broadcast live**

This session is being **recorded** and the recording will be available through the **EMA Corporate Website** and at **EMA YouTube Channel**.

Audience will be able to interact/send questions via **Slido**.

Join Slido.com using the code **#PMS-INFO** or scanning the **QR code** here →

By participating in the session and interacting with Slido, ***you consent to the processing of your personal data*** *as explained in the EMA Data Privacy Statement for Slido.*

Q&A session at the conclusion of each agenda topic:

- We will answer **a couple of questions** from **onsite participants,** followed by **a couple from Slido**
- Any additional Q&A requirements will be evaluated post-event and organised/ distributed accordingly.

Housekeeping notes for on-site participants

Please sing the **induction sheet** and pass it around

Join the Network **'Guest Wi-Fi'**

password: W!rel3ss@3m@!2022

Please raise your hand and then use the microphone next to your seat to ask questions

What do we want to achieve today?

Today's event aims to:

- Show you how **PMS is key** in the Digital Transformation
- The **systems that will use PMS** to benefit the EU Network and industry
- Share the **medium and long-term objectives for PMS** and **key applications of PMS**
- Explain and illustrate **industry's crucial contribution to PMS success**

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Agenda

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1. **Welcome & Opening remarks**
   9:15 – 9:45
2. **PMS in the context of the network portfolio**
   9:45 – 10:20

Coffee break (20 min)

3. **How EMA systems use PMS data**
   10:40 – 12:00

Lunch (60 min)

4. **How is PMS enabling value**
   13:00 – 14:15
5. **How are SOR & XEVMPD services supporting PMS**
   14:15 – 15:00

Coffee break (20 min)

6. **How are NCAs mobilising - case study**
   15:20 – 15:50
7. **How is Industry mobilising - case studies**
   15:50 – 16:50
8. **Conclusions and general questions**
   16:50 – 17:30

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Opening remarks

Peter Arlett, Chair of EMA Data Board *and Head of Data Analytics and Methods Task Force*
Emmanuel Cormier, ESMP Business Sponsor *and Head of Regulatory Science and Innovation Task Force*

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Chairs for today

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PMS in the context of the network portfolio

Chair: Zaide Frias, Chair of the Network Portfolio Board *and Head of Digital Business Transformation Task Force*

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PMS in the centre of the Digital transformation

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Vision

Transform our stakeholders experience during the interaction with the regulatory Network by providing ***an integrated customer and data digital journey through medicines*** **regulatory processes*, to the benefit of public and animal health in EU***

Portfolio Objectives

Data Driven Agency

Operational Efficiency

Legislative Priorities

Cybersecurity & Technology Modernisation

Portfolio IT Products enabled by PMS today

PMS

Single source of truth for trustworthy , enriched, validated , **authorised medicinal product data**

eAF

ePI

RPM

Product UI

ASU

ESMP

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PMS in the context of the network portfolio

Isabel Chicharo, PMS Epic Owner and Head of Regulatory Data Management
Chair: Zaide Frias, Chair of the Network Portfolio Board *and Head of Digital Business Transformation Task Force*

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PMS: Single source of truth for medicinal product data

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Vision

To make available, for human and machine interaction, ***structured, standardised and consistent authorised product data*** *from across the European Medicines Regulatory Network.*

PMS data will be used by regulators and industry in ***regulatory and non-regulatory procedures*** *as well for the general benefit of European citizens.*

Key changes

Enriched data set in ISO IDMP-compliant structure

Integrated data journey through regulatory procedures

Trustworthy and quality data in one single source

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Quality product data built into all new digital tools

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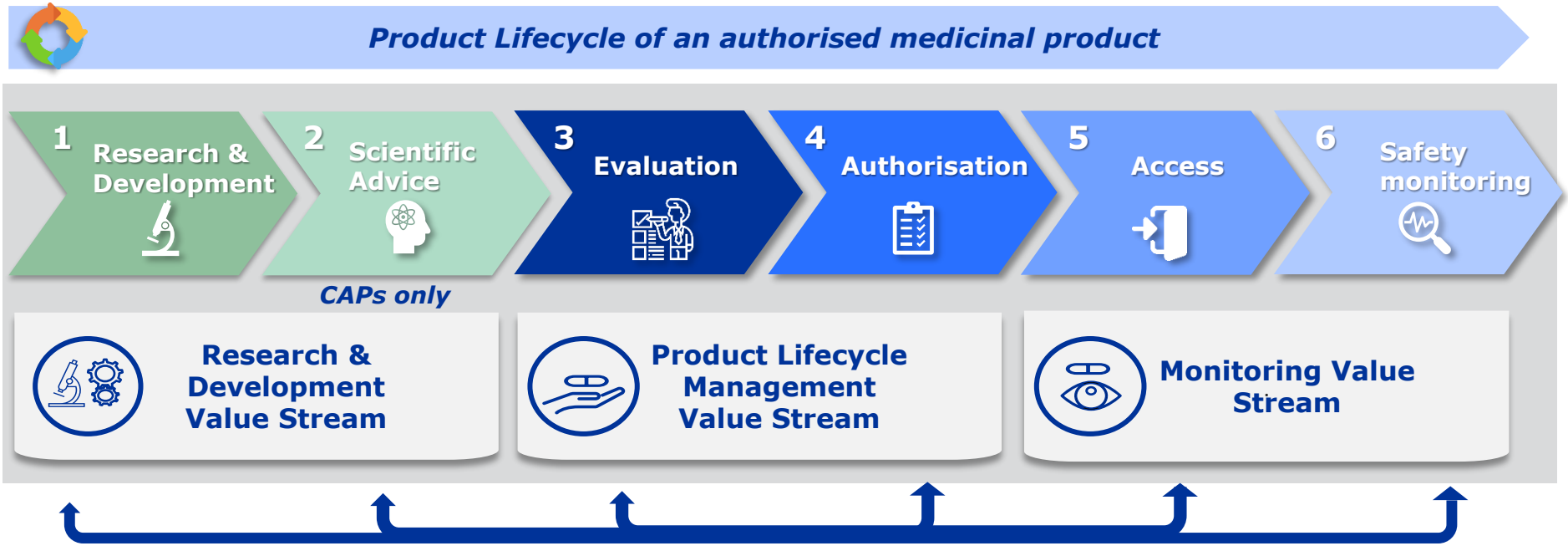

- **SPOR Master Data Management (S**ubstances, **P**roduct, **O**rganisations, **R**eferentials)
- **PMS: Product Management Services**

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Current focus: integrated product data for PLM & Monitoring VS

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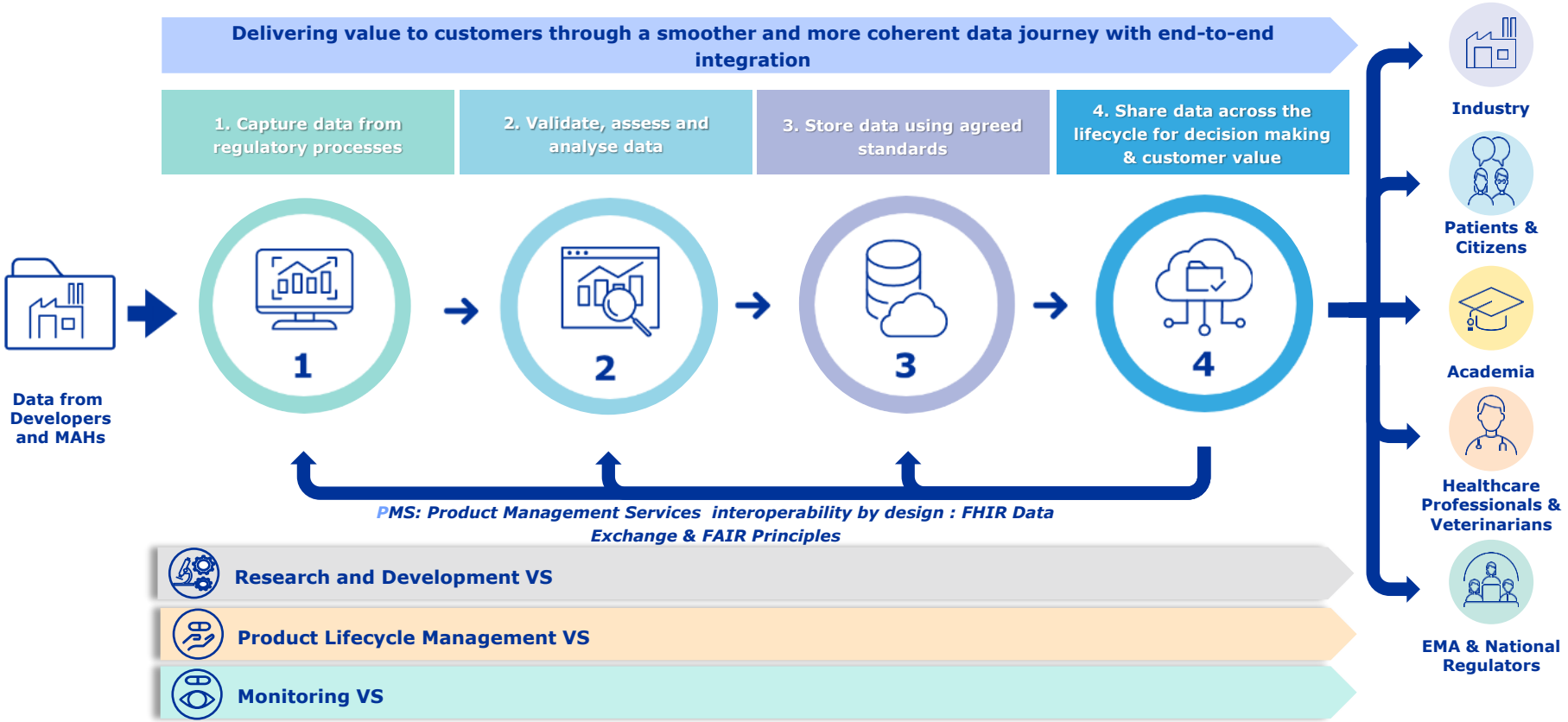

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PMS enables key VS systems to realise benefits

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Product Lifecycle Management VS Products

ePI

Up-to-date and easily accessible, authorised electronic product information in all available EU languages for all EU citizens

RPM

End-to-end Regulatory Procedure Management for CAP products for increase of efficiency, transparency and collaboration

eAF

Web-based, user-friendly forms, for H & V medicinal product applications enabling data integration

Product UI

Customer facing interface to access, review, update and enrich product data

PMS

Single source of truth for trustworthy , enriched, validated , **authorised medicinal product data**

Monitoring VS Products

ESMP

Prevention and management of human medicines shortages, ensuring availability of medicines during public health emergencies or major events

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EV Human

In transition to Value Stream

Manage and analyzing information on suspected adverse reactions to medicines which have been authorised or are being studied in clinical trials in the EEA

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Following the path of regulatory data (as-is & state by end 2024)

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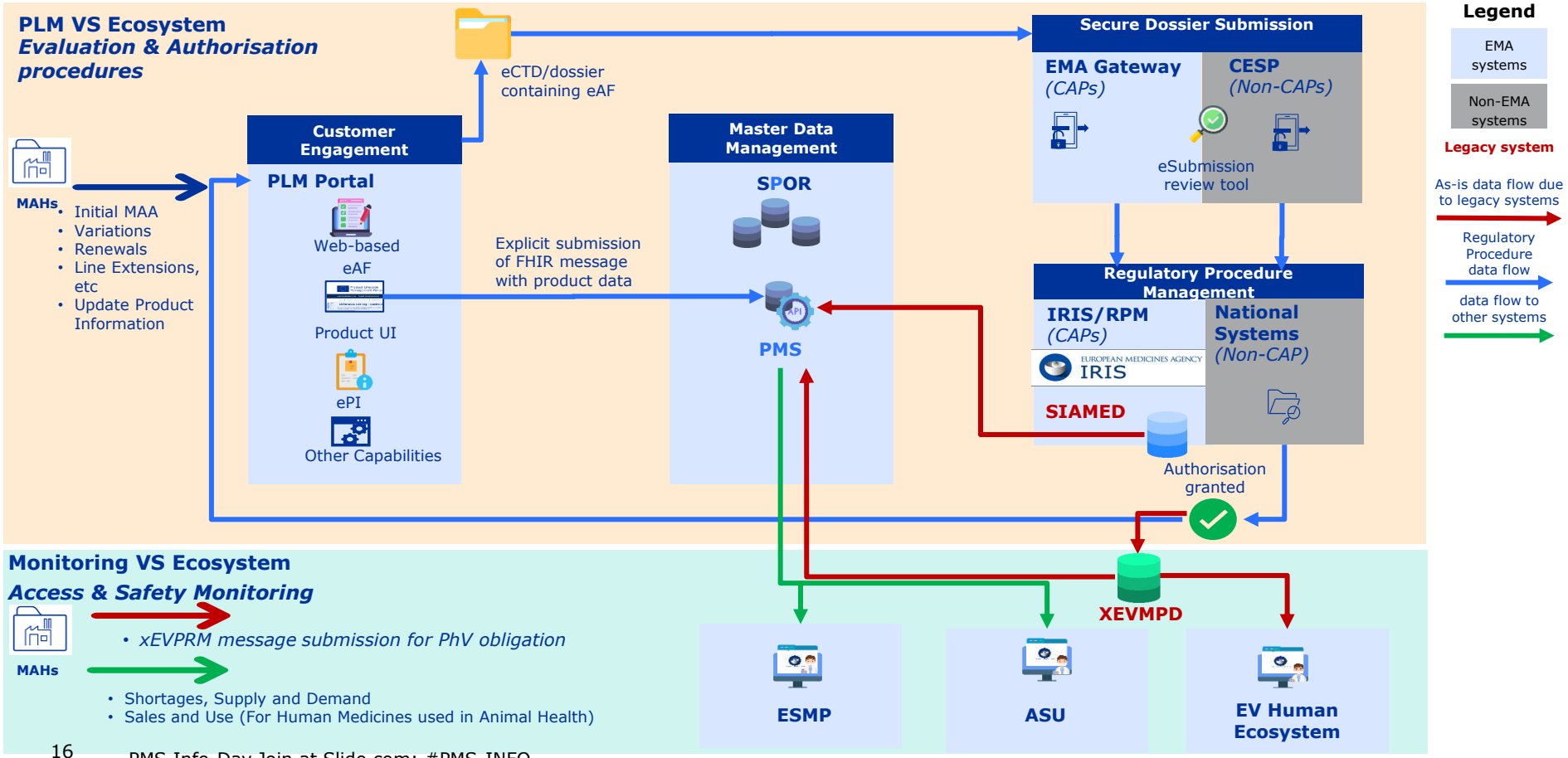

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Following the path of regulatory data (target state)

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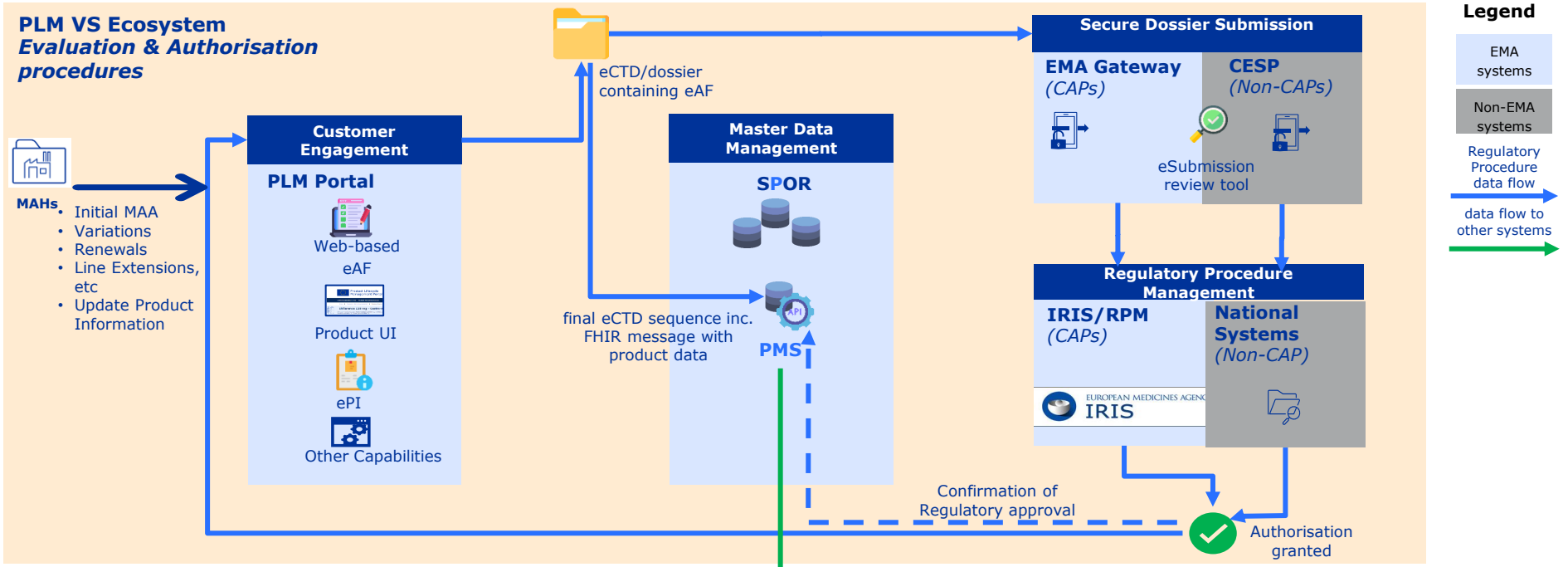

CESP: Common European Submission Portal

eCTD: electronic Common Technical Document

ICSRs: Individual Case Safety Reports

MAHs: Marketing Authorisation Holders

MAA: Marketing Authorisation Application

Benefits and business outcomes enabled by target state

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- **Integrated data quality steps** for more trustworthy data
- Open the door to data validation and **integration with NCA systems**
- **Support regulatory and non-regulatory procedures** with an enriched and validated data set
- **Better** and **faster decision making** based on increased data availability
- **Operational efficiencies** for regulators and industry
- Enable **Once-Only Principle – reducing/eliminating** separate submissions (xEVPRM)
- Enabling **simplified business and IT architecture** landscape for regulators and industry

Preparations for future work are underway

EMA's current focus:

- **Update the PMS business strategy** to enable the transition to ISO IDMP compatible submissions for product data throughout entire product lifecycle
- Accelerate the **replacement of legacy systems and interfaces**, including xEVMPD
- Further develop the **architecture for better customer and data journeys** throughout the lifecycle of medicines
- **Investigate options for use of PMS** in the research and development phase of medicines

How are we getting to our target state

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PMS will:
- Make data available – CAPs & NAPs
- Deliver capabilities to complete/enrich data (Manufacturers, pack sizes, data carrier)

Integrate PMS with business solutions:
- eAF variations
- RPM
- Critical Medicinal Products available in ESMP
- Human Medicinal Products subject to ASU reporting available in ASU

What's happening in 2024?

PMS will collect and improve missing/incomplete product data

PMS will deliver:
- Capabilities to create/edit all product data
- Capabilities to manage/improve Data Quality
- Enable XEVMPD replacement (TBC - Sync PMS to XEVMP data)

Integrate PMS with business solutions:
- eAF variations structured changes
- eAF Marketing Authorization Application (MAA)
- ePI linking to PMS (link to product & GTIN)

To be prioritised in 2025

PMS will deliver capabilities for NCA product data integration

PMS will improve Product data Quality gradually (completeness, consistency and accuracy)

Integrate PMS with eAF renewals, etc

Product data created/managed via regulatory procedures when all eAFs and regulatory processes integrated

Disable XEVMPD submissions for Authorised Medicinal Products

XEVMPD replacement for Investigational Medicinal Products and other XEVMPD capabilities

2026 and beyond

PMS enabling activities

Business solutions development to realise benefits

Takeaways

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1

- PMS is an enabler of the Network Portfolio and is addressing the **needs of the prioritised portfolio products** (eAF, RPM, ePI, ESMP, ASU)

2

- EMA is integrating PMS into its regulatory procedures in a **multi-year effort** using Agile methodology (building piece by piece as we learn)
- While replacing inefficient processes and old technology we are also **looking into future customer needs**, including the entire product lifecycle

3

Benefits and business outcomes are achieved **for** and **with the collaboration** of the **EMA, Network and industry**

Q&A session

On-site participants

- Raise your hand then ask your question orally (please unmute your microphone)
- We will answer **a few questions,** before checking online

Online participants

- **Join Slido.com** using this code **#PMS-INFO** or scanning the QR code here
- Ask your questions or vote the ones you would like to be answered
- We will read out **selected questions** that will be answered verbally

Break (10:20 – 10:40)

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Coffee break

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Product Management Service (PMS)
Quick recap

Veronica Lipucci Di Paola, EMA PMS Product Owner
Chair: Zaide Frias, Chair of the Network Portfolio Board *and Head of Digital Business Transformation Task Force*

PMS vision & key changes it brings

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Vision

To make available, for human and machine interaction, ***structured, standardised and consistent authorised product data*** *from across the European Medicines Regulatory Network.*

PMS data will be used by regulators and industry in ***regulatory and non-regulatory procedures*** *as well for the general benefit of European citizens.*

Key changes

Enriched data set in ISO IDMP-compliant structured data

Trustworthy and quality data in one single source

Integrated data journey through regulatory procedures

What will PMS deliver (1/2)

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Product Management Service focuses in making available:

What?

✓ **In scope: Authorised Medicinal Product data** for **Human use** only.

✗ **Out of scope:**

- Authorised Medicinal Product data for Veterinary use is managed in Union Product Database (UPD)
- Investigational Medicinal Products (IMP) are managed in XEVMPD (at this stage)

How?

- Product data is **structured**, **standardised** and **consistent** as per **ISO IDMP standards 11616** and business rules specified in **EU Implementation Guide.**
- Product data is accessible for **human and machine interactions** through the **Product User Interface** and **PMS Application Programming Interface**, as well as **several EMA systems** re-using this data (e.g. eAF, ESMP)

What will PMS deliver (2/2)

Product Management Service focuses in making available:

Where from?

- Product data originates from across the **European Medicines Regulatory Network**
- **CAPs** data taken from EMA Database (SIAMED) and matched and merged with **XEVMPD; NAPs** data taken from XEVMPD only
- Specific PMS data elements not present in XEVMPD/SIAMED can be enriched by MAHs
- Exploration of potential NCA data upload and prospective data validation

Whom?

- PMS data can be **accessed and used by Regulators and MAHs** to fulfil their legal obligations
- **Limited** PMS dataset can be accessed by the **General Public** (e.g. Patients, EU citizens, HCP) through **public PMS API** and **PUI Portal**

Why?

- Reusing within **regulatory and non-regulatory procedures** (e.g. eAF, RPM, ESMP, PhVig, etc)
- Enabling the **identification of medicinal products (IDMP)**, allowing everyone to align to one standard set of rules and exchange product data more efficiently across the European Medicines Regulatory Network
- Achieving more **transparency for the general benefit of European citizens** (PMS API/PUI, Medicine WebPortal)
- Enable to the generation of **Global PhPID** and other use cases

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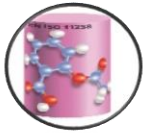
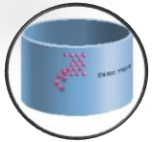
Introduction to IDMP



SMS Ibuprofen

RMS Tablet
Oral Use
Blister

RMS 200 mg



PMS Tablet of 200 mg of ibuprofen

PMS

30 Tablets of 200 mg of ibuprofen
Oral Use
Blister Alu/Alu
Indicated for pain
Authorised in Spain
MAH is ORG123

PMS will be consuming master data from the other three domains (**S,O & R**) to be able to uniquely identify medicinal products

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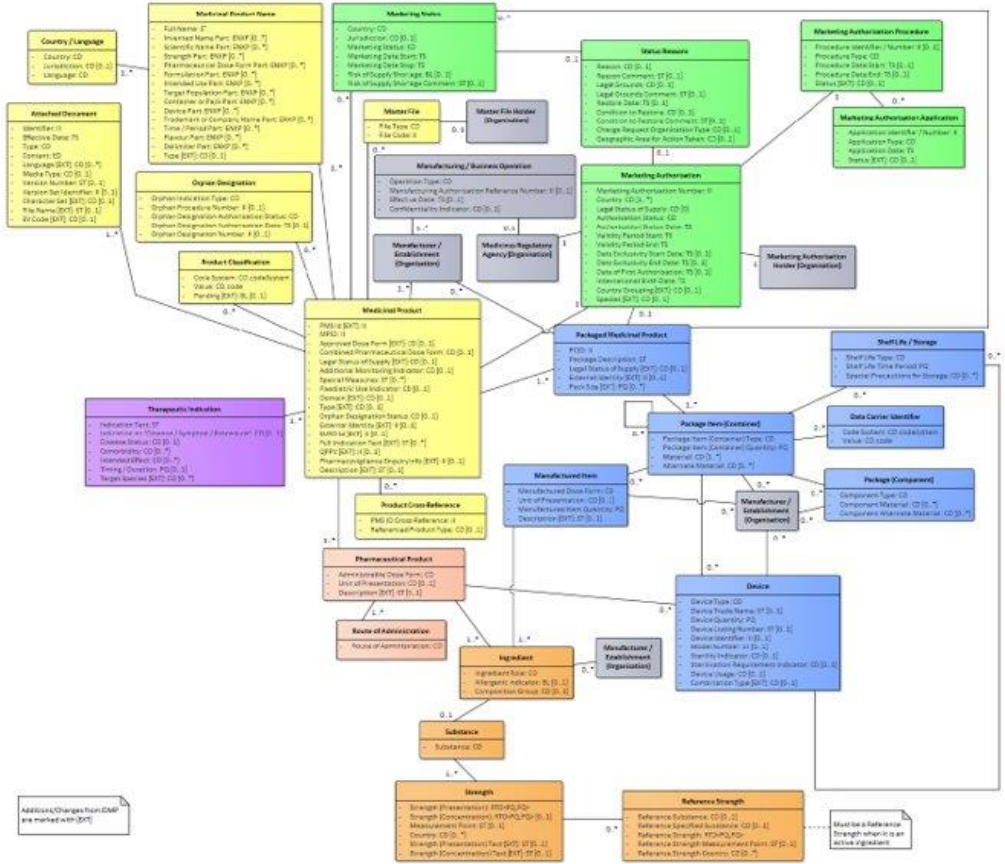
PMS Data model



- The PMS data model contains **more than 180 fields**.
- All of them can be found in **Chapter 2** of the **EU Implementation Guideline (EU IG)** together with the information on their conformance, repeatability, RMS lists linked to each field, business rules, etc.
- PMS is implementing a data model for **Authorised Medicinal Products** that is compliant with ISO IDMP however only a subset of fields from ISO IDMP are implemented.

Colour legend

- Medicinal Product definition
- Regulated Authorisation (Marketing Authorisation)
- Manufacturer / Organisation definition
- Therapeutic indication
- Packaged Medicinal Product Definition
- Pharmaceutical Product
- Ingredient

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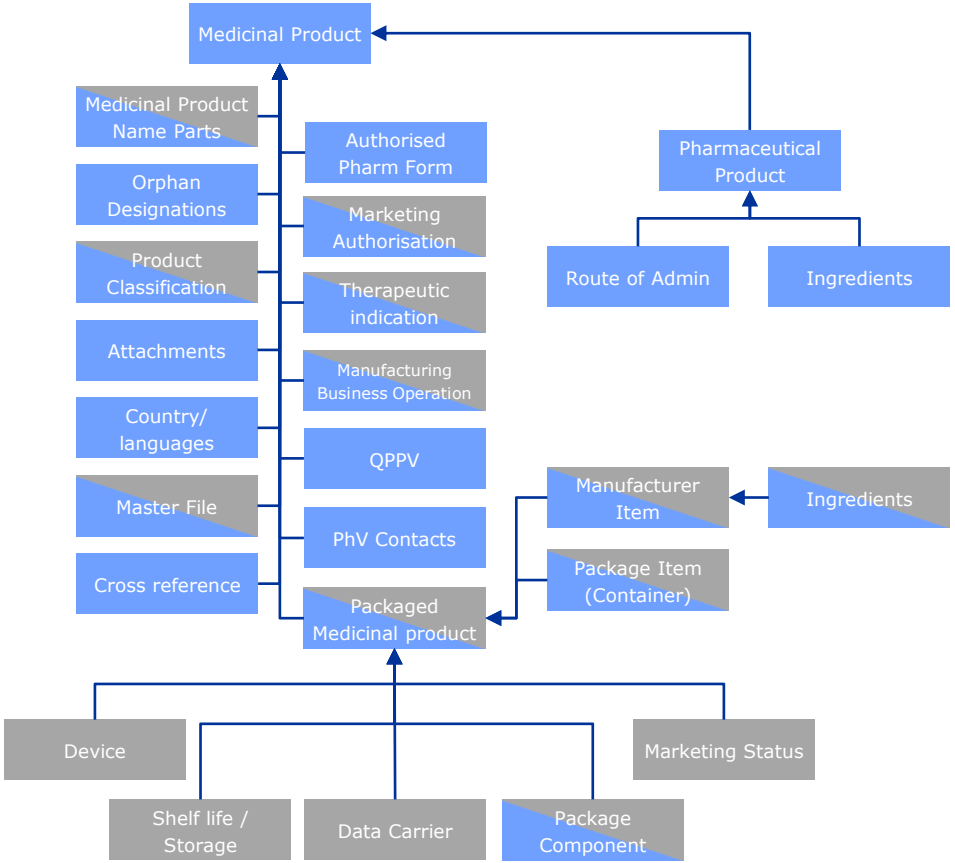
PMS Data model fields sources

The PMS data model will be completed with data from both SIAMED and XEVMPD.



Data in PMS

Data not available & to be enriched by MAHs

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electronic Application Form (eAF)

Kristiina Puusaari, EMA eAF Product Owner

Noel Diamant, Network eAF Product Owner

Chair: Zaide Frias, Chair of the Network Portfolio Board *and Head of Digital Business Transformation Task Force*

PMS enabling key VS products

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Product Lifecycle Management VS Products

ePI

Up-to-date and easily accessible, authorised electronic product information in all available EU languages for all EU citizens

RPM

End-to-end Regulatory Procedure Management for CAP products for increase of efficiency, transparency and collaboration

eAF

Web-based, user-friendly forms, for H & V medicinal product applications enabling data integration

Product UI

Customer facing interface to access, review, update and enrich product data

PMS

Single source of truth for trustworthy , enriched, validated , **authorised medicinal product data**

Monitoring VS Products

ESMP

Prevention and management of human medicines shortages, ensuring availability of medicines during public health emergencies or major events

ASU

European surveillance for sales and use data of antimicrobials in animals to detect patterns and help develop measures against antimicrobial resistance

EV Human

In transition to Value Stream

Manage and analyzing information on suspected adverse reactions to medicines which have been authorised or are being studied in clinical trials in the EEA

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eAF vision & key changes

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Vision

*Streamline **user-friendly data input** for marketing authorisations, variations, and renewals, maintain **consistency in IT systems** and provide **high-quality ISO IDMP compliant information**, through the **creation of web-based forms for Human & Veterinary medicinal product applications***

Key changes

New web-based eAFs

Use of ISO IDMP/ FHIR compliant structured data

Streamlined & simplified processes

Using PMS data to support Regulatory applications (eAF)

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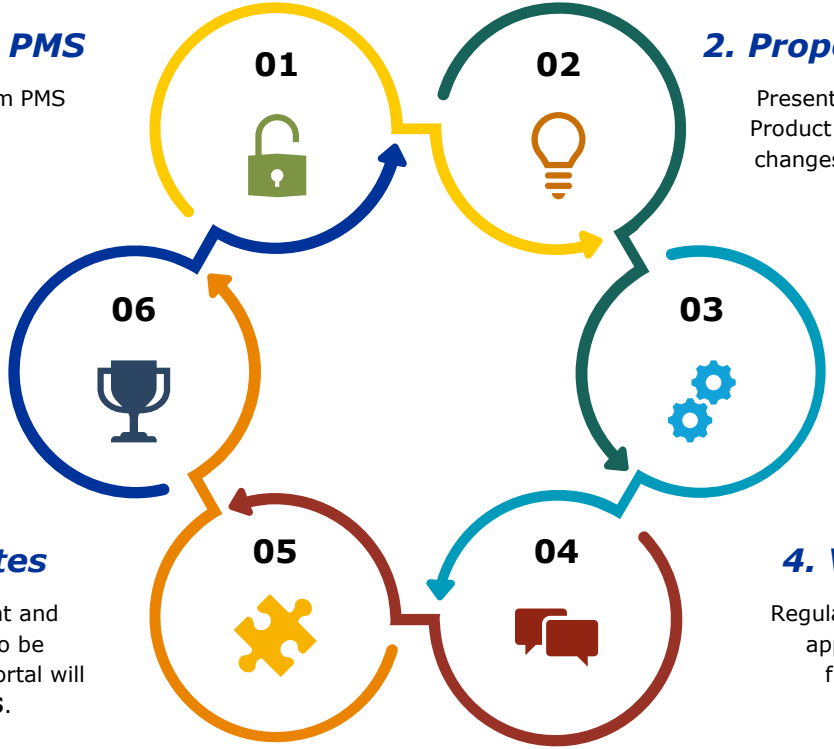
1. Load Product from PMS

The eAF uses mastered data from PMS

2. Propose changes in the eAF

Present data is shown in the eAF via the Product UI and the applicant can propose changes that fit the Scope of the change



3. Submit eAF with eCTD to EMA & NCAs

The eAF is packaged in an eCTD and submitted to all case management systems via Gateway or CESP

4. Validate & Assess data

Regulators validate and assess the data in the application. Changes to the product are finalized together with the applicant

5. Resolve parallel updates

In case of parallel variations or enrichment and variations updates to the product need to be consolidated. Opening the eAF in the PLM portal will include the **latest update from PMS**.

6. Submit data to PMS

The eAF containing the valid proposed product data is transformed to fit the PMS API and submitted.

PMS Data in eAF (prepared for full release)

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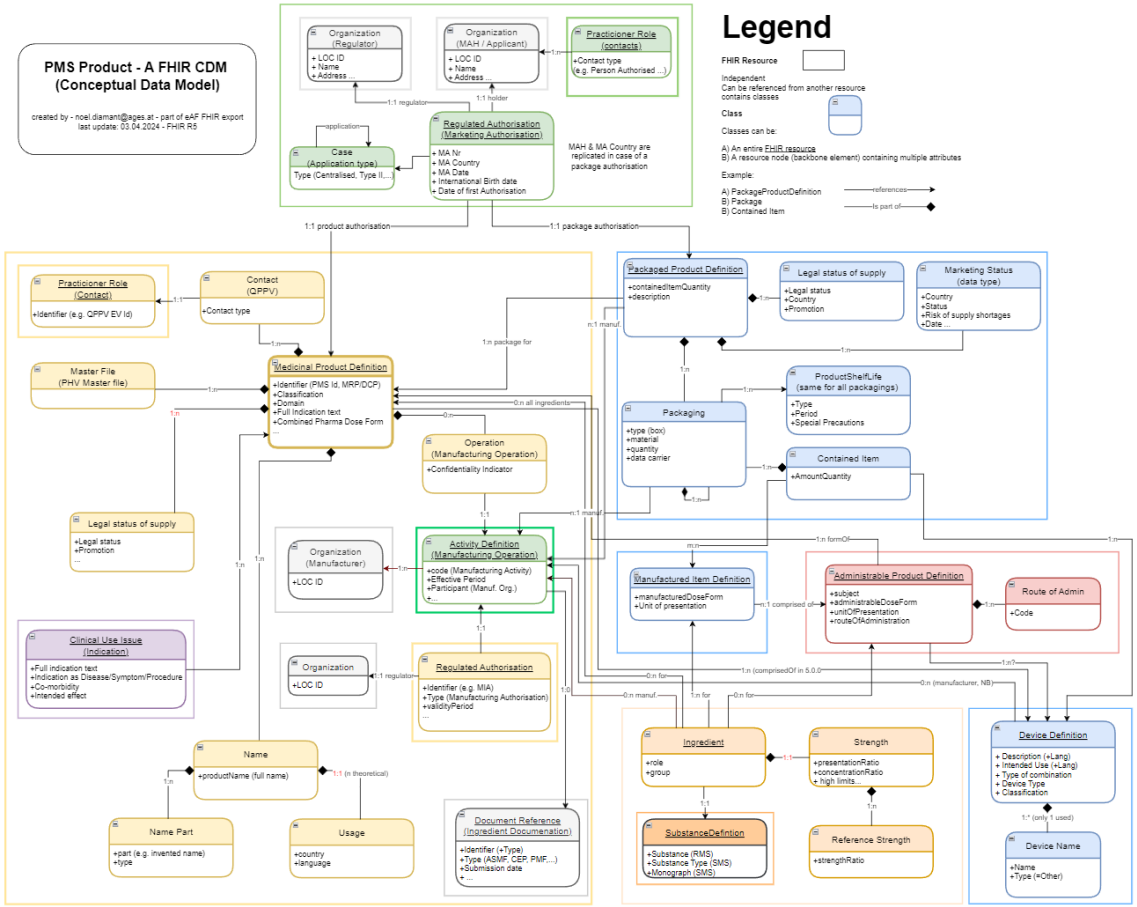
Longterm Vision

The eAF will be able to create/change any part of the product

Live today we start by reading PMS and ~ 15 data elements



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PMS Data in eAF (used today)

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Medicinal Product

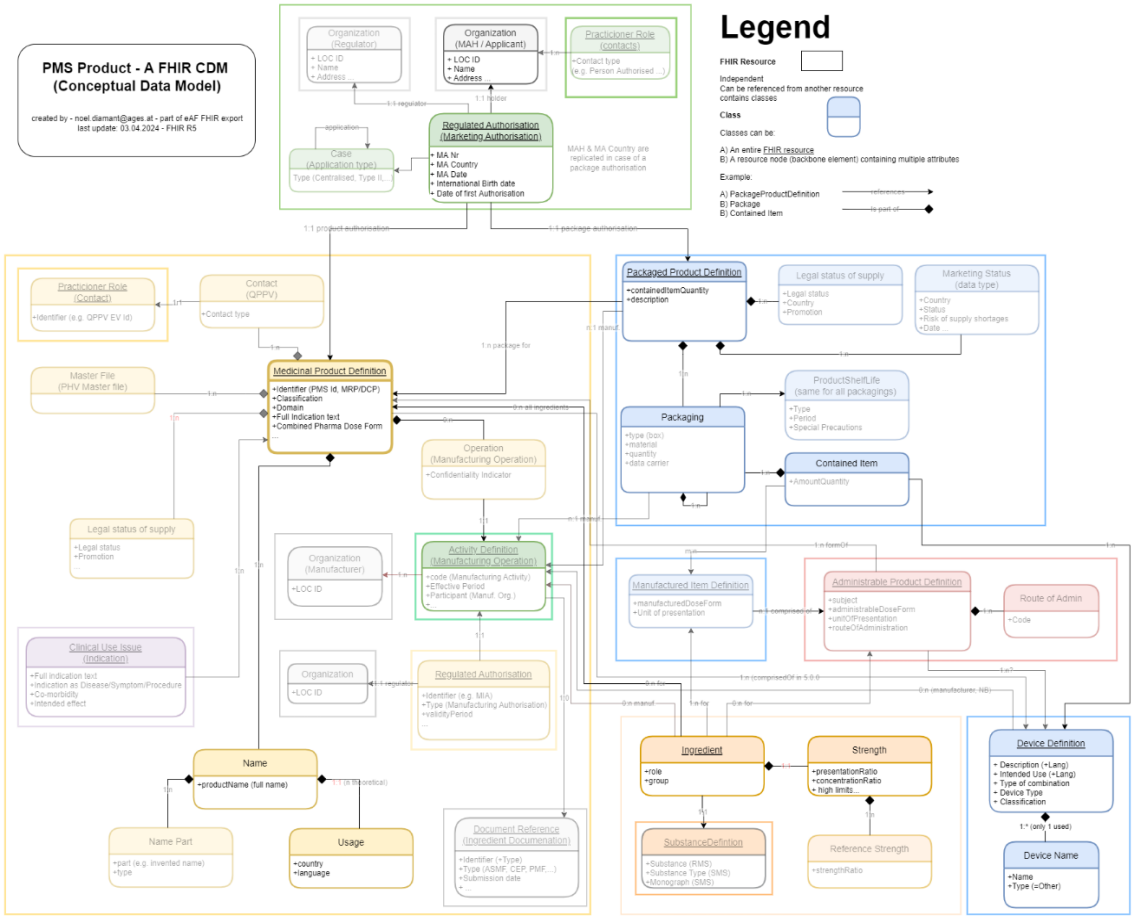
- ✓ Full Name
- ✓ Authorised Dose Form
- ✓ Active Substance
- ✓ Authorisation Country
- ✓ Authorisation Status
- ✓ Authorisation Number
- ✓ MA Holder Details
- ✓ MRP/DCP/CP Nr.
- ✓ PMS ID
- ✓ MP ID

Package

- ✓ ID
- ✓ MA Nr.
- ✓ Pack size
- ✓ Pack description
- ✓ Authorisation status

Other…

- ✓ Medical Device
- ✓ ATC, GMO (as a proof of concept) – will be replaced



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eAF benefits of using PMS data

- Ensure **data consistency** across the EMRN
- Long-term **increase in PMS data quality** by using PMS products in regulatory processes
- **Reduce manual data entry** by using PMS attributes to calculate procedure related information
- WYSIWYG principle for requesting product changes
  → **W**hat **Y**ou **S**ee **I**s **W**hat **Y**ou **G**et

electronic Product Information (ePI)

Elizabeth Scanlan, EMA ePI Product Owner

Chair: Zaide Frias, Chair of the Network Portfolio Board *and Head of Digital Business Transformation Task Force*

PMS enabling key VS products

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In transition to Value Stream

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ePI vision & key changes

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Vision

*Make available **up-to-date and easily accessible, regulator-authorised electronic product information** on safe and effective use of human medicines in all available EU languages for all EU citizens*

Key changes

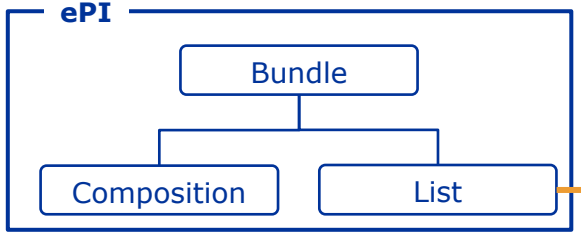
Harmonised ePI on medicines within EU

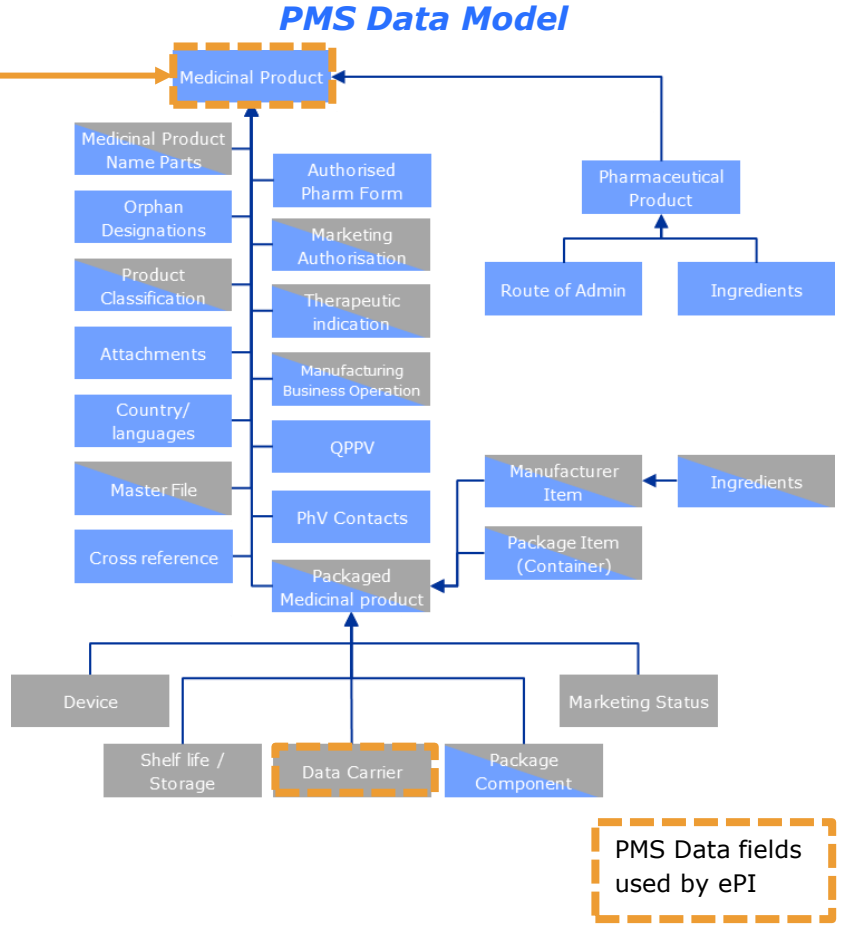
Product Information stored in FHIR and freely available via API

ePI facilitates access to PI in different languages

How ePI uses PMS data

- ePI will be linked to the relevant medicinal product(s) enabling consuming systems to leverage both ePI data and product data from PMS
- ePI documents (e.g., PL, SmPC) will be associated with the relevant GTINs using the Data Carrier field enabling use of ePI data in applications linking to ePI by scanning the data matrix code on the medicine package





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Using PMS data to link the package to the leaflet

Potential scenario demonstrating how ePI and PMS data can facilitate linking electronic information for consumers to the medicine package.

Existing DMC on package carrying GTIN

Scan with camera

Scan with app

Match GTIN to product information

Package leaflet displayed to patient

Content generated with data from EMA-HMA-EC FHIR ePI repository

ePI benefits of using PMS data

- **Facilitating search within and across data** — PMS data can be searched within and across products and linked product information in the desired language
  - *Search for medicines by active substance/strength/form and provide package leaflet to patient in preferred language*
  - *Search all medicines with same active substance and compare sections of interest of the package leaflet such as fertility, pregnancy and lactation*
- **Linking from the medicine package to ePI** — apps scan the data matrix code on the medicine package to display the electronic package leaflet and summary of product characteristics
  - *Apps for users who want to access medicines information from their phone/device*
  - *Apps providing accessible information eg read-aloud information*

Regulatory Procedure Management (RPM)

Madalina Duta-Mare, EMA RPM (for PLM) Product Owner

Chair: Zaide Frias, Chair of the Network Portfolio Board *and Head of Digital Business Transformation Task Force*

PMS enabling key VS products

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RPM for PLM vision & key changes

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Vision

*Enhance **end-to-end medicinal product lifecycle management in IRIS platform** for Centrally Authorised Products by improving efficiency, data quality and collaboration, thus facilitating easier and secure access to information.*

*It enables **consistency of data** in an end-to end information flow by **exchanging and reusing ISO IDMP data** across IT systems*

Key changes

New cloud-based technology

Standardised functionalities for Human and Vet & automated checks

Re-use of SPOR master data

How RPM for PLM uses PMS data

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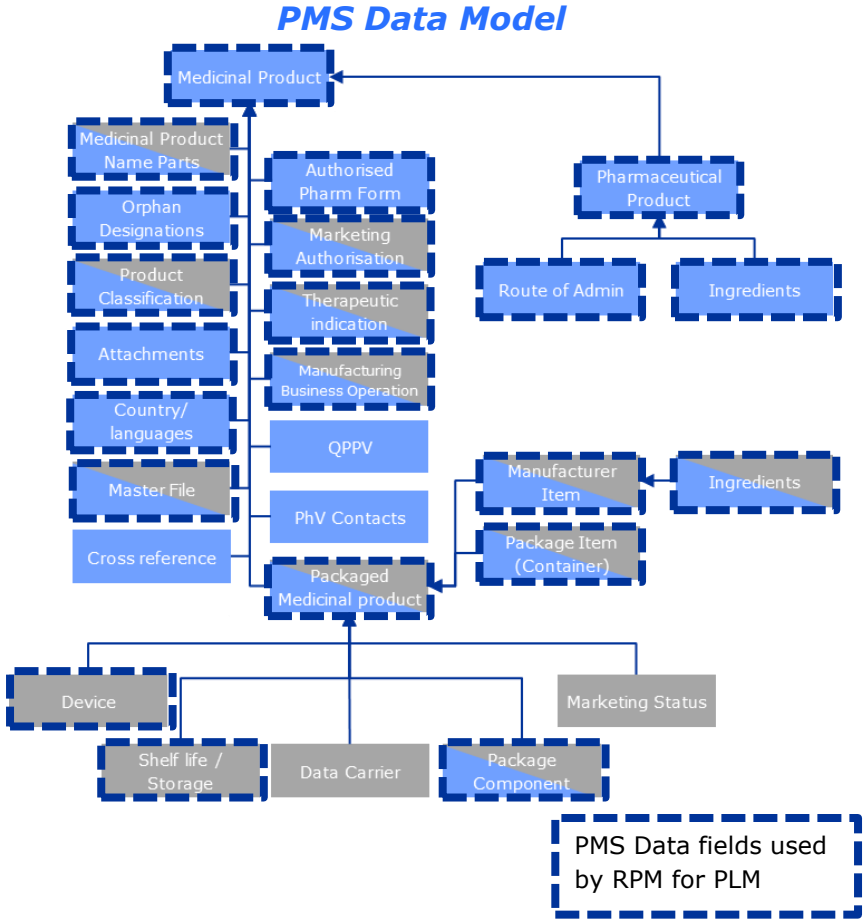
- PMS will be used to retrieve product data for regulatory procedures applications & case management;
- Any part of the product data can be subject to a change;
- following a regulatory outcome, the updated product data is stored in PMS



PMS Info-Day Join at Slido.com: #PMS-INFO

Using PMS data to support regulatory procedures

EUROPEAN MEDICINES AGENCY

Potential scenario demonstrating how PMS data is used to fill in application forms and within case management

PMS Data

Fill in the applications forms (eAF, IRIS Portal) required for **submission of regulatory procedures applications** (e.g., variations, PSUR, etc.)

EUROPEAN MEDICINES AGENCY
IRIS

Evaluation of the submitted data, with no need to cross validate the application forms against the product data → **fewer validation issues caused by the data inconsistencies.**

Outcome will be reflected on the product via a single **PMS update (in Product UI)** → **no duplication of work for data entry.**

RPM for PLM benefits of using PMS data

- **Transparency and security:** secure access and real-time data available for relevant stakeholders in a synchronised manner among various systems
- **Quality and consistency of data:** re-use and update master data will reduce duplication of work and errors due to manual operations (e.g., data entry) thanks to single data source throughout systems and regulatory processes (handle and store data in a reliable manner)
- **Efficiency:** Availability of data for non-centrally approved products will enable EMA-led procedure management with accurate overview of all products involved (e.g. Variations, PSUSA, Referral, PASS); no need to perform data validations across systems (e.g. eAF and case management information)

European Shortages Monitoring Platform (ESMP)

Sofia Zastavnik, EMA ESMP Product Owner

Chair: Zaide Frias, Chair of the Network Portfolio Board *and Head of Digital Business Transformation Task Force*

PMS enabling key VS products

EUROPEAN MEDICINES AGENCY

Product Lifecycle Management VS Products

ePI

Up-to-date and easily accessible, authorised electronic product information in all available EU languages for all EU citizens

RPM

End-to-end Regulatory Procedure Management for CAP products for increase of efficiency, transparency and collaboration

eAF

Web-based, user-friendly forms, for H & V medicinal product applications enabling data integration

Product UI

Customer facing interface to access, review, update and enrich product data

PMS

Single source of truth for trustworthy , enriched, validated , **authorised medicinal product data**

Monitoring VS Products

ESMP

Prevention and management of human medicines shortages, ensuring availability of medicines during public health emergencies or major events

ASU

European surveillance for sales and use data of antimicrobials in animals to detect patterns and help develop measures against antimicrobial resistance

EV Human

In transition to Value Stream

Manage and analyzing information on suspected adverse reactions to medicines which have been authorised or are being studied in clinical trials in the EEA

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ESMP vision & key changes

EUROPEAN MEDICINES AGENCY

Vision

*ESMP will enable i**nformation exchange for better prevention, identification and management of shortages, and communication between the EMA**, and Stakeholders in the supply chain medicinal products, **in order to ensure medicines are available for patients during PHEs/MEs**.*

Key changes

Accelerate the decision-making process

Increase efficiency and predictability

Mitigate impact on patients

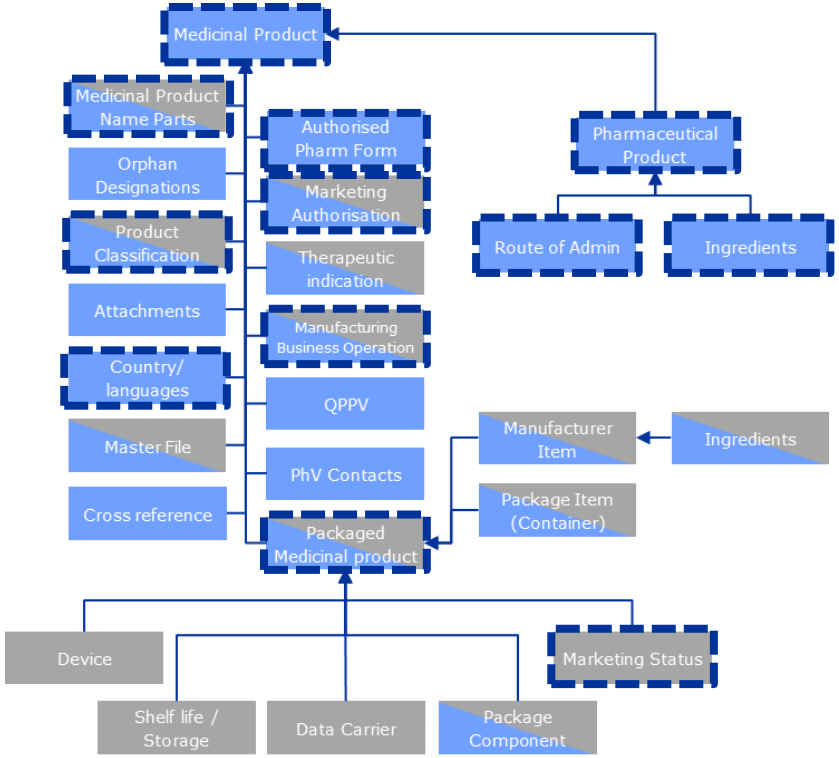
How ESMP uses PMS data (1/2)

PMS will be used to retrieve data on **medicinal products** to pre-populate reporting templates in the ESMP, to **facilitate data collection, insertion, analysis,** and **management**

Examples of data uses:

- **pack sizes** for precise data submission, linkage to Industry and NCA databases and quantitative data analysis in matching of supply and demand
- **ATC codes** to identify and classify products
- **manufacturing site** information to assess supply chain vulnerabilities
- **marketing status** information for medicine availability

PMS Data Model



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How ESMP uses PMS data (2/2)

EUROPEAN MEDICINES AGENCY

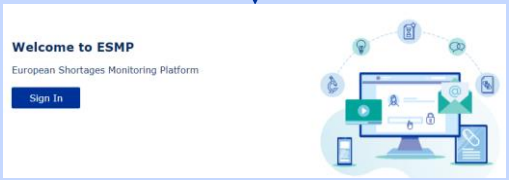
Member State data systems

NCAs report critical national shortages and provide data on demand for medicinal products in crisis and in preparedness situations

Industry data systems

MAHs perform routine shortage reporting and provide data on supply of medicinal products in crisis and in preparedness situations

ESMP



Users access ESMP and download reporting templates or submit data through machine-to-machine interface

Packaged medicinal product data (PMS)

Prefilled in ESMP templates/Machine-to-Machine

Users **complete ESMP templates** with availability information per product

ESMP Data Analytics platform

Matching of supply and demand data

Regulatory coordination

SPOC WP, MSSG, and EC

Measures to prevent, manage and mitigate shortages in EU/EEA, such as exploring MAHs supply capacity and possibility to increase production, regulatory support, etc.

Prevent, monitor and manage shortages

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ESMP benefits of using PMS data, required at pack level

- **Interoperability and streamlined data collection:** establishes a direct link to data across national and industry databases, enabling interoperability and seamless machine-to-machine data exchange, harnessing exiting data on the supply chain of products
- **Precise data analysis:** matching of supply and demand through quantitative data collected at the same granularity, facilitating data collection and analysis to foster harmonisation and precision
- **Data quality and consistency:** minimised duplication and errors through centralised and standardised EU product master data management
- **Efficiency and validation:** facilitated identification of products in scope of reporting requirements and enabled pre-population of product data in templates for ESMP data submission

Antimicrobial Sales and Use (ASU)

Anastasia Pickford, EMA ASU Product Owner

Chair: Zaide Frias, Chair of the Network Portfolio Board *and Head of Digital Business Transformation Task Force*

PMS enabling key VS products

EUROPEAN MEDICINES AGENCY

Product Lifecycle Management VS Products

ePI

Up-to-date and easily accessible, authorised electronic product information in all available EU languages for all EU citizens

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Monitoring VS Products

ESMP

Prevention and management of human medicines shortages, ensuring availability of medicines during public health emergencies or major events

ASU

European surveillance for sales and use data of antimicrobials in animals to detect patterns and help develop measures against antimicrobial resistance

EV Human

In transition to Value Stream

Manage and analyzing information on suspected adverse reactions to medicines which have been authorised or are being studied in clinical trials in the EEA

PMS Info-Day Join at Slido.com: #PMS-INFO

ASU vision & key changes

EUROPEAN MEDICINES AGENCY

Vision

*A **reference European surveillance system** for EU/EEA member states to **submit data on sales and use of antimicrobials in animals**, enabling data intelligence to detect patterns and help develop **measures against antimicrobial resistance**, thus contributing towards the One Health goal of safeguarding animal and public health.*

Key changes

Enhanced data collection of sales and use of antimicrobial in animals

Reduced administrative burden due to integration with other IT systems (UPD, PMS)

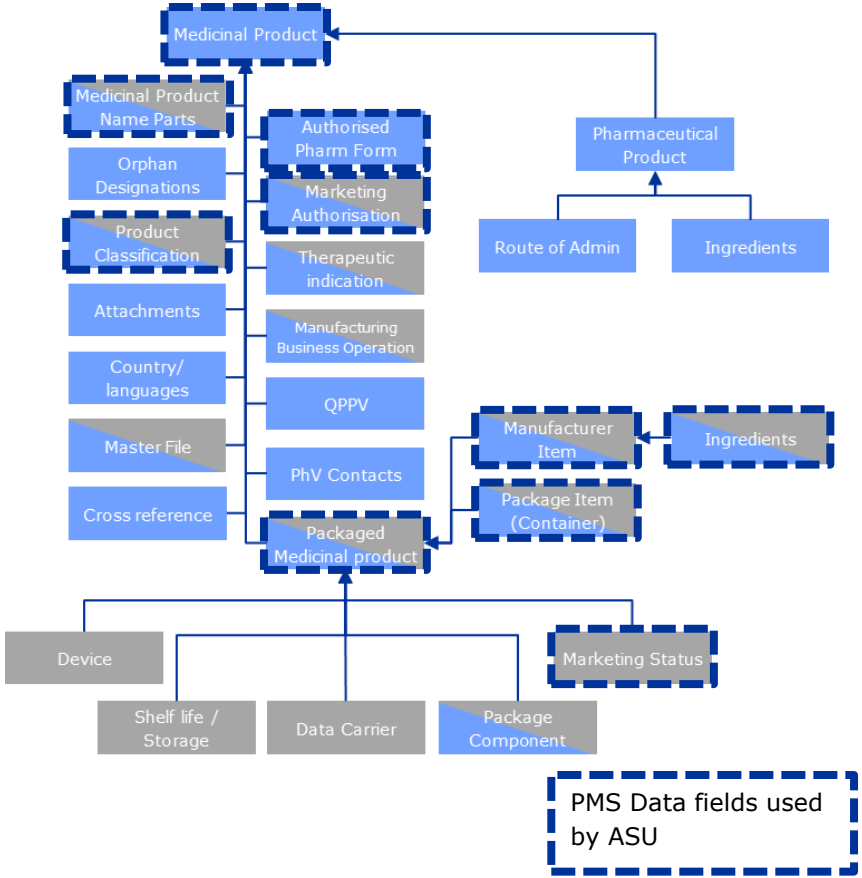
Improved data analytics and reporting gained via integrated Power BI application.

How ASU use PMS data

- As per Art. 57 of Reg. (EU) 2019/6, Member States **shall report to the Agency data on the use of antimicrobial in animals** and this includes use of any human antimicrobial medicinal product that may have been prescribed to animals as per Articles 112, 113 and 114 of the same regulation.

- ASU will enable all users **to search across all human medicinal products that fall in the ASU reporting scope** to pick the ones they want to report on.

PMS Data Model



PMS Info-Day Join at Slido.com: #PMS-INFO

Using PMS data to analyse Antimicrobial Use

EUROPEAN MEDICINES AGENCY

Member State National data collection systems

Member States collect data on sales and use of antimicrobials in animals in their national data collection systems

Antimicrobial Sales and Use (ASU) Platform

EUROPEAN MEDICINES AGENCY
UNION PRODUCT DATABASE

Home ASU Logout

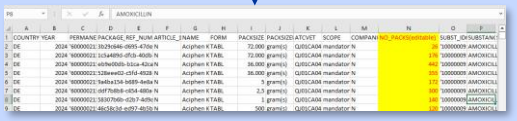
Users access ASU Platform and download the sales and use data templates

Veterinary Medicinal Products (UPD)

Prefilled in ASU templates

Human Medicinal Products (PMS)

Searched for and added to ASU Use data templates by the users



Users **complete ASU templates** with number of packs sold/used per product

Antimicrobial Sales and Use (ASU) Power BI

Power BI

Data validated and analysed in ASU Power BI application

Data Publication

Data published in annual report and public database

Monitor trends

Monitor trends of use of antimicrobials in animals in the EEA as part of One health EU strategy against the spread of antimicrobial resistance

PMS Info-Day Join at Slido.com: #PMS-INFO

ASU benefits of using PMS data

- **Compliance with legal requirements**
- **Collection of data and monitoring of trends of use of antimicrobial HMPs in animals** for the first time (e.g., the amount of antimicrobial HMPs used in animals, in which species and of which antimicrobial substances/classes).
- Availability of good-quality PMS data will enable the **collection of data on use of antimicrobial HMPs in animals via the ASU Platform** and their analyses in the ASU Power BI application
- **The data collected via ASU will serve as a basis to help guide decision-making** and the development of measures against antimicrobial resistance.

Q&A session

On-site participants

- Raise your hand then ask your question orally (please unmute your microphone)
- We will answer **a few questions,** before checking online

Online participants

- **Join Slido.com** using this code **#PMS-INFO** or scanning the QR code here
- Ask your questions or vote the ones you would like to be answered
- We will read out **selected questions** that will be answered verbally

Lunch break arrangements

Network representatives:

Lunch served in the canteen on the 2nd floor. Payment by card.

Option 1) Consume lunch at the canteen

Option 2) Consume your lunch at the Industry lounge. In that case, please opt for lunch that can be carried without the tray.

Industry representatives:

Industry lunch arranged in Industry lounge on ground floor, where the set menu is being served. *E-mail has been sent regarding the menu and the payment.*

Please gather in front of the meeting room where the host is awaiting to escort you to the Industry lounge. Note you need to be accompanied by the host at all times in the building.

Break (12:00 – 13:00)

EUROPEAN MEDICINES AGENCY

Lunch break

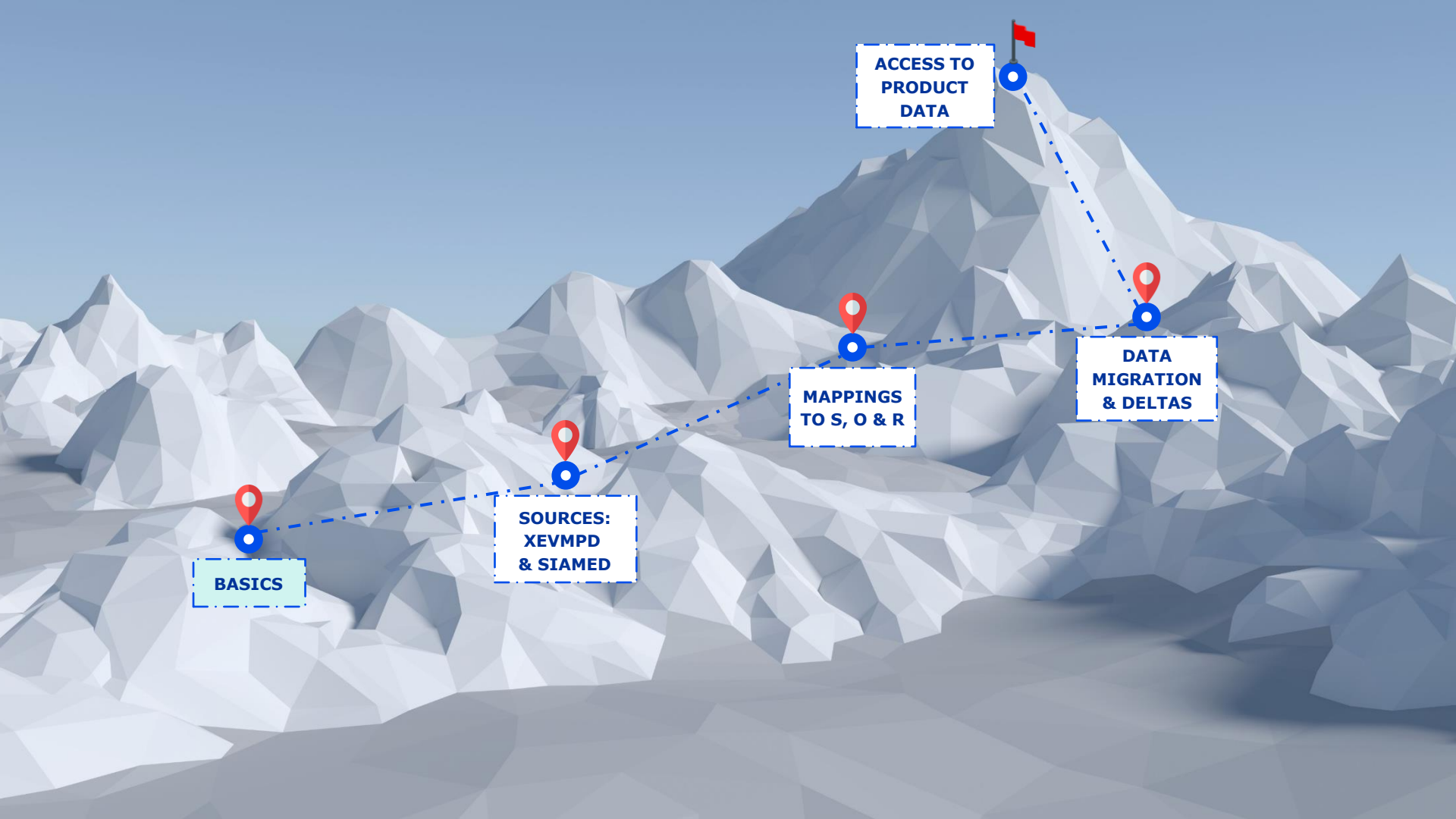
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

How is PMS enabling value

Marcos Fernandez, EMA PMS Product Owner

Chair: Alexis Nolte, SPOR *Business Owner* & *Head of Human Medicines Division*

PMS Info Day


ACCESS TO PRODUCT DATA
DATA MIGRATION & DELTAS
MAPPINGS TO S, O & R
SOURCES: XEVMPD & SIAMED
BASICS

Introduction

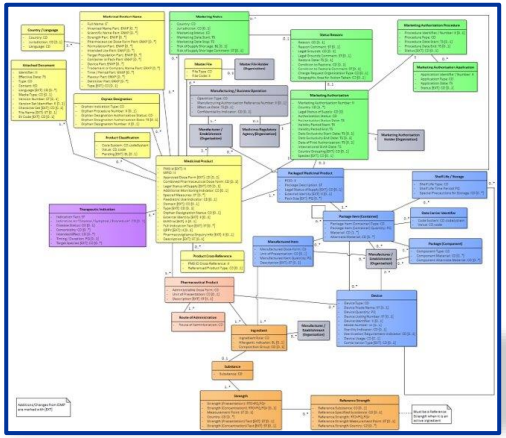
PMS vision

Vision

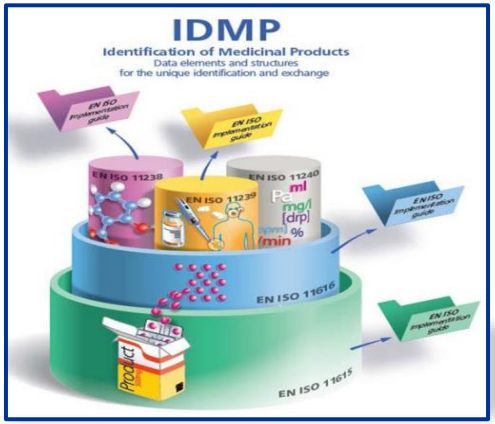
*Product Management Service (PMS) will make available, for human and machine interaction, **structured, standardised and consistent authorised product data** from across the European Medicines Regulatory Network.*

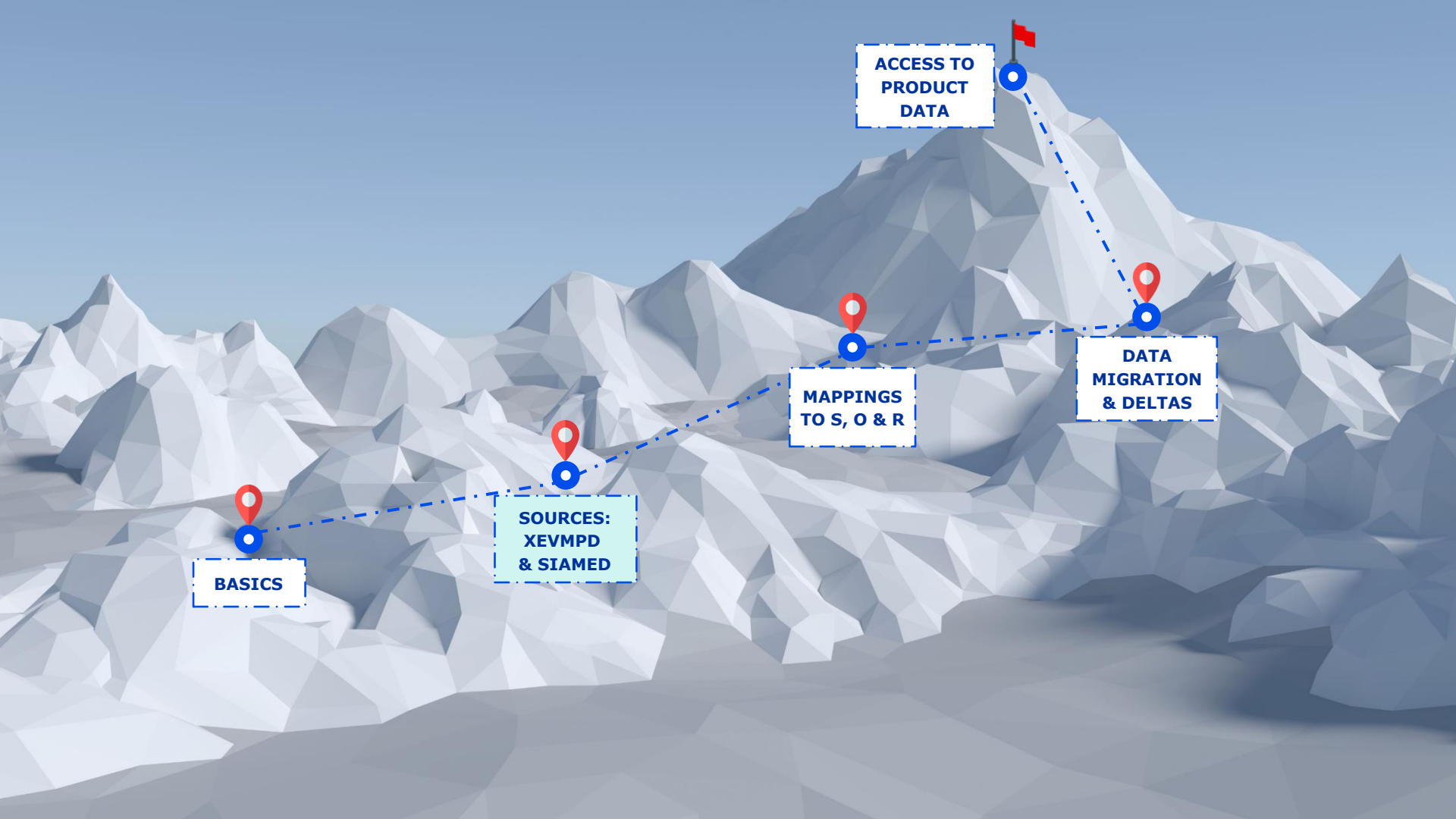
*PMS data will be used by regulators and industry in **regulatory and non-regulatory procedures** as well for the general benefit of European citizens.*

PMS data model



ISO standards

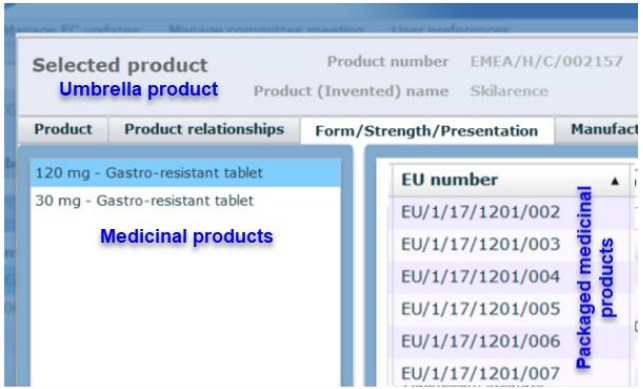



ACCESS TO PRODUCT DATA
DATA MIGRATION & DELTAS
MAPPINGS TO S, O & R
SOURCES: XEVMPD & SIAMED
BASICS

Data sources

SIAMED II is the internal EMA database and contains all centrally authorised medicinal products authorised in the EU.

In SIAMED II, a "product" is an umbrella term which can contain several IDMP medicinal products, and each medicinal product can contain multiple presentations.



EUROPEAN MEDICINES AGENCY

XEVMPD is a database maintained by marketing authorisation holders and contains central and national medicinal products authorised in the EU and EEA.

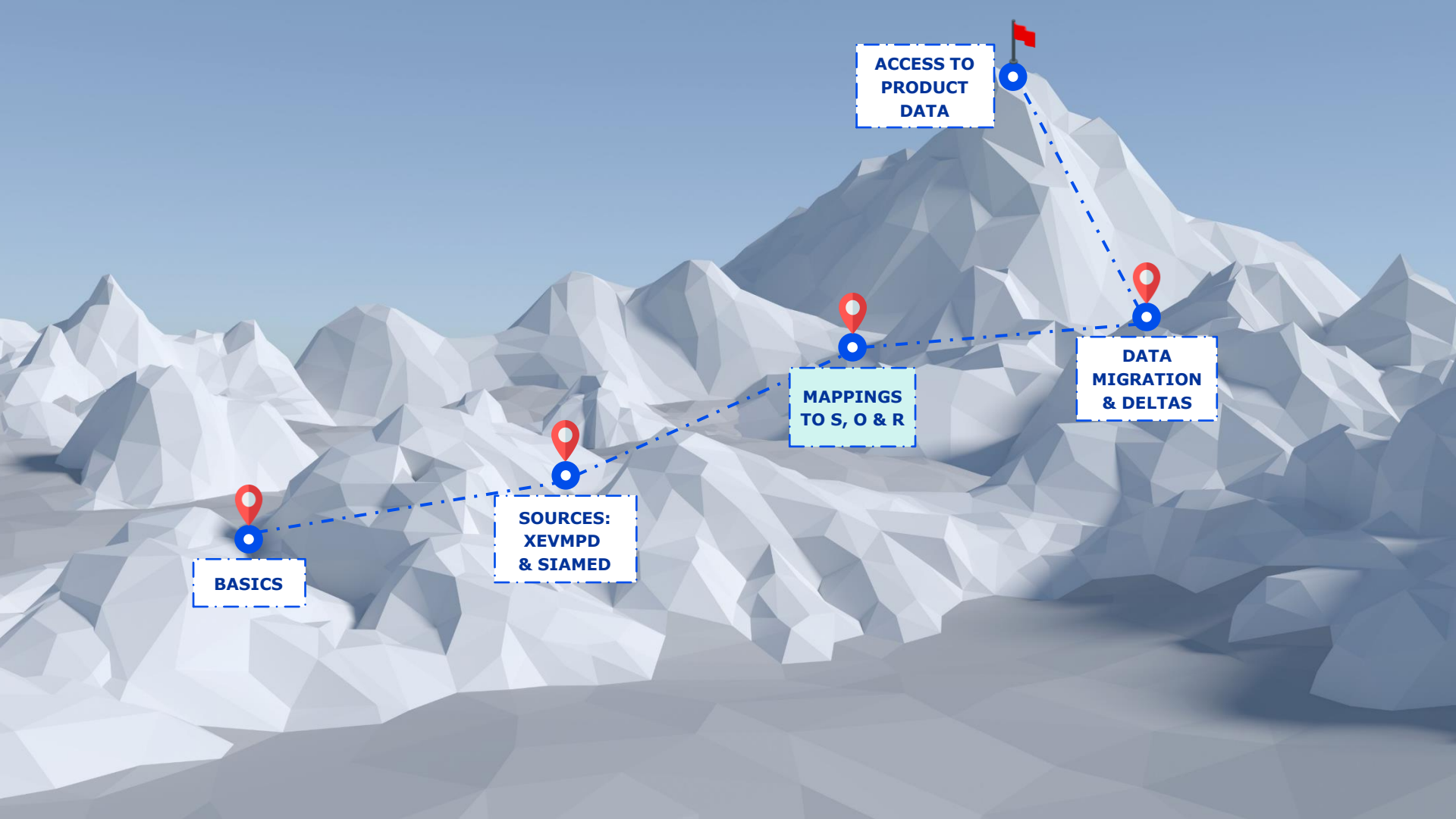
This database is maintained following the Art. 57 legal obligation and medicinal products can be submitted following different strategies and business rules explained in Chapter 3.II: XEVPRM User Guidance

Authorisation Country	Substance names	Pharmaceutical For	Full Presentation Nam	Authorisation Number
Romania	CROSPOVIDONE, LACTOSE MONOHYDRATE, MAGNESIUM STEARATE, SILICA, CO	TABLET	Flamexin, 20 mg, comprimate	7146/2006/03
Romania	CROSPOVIDONE, LACTOSE MONOHYDRATE, MAGNESIUM STEARATE, SILICA, CO	TABLET	Flamexin, 20 mg, comprimate	7146/2006/01
Romania	CROSPOVIDONE, LACTOSE MONOHYDRATE, MAGNESIUM STEARATE, SILICA, CO	TABLET	Flamexin, 20 mg, comprimate	7146/2006/02

Authorisation Country	Substance names	Pharmaceutical Form	Full Presentation Name	Authorisation Numbe
Spain	HYDROGENATED VEGETABLE OIL, HYDROXYPROPYL DISTARCH PHOSPHAT PROLONGED-RELEASE TABLET		DOLPAR 300 mg comprimidos de liberación prolongada	67.587
Spain	HYDROGENATED VEGETABLE OIL, HYDROXYPROPYL DISTARCH PHOSPHAT PROLONGED-RELEASE TABLET		DOLPAR 100 mg comprimidos de liberación prolongada	67.585
Spain	HYDROGENATED VEGETABLE OIL, HYDROXYPROPYL DISTARCH PHOSPHAT PROLONGED-RELEASE TABLET		DOLPAR 200 mg comprimidos de liberación prolongada	67.586

EudraVigilance Human

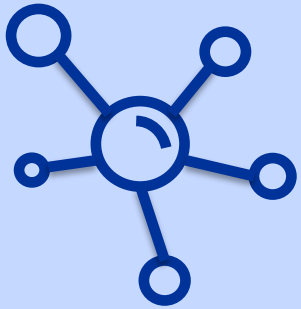
XEVMPD


ACCESS TO PRODUCT DATA
DATA MIGRATION & DELTAS
MAPPINGS TO S, O & R
SOURCES: XEVMPD & SIAMED
BASICS

SUBSTANCES

ORGANISATIONS

REFERENTIALS



SUBSTANCES

View :Dimethyl fumarate	
Term	Dimethyl fumarate
Identifier	100000079228
Status	Current

Extended EudraVigilance Medicinal Product Dictionary - xEVMPD

Source Term ID SUB13608MIG

SUBSTANCES

ORGANISATIONS

REFERENTIALS

ORGANISATIONS

Organisation Details

Organisation ID:	ORG-100000571
Organisation Name:	Almirall S.A.

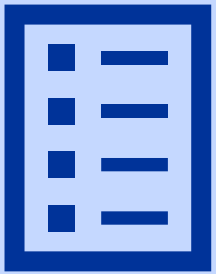
Location Details

Location ID:	LOC-100071064
Address:	Ronda General Mitre 151 Barcelona 08022 Spain
xEVMPD Code:	ORG2236, ORG3844

SUBSTANCES

ORGANISATIONS

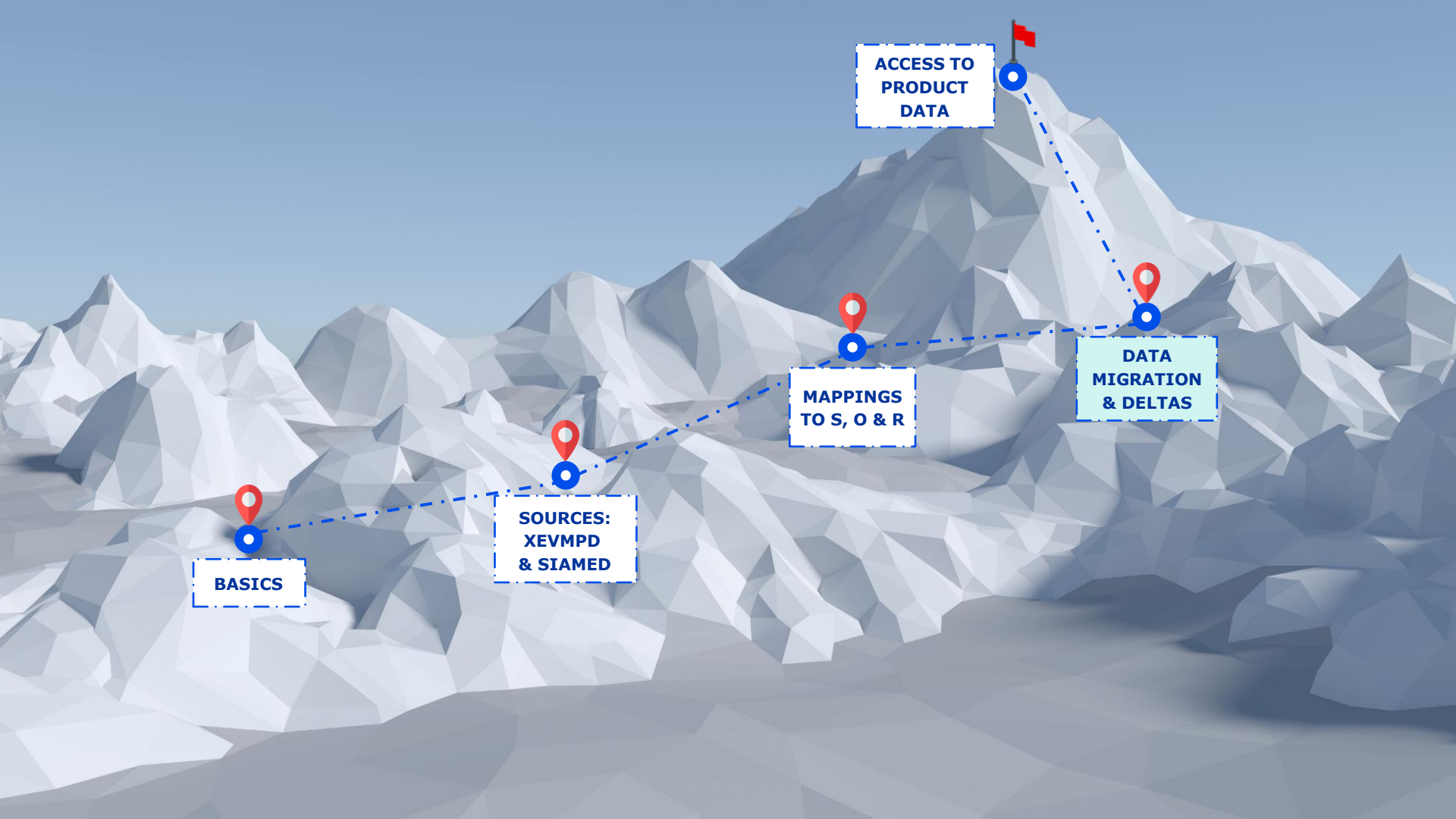
REFERENTIALS



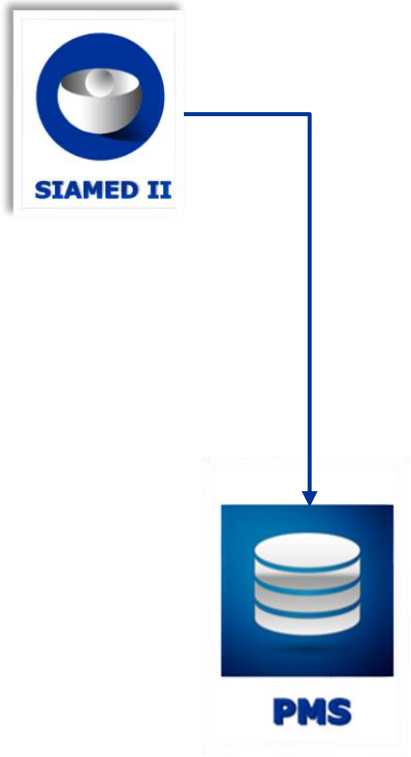
REFERENTIALS

Art. 57 list	RMS list
Administrable Pharmaceutical Forms	Pharmaceutical Dose form
ATC types	ATC Human + National classification system list
Authorisation Procedure	EU Regulatory Authorisation Procedure
Authorisation Status	Regulatory Entitlement Status
Authorised Pharmaceutical Forms	Pharmaceutical Dose form + Combination Package + Combined Term + Combined Pharmaceutical Dose form
Countries	Country
Legal Basis	Marketing Authorisation Application Legal Basis
Medicinal Product Types	XEVMPD Medicinal Product Type
Name Part Types	Medicinal Product Name Part Type
Route of Administration	Routes and Methods of Administration
Units of Presentation	Units of Presentation

Terms in xEVMPD were mapped to 11 RMS lists


ACCESS TO PRODUCT DATA
DATA MIGRATION & DELTAS
MAPPINGS TO S, O & R
SOURCES: XEVMPD & SIAMED
BASICS

Data migration & deltas to PMS



Migration rules for SIAMED

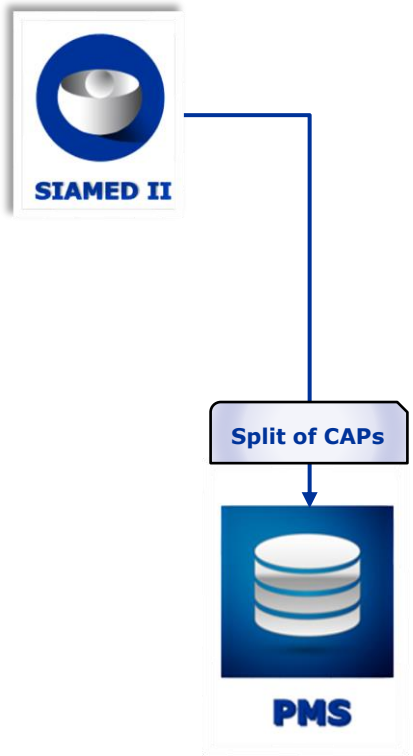
Products for which there has ever been a Marketing Authorisation were migrated to PMS:

- **Valid**: Application for Marketing authorisation approved.
- **Revoked**: Withdrawn after Marketing authorisation by the Regulatory Authority.
- **Expired**: Renewal application not received.
- **Suspended**: Marketing authorisation is still valid but the medicinal product must not, for some reason, be placed on the market, in the meantime.
- **Surrendered**: Regulatory entitlement withdrawn by the holder after it has been granted.

Refused or invalid medicinal products stored in SIAMED II were not migrated into PMS (i.e. products that were never authorised)

Pending CAPs (products or presentations) are not migrated to PMS

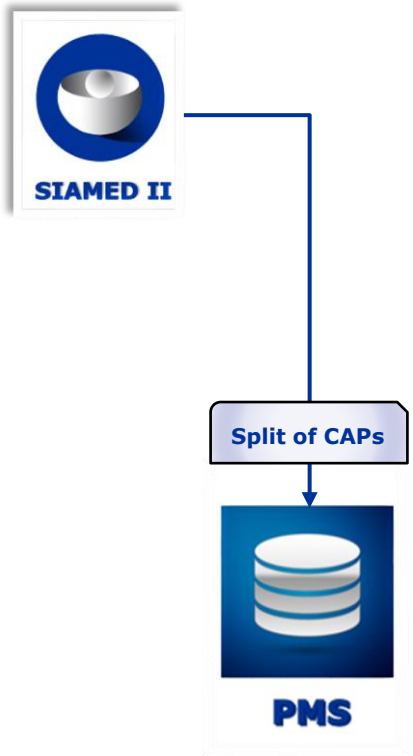
Data migration & deltas to PMS



PMS ID	Medicinal product name	Packaged medicinal product
600000001234	Skilarence - 30 mg – Gastro-resistant tablet	EU/1/17/1201/001 EU/1/17/1201/013 EU/1/17/1201/014
600000005678	Skilarence - 120 mg – Gastro-resistant tablet	EU/1/17/1201/005 EU/1/17/1201/006 EU/1/17/1201/007

PMS ID	Medicinal product name	Packaged medicinal product
600000001234	Aimovig - 140 mg - solution for injection	EU/1/18/1239/004 EU/1/18/1239/005 EU/1/18/1239/006
600000005678	Aimovig - 70 mg - solution for injection	EU/1/18/1239/001 EU/1/18/1239/002 EU/1/18/1239/003

Data migration & deltas to PMS



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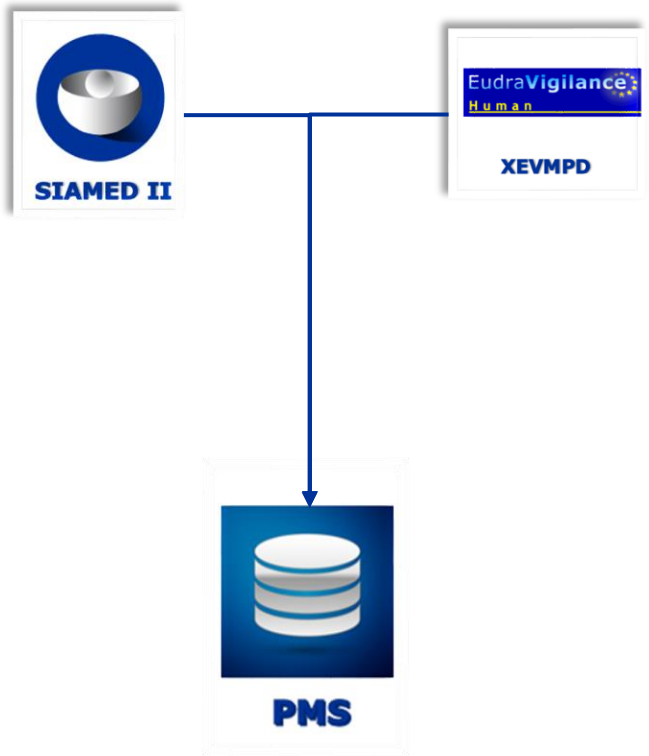
600000005678	Skilarence - 120 mg – Gastro-resistant tablet	EU/1/17/1201/005 EU/1/17/1201/006 EU/1/17/1201/007

PMS ID	Medicinal product name	Packaged medicinal product
600000001234	Aimovig - 140 mg - solution for injection	EU/1/18/1239/004 EU/1/18/1239/005
600000009012	Aimovig - 140 mg - solution for injection	EU/1/18/1239/006
600000005678	Aimovig - 70 mg - solution for injection	EU/1/18/1239/001
600000003456	Aimovig - 70 mg - solution for injection	EU/1/18/1239/002 EU/1/18/1239/003

Data migration & deltas to PMS



Migration rules for XEVMPD

Business rules are built to group records (EV codes) belonging to the same medicinal product.

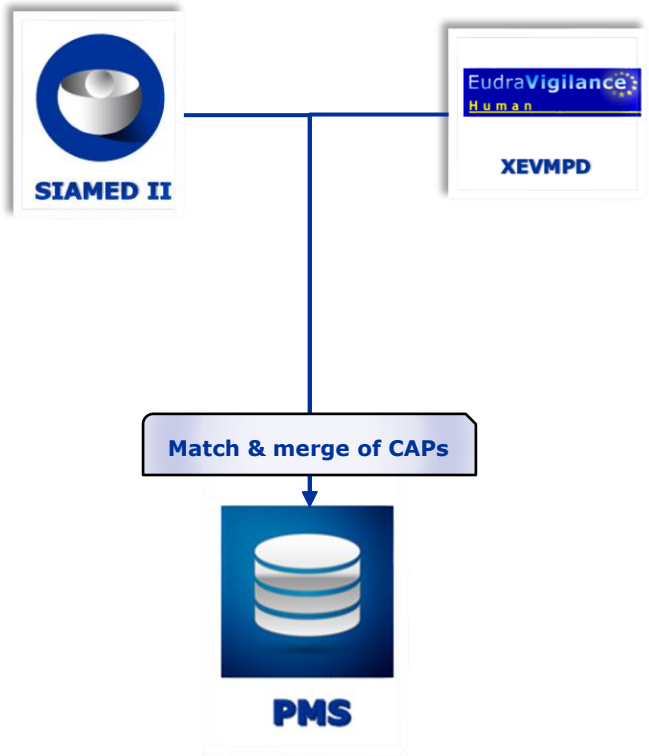
Marketing Authorisation Holder	Authorisation Country	Active Substance(s)	Strength of active substance(s)
Authorised pharmaceutical dose form	Product full name*	Authorisation number**	MRP/DCP number***

*All countries except BE, FI and LU
**FI and LU
*** BE

Business rules to migrate records from XEVMPD to PMS:

- Last version of non-nullified records is migrated to PMS (i.e. if a record is nullified, it is not migrated). Last version can be a version validated by EMA or not.
- Authorisation status is different from *Not Valid - Superseded by Marketing Authorisation Transfer* or *Not Valid - Superseded by Marketing Authorisation Renewal/Variation* (i.e. records with these statuses won't be migrated)
- Record should contain data in the following fields, otherwise, it is not migrated to PMS:
  - Authorised Pharmaceutical Form
  - Legal basis
  - Medicinal product type

Data migration & deltas to PMS



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600000005678	Skilarence - 120 mg – Gastro-resistant tablet	EU/1/17/1201/005 EU/1/17/1201/006 EU/1/17/1201/007

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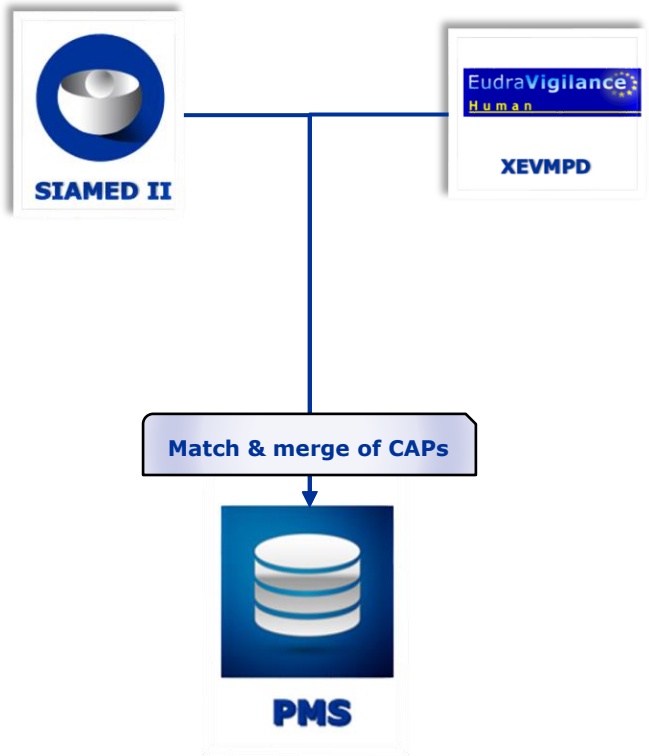
600000009012	Aimovig - 140 mg - solution for injection	EU/1/18/1239/006
600000005678	Aimovig - 70 mg - solution for injection	EU/1/18/1239/001
600000003456	Aimovig - 70 mg - solution for injection	EU/1/18/1239/002 EU/1/18/1239/003

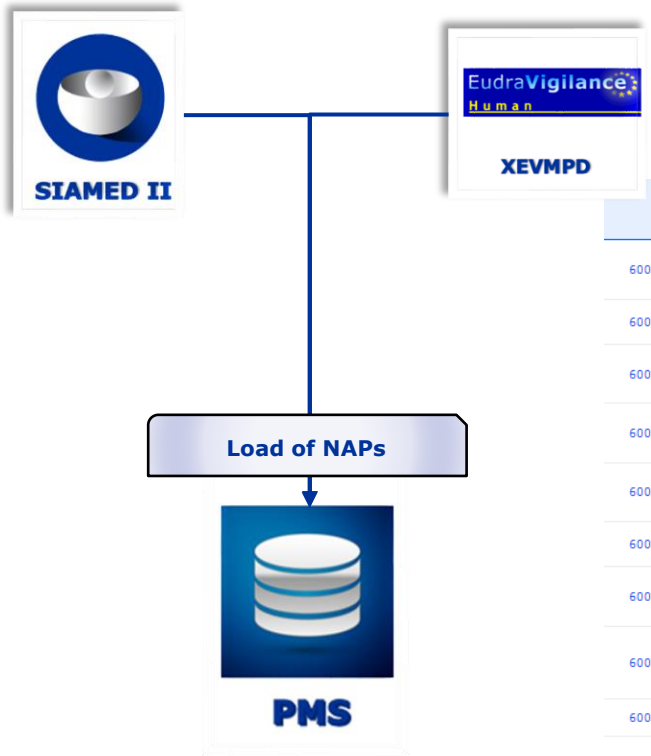
Data migration & deltas to PMS



PMS ID	Full Name	Authorised Dose Form	MA Holder	↑ MA Nr.
600000003227	Skilarence 30 mg gastro-resistant tablets	Gastro-resistant tablet	Almirall S.A.	EU/1/17/1201
600000001121	Skilarence 120 mg gastro-resistant tablets	Gastro-resistant tablet	Almirall S.A.	EU/1/17/1201

PMS ID	Full Name	Authorised Dose Form	MA Holder	↑ MA Nr.
600000252719	Aimovig 70 mg solution for injection in pre-filled pen	Solution for injection	Novartis Europharm Limited	EU/1/18/1293
600000252718	Aimovig 70 mg solution for injection in pre-filled syringe	Solution for injection	Novartis Europharm Limited	EU/1/18/1293
600000252662	Aimovig 140 mg solution for injection in pre-filled pen	Solution for injection	Novartis Europharm Limited	EU/1/18/1293
600000252661	Aimovig 140 mg solution for injection in pre-filled syringe	Solution for injection	Novartis Europharm Limited	EU/1/18/1293

Data migration & deltas to PMS



PMS ID	Full Name	Authorised Dose Form	↓MA Holder	MA Nr.	Active substance
600001127703	Ebastina Viatris 20 mg comprimidos recubiertos con película EFG	Film-coated tablet	Viatris Pharmaceuticals S.L.	67708	Ebastine
600001127663	Synalar forte 2 mg/g crema	Cream	Tora Laboratories S.L.	46.441	Fluocinolone acetonide
600001127504	Olmesartán/Hidroclorotiazida Teva 20 mg/25 mg comprimidos recubiertos con película EFG	Film-coated tablet	Teva B.V.	86787	Hydrochlorothiazide, Olmesartan medoxomil
600001127912	Itraconazol TecniGen 100 mg cápsulas duras EFG	Capsule, hard	Tecnimede Espana Industria Farmaceutica S.A.		Itraconazole
600001128156	Valsartán/Hidroclorotiazida SUN 80 mg/12,5 mg comprimidos recubiertos con película EFG	Film-coated tablet	Sun Pharmaceutical Industries (Europe) B.V.	73.572	Hydrochlorothiazide, Valsartan
600001127657	Donepezilo SUN 5 mg comprimidos recubiertos con película EFG	Film-coated tablet	Sun Pharmaceutical Industries (Europe) B.V.	70.051	Donepezil hydrochloride
600001127641	PERMIXON 160 mg cápsulas duras	Capsule, hard	Pierre Fabre Iberica S.A.	61.729	LIPIDOSTEROLIC EXTRACT OF SERENOA REPENS
600001127658	Efavirenz/Emtricitabina/Tenofovir disoproxilo Macleods 600mg/200 mg/245 mg comprimidos recubiertos con película EFG	Film-coated tablet	Macleods Pharma Espana S.L.	84473.	Tenofovir disoproxil, Efavirenz, Emtricitabine
600001127600	Zeliderm 200 mg/g crema	Cream	Laboratorios Vinas S.A.	60159	Azelaic acid
600001127551	mirtazapina cinfa 30 mg comprimidos recubiertos con película EFG	Film-coated tablet	Laboratorios Cinfa S.A.	67.068	Mirtazapine
					Paracetamol,

Data migration & deltas to PMS

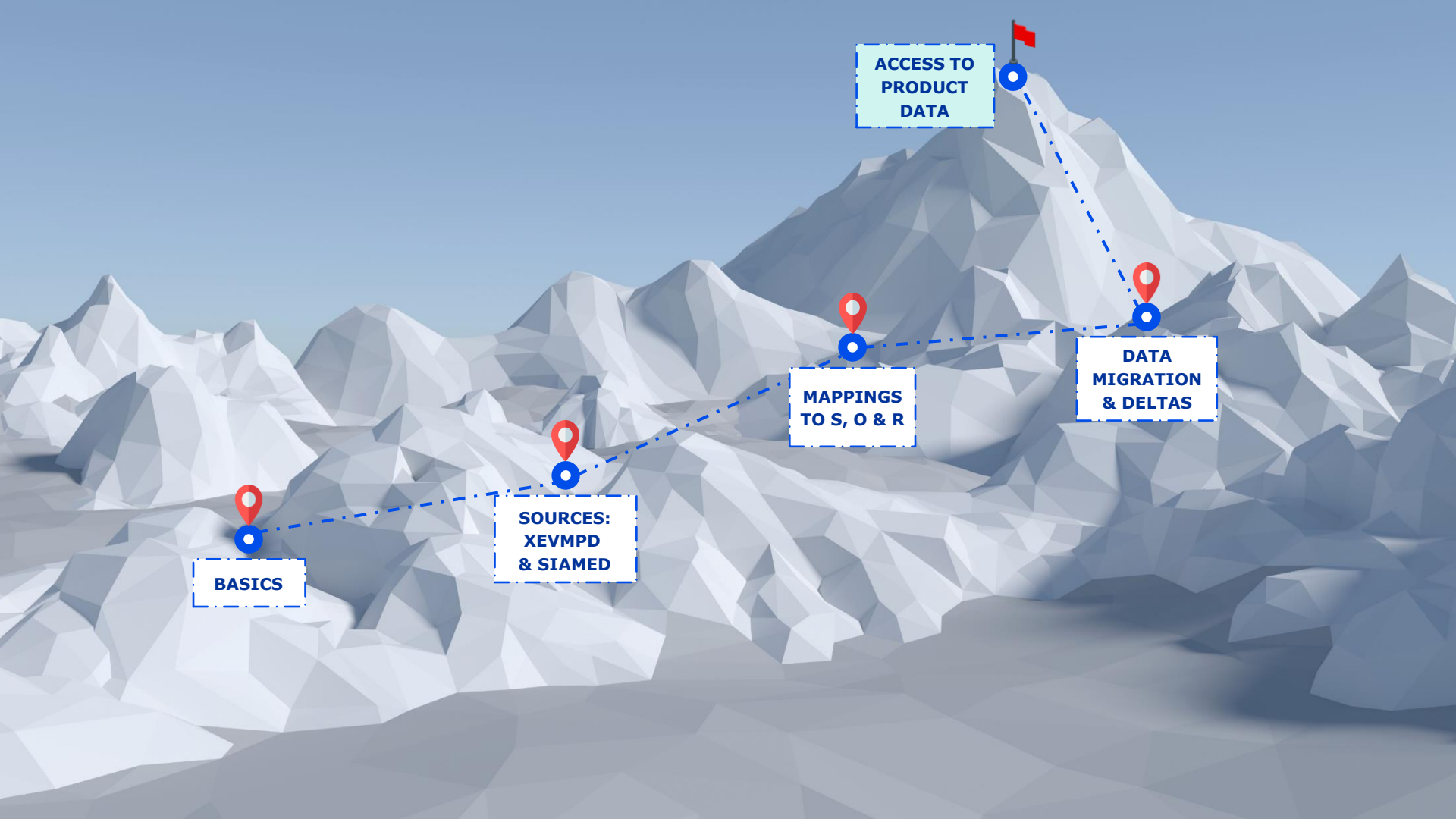
EUROPEAN MEDICINES AGENCY

XEVMPD and SIAMED II are now synchronised with PMS

As of today, we can confirm that **SIAMED II & XEVMPD data has been completely migrated to PMS** and it is kept **up to date with the deltas from those systems**

This is the last key milestone before you can access this data through PMS platforms!

+4500 CAPs
+400K NAPs


ACCESS TO PRODUCT DATA
DATA MIGRATION & DELTAS
MAPPINGS TO S, O & R
SOURCES: XEVMPD & SIAMED
BASICS

Access to PMS data

EUROPEAN MEDICINES AGENCY

Data is already in the PMS database, nevertheless, access to it is still unavailable.

By the end of May, **users will be able to access and read their data through**:

PMS API

```
<?xml version="1.0" encoding="utf-8"?>
<Bundle xmlns="http://hl7.org/fhir">
    <id value="600009529467" />
    <meta>
        <versionId value="2" />
        <lastUpdated value="2024-01-17T23:58:05.603+00:00" />
    </meta>
    <type value="searchset" />
    <entry>
        <fullUrl value="MedicinalProductDefinition/600009529467" />
        <resource>
            <MedicinalProductDefinition>
                <id value="600009529467" />
                <contained>
                    <Provenance>
                        <target>
                            <reference value="#" />
                        </target>
                        <occurredDateTime value="2024-01-17T18:15:03+01:00" />
                        <recorded value="2024-01-18T00:58:00.548+01:00" />
                        <reason>
                            <text value="Data modification(s)" />
                        </reason>
                        <agent>
                            <role>
                                <coding>
                                    <system value="http://terminology.hl7.org/CodeSy
                                    <code value="author" />
                                </coding>
                            </role>
```

Product User Interface

PMS User Registration Process

EUROPEAN MEDICINES AGENCY

PMS User roles

Admin roles

User	Admin role names
Industry user(s)	IRIS/PLM Industry Admin
NCA user(s)	IRIS/PLM NCA Admin
EMA user(s)	IRIS/PLM EMA Admin

New releases in Mid-May 2024:

- EU IG Chapter 1 version 3 (EMA website)
- EU IG Chapter 5 version 2 (EMA website)
- New PUI Registration guide (PLM portal)

Industry roles

User	Admin role names	PMS Access Level (*EU IG Ch.5)*
Industry user(s)	PUI Industry User	Level 2b
	PUI Industry Qualified User	Level 2a

Regulator roles

User	Admin role names	PMS Access Level (*EU IG Ch.5)*
NCA user(s)	PUI Competent Authority User	Level 3
	PUI Competent Authority Qualified User	Level 3

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PMS User Registration Process

IRIS/PLM Industry/NCA Admin user roles

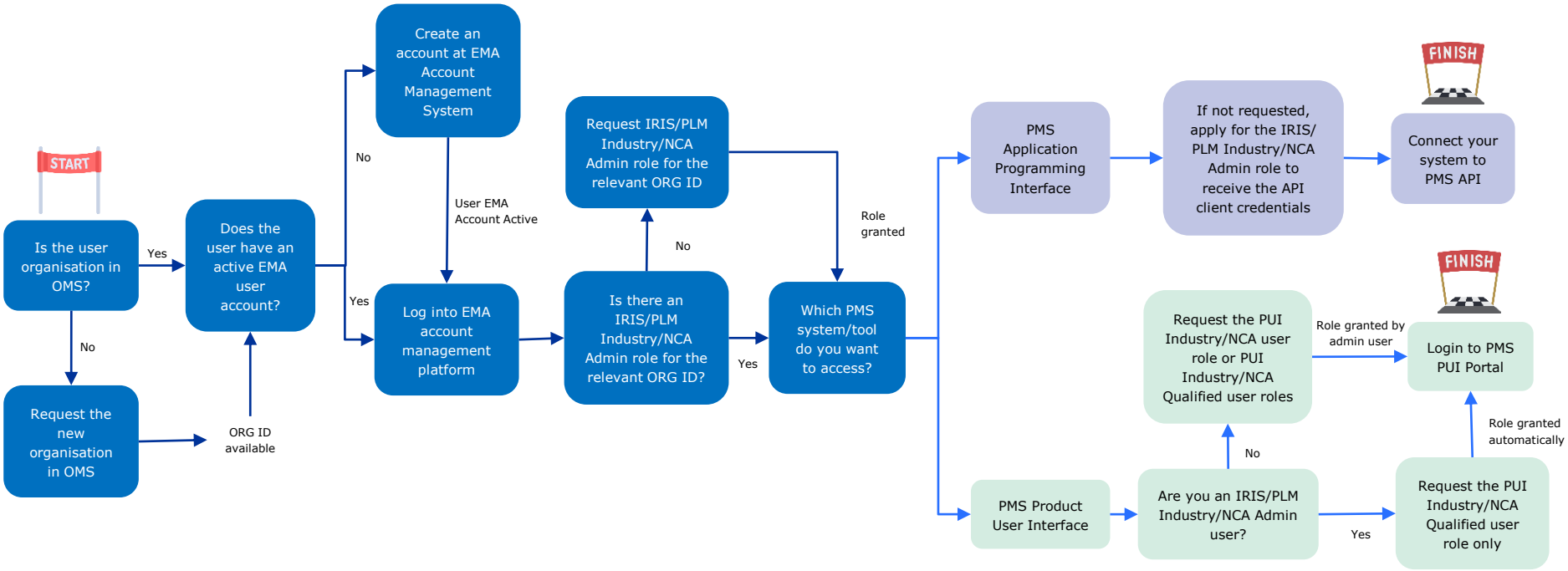
- **Existing role in IAM!** previously named IRIS / eAF Industry/Competent Authority Admin role(s)
- Merged with eAF/ePI/IRIS privileges
- **No direct READ access to PMS API/PUI**
- Allow to receiving **PMS API Client Credentials** generated only upon request by the Administrator users in IAM to **READ PMS API**
- Allow **revoking/granting** other **PMS Product UI's user** roles
- **1st Admin** of Organisation is **approved by IRIS / PLM EMA Admin;** from 2nd Admin onwards Org Admin can approve it
- Recommended each organisation to have **at least two Admin users**
- Multiple roles for the **same ORG ID** are allowed (user can also request either **User or Qualified User**)
- If also request User or Qualified User role, requests are **automatically approved in IAM**

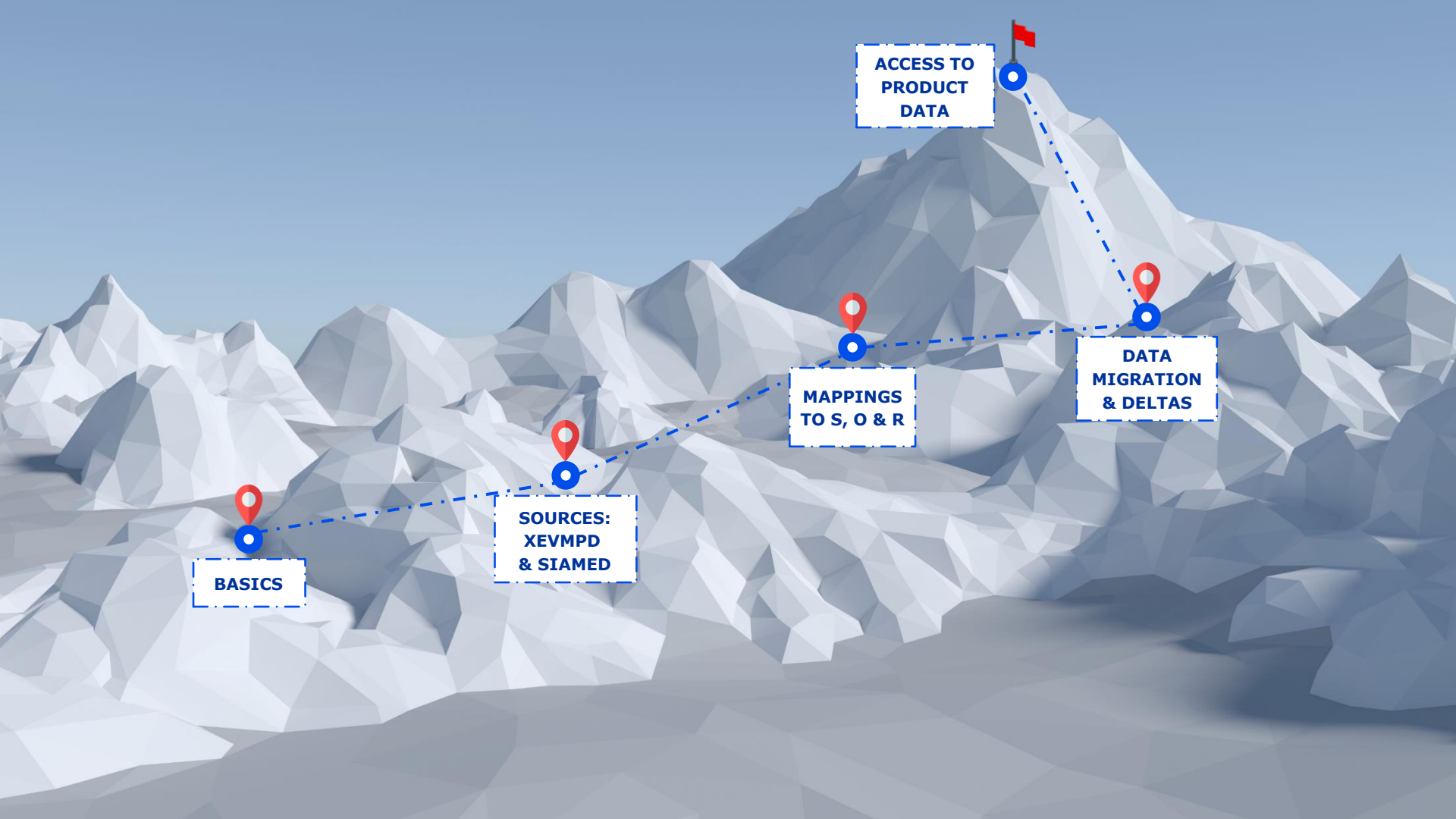
PMS User Registration Process

Industry/NCA User/Qualified User roles

- **New roles in IAM!** Valid to access **PMS PUI** only
- PMS PUI access based on **Multi-factor authentication (MFA)**, additional verification of identity
- Allow **READ of PMS products data**
- Assigned to single user in IAM and at **ORG level**
- **Approved** by relevant **IRIS/PLM Industry/NCA Admin** user(s) only
- **Multiple roles** (User and Qualified User) **shall not** be requested for the **same Organisation.** If so, this will result in the Qualified User role privileges to prevail
- In PLM portal, PMS PUI roles are synchronised with eAF roles:
  - PLM Users having **eAF Contributor** role shall request **PUI User role**
  - PLM User having **eAF Coordinator/Manager** roles shall request **PUI Qualified User role**
  - PLM Users **shall not request mixed eAF/PMS PUI roles for the same organisation** as this will result in the higher privileges bypassing the lower ones
  - PLM User can have **different roles** across **different organisations**

PMS User Registration Process

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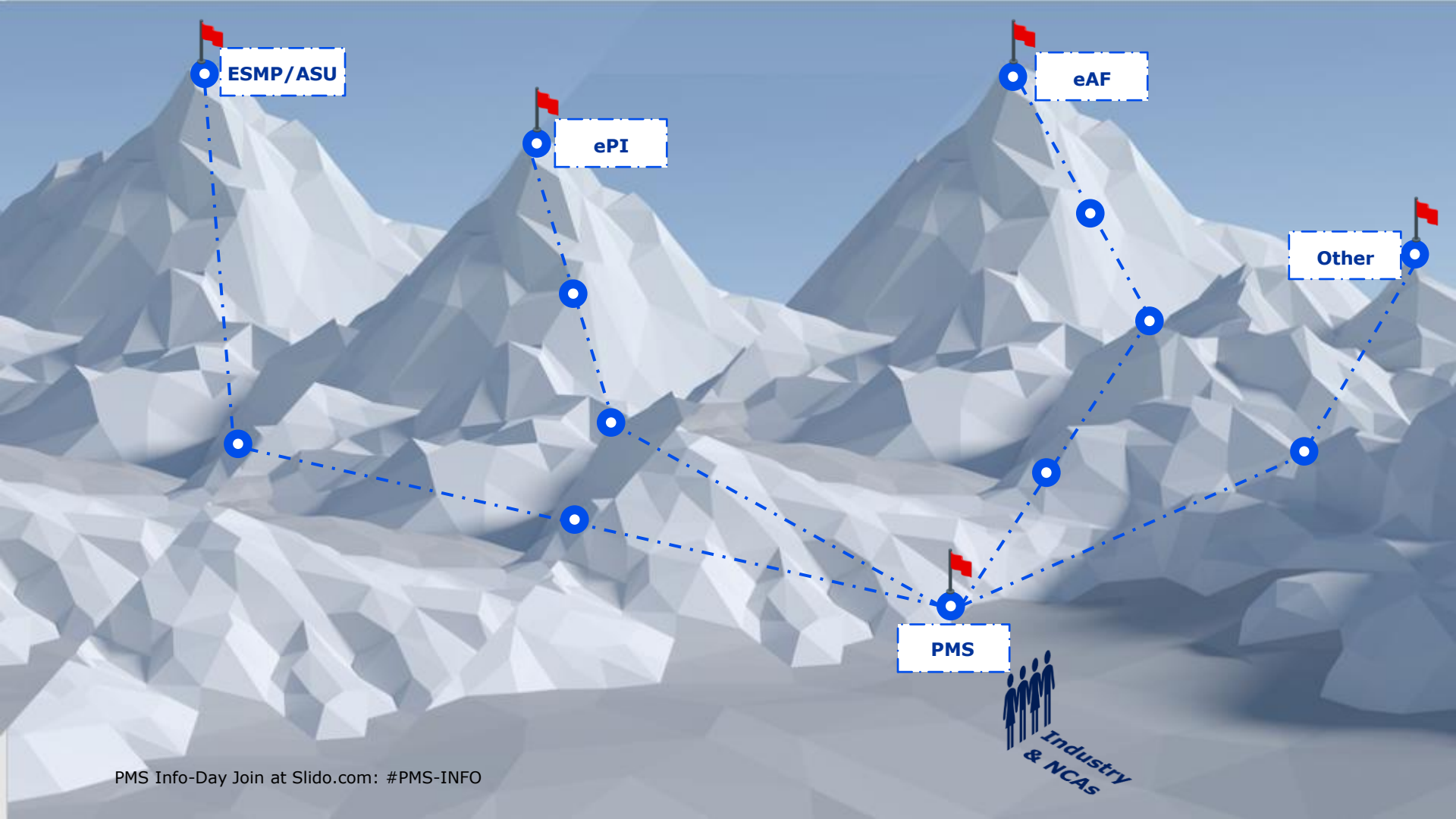

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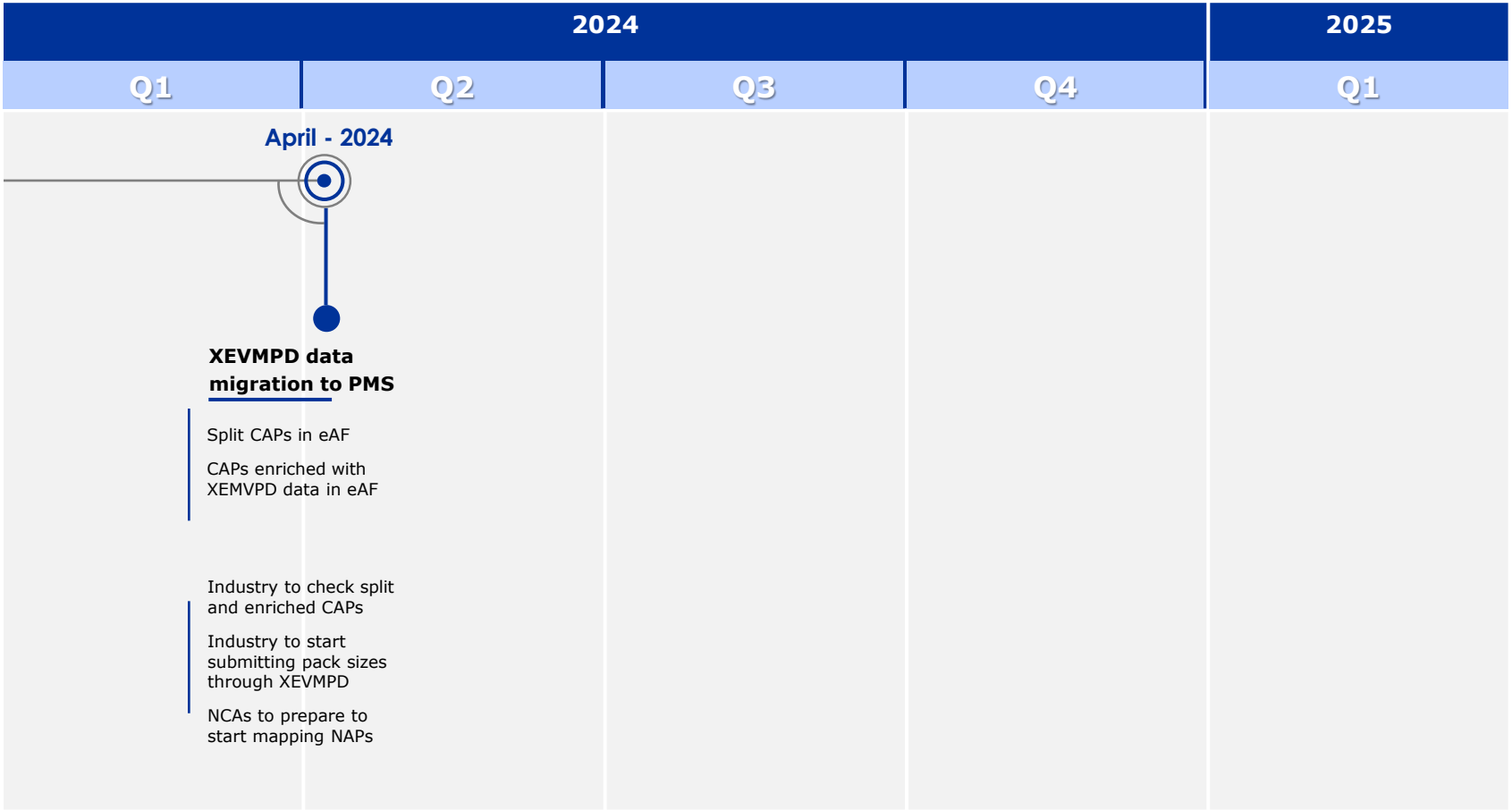
Timelines and actions



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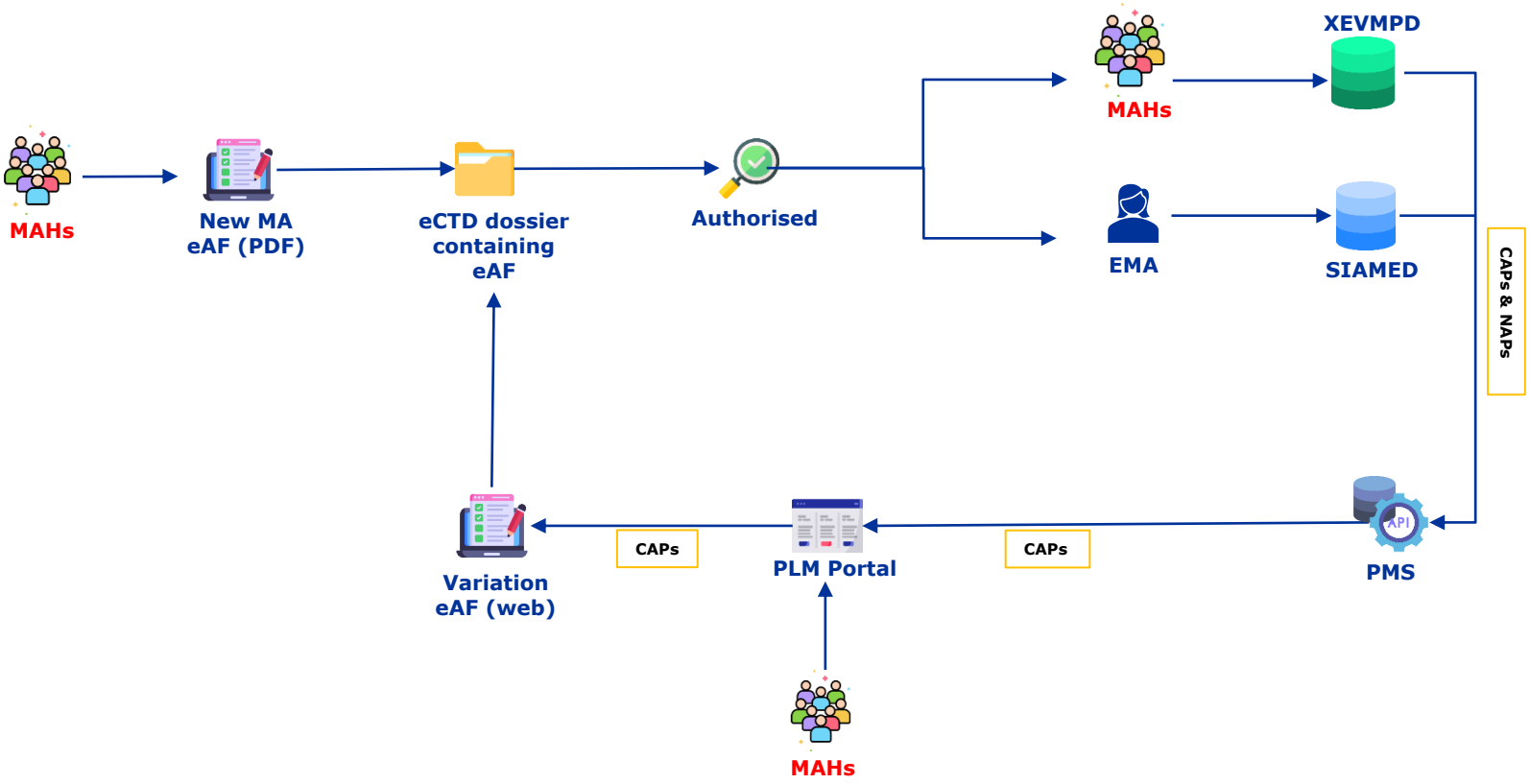
What happens after XEVMPD migration to PMS?



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Recommendation to applicants

Ensure data quality in your XEVMPD records

- **Monitor the 3rd AcKs** after EMA perform validations in XEVMPD and if needed, update your internal systems.

  If you don't agree with the change: raise a ticket to Service Now

  - If internal industry systems are not updated, same wrong data will be submitted with the next XEVMPD update
  - This might impact the structure of the medicinal product if the change is performed in a field use for grouping (product name, authorised dose form, active substance/strength, authorization number or MAH)

- For **records in XEVMPD where "Product Validity" is "Not Assessed"**, please, **review the reason why** it was not assessed: it might be a duplicate of another record or there is missing information/documentation.

- Make sure you **don't send emails from Art57-QC@ema.europa.eu** to the **spam folder,** EMA is sending notifications to QPPVs using that email account.

Recommendation to applicants

Start CAPs review in eAF

Check that valid products have changed the name - now capturing the XEVMPD full presentation name.

Check presentations for split CAPs are correctly allocated to the newly created products.

If not, you can open a ticket in Service Now.
You can also wait for the API & Product UI to be released to make this check.

Support web-based eAF

- XEVMPD can also store **products not in scope of Art. 57** such as herbal or homeopathic products.
- If needed in a variation form, you can **submit these products to XEVMPD** following instructions in chapter 3.II of XEVMPD
- **Pending MRPs and DCPs** cannot be submitted to XEVMPD for the time being as eAF does not accept variations on NAPs.

EUROPEAN MEDICINES AGENCY

Support ESMP and future regulatory processes

Applicants should prepare to submit and maintain manufacturers data and structured data on pack sizes

- In particular:
  1. Focus on union list of critical medicines first
  2. Map manufacturing operations to the terms in the RMS list (manufacturing business operations)
  3. Map your manufacturers to OMS
- Start submitting individual valid pack sizes for products impacted by the union list of critical medicines list to XEVMPD.

EMA/528805/2023
6 December 2023

Union list of critical medicines - version 1

ATC level	ATC description The Anatomical Therapeutic Chemical code: a unique code assigned to a medicine according to the organ or system it works on and how it works. The classification system is maintained by the World Health Organization (WHO).	Date of inclusion
A - Alimentary tract and metabolism		
A02B - Drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD)		
A02BC05	ESOMEPRAZOLE	1 December 2023
A03B - Belladonna and derivatives, plain		
A03BA01	ATROPINE	1 December 2023
A03F - Propulsives		
A03FA01	METOCLOPRAMIDE	1 December 2023
A07A - Intestinal antiinfectives		
A07AA09	VANCOMYCIN	1 December 2023
A07AA12	FIDAXOMICIN	1 December 2023

Submission of individual pack sizes to XEVMPD

- Check ATC codes in the union list
- Check products in XEVMPD with these ATC codes
- Review data quality of these products (RoA, dose form, ATC)
- For countries where MA number is assigned at pack level → all pack sizes should already be in XEVMPD
- For countries where MA number is assigned at product level → start submitting all authorised and valid pack sizes (use package description field to differentiate them)
- Follow Chapter 3.II of XEVMPD instructions

Activities for applicants

EUROPEAN MEDICINES AGENCY

Support ESMP and future regulatory processes

- Applicants should prepare to submit and maintain manufacturers data and structured data on pack sizes
- In particular:
    1. Focus on union list of critical medicines first
    2. Map manufacturing operations to the terms in the RMS list (manufacturing business operations)
    3. Map your manufacturers to OMS
- Start submitting individual valid pack sizes for products impacted by the union list of critical medicines list to XEVMPD.

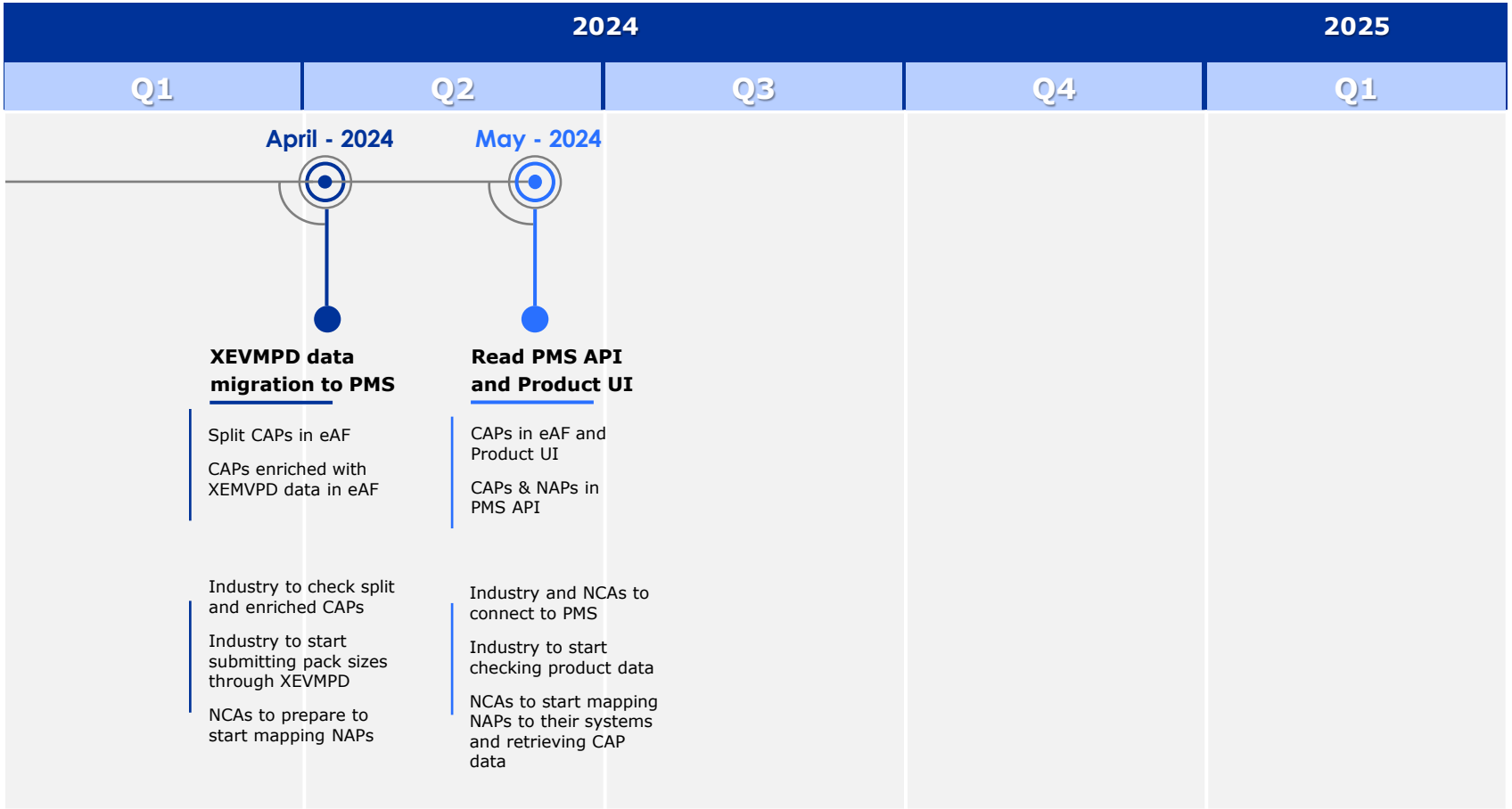
Crisis-specific list and MSSG-led exercise for crisis preparedness

In case a crisis is declared or there is a MSSG-led exercise for crisis preparedness , MAHs will be required to submit pack sizes for impacted NAPs to XEVMPD **within 2 weeks**.

Submission of individual pack sizes to XEVMPD

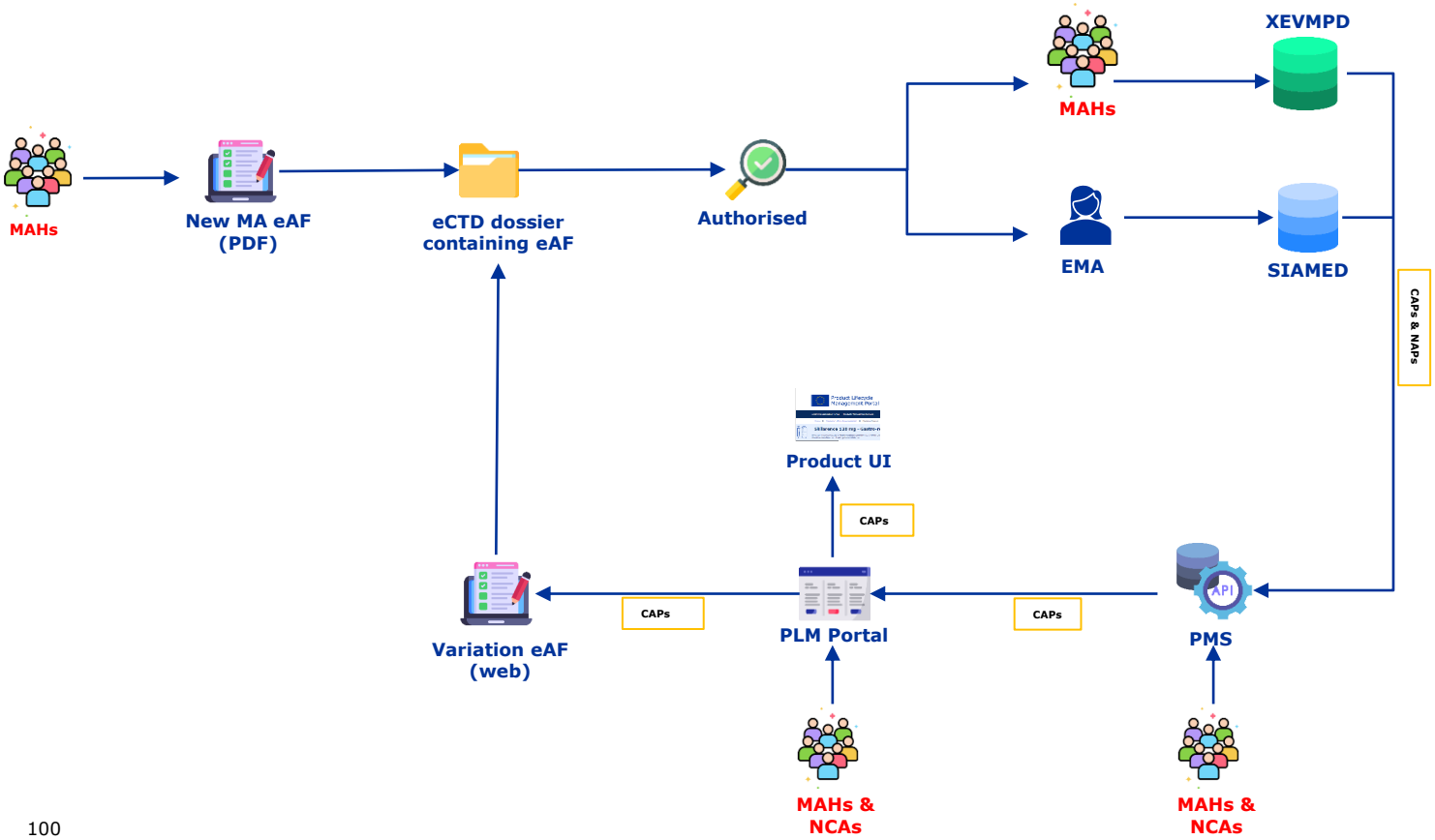
- Check ATC codes in the union list
- Check products in XEVMPD with these ATC codes
- Review data quality of these products (RoA, dose form, ATC)
- For countries where MA number is assigned at pack level → all pack sizes should already be in XEVMPD
- For countries where MA number is assigned at product level → start submitting all authorised and valid pack sizes (use package description field to differentiate them)
- Follow Chapter 3.II of XEVMPD instructions

Timelines and actions



PMS Info-Day Join at Slido.com: #PMS-INFO

What happens after PUI and API are released?



PMS Info-Day Join at Slido.com: #PMS-INFO

Recommendation to applicants

EUROPEAN MEDICINES AGENCY

PMS API

Product UI

Industry

Check your CAPs & NAPs

Review your products:
- data
- mappings to R, O & S
- grouping of records from XEVMPD

You can map your records using the EV code

Software vendors can have access to the API on behalf of an applicant

PMS API

NCAs

Check you have access to CAPs & NAPs

You can **start mapping your records** using:
- Authorisation number
- Procedure number
- Product full name

Start importing CAP data into your system

Recommendation to applicants

EUROPEAN MEDICINES AGENCY

PMS API

Product UI

Industry

Check your CAPs

Review your products:
- data
- mappings to R, O & S
- grouping of records from XEVMPD

You can map your records using the EV code

Product UI

NCAs

Check you have access to CAPs

If needed, you can retrieve data on CAPs

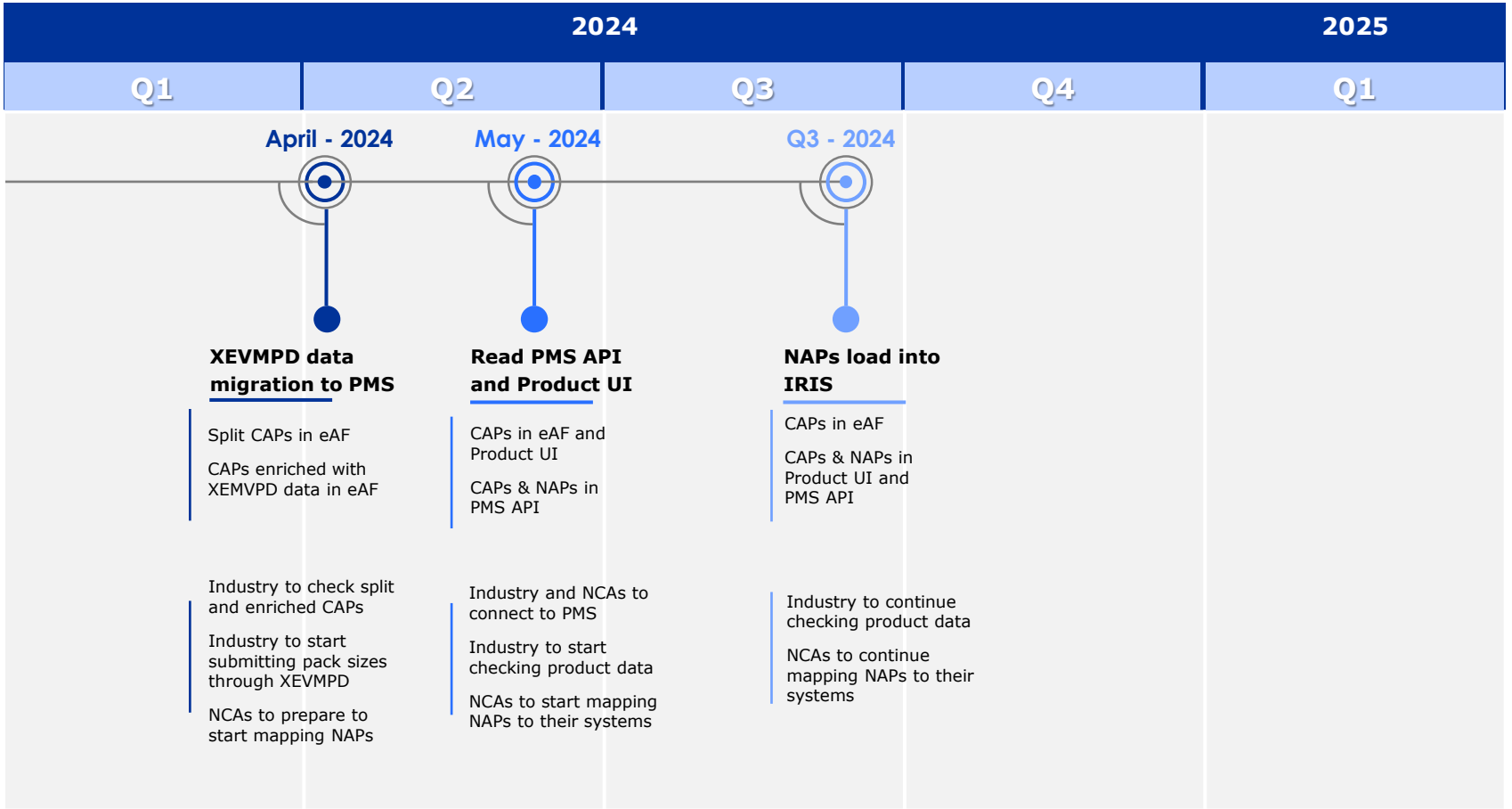
Recommendation to applicants

Issues identified through Product UI or PMS API on product data

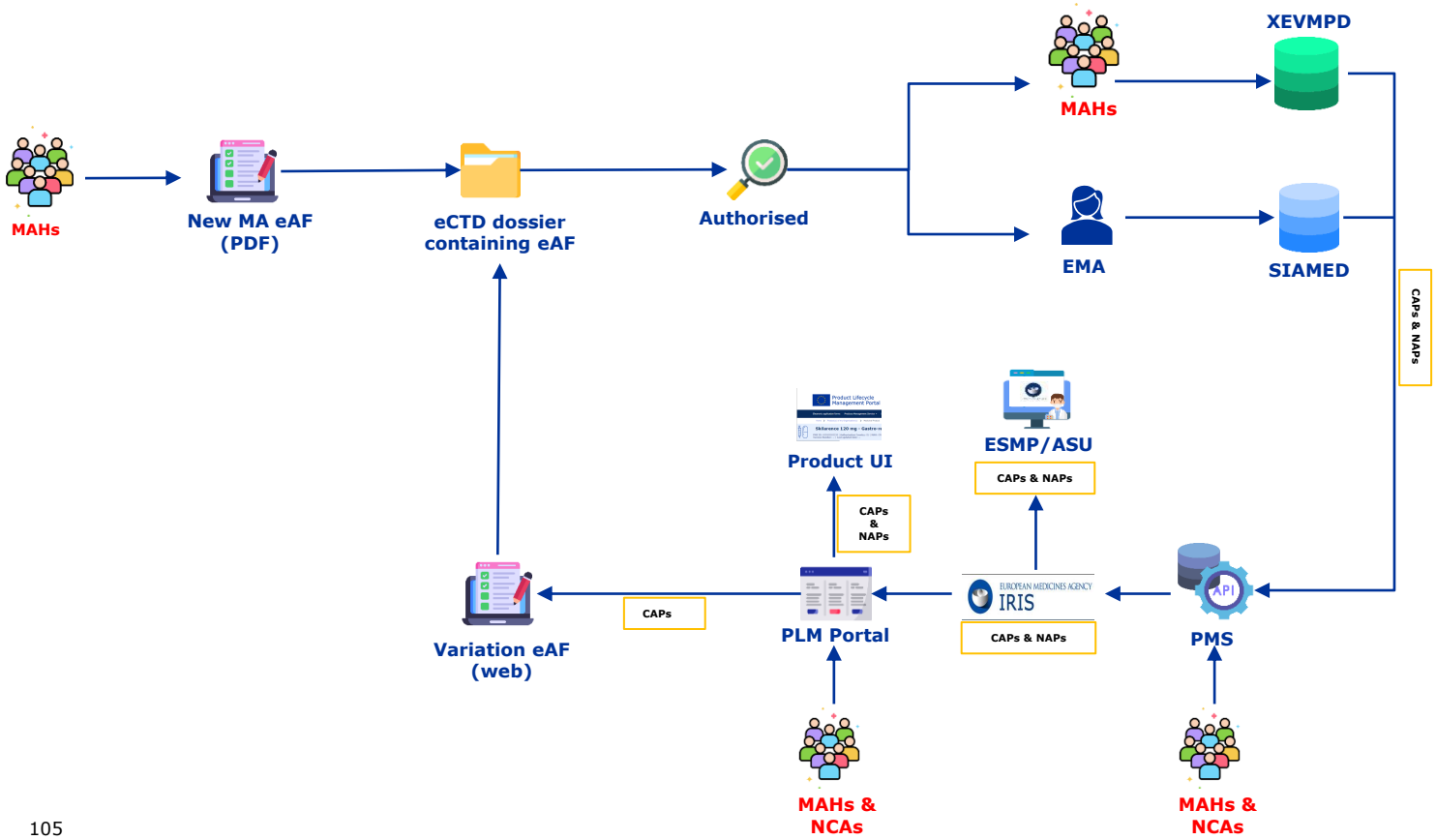
- **Issues in CAP data can be reported via PMS Service Desk.**
  - If you have spotted missing data or wrong migration, please, create a request in Service Now for PMS
  - Please, provide as much information as possible (PMS IDs, MA numbers, documents if needed, etc)

- **Issues in NAPs can be solved through XEVMPD or PMS Service Desk.**
  - Depending on the issue, an update to XEVMPD can be submitted to resolve the issue
  - If not, you can open a request for PMS in Service Now
  - If you can't find your product in PMS, make sure that it complies with the requirements to be migrated (Chapter 7 of EU IG), the MAH is mapped and you have logged to PMS with the same MAH ORG.
  - Disagreement on data mappings can also be discussed through Service Desk.

Timelines and actions



What happens after NAPs are loaded in IRIS?



PMS Info-Day Join at Slido.com: #PMS-INFO

Recommendation to applicants

EUROPEAN MEDICINES AGENCY

Request access to the PMS API/Product UI

Industry:

Make sure you have access and you can see your products (CAPs and NAPs).

Review your products:

- data
- mappings to R, O & S
- grouping of records from XEVMPD

You can map your records using the EV code

NCAs:

Make sure you have access and you can see all CAPs and NAPs.

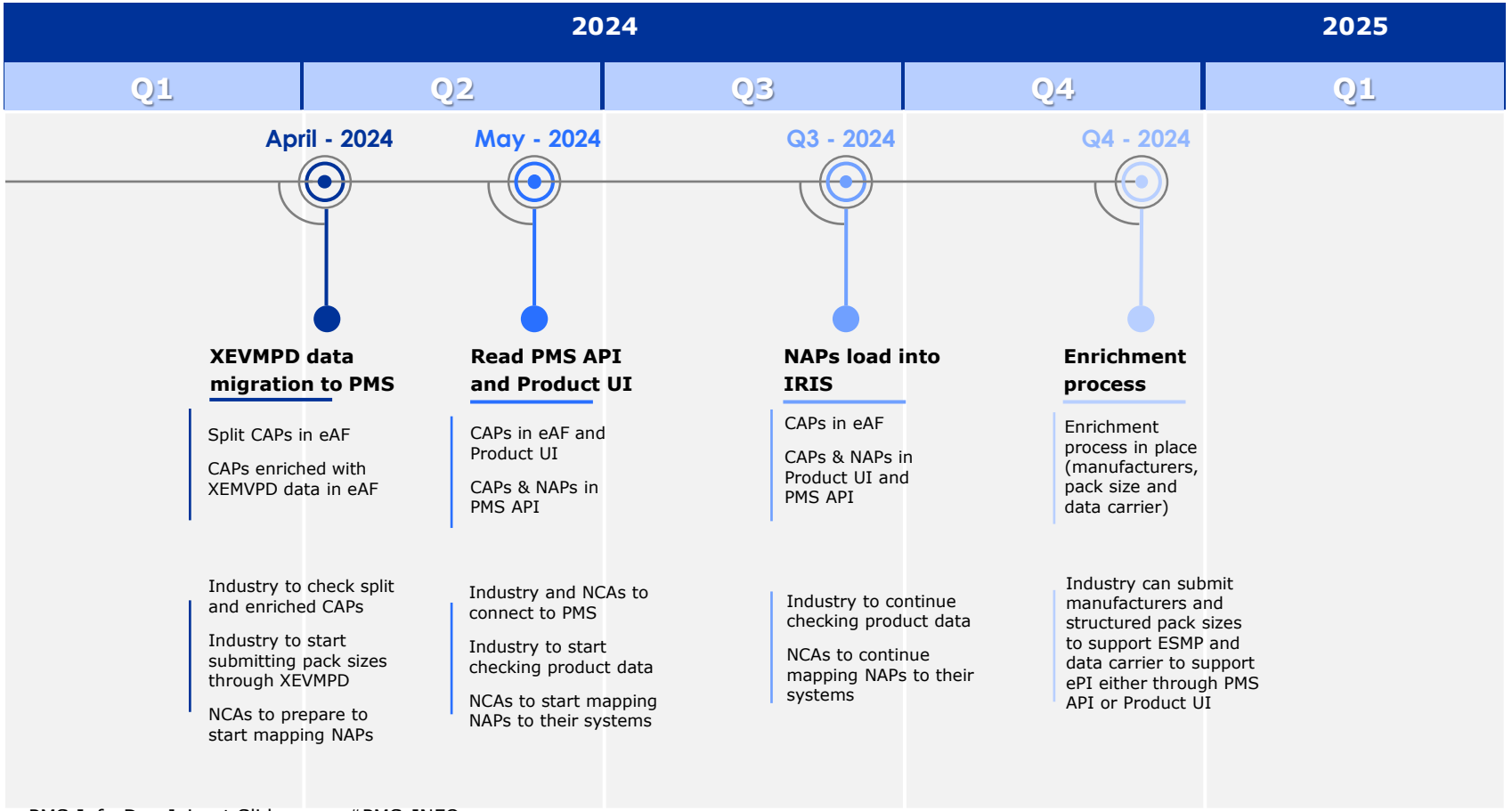
You can start mapping NAPs from PMS to your systems using:

- Authorisation number
- Procedure number
- Product full name

Users accessing through the Product UI will see NAPs, so they can start doing the same activities as the ones already having access to API

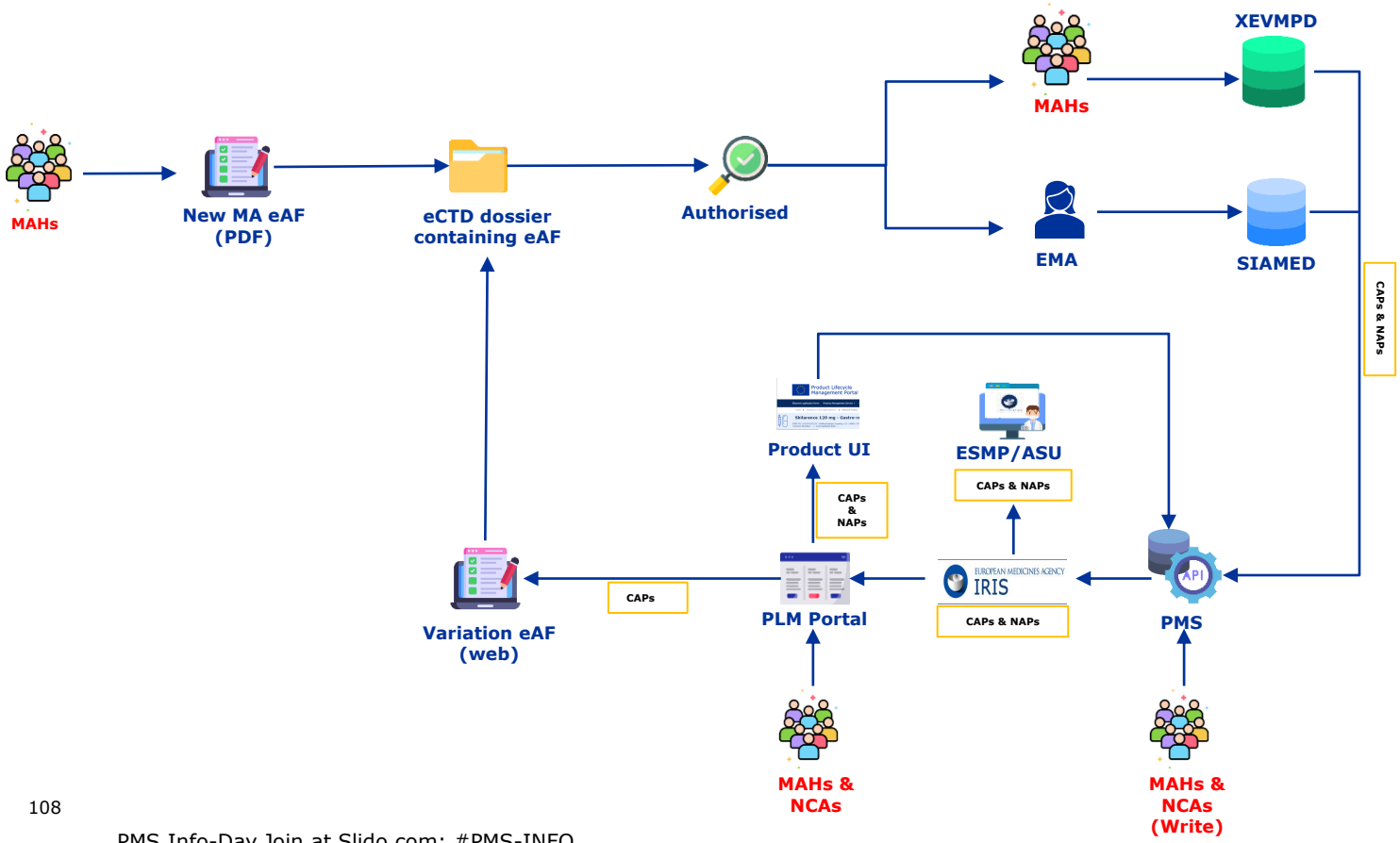
There will be Power BI reports in the Product UI

Timelines and actions



PMS Info-Day Join at Slido.com: #PMS-INFO

What happens after release of the enrichment process?



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Activities for applicants

Industry

NCAs

Industry

Manufacturing business operations:

Submit all current manufacturers and manufacturing business operations for NAPs impacted by the union critical medicines list and maintain them by December 2025

CAPs manufacturers will come from SIAMED II

Check manufacturing business operation section in Chapter 2 for additional information on fields to be submitted.

Pack size:

Submit pack size structure data for pack sizes submitted through XEVMPD for NAPs before December 2025

Applicants will need to include a value and the units of presentation (i.e: 18 tablet, 2 vial)

CAP data will come from SIAMED II

Data carrier ID:

Voluntary submission of data carrier ID for CAPs and NAPs.

This information will be used to link ePI to the relevant Medicinal Product and Packaged Medicinal Product.

Activities for NCAs

Industry

NCAs

NCAs

Priority 1:

Keep mapping NAP products to their databases.

Fields to be used for mapping:

- Authorisation number
- Procedure number
- Product full name

NCAs will have to submit data to support ESMP and therefore, they need to have their mappings ready.

Priority 2:

Data submitted by applicants (manfuacturers, can be reviewed by NCAs.

Discrepancies can be highlighted directly to MAHs.

Milestones and benefits

EUROPEAN MEDICINES AGENCY

2024

Q1

Q2

XEVMPD data migration

CAPs and NAPs are available in PMS in ISO IDMP compatible format

EU IG & PMS info day

MAHs and NCAs have information to support their implementation

Release of Product UI and API

MAHs and NCAs planning to use **Machine-to-machine** (e.g. PMS API) can access all products!

MAHs and NCAs can start reviewing and mapping PMS products to their internal systems.

Q3

Load of NAPs in IRIS

PMS data is made available, to other projects such as the web-based eAF, ePI or ESMP.

MAHs and NCAs planning to use **only user Interface** can access all products.

NAPs release in eAF

eAF – NAPs release

Variations can also be submitted for NAPs using the web-based eAF.

Q4

Release of PMS enrichment process

Missing/incomplete product data (manufacturers, structured pack sizes, data carriers) can be collected from MAHs manually (PUI) or via machine-to-machine integration (PMS API)

This data will be used by other regulatory processes and solutions such as ESMP and ASU or ePI

2025+

Submission of additional information to PMS

UCLM Packages in XEVMPD Feb 2025

Key product data (MP data and all packages) is available for the analysis of shortages on Critical Medicines.

Manuf/Structured Pack sizes in PMS Dec 2025

All required product data (PMS data, all packages with structured details, manufacturers) is available **for a more efficient** analysis of shortages on Critical Medicines.

eAF

eAF Var transition period

Variations should be submitted for CAPs& NAPs using the web-based eAF.

eAF Var mandatory

Variations can only submitted for using the web-based eAF (no more PDF).

ePI

ePI-PMS linking

ePIs can be linked to PMS and annotated with available Data carrier/GTIN

Actions and Timelines for Industry and NCAs

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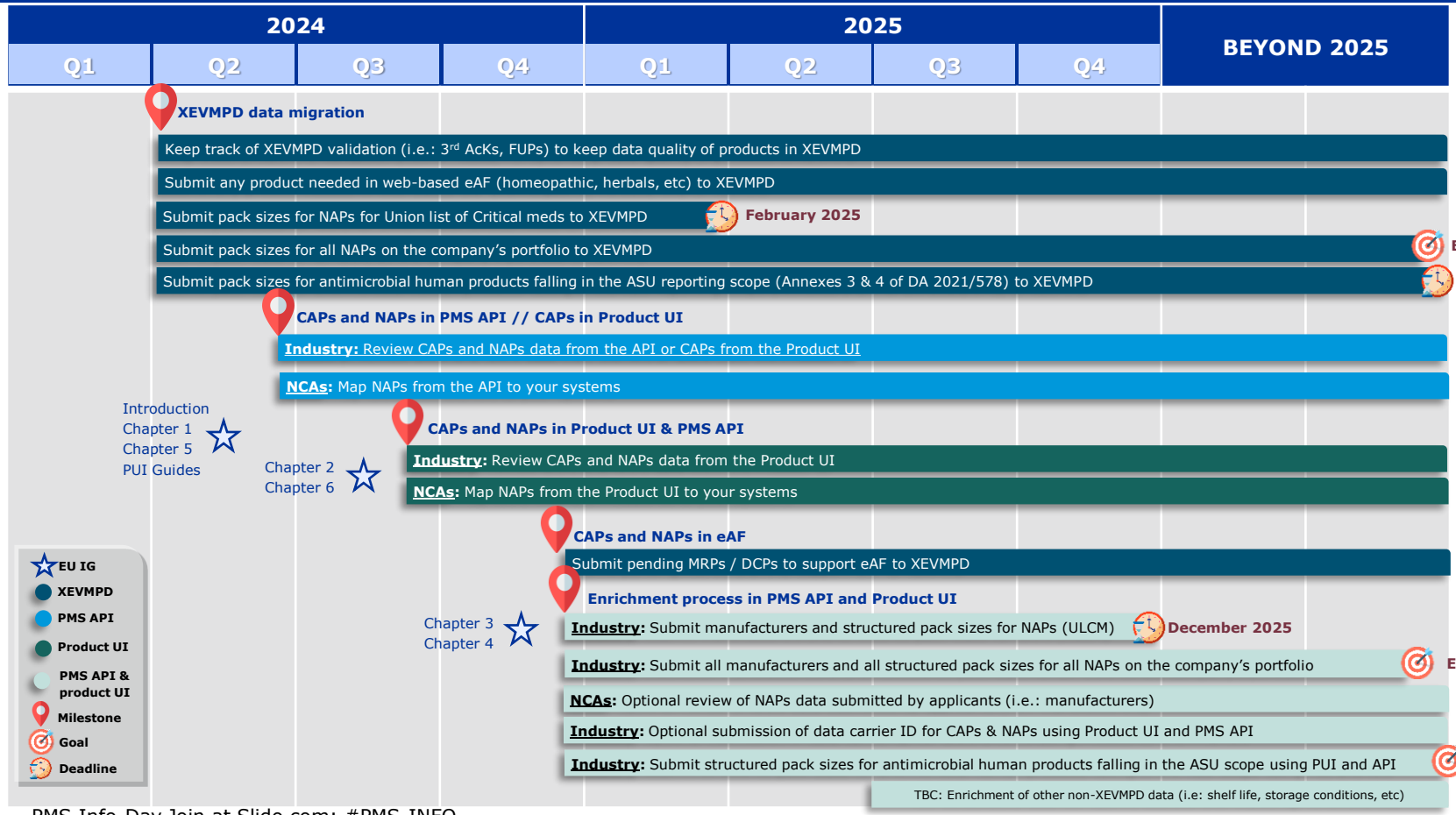

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Takeaways

EUROPEAN MEDICINES AGENCY

1. **SIAMED II and XEVMPD data migration** and continuous synchronisation with PMS has been **completed**.
   With this milestone, CAPs and NAPs are available in PMS in ISO IDMP compatible format.

2. MAHs can start **providing additional information now through XEVMPD** to support solutions:
   - Pack sizes for NAPs under the union list of critical medicines (ESMP) - by February 2025
   - Herbal or homeopathic products used in the variation eAF – no deadline

3. From end of May 2024, MAHs and NCAs will have **read access** to product data through **Product UI** and **PMS API**
   - **MAHs** should review their medicinal products in PMS
   - **NCAs** can use CAP data and should map their NAPs to national databases

4.
   - **MAHs** should enrich data for Manufacturing operations, Pack sizes for NAPs under the union list of critical medicines (ESMP) - by Dec 2025
   - Additional **Product data may be requested 2025+** for other solutions

Q&A session

On-site participants

- Raise your hand then ask your question orally (please unmute your microphone)
- We will answer **a few questions,** before checking online

Online participants

- **Join Slido.com** using this code **#PMS-INFO** or scanning the QR code here
- Ask your questions or vote the ones you would like to be answered
- We will read out **selected questions** that will be answered verbally

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

SOR & XEVMPD services supporting PMS

Pedro Batista, SMS Business Lead
Debora Martins Braga, OMS Business Lead
Veronica Lipucci Di Paola, PMS Product Owner and RMS Business Lead

Chair: Alexis Nolte, SPOR *Business Owner* & *Head of Human Medicines Division*

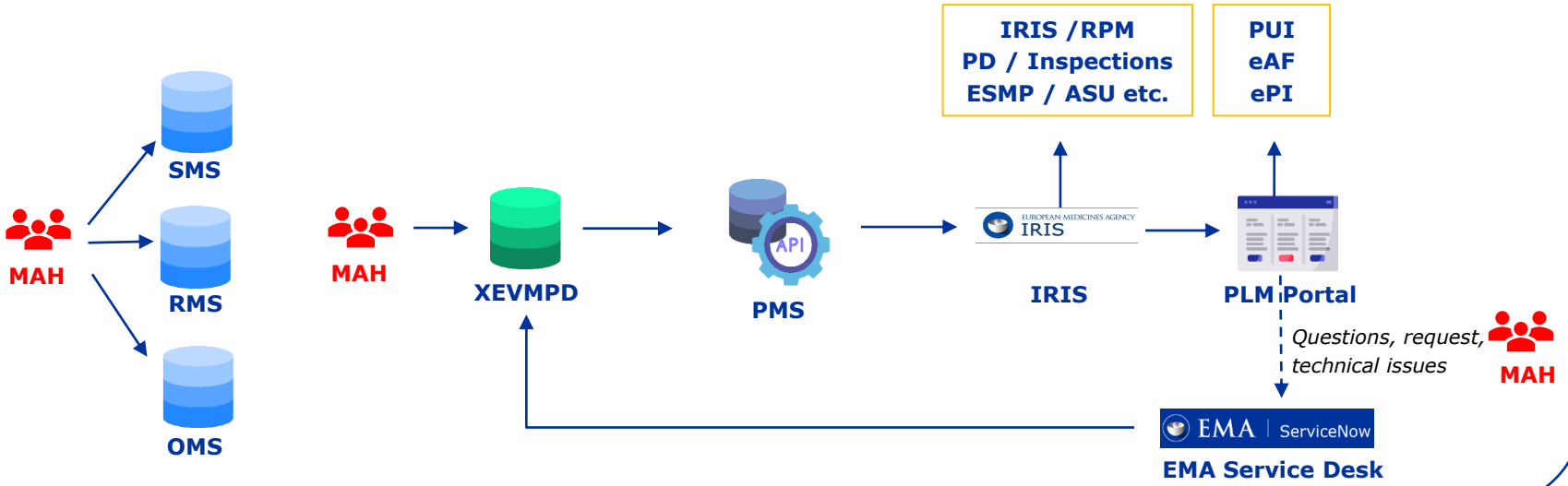
PMS Info Day

How SPOR, XEVMPD/PMS fit together

Pedro Batista, SMS Business Lead

SPOR, XEVMPD/PMS and other processes

What is registered in **SMS, OMS and RMS** and **how data is mapped affects** what Industry will see in **XEVMPD, PMS and other solutions!**



- Industry can request Substances Terms and Organisations/locations ahead of application/ XEVMPD submissions
- Industry cannot update data in PMS or different solutions; if update is required, **product data must be updated in XEVMPD**

- For questions related to **substance/ organisation/ referential terms** contact SMS/OMS/RMS team via EMA Service Desk
- For questions related to **data in PMS** contact PMS team via EMA Service Desk
- For questions related to **data in XEVMPD**, contact XEVMPD team via EMA Service Desk

PMS Info-Day Join at Slido.com: #PMS-INFO

SMS

Pedro Batista, SMS Business Lead

How are substance EV codes mapped against SMS?

- **Which XEVMPD terms were mapped?** All substance EV codes have an SMS ID mapped 1:1
- **Which products are impacted**? All authorised (and development) medicinal products submitted in XEVMPD
- **How will it work in PMS?** PMS will display the SMS substance preferred term name, in the latest version, which is aligned with the substance name used in XEVMPD

EUROPEAN MEDICINES AGENCY

Where can I find information on XEVMPD-SMS data mapping?

1. **Export of SMS lists (current and non-current)** available in SPOR Portal, SMS tab, without login required, as CVS file, as "External_Code_XEVMPD"
2. **SMS API as:**
   <system value="https://spor.ema.europa.eu/v1/lists/100000000009/terms/100000075665" /><code value="substance EV Code" />
3. **Term detail view page in EUTCT** displays XEVMPD-SMS mapping

View :Paracetamol

Term	Paracetamol — See Operational Attributes
Identifier	100000090270
Status	Current
Term Name	en ga it fr mt sl da de lt lv hr nl pl es et pt bg ro sk cs la fi hu el no is sv — Paracetamol — See Operational Attributes
Domain	Human use - H
Visibility	PUBLIC
Mappings	
	Source of Information Extended EudraVigilance Medicinal Product Dictionary - xEVMPD **Source Term ID** SUB09611MIG

*Disclaimer: ATC code list only downloadable by EMA and NCA, not by Industry users.

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Substance cleansing

- **What is happening?** Substances are being cleansed by the SVG, in order to address duplicates and invalid substances and select the most correct substance preferred term. This will improve the data quality of substances in all consuming systems, including PMS.
- **What is the cleansing status**? Currently, around 40% of substances have been cleansed in SMS:
  - All chemicals
  - Almost all veterinary vaccines
  - Proteins used in all authorised products
  - Polymers used in most authorised products
  - Colorcon excipients
- **How stakeholders can know that a substance has already been cleansed?** By the SVG cleansing flag (next slide)
- **How stakeholders can know that a substance has been nullified?** The substance status will be changed to non-current, which will have the following effects:
  - SMS API: status will be displayed as "Non-current" and a replacement substance will be present for duplicates
  - CSV exports in SPOR Portal: the substance will no longer appear in the "Current" export and, instead, will appear in the "Non-current" export. Replacement substance will be present for duplicates
  - XEVMPD: substance will be displayed as "Nullified"
  - EUTCT: substance status will be changed to "Non-current"
  - IRIS: substance will no longer be displayed/available in the substance UI in IRIS

Substances

What is the impact to Industry?

Scenario of mapped XEVMPD-SMS terms	Impact to MAHs - SMS	Impact to MAHs - XEVMPD
If External_Code_SVG = 1 Comment: (empty) / External_Code_XEVMPD: SUB14568MIG, SUB14571MIG, SUB14573MIG, SUB14580MIG / External_Code_SVG: 1	Substance has been reviewed and considered valid. **No action is required**	**No action is required**
If External_Code_SVG = 0 Comment: Duplicate of 100000076078/SUB11847MIG; Duplicate of 100000076084/SUB11890MIG; Duplicate of 100000076084/SUB11890MIG; Duplicate of 100000076095/SUB11901MIG / External_Code_XEVMPD: SUB13460MIG, SUB23388, SUB69012, SUB29191 / External_Code_SVG: 0	Substance has been reviewed and considered invalid or a duplicate. However, it cannot yet be nullified because it is linked to products in XEVMPD. MAH **should** start using the replacement substance provided in the Comments section.	Product **should** be updated in XEVMPD by selecting the replacement substance
If External_Code_SVG is *null* Comment: (empty) / External_Code_XEVMPD: SUB11228MIG, SUB05282MIG, SUB21226, SUB32844 / External_Code_SVG: (empty)	Substance has not yet been reviewed. There is a possibility that the substance might be nullified in the future. **No action is required for the moment.**	**No action is required for the moment.**

Any question in relation to the mappings performed can be raised in **Service Now – Request for Information - SMS**.
If additional substances terms are needed – raise a change request in **Service Now – Request SMS Services**

Substances

What is Industry expected to do?

Mappings & Analysis

- **Review SMS export**
- **Check if your AMPs use any of the substances with SVG flag = 0, see replacement substance in 'Comment' section**

SMS

No action is required

*In case of questions contact **SMS service desk** via 'Request for Information':*
Service: SPOR
Service Offering: SMS

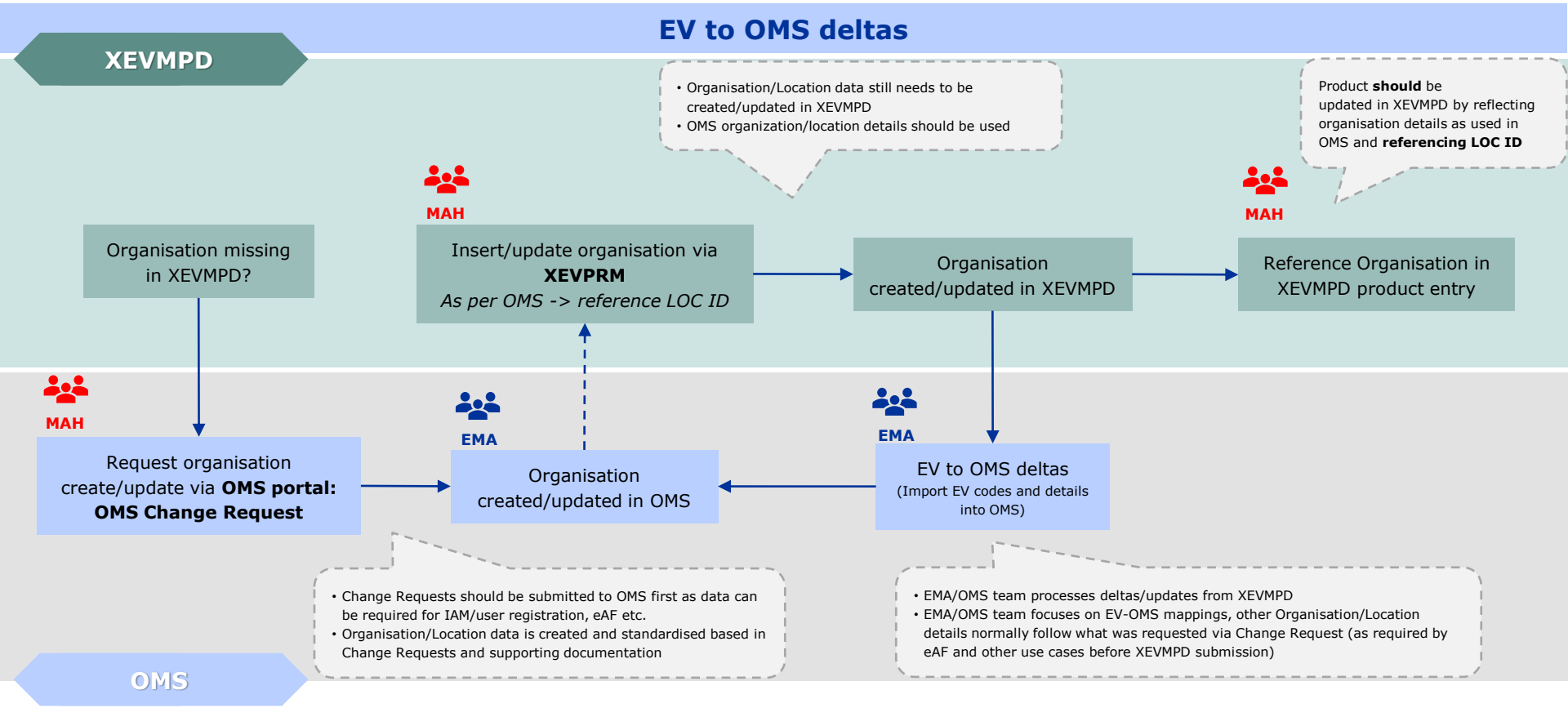
XEVMPD

- If Product is using a substance with **SVG flag = 0** -> Update product information in XEVMPD to **reference the current/replacement** substance
- Further information will be made available about a **substance data cleansing exercise** in the SPOR Status update webinar in July

OMS

Debora Martins Braga, OMS Business Lead

Organisations



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How are EV codes mapped against OMS?

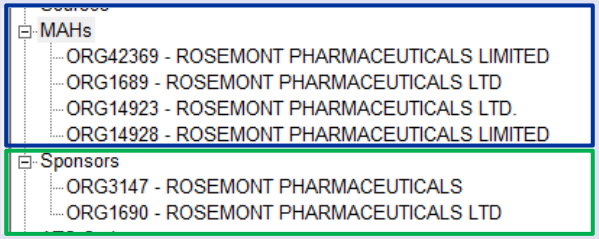
- **Which XEVMPD codes were mapped?** All MAH (and Sponsors) EV codes have been mapped to an OMS ID (LOC ID) - 1 LOC ID can have more than 1 EV code (if duplicates exist in XEVMPD)

OMS

Location Details

Location ID:	LOC-100000383
Address:	Rosemont House Yorkdale Industrial Park Braithwaite Street Leeds LS11 9XE United Kingdom
GPS Location:	53.788549, -1.562502
xEVMPD Code:	ORG3147, ORG42369, ORG1689, ORG1690, ORG14923, ORG14928
EudraGMDP Number:	6723, 6846
National Business Registry number:	00924648
Last Modified Date:	2024-02-06T10:34:22
Status:	ACTIVE

XEVMPD



- **Which products are impacted**? All **authorised** medicinal products submitted in XEVMPD
- **How will it work in PMS?** PMS will display the OMS organisation name, in the latest version, regardless the of the organisation name used in XEVMPD

EUROPEAN MEDICINES AGENCY

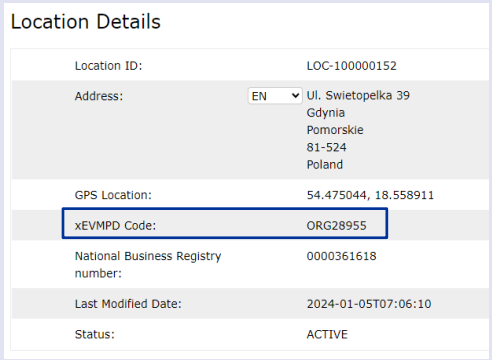
Where can I find information on XEVMPD-OMS data mapping?

1. **Export of OMS lists & contents (active only)** available in OMS Portal, upon login to SPOR portal as CVS/XML files, as Mapping code - Extended EudraVigilance Medicinal Product Dictionary

U	
Mapping Code System Name	Mapping Code
European Inspections Database organisation system key¦National Business Registry number¦Extended EudraVigilance Medicinal Product Dictionary	17557¦0000361618¦ORG28955
Extended EudraVigilance Medicinal Product Dictionary	ORG00008MIG

2. **OMS API** as xEVMPD code/XEVMPD-OMS mapping – XEVMPD <mapping code-system="100000075665" code-system-name="Extended EudraVigilance Medicinal Product Dictionary"><code>ORG28955</code>

3. **Organisation location detail view page** displays OMS-XEVMPD mapping



Organisations

EUROPEAN MEDICINES AGENCY

What is the impact to Industry?

Scenario of mapped XEVMPD-OMS locations	Impact to MAHs - OMS	Impact to MAHs - XEVMPD
Exact/close match to standardised data **XEVMPD:** ITF MEDILAB FARMA, S.A. C/ SAN RAFAEL 3 ¦ ALCOBENDAS ¦ MADRID ¦ 28108 ¦ Spain **OMS:** Itf Medilab Farma S.A. Calle De San Rafael 3 ¦ **Poligono Industrial Calabozos** ¦ Alcobendas ¦ Madrid ¦ 28108 ¦ Spain **XEVMPD:** **VETA PHARMA** **32, DALGA LUKA** ¦ VELIKO TARNOVO ¦ 5000 ¦ Bulgaria **OMS:** Veta Pharma **AD** **Dalga Laka Str 32** ¦ Veliko Tarnovo ¦ 5000 ¦ Bulgaria **XEVMPD:** TILMAN **N.V./S.A.** Z.I. SUD 15 ¦ BAILLONVILLE ¦ 5377 ¦ Belgium **OMS:** **Tilman** **Zone D'Activites** Sud 15 ¦ Somme-Leuze ¦ Namur ¦ 5377 ¦ Belgium	Mapping to the standardised data was done in OMS > information is equivalent and consistent to supporting documentation, but NOT a copy **Please review XEVMPD to OMS mapping:** - If question – OMS Service Desk - If mapping incorrect – OMS Service Desk	**No action is required** Organisation details **can** be updated as used in OMS with mandatory **reference to LOC ID** > this minimizes XEVMPD validation issues and simplifies XEVMPD to OMS Deltas
Mapping to latest version of data **XEVMPD:** **MAP MEDICAL TECHNOLOGIES OY** ELEMENTTITIE 27 ¦ TIKKAKOSKI ¦ 41160 ¦ Finland **OMS:** **Curium Finland Oy** Elementtitie 27 ¦ Tikkakoski ¦ Central Finland ¦ 41160 ¦ Finland **XEVMPD:** **SANQUIN PLASMA PRODUCTS B.V.** PLESMANLAAN 125 ¦ AMSTERDAM ¦ The Netherlands ¦ 1066 CX ¦ Netherlands **OMS:** **Prothya Biosolutions Netherlands B.V.** Plesmanlaan 125 ¦ Amsterdam ¦ Noord-Holland ¦ 1066 CX ¦ Netherlands	Mapping and mastering of legacy data was done in OMS, **latest version of the data is indicated**, where possible **No action is required**	- If Product references a NOT valid MA status > **No action is required** - If Product references a valid MA status > Product **can** be updated • *as-is* in the SMPc or • as in OMS with mandatory **reference to LOC ID**

Organisations

EUROPEAN MEDICINES AGENCY

What is the impact to Industry?

Scenario of mapped XEVMPD-OMS locations	Impact to MAHs - eAF/PML & PMS
Exact/close match to standardised data **XEVMPD:** TILMAN **N.V./S.A.** Z.I. SUD 15 ¦ BAILLONVILLE ¦ 5377 ¦ Belgium **OMS:** **Tilman** **Zone D'Activites** Sud 15 ¦ Somme-Leuze ¦ Namur ¦ 5377 ¦ Belgium	Mapping to the standardised data was done in OMS > information is **equivalent and consistent** to supporting documentation, but NOT a copy **No action is required**

Mapping to latest version of data
 	
XEVMPD: **MAP MEDICAL TECHNOLOGIES OY**
ELEMENTTITIE 27 ¦ TIKKAKOSKI ¦ 41160 ¦ Finland
 	
OMS: **Curium Finland Oy**
Elementtitie 27 ¦ Tikkakoski ¦ Central Finland ¦ 41160 ¦ Finland
 	
XEVMPD: **SANQUIN PLASMA PRODUCTS B.V.**
PLESMANLAAN 125 ¦ AMSTERDAM ¦ The Netherlands ¦ 1066 CX ¦ Netherlands
 	
OMS: **Prothya Biosolutions Netherlands B.V.**
Plesmanlaan 125 ¦ Amsterdam ¦ Noord-Holland ¦ 1066 CX ¦ Netherlands
	KNOWN issue & workarounds:
	• Current Mapping to OMS always defaults to latest/current version
	• **Issue:** data can appear changed in IAM, eAF, PLM Portal and PMS
	
	• **Solution:** Next version of PMS will enable mapping to specific OMS version – date TBC
	
	• **Temporary work arounds/mitigations:**
	  ○ In IAM should use same Org/Loc ID – no impact! - it does not matter the version/name - user need to be affiliated to right Org/Loc ID to see product
	  ○ eAF PDF version should be used

IMPORTANT: MAH EV code = OMS Loc ID = OMS Loc ID used in IAM
MAH EV code must correspond to the same OMS Loc ID that users are affiliated to - if not users will have issues to access PLM portal and seeing relevant products!!

Organisations

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Access to PMS product(s) is managed by **EV** code **mapping in OMS**,
incorrect OMS mappings will lead to products not visible or may be visible to the wrong MAH

Checklist

to ensure you will be able to see all relevant products in PMS

☑ Ensure **organisation and locations** details are **available in OMS** – details are created in OMS as per OMS Data quality standards i.e. details may not be a copy of supporting documentation

☒ If not, access to PMS cannot be requested and eAF cannot be submitted

☑ Ensure XEVMPD-OMS data **mappings are correct**

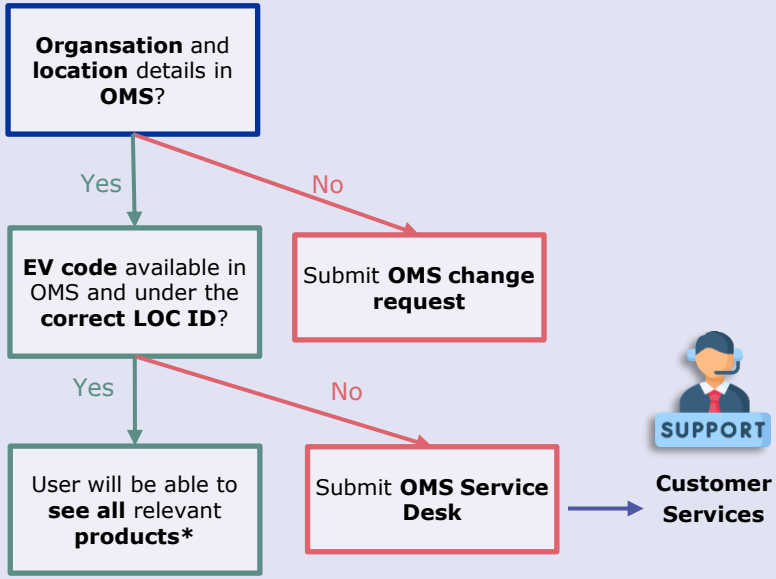
☒ If not, no products will be available in PMS or products will be visible to the wrong MAH

☑ Ensure the **same LOC ID**, with XEVMPD-OMS mapping, is used when requesting any role in **EMA Account Management**

☒ If not, no products will be available in eAF/PML portal & PMS

Organisations

What can MAHs do in case of issues?



Ask a Question in Service Desk

Please submit a '*Request for Information*' (with Service: SPOR + Service Offering: OMS) and OMS team will provide the relevant clarification:

- If XEVMPD-OMS data **mapping is NOT clear** to user
- If XEVMPD-OMS data **mapping is NOT correct**

Report an Issue in Service Desk

If **OMS mappings are correct** and you still experience **issues accessing product data** in PLM, please submit a '*Report an Issue*' (with Service: PLM Portal + Service Offering: PMS Product Data) in cooperation with OMS, PMS, SIAMED, IRIS teams we will investigate:

- Root cause of the reported incident
- If the propagation of the data mapping has failed and at which stage

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What is Industry expected to do?

Mappings & Analysis

Review xEVMPD-OMS data mappings

OMS

No action is required

*In case of questions contact **OMS service desk** via 'Request for Information':*
Service: SPOR
Service Offering: OMS

XEVMPD

If Product references a NOT valid MA status > **No action is required**

If Product references a valid MA status > Product **can** be updated

- *as-is* in the SMPc or
- as in OMS with mandatory **reference to LOC ID**

IMPORTANT: MAH EV code = OMS Loc ID = OMS Loc ID used in IAM
MAH EV code must correspond to the same OMS Loc ID that users are affiliated to - if not users will have issues to access PLM portal and seeing relevant products!!

RMS

Veronica Lipucci Di Paola, PMS Product Owner and RMS Business Lead

Referentials – EV & PMS lists

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How are EV codes mapped against RMS ID/Terms?

- **Which are the mapped lists?** 15 XEVMPD lists were mapped to 19 RMS lists

XEVMPD list	RMS list
Administrable Pharmaceutical Forms	Pharmaceutical Dose form
ATC Codes	ATC Human; National Classification List
Authorisation Procedure	EU Regulatory Authorisation Procedure
Authorisation Status	Regulatory Entitlement Status
Authorised Pharmaceutical Forms	Combined Pharmaceutical Dose form; Pharmaceutical Dose form; Combination Package; Combined Term;
Authorisation Country Code	Country
Legal Basis	Marketing Authorisation Application Legal Basis
Medicinal Product Types	XEVMPD Medicinal Product Type
Name Part Types	Medicinal Product Name Part Type
Route of Administration	Routes and Methods of Administration
Units of Presentation	Units of Presentation
Units of Measure	Units of Measurement
Amount Value Type	Quantity Operator
Role of Ingredient	Ingredient Role
Medical Device	XEVMPD Medical Devices

- **Which XEVMPD terms were mapped?** All not-nullified EV code (Standard/Proposed terms) used in authorised medicinal products were mapped against the relevant RMS ID (Current/Non-Current terms)
- **Which products are impacted**? All authorised medicinal products submitted in XEVMPD
- **How will it work in PMS?** PMS will display the RMS preferred term name, in the latest term version, regardless the of term name used in XEVMPD

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Where can I find information on RMS-XEVMPD data mapping?

1. **XEVMPD-RMS data mapping** excel files are accessible in RMS portal (Documents section) for key lists:
   - XEVMPD-RMS/EDQM Route of Administration terms mapping
   - XEVMPD-RMS/EDQM Pharmaceutical Dose Form terms mapping (Including: Authorised Pharmaceutical Forms to Pharmaceutical Dose Form; Combined Pharmaceutical Dose form; Combination Package; Combined Term)
   - XEVMPD-RMS/WHO-National ATC codes mapping including ATC (Human) & National Classification List

   NEWS ***National Classification List is publicly accessible***

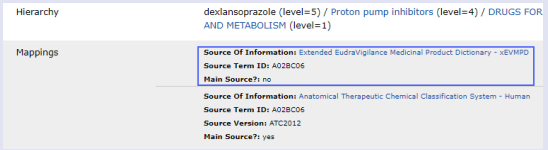
2. **Export of RMS lists & contents** from RMS upon login to SPOR portal as CVS/XML files*

3. **RMS API as:**

```
<mapping spor:rowid="141854" is-main-source="false">
    <source-id id="100000075665" name="Extended EudraVigilance Medicinal Product Dictionary" short-name="xEVMPD" status="CURRENT">
        <link href=http://spor.ema.europa.eu/v1/lists/100000000009/terms/100000075665/>
    </source-id>
    <source-term-id>A02BC06</source-term-id>
</mapping>
```

Mapping Source ID	Mapping Source Term ID	Source Provided Name	Is Main Term Source
100000093553	100000075665	J01DA17 J01DA17	Y N
100000093553	100000075665	L01XX28 L01XX28	Y N
100000075665	100000093553	A02BC06 A02BC06	N Y
100000075665	100000093553	A02BC06 A02BC06	N Y

4. **Term detail view page** displays RMS-XEVMPD mapping



*Disclaimer: ATC code list only downloadable by EMA and NCA, not by Industry users.

Referentials – EV & PMS lists

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What is the impact to Industry?

Scenario of mapped XEVMPD-RMS terms	Impact to MAHs - RMS	Impact to MAHs - XEVMPD
Exact match to current/standard term or new "valid" standard term XEVMPD: Tablet → RMS: Tablet XEVMPD: Prolonged-release pessary → RMS: Prolonged-release pessary (new ST)	Mapping to the standard term was done in RMS **No action is required**	**No action is required**
Typo/close match to current/standard terms XEVMPD: Scored Film-coated Tablet → RMS: Film-coated tablet XEVMPD: Tablets → RMS: Tablet	**Please review XEVMPD to RMS mapping** - If doubt/question – RMS Service Desk - If mapping correct/applies to all products – no action - If mapping incorrect – RMS CR - If mapping does not apply in some products – see XEVMPD	Product **should** be updated in XEVMPD by selecting correct term
Mapping to newly created RMS legacy term XEVMPD: Solution for infusion (RoA) → RMS: Solution for infusion (non-current) XEVMPD: Oromucosal spray → RMS: Oromucosal spray (non-current)	Mapping and creation of legacy term was done in RMS, current term is indicated where possible **No action is required**	Product **should** be updated in XEVMPD to use current standard term (variation)

Any question in relation to the mappings performed can be raised in **Service Now – RMS**.
If additional/new terms are needed – raise a change request in RMS

Referentials – EV & PMS lists

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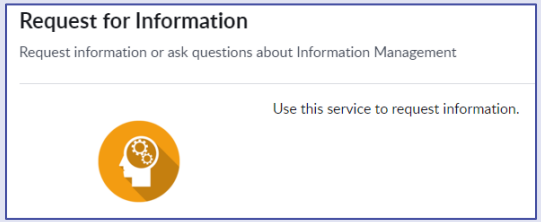
What can MAHs do in case of issues?

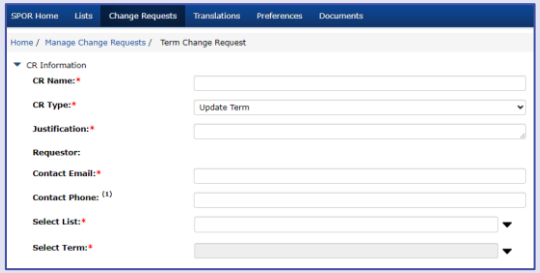
Requestor

Ask a Question in RMS Service Desk → **Customer Services**



- If XEVMPD-RMS data mapping is NOT clear to user, please submit a '*Request for Information*' (Service: SPOR + Service Offering: RMS)
- RMS team will provide the relevant clarification.

Submit **Change Request** in RMS Portal → **EMA Data Stewards**



- If XEVMPD-RMS data mapping is clear to user, it is deemed incorrect and has been incorrectly applied across all products, please submit an **CR to Update RMS Term**.
- RMS team will assess the CRs using guidance/references & tools in consultation with List owner(s)

Referentials – EV & PMS lists

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*Submit **Change Request** in [RMS Portal]*

EDQM lists

- When a new EDQM term is required for the electronic submission of medicinal products
- When the approved SmPC contains legacy terms not yet available/mapped in RMS/XEVMPD
- Note: Supporting documentation shall be provided when requesting new terms

ATC Code (Human) list

- Only ATC codes officially assigned by WHO are created in Anatomical Therapeutic Chemical classification system – Human
- Other National "ATC like codes" (non-WHO ATC) are created in National Classification list
- The structure of National "ATC like codes" is similar to the official ATC codes i.e. it consists of combination of letter and number – A00AA00
- When no available term applies "Not applicable" or "Not assigned" from National Classification list should be used
- Note: Supporting documentation shall be provided when requesting ATC codes

Referentials – other PMS related & most requested lists

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*Submit **Change Request** in [RMS Portal]*

Manufacturing Activity list

- List reviewed in **Q1 2024** by multidisciplinary group of experts (QWP/BWP/IWG/CMDv/CMDv)
- List is **finalised** and next review will be in Q3/Q4 2024
- Industry should map/use **available RMS terms** to **enrich required PMS Manufacturer's elements**
- Given the recent list review, **CR should not be submitted** as they will be rejected and discussed in the next SME consultation.

Shelf-Life Type & Special Precautions for Storage list

Not required for PMS

- **Revision** by multidisciplinary group of experts is **planned in 2024**
- Data elements are **NOT required as PMS data enrichment** in 2024
- **CRs submitted in the context of PMS will be put on hold/rejected**
- **CRs should be submitted if related to eAF**

Material list

Not required for PMS

- Data elements are **NOT required as PMS data enrichment** in 2024
- Add/Update term CR for single material are acceptable and reviewed by SMS Team
- Add/Update term CR for combination of materials CR should not be submitted as they will be rejected.

Referentials – EV & PMS lists

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What is Industry expected to do?

Mappings & Analysis

1. **Review XEVMPD-RMS data mapping files**
2. **Map your terms to RMS Manufacturing activities**

RMS

When Typo/close match to current/standard terms:

- If mapping **correct**/applies to all products: **no action** is required
- If mapping is **incorrect**/incorrectly applied to all products: user should **submit a CR to Update RMS Term**

CRs to Update term of:

- **Manufacturing activity list shall not** be submitted (will be rejected)
- **other PMS lists** (i.e. Material, Shelf life etc) not yet required

*In case of questions contact **RMS service desk** via 'Request for Information':*
Service: SPOR
Service Offering: RMS

XEVMPD

- If **Typo/close match to current/standard terms:** Product **should** be updated in XEVMPD by selecting correct term
- If **Legacy term:** Product **should** be updated in XEVMPD to use current standard term

Further information will be made available about a **term data cleansing** exercise in the SPOR Status update webinar in July

Take aways

Veronica Lipucci Di Paola, PMS Product Owner and RMS Business Lead

Key takeaways

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1

Missing/incorrect Substance, Organisation, Referentials mapping may impact you.

Mitigate any impacts to you by**:**

- Reviewing SMS and RMS exports and ensuring your Products in XEVMPD do not use any of the data that is or will be made non-current. Use replacement substances/terms whenever possible.
- Reviewing MAH organisation information in OMS and ensuring MAH organisation in XEVMPD is aligned with OMS.
- Contacting SMS/OMS/RMS Service Desk for questions or issues

2

Prepare for PMS by:

- Mapping your terms to RMS **Manufacturing activities** as it has been finalised by relevant SMEs.
- Submit SMS/OMS/RMS Change Request for any missing data
- There is **no need to submit Change requests** for data elements that are **not required as PMS data enrichment** in 2024 – shelf life, storage conditions, material.

Q&A Session

On-site participants

- Raise your hand then ask your question orally (please unmute your microphone)
- We will answer **a few questions,** before checking online

Online participants

- **Join Slido.com** using this code **#PMS-INFO** or scanning the QR code here
- Ask your questions or vote the ones you would like to be answered
- We will read out **selected questions** that will be answered verbally

Break (15:00 – 15:20)

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Coffee break

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SCIENCE MEDICINES HEALTH

IDMP Implementation case study - NCA

Georg Neuwirther, Head of IT Austrian Medicines and Medical Devices Agency (AGES)

Chair: Hilmar Hamann, *Head of Information Division*

UNICOM
Up-scaling the global univocal identification of medicines

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 875299

Bundesamt für Sicherheit im Gesundheitswesen
BASG

Information exchange between NCA-IT systems and SPOR PMS

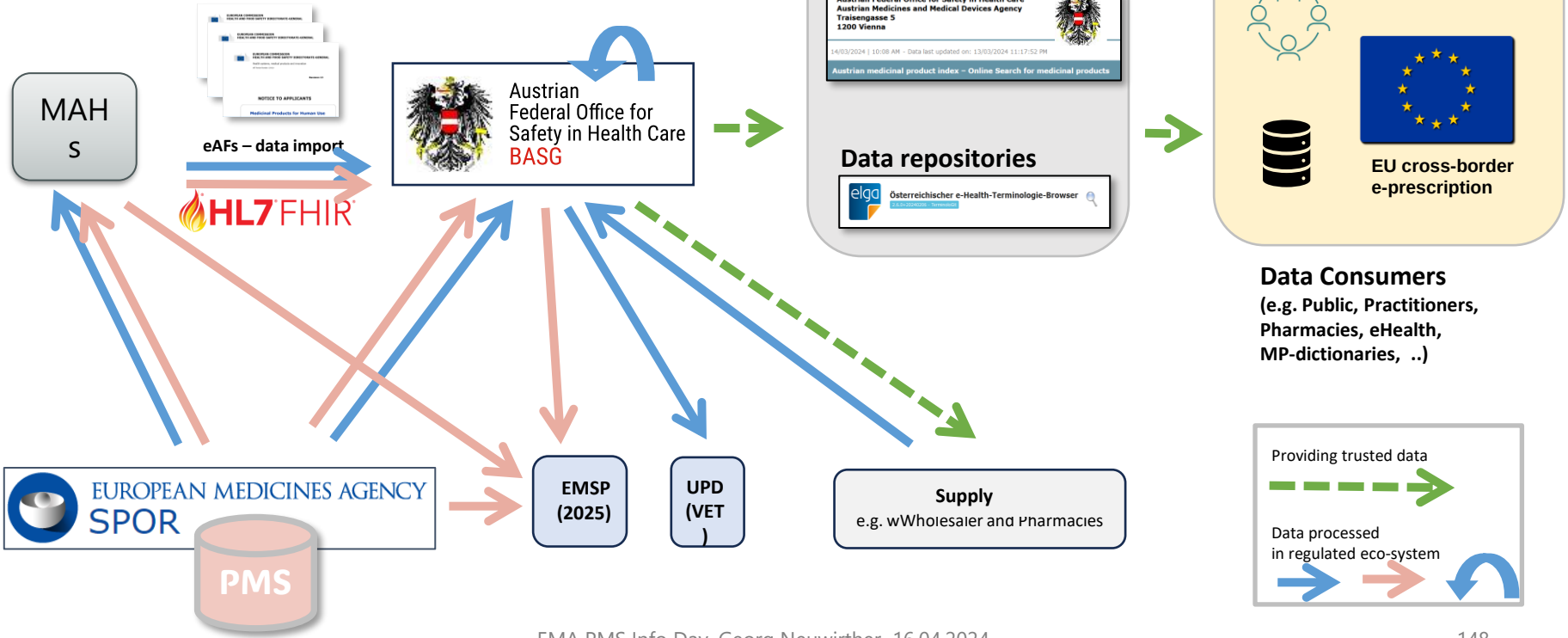
EMA PMS-Info day, 16.04.2024

Georg Neuwirther, Head of IT AGES - Austrian Medicines and Medical Devices Agency

Medicinal Products – Data Flow

simplified view for better readability

Austrian Federal Office for Safety in Health Care
BASG



Findings

Austrian
Federal Office for
Safety in Health Care
BASG

- A valuable information flow of medicinal product data is existing and **it's not a simple one**
  - Stakeholders are using data for several business cases

- **SPOR PMS will have a wider purpose than xEVMPD ("Art 57")**
  - **SPOR PMS will have impact on regulatory activities**

- For medicinal product data we see **multiple "contributors"** of data fragments
  - Creators **are re-using data** provided from other contributors **to create something new** (e.g. an eAF),
    -- MAHs combine data from RIMs with data from (OMS, RMS, SMS) → NCA adding authorisation details → … →
  - **Leading creators can be identified** (e.g. NCAs for authorisation numbers)

- Data is stored and processed **in multiple "places"** – inside and outside the EMRN
  - **Data duplication is a reality**

- Some data consumers are used to process data in different standards ("languages")
  - e.g. EMRN (SPOR), eHealth (SNOMED) - also different in different regions worldwide

Interoperability

Austrian
Federal Office for
Safety in Health Care
BASG

To ensure efficient data flows and trustworthy data <u>interoperability measures</u> are required

Semantic measures

We agree on the exact meaning and business rules for data elements, so that information can be understood and therefore used by all stakeholders

! Essential in PMS because **IDMP** introduced new concepts**!**

" .. manufactured item .."
" .. package item layers .."

Technical measures

We agree **technical** identifiers, interfaces, message formats, rules, ..

! Essential to enable **machine-to-machine communication**

Interoperable Europe Act

For information

Interoperable Europe is the initiative of the European Commission for a reinforced public sector interoperability policy. The Interoperable Europe Act proposes a strategic interoperability cooperation mechanism across the European Union.

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2. Interoperability layers

Source: https://joinup.ec.europa.eu/interoperable-europe

Legal The relevant legal frameworks must allow exchange of data across boundaries, define the licence models, regions for storing data.	
Organisational Way in which public administrations align their business processes, responsibilities and expectations to achieve commonly agreed and mutually beneficial goals. Actors (e.g. providers and consumers) in the interactions must have clearly defined relationships;	Business process definition Needs to start urgently but not focus of this presentation
Semantic Addresses both the *semantic* of the data element exchanged and their *syntax*; **Technical** Interface specifications, interconnection services, data integration services, data presentation and exchange, and secure communication protocols. 4	**Focus of this presentation**

Source: ESMP MSSG, 12.07.2023

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Focus on SPOR PMS

Interoperability considering the upcoming SPOR PMS

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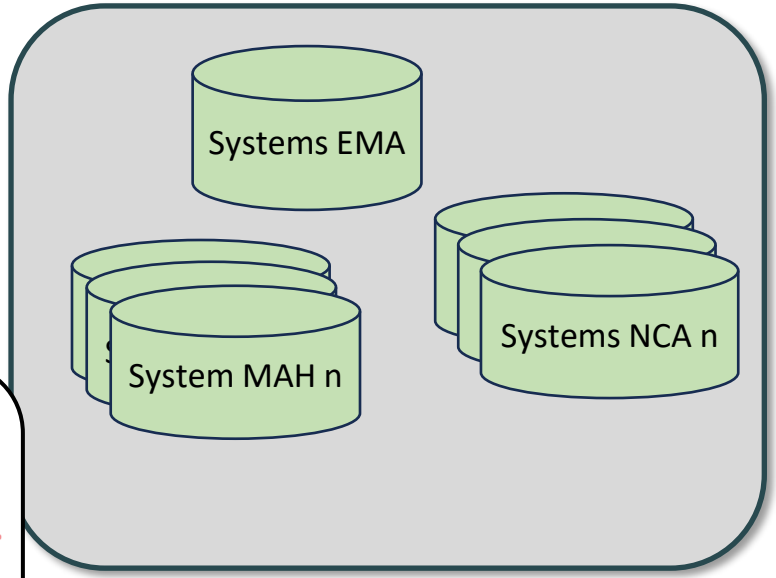
Shared data repository



IT-systems in the EMRN

Interoperability measures, e.g.

- ISO-IDMP standards and annexes
- European IDMP Implementation guide

ISO IDMP

- FHIR definitions
- FHIR implementation guides and profiles

HL7 FHIR

- Shared common dictionaries
- SPOR interface (API)

S(P)OR

Interoperability considering SPOR PMS /2

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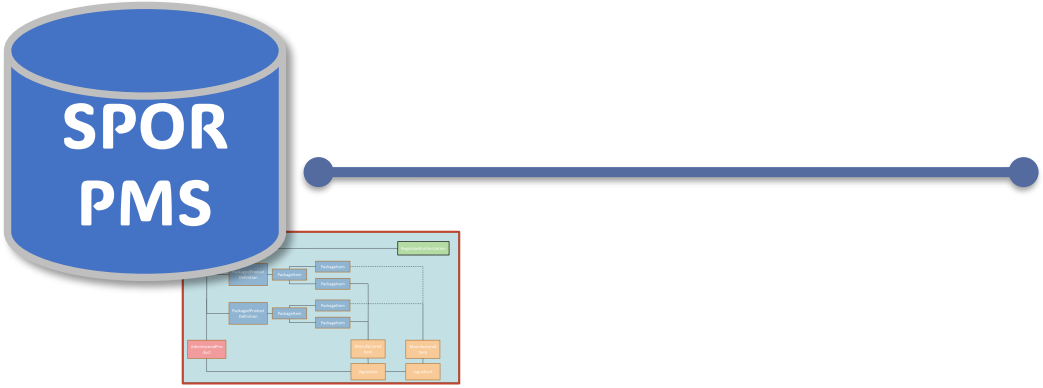

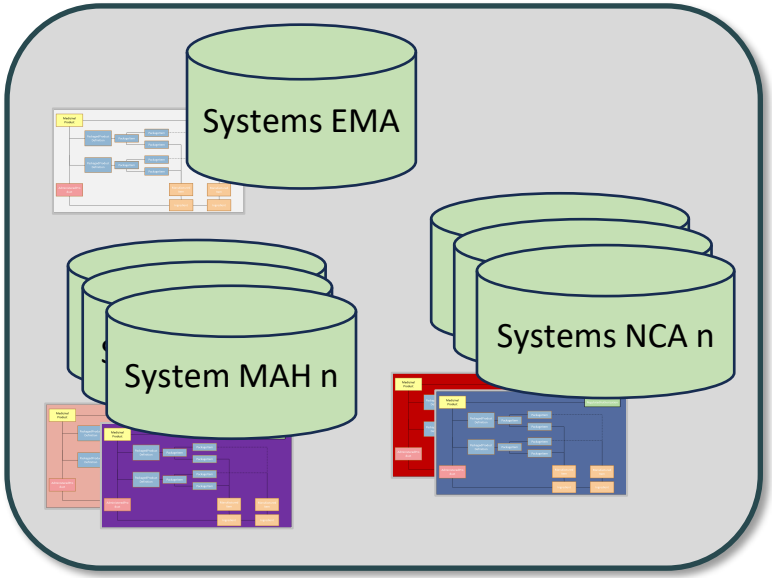

IT-systems in the EMRN

Measures will result in:

- Compatible data models
- IT-enabled business rule execution and validation
- Shared unique identifiers across systems
- Efficient exchange and synchronisation processes

→ Trust in data (flows)

SPOR PMS structures MP data according to IDMP

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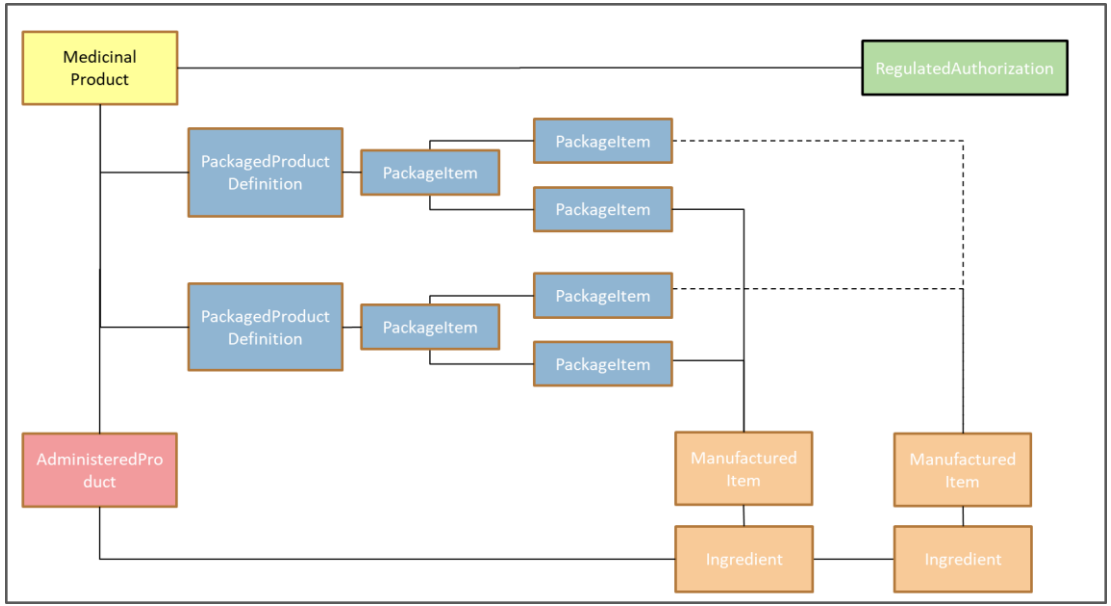
Some details …

IDMP introduces **a very granular and beneficial data class concept,** each with a specific purpose and unique identifiers. To gain benefits it is essential that all partners agree on these concepts and identifiers.



Example of a MP representation: simplified

Benefits, e.g.:

- Data can be
  - uniquely identified
  - created
  - updated
  - "deleted" or "archived"
- Unique and simple electronic identification of "product packages" in eAFs
- Ingredients and manufactured components data is

Common and consistent view on data

Virtual connections

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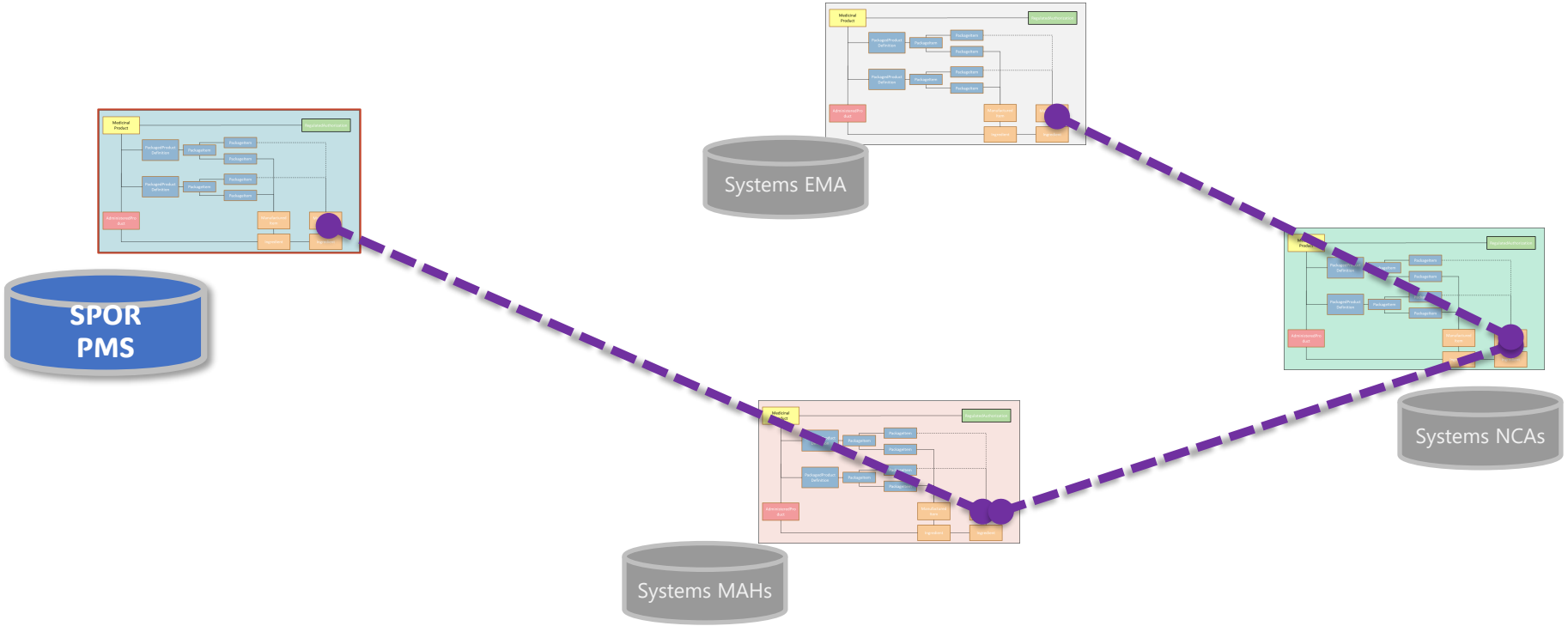
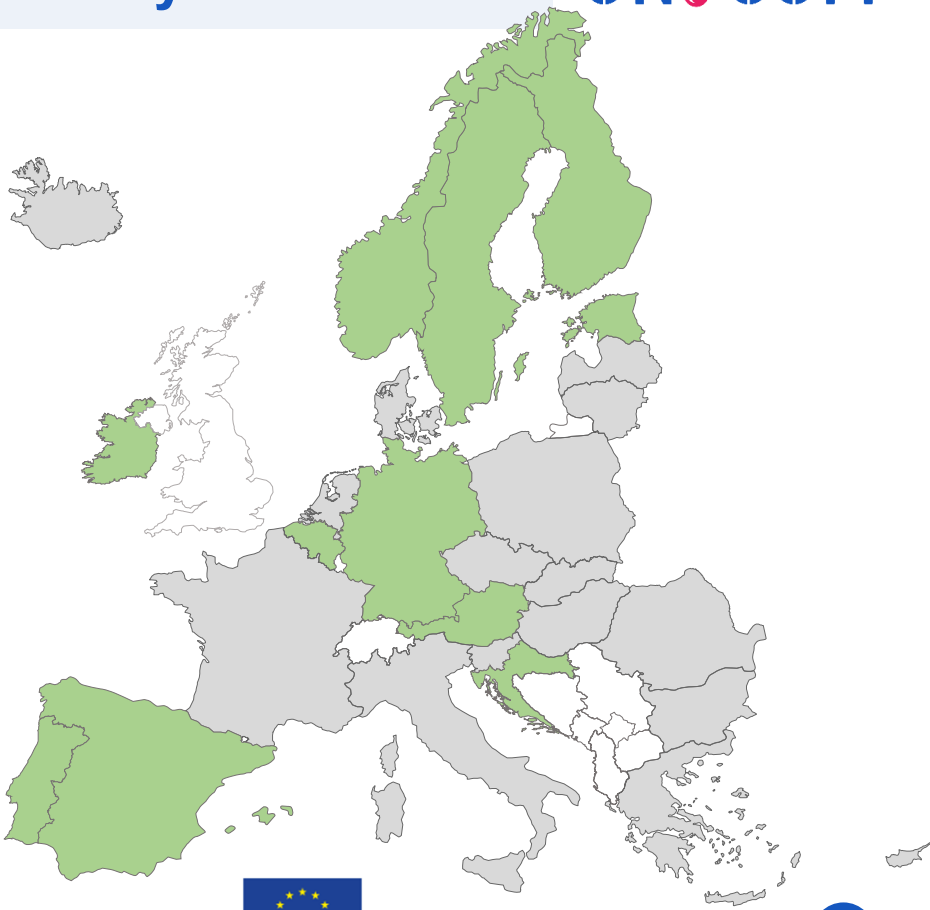


UNICOM's contribution to interoperability

11 NCAs plus partners from eHealth and other disciplines are working together to increase the value of data by implementing shared concepts that are compliant with ISO IDMP, EU IGs, FHIR, by e.g.

- Refactoring or building new databases/systems
- Mapping and transforming legacy data
- Utilising EMA SPOR services
- Building up knowledge in the network
- Contributing to EU-SRS
- Contributing to the new PLM portal (PO)



More information available here: UNICOM Up-scaling the global univocal identification of medicines
https://unicom-project.eu/

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

PMS / IDMP / FHIR
A milestone for our data flows in regulatory activities ?!

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- New eAFs, created by the PLM Portal, will use data from PMS
  - Less effort and less error-prone when authoring variations
- NCAs will electronically import eAFs containing PMS fragments, in a new FHIR format
  - Less effort; future proof format, less error-prone
- NCAs will be able to download and keep CAP-data updated via an automatic PMS synchronisation
  - Less effort; timely availability of CAP data in national data flows
- RIM systems will align with the „common data language IDMP/FHIR“
  - More efficient data submission to regulators – systems will speak the same language

**Assumption: High potential,
if interoperability measures are well considered and implemented!**

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Take Home Message and Summary

Antipasti

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- **Ramp-up knowledge - see EMA's website, useful information also provided by the UNICOM consortium here:**
  - https://www.youtube.com/channel/UCBsNj4B33Q7-50XTXdqAGIg
  - Home - UNICOM (unicom-project.eu)

- **Raise awareness that xEVMPD → PMS data will be used in regulatory activities!**
  - Already in place for CAPs in **eAF Variation forms**
  - **PMS data quality** will have impact on regulatory activities!

- **Bring experts together to evaluate your status of interoperability readiness**
  - Business and IT experts need to work together for this

Secondi Patti

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- **Make your IT systems and data ready for IDMP concepts and FHIR messaging**
  - Extended models, ensure mandatory use of SPOR OMS, RMS und SMS, enrich PMS identifiers in your IT system for data exchange

- **SPOR PMS and PLM Portal implementation at EMA**
  - Make sure that **stable identifiers** are in place for **PMS data structures** and are available in **eAFs right from the start of regulatory activities**

    → in such a way that initial data feeds and continuous data synchronisation can be realised

Dolce

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- **Start realising first benefits**
  - NCAs might start downloading CAP information into national IT systems
  - NCAs will import data from eAFs into national IT systems based on the new future proof format
  - Applicants will select existing master data from PMS when authoring variation forms

- **For NCAs and EMA:** Monitor closely if there will be a call for a UNICOM successor
  - It's important that all regulators will be supported to build up interoperability measures!
  - Status April 2024 – we are working on a follow-up project, no decisions yet
  - Contacts: Georg.Neuwirther@ages.at, pelle.persson@lakemedelsverket.se, christer.backman@lakemedelsverket.se

Summary

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Interoperability is a key factor for processing and providing trustworthy data.

Let's work on it together!

Georg Neuwirther, Head of IT AGES - Austrian Medicines and Medical Devices Agency
georg.neuwither@ages.at

Q&A Session

On-site participants

- Raise your hand then ask your question orally (please unmute your microphone)
- We will answer **a few questions,** before checking online

Online participants

- **Join Slido.com** using this code **#PMS-INFO** or scanning the QR code here
- Ask your questions or vote the ones you would like to be answered
- We will read out **selected questions** that will be answered verbally

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IDMP Implementation case studies - Industry

Merk Group case study

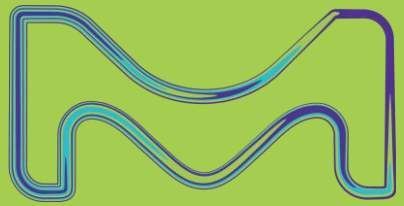
Kepa Amutxastegi Gabiola, Associate Director Regulatory Information Management, *Merck Serono Limited*

Chair: Hilmar Hamann, *Head of Information Division*

EMA PMS Info Day – Industry presentation

Merck Group

Kepa Amutxastegi Gabiola
16 April 2024



MERCK

The journey to IDMP driven Data Management
Implementation of IDMP at Merck

Agenda

i **IDMP Implementation since 2017**

1 **xEVMPD to IDMP Data Transformation**

2 **xEVMPD 3rd Acknowledgement (ACK)**

3 **SPOR data synchronization with the internal systems**

4 **Data governance and processes - the new EMA solutions e.g. eAF, ePI, IRIS, ESMP**

Positioned strategically as a Master Data Management Initiative
IDMP Implementation since 2017

Achieve IDMP compliance

- ✓ Become compliant to IDMP Organizations
- ✓ Become compliant to IDMP Referentials
- ✓ Become compliant to IDMP Substances
- ✓ Become compliant to IDMP Products
- ✓ Become compliant to SPOR-dependent use cases in the EU network (eAF, ESMP, ePI, etc.)

Realize benefits beyond compliance

- ✓ Establish one language across the organization
- ✓ Develop a central repository for products
- ✓ Connect the clinical, manufacturing, supply chain spheres to regulatory
- ✓ Develop one view of the product across the value chain through data integration

Having a clear set of strategic goals and a strong IDMP business case helped us realize benefits throughout the IDMP implementation journey

SPOR = Substance Product Organization Referentials; **eAF** = Electronic Application Form; **ESMP** = European Shortages Monitoring Platform; **ePI** = electronic Product Information;

xEVMPD to IDMP Data Transformation

1 RIM System

Upgraded Regulatory Information Management (RIM) system is implemented with IDMP alignment and xEVMPD data mapping in mind – work in progress

- Substances, Organizations, and Packaged MPs with EV codes

2 IDMP Terminology

Use of IDMP (S/O/R) terminologies in the RIM system based on an MDM solution integrated with the RIM system and mapped to internal data

3 Data Cleansing & Enrichment

Data cleansing & enrichment in RIMS on the data supporting xEVMPD initially, progressing with cleansing of product data beyond xEVMPD and in alignment with IDMP Implementation Guide e.g.,

- eAF 'structured data'
- all authorized packages

4 Submissions to xEVMPD

Data enrichment initiated with the creation of additional authorized packaged medicinal products and their submissions to xEVMPD

The strategy of data submissions to xEVMPD has evolved taking the IDMP (PMS) future data requirements into consideration

- Packaging description
- Authorization number
- MP Full name

XEVMPD 3rd Acknowledgement (ACK)

Use of the Gateway data submission process

3rd Acknowledgements are tracked in the RIM system and reviewed with the required follow up to have the data corrections applied

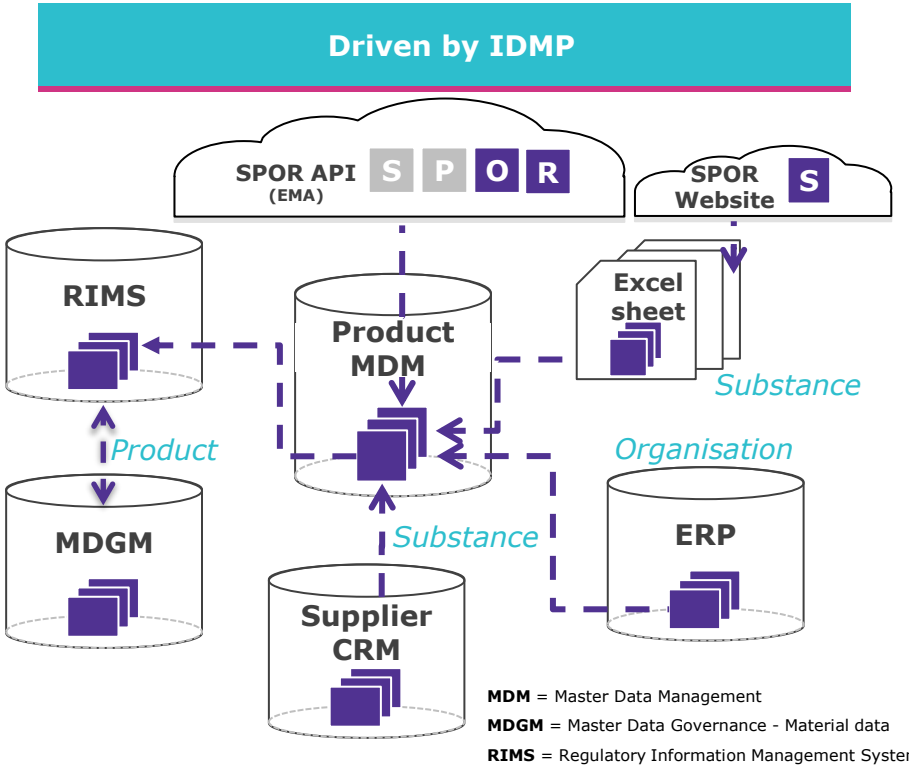
Discrepancies in the approved data against the submitted data is at times questioned

- In cases when coded indication is not accepted , this needs to be reflected internally in the RIM system
- Product Full Name is not accepted when it is not aligned with product name in the SmPC section 1*

*even in those cases where the information in the SmPC contains erroneous symbols, and in cases when the dose form or strength may not fully match with the data submitted – this is mostly applicable for NAPs and can create issues on how the medicinal products are created

SPOR data synchronization with the internal systems

Use of SPOR data in the Organization



S **Substance**

MDM system integrates and maps the internal substance identifiers with the **SRS, SMS & EV** substances. All substances used in RIMS are cleansed i.e., SMS & xEVMPD substances. Substance ontology/semantic model implemented.

P **Product**

All Packaged MPs in RIMS mapped with **EV codes**.
When MPs are readily available in PMS, the **PMS and MP IDs** to be added first in the RIM system and other IDs later.

O **Organization**

The internal identifiers are mapped to the **OMS identifiers** in the MDM system and these identifiers are also stored in the RIM system.

R **Referential**

Providing controlled vocabularies (e.g., pharmaceutical forms, storage conditions) for a medicine, which are also used for registrations globally.
Terms mapped to **RMS IDs**.

Requests to update SMS, OMS and RMS are manually raised following the stablished process using the SPOR portal and the EMA SNOW ticketing system

Data Governance and Processes

EMA Solutions e.g. eAF, ePI, IRIS, ESMP, …

STRATEGY

The strategy for data **cleansing and enrichment** has been initially driven by the implementation of a new RIM system together with the legacy data migrations

- The **data maintenance in xEVMPD** (Art 57) recognized as a fundamental building block to support the future IDMP use cases
- Key pillars of the strategy must be set around **data readiness, governance and business processes** – internally and on the engagements with the Health Authorities (HA)
- **End to end processes** considered (from data creation in the organisation, to recording in the RIM system until it is submitted to the EU HAs)

PREPARATION

The newly implemented RIM system has required data initiatives to establish improved **data quality** and start sourcing additional data in view of the planned EU Regulators' use cases

TRANSITION

Transition process to implement IDMP is challenged by limited certainty on the regulators' roadmap incl. **timelines**, **business processes** and the **data requirements**

- **Project** definitions and approvals issued minimum 6-12 months in advance
- Data cleansing (existing data in the RIM system) and enrichment (new data sourcing) take **considerable time to be data ready for submissions** to the Health Authorities

IMPLEMENTATION

e.g., Use of PLM - changes to the process of authoring the variation application form for all the CAP variation application submissions to EMA

- PLM used for all variation AFs for CAPs incl. onboarding
- **Quality checks** introduced before completion of the AF authoring incl. DQ tool
- **IDMP expertise** found necessary
- Considerable **training, stakeholder and change management** required

eAF = Electronic Application Form; **ePI** = electronic Product Information; **IRIS** = Platform for handling product-related scientific and regulatory procedures; **ESMP** = European Shortages Monitoring Platform;

THANK YOU!

Q&A

Kepa Amutxastegi Gabiola
Kepa.amutxastegi-gabiola@merckgroup.com

Roche case study

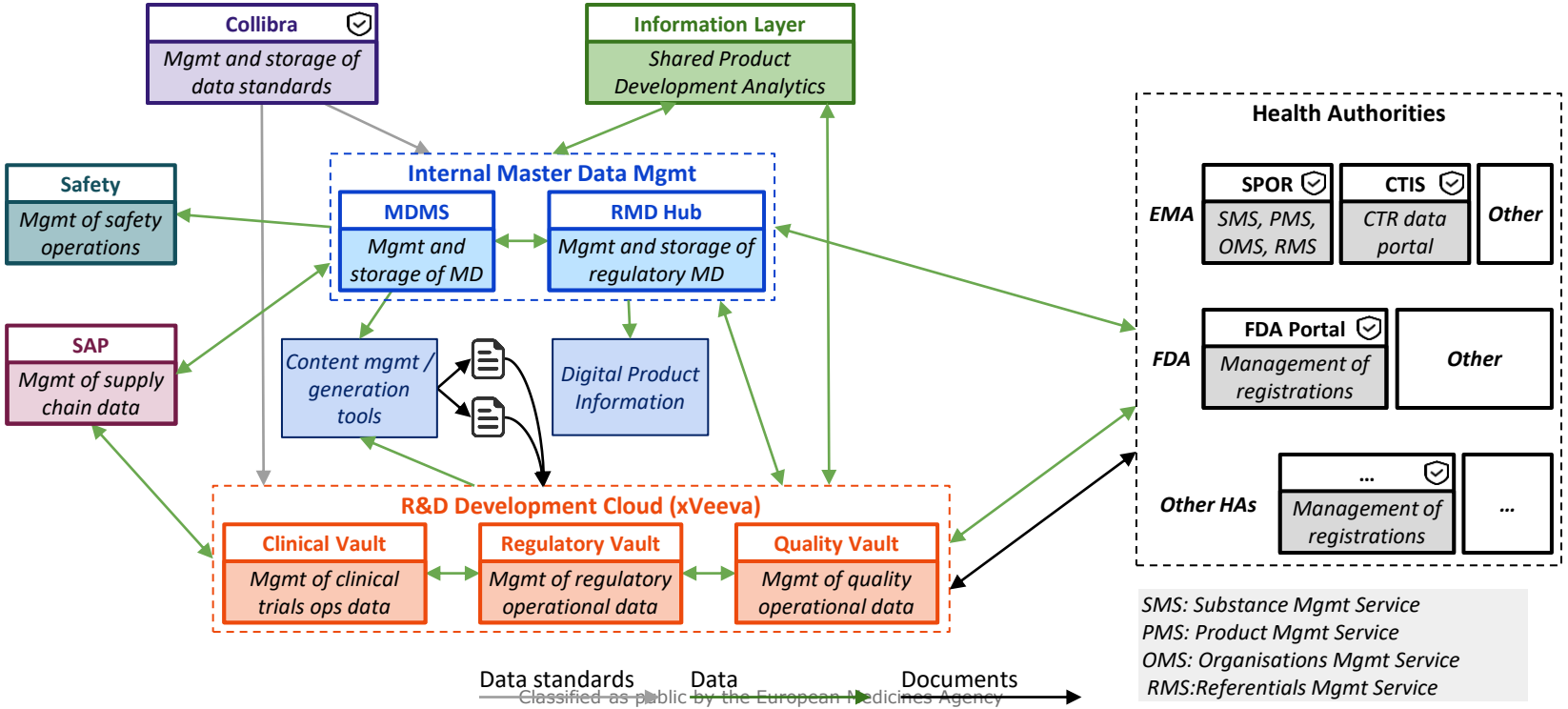
Vanni Carapetian, Senior Director, Data, Roche

Chair: Hilmar Hamann, *Head of Information Division*

EMA PMS Day Presentation from Roche
Case study of data capabilities in service of IDMP Compliance and Value

Across Pharma, we are building a FAIR data landscape

We envision a system landscape that unlocks the potential of data, enabling business to address the challenges of tomorrow



Supported by data governance, essential for trustworthy data

Identifying data domains, their relevant data components, and data accountabilities, which we created new Regulatory roles but no new Regulatory jobs

IDMP&MDA programme

Data Roles

- Data domain leader
- Data steward
- Data and content admin
- Data principals

Data Domains

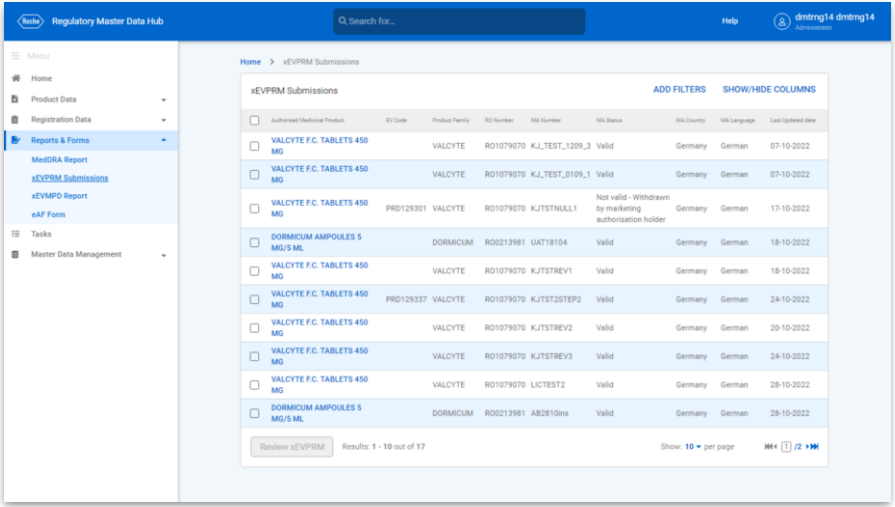
- Product
- Registration Interactions
- Parties
- CMC + Lot Release
- Packaging
- Events
- Dossier Content
- Clinical

Priority 1 | Priority 2 | Priority 3 | Priority 4

- **Domain leader:** Accountable for data lifecycle management, including data quality monitoring. Strategic owner of data domain components across organisation.
- **Data steward**: Tactical end to end management of master data and data standards.
- **Data and content admin:** Responsible for data quality management, data lineage, issue resolution.
- **Data principal:** Varied roles to build data capabilities across organisation and embed IDMP&MDA principles in other initiatives.

IDMP allowed us an opportunity to invest in sustainable data

Roche developed a Regulatory Master Data (RMD) Hub and chose to implement data standards in the systems and processes feeding this platform



Regulatory Registration Data

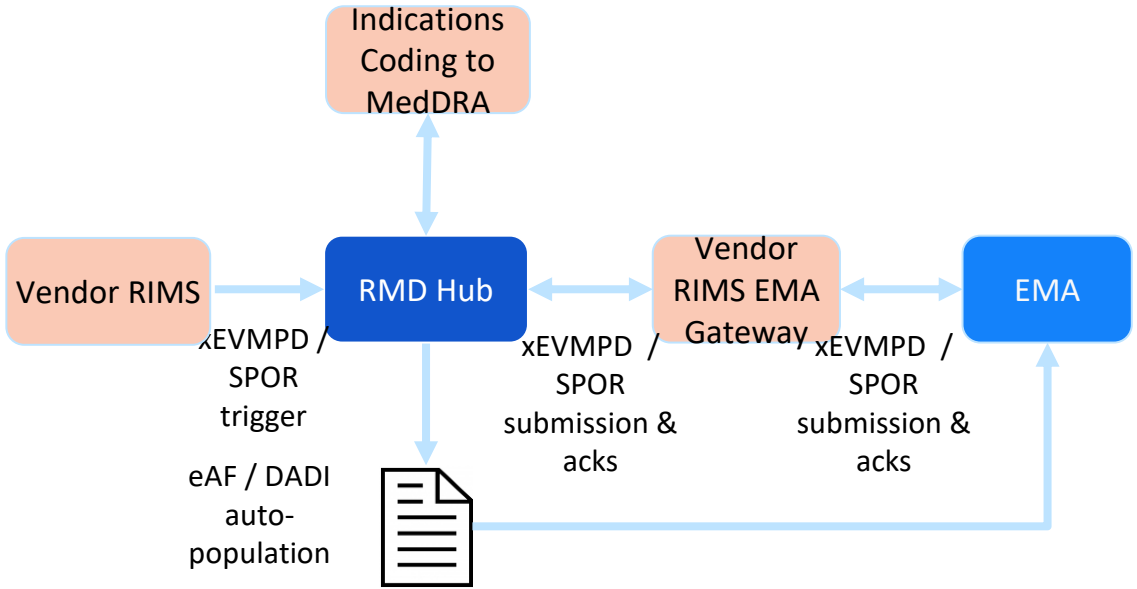
- Product Family
- Medicinal Product Dictionary
- Packaging
- Medical Device Product
- Pharma-ceutical Product
- Substance
- Authorised Medicinal Product
- Investigational Medicinal Product

- **Product Data:** Finance/Pharma Technical controlled Master Data is served to Regulatory, where it is standardised to IDMP/SPOR compliant values and served to transactional systems throughout product development
- **Organisation data** is managed directly in Finance/PT to IDMP standards and served for consumption to RIMs
- High quality product data permitted RMD Hub expansion in 2021-2022 to facilitate **electronic Product Information,** which we are now trying to link back to supply batches; internal regulatory data services to Clinical and Safety
- RMD Hub serves as source for **document generation** in service of electronic Application Form for submission through RIMs gateway

What that looks like for us

Integration between our internal systems and external offerings, all supported by experts and automation, has reduced hand-offs, increased data quality, and enables agility

Regulatory Data Submission Process



Business value areas for discussion

- Direct submission of xEVMPD data to Health Authorities; extensible model to support concurrent XEVMPD + API
- **Substance -** Corrections are made holistically in RMD Hub
- **Product -** XEVMPD Acks volume not prohibitive for us due to portfolio
- **Organisations** - IAM administration duties associated to OneReg Data Governance “Parties”
- **Referentials** - Historically we have made small requests; benefit from industry review

Considerations for discussion

We are emboldened by …

- EMA-Industry partnership
- PMS UAT was very aligned to internal vision
- Potential global vision of IDMP, learning from EMA journey

We would like to see …

- A unified data driven submission process for EU
- A data governance model at EMA for shared trustworthy data

Doing now what patients need next

Q&A Session

On-site participants

- Raise your hand then ask your question orally (please unmute your microphone)
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Online participants

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Conclusions and Questions

Peter Arlett, Chair of EMA Data Board *and Head of Data Analytics and Methods Task Force*

Emmanuel Cormier, ESMP Business Sponsor *and Head of Regulatory Science and Innovation Task Force*

Key take aways

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1 PMS is the **key to a digitally enabled European regulatory procedures**

2 It's time for us all to take a step forward with PMS, make the investment in data mapping and enrichment and step into the future

3

- Starting now, MAHs and NCAs have the **instructions** they need to clean/complete/map their data in XEVMPD by February 2025
- As of May 2024, MAHs can **view product data** through Product UI and PMS API to prepare
- As of November 2024, MAHs should **enrich product** the CAPs &NAPs data in PMS by December 2025

4

- Early adopters from both Industry and NCAs have illustrated how **implementations are realistic and can already bring benefits**, you just need to start the journey!

How to stay informed on PMS Work

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Quarterly System Demos

- See and discuss the latest developments of the system
- Give your feedback on features and priorities

Announced via EMA's Website Events Pages

PMS Web Page

Find:

- PMS overview
- EU Implementation Guide

Check regularly

PLM Portal Forum

+ PMS News page soon available

- Check:
  - News
  - Release notes
  - Downtime comms
- Ask questions (Forum)

Check regularly

Industry & Network SMEs

The Industry & Network SMEs are your connection to product development.

Engagement to be determined by NPO & SMEs

Upcoming communication & engagement activities for PMS

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2024

Q2			Q3			Q4		
Apr	**May**	**Jun**	**Jul**	**Aug**	**Sep**	**Oct**	**Nov**	**Dec**
PMS Info-day	• ***EU IG Ch 1, 5 update*** • ***Product UI guides publication***		***Product UI UAT round 2***			***PMS update webinar***	***EU IG Ch 3, 4 update***	
PMS Info-day recording & presentation	• ***Product UI & API Go-live (view-only)*** • ***PLM Portal new landing page go-live (incl. PMS news page)***	***Public system demo***	***EU IG Ch 2, 6 update***		***Public system demo***		***Training session on NAPs H var submissions in web-based eAF***	***Public system demo***
PLM Newsletter publication	***Product UI & API Access & navigation training session***		***PLM Newsletter publication***			***PLM Newsletter publication***		

Further details on **planned PMS engagement activities for Q2 2024** & key reflections on this event coming on the **quarterly PLM Newsletter**.

1st edition** to be published on **22 April 2024

Subscribe by scanning the **QR code** or through this link.

Last reflections

On-site participants

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Online participants

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Your feedback matters

- Please spare **5 minutes to complete the survey** we have launched on Slido, sharing your feedback on today's event.
- **Your input will guide us in tailoring future sessions** and engagement activities to better meet your needs and preferences.

Join Slido.com using this code **#PMS-INFO** or scanning the QR code here

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Closing remarks

Peter Arlett, Chair of EMA Data Board *and Head of Data Analytics and Methods Task Force*

Emmanuel Cormier, ESMP Business Sponsor *and Head of Regulatory Science and Innovation Task Force*

Closing remarks

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- Today was about raising **awareness and understanding** of the work of EMA and NCAs and the role of Industry in creating and maintaining this new data landscape
- The event offered **diverse engagement options**, including face-to-face interaction and online broadcasting
- **High attendance and active engagement** marked the event, with numerous thought-provoking questions from participants
- Industry and NCAs stakeholders received clarification of key messages and practical recommendations, along with guidance on accessing relevant information
- Industry & NCAs stakeholders were informed about **next engagement activities & key actions** for this year

Thank you for your interest!

Further information

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Telephone +31 (0)88 781 6000
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