EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# Product Management Service (PMS) Progress Webinar

30 May 2023, 10:00 – 11:30 Central European Summer Time (CEST)

# Welcome

**Marcos Fernandez Gomez**, *PMS Product Co-owner, EMA*

**Veronica Lipucci Di Paola**, *PMS Product Co-owner, EMA*

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*Please note that **this session is being recorded** and **will be made available** through **EMA Corporate Website and YouTube channel.***


*At certain points throughout the session, participants will be able to ask questions or give their input via the audience interaction tool **Slido**.*

*Interaction via Slido is voluntary, and you may opt to remain anonymous. If you chose to use Slido, **you consent to the processing of your personal data** as explained in the EMA Data Privacy Statement for Slido.*

# Send your questions via Slido

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**1. Join via the QR code or link**


**2. Send or upvote the questions you want to hear answered**


**3. Questions will be shown on the screen and managed live in the Q&A session**

# Agenda

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| | | |
|---|---|---|
| 1 | **Welcome**<br>10:00 – 10:05 (5 min) | **Marcos Fernandez Gomez,**<br>*PMS Product Co-Owner, EMA*<br>**Veronica Lipucci Di Paola,**<br>*PMS Product Co-Owner, EMA* |
| 2 | **PMS Achievements so far**<br>10:05 – 10:25 (20 min) | **Marcos Fernandez Gomez,**<br>*PMS Product Co-Owner, EMA*<br>**Veronica Lipucci Di Paola,**<br>*PMS Product Co-Owner, EMA* |
| 3 | **Ongoing PMS Work**<br>10:25 – 10:45 (20 min) | **Marcos Fernandez Gomez,**<br>*PMS Product Co-Owner, EMA*<br>**Veronica Lipucci Di Paola,**<br>*PMS Product Co-Owner, EMA* |
| 4 | **Future PMS Work**<br>10:45 – 11:05 (20 min) | **Marcos Fernandez Gomez,**<br>*PMS Product Co-Owner, EMA*<br>**Veronica Lipucci Di Paola,**<br>*PMS Product Co-Owner, EMA* |
| 5 | **Q&A Session**<br>11:05 – 11:25 (20 min) | **Marcos Fernandez Gomez,**<br>*PMS Product Co-Owner, EMA*<br>**Veronica Lipucci Di Paola,**<br>*PMS Product Co-Owner, EMA*<br>**Moderator: Caterina Scarpati,**<br>*PMS Change Management Team* |
| 6 | **Closing**<br>11:25 – 11:30 (5 min) | **Marcos Fernandez Gomez,**<br>*PMS Product Co-Owner, EMA*<br>**Veronica Lipucci Di Paola,**<br>*PMS Product Co-Owner, EMA* |



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# Goals of the session



Provide a summary of the **recent achievements in PMS**

Explain the **work currently under implementation/development**

Inform the attendees about the **next work the PMS team has planned**



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# PMS Achievements so far

**Marcos Fernandez Gomez**, *PMS Product Co-owner, EMA*

**Veronica Lipucci Di Paola**, *PMS Product Co-owner, EMA*

# PMS Background

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## Context

- **Product Management Services (PMS)** is a Network project led by EMA in cooperation with European medicines regulatory network and industry and is part of the SPOR Programme
- PMS will enable the **implementation of globally recognised ISO standards** for the identification of medicinal products (IDMP)
- It will **deliver comprehensive and consolidated** trusted and good-quality **medicinal product data** from different sources
- PMS will **support the implementation of the target operating model** (TOM) for managing medicinal product data

## The PMS product will change:

- **Product data storage** from the EMA database (SIAMED) and the XEVMPD (Article 57) database to the PMS database
- Delivery of comprehensive and consolidated product data, following one standard set of rules for product data (**ISO IDMP standards)**
- **User Interface** to check the data in PMS



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# PMS moved in Product Lifecycle Value Stream

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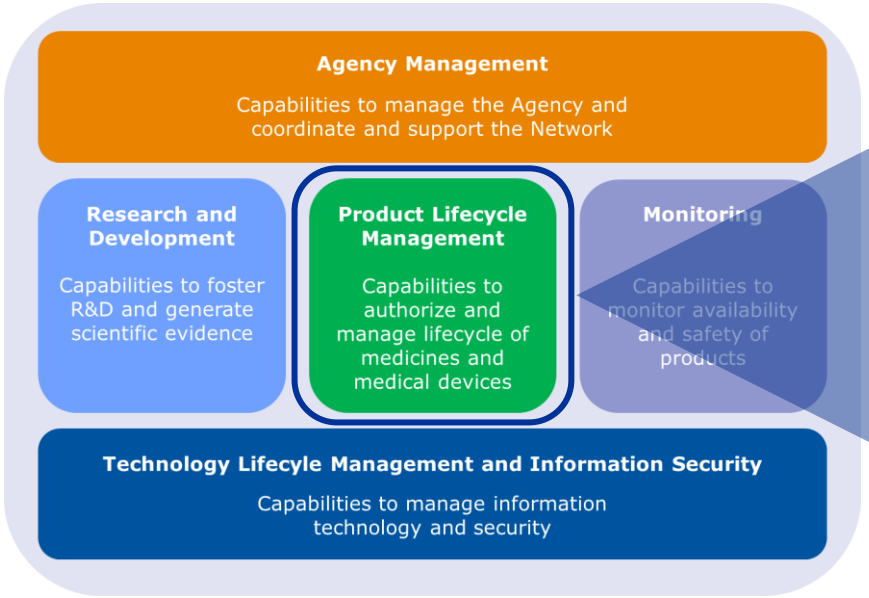


***Product Lifecycle Management Value stream***

*It works on the development and delivery of systems to manage the authorisation and lifecycle of medicinal products and medical devices within the remit of EMA.*

**PLM VS Products**

| | | | |
|---|---|---|---|
| **eAF** | **EURS Next** | **UPD** | **ePI** |
| **EXPAMED** | **ECTD v4.0** | **PMS** | **Reg Procedures Mgmt** |

**PMS** is part of the **Product Lifecycle Management VS**

*"PMS enable the **seamless exchange of regulatory data** within the Network by establishing an integrated human medicinal product data foundation [Data-driven Network Portfolio Objective]"*



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# PMS Product Owners & Subject Matter Experts nominees

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*Nomination selected based on their expertise, SMEs to represent Industry and Network's voices within PMS product team.*

## Industry Subject Matter Experts

- **Elisabeth Godet** - *Sanofi-Aventis Research and Development; member of Vaccines Europe*
- **Laurent Desqueper** - *MSD; member of EFPIA*
- **Nora Weitbrecht** - *Sandoz AG; member of Medicines for Europe*
- **Roberta Bernardelli –** *Gilead; member of EUCOPE*

## Network Subject Matter Experts

- **Barbara Yutzy** - *Germany; PEI*
- **Fakhredin Sayed Tabatabaei** - *The Netherlands; MEB*
- **Katarina Sundberg** - *Sweden; MPA*
- **Peter Bachmann** - *Germany; BfArM*

## PMS Product Owners

- **Veronica Lipucci Di Paola**, EMA
- **Marcos Fernandez Gomez**, EMA

## Network Product Owners

- **Dino Soumpasis -** *Germany; BfArM*



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# Publication of PMS-related documents

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## Event Presentations

**Training Session on Human Variations electronic Application Form (eAF)**
(2 February 2023)

**PMS Webinar on Data Migration**
(23 February 2023)

**PLM Portal Access Management Webinar**
(25 May 2023)

## News and Q&A Documents

- **eAF-PMS Newsletter issue 3** (May 2023)
- **Joint eAF (DADI)-PMS general Q&A document**
- **Human Variations eAF-PMS Frequently Asked Questions (FAQs) document**

# Publication of EU IDMP Implementation Guide

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**Where?** Substance and product data management services | European Medicines Agency (europa.eu)

## Published*

**Introduction –** EU Implementation Guide

**Chapter 1 -** Registration requirements

**Chapter 2 -** Data elements for the electronic submission of information on medicinal products for human use

**Chapter 6 –** Technical specifications on structure and format

**Chapter 7 –** Migration guide

**Chapter 8 –** Practical examples / Annex I – Complete representations

**Chapter 3 -** Process for the electronic submission of medicinal products information (*removed in 2022*)

## To be Published

**Chapter 3 -** Process for the electronic submission of medicinal products information

**Chapter 5 –** Data access export

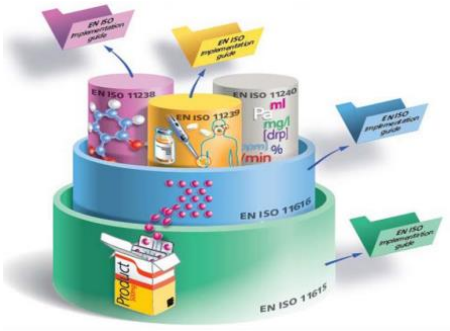
**Chapter 4 –** Data quality assurance

**Chapter 9 –** Process for submitting existing data on medicinal products authorised for human use



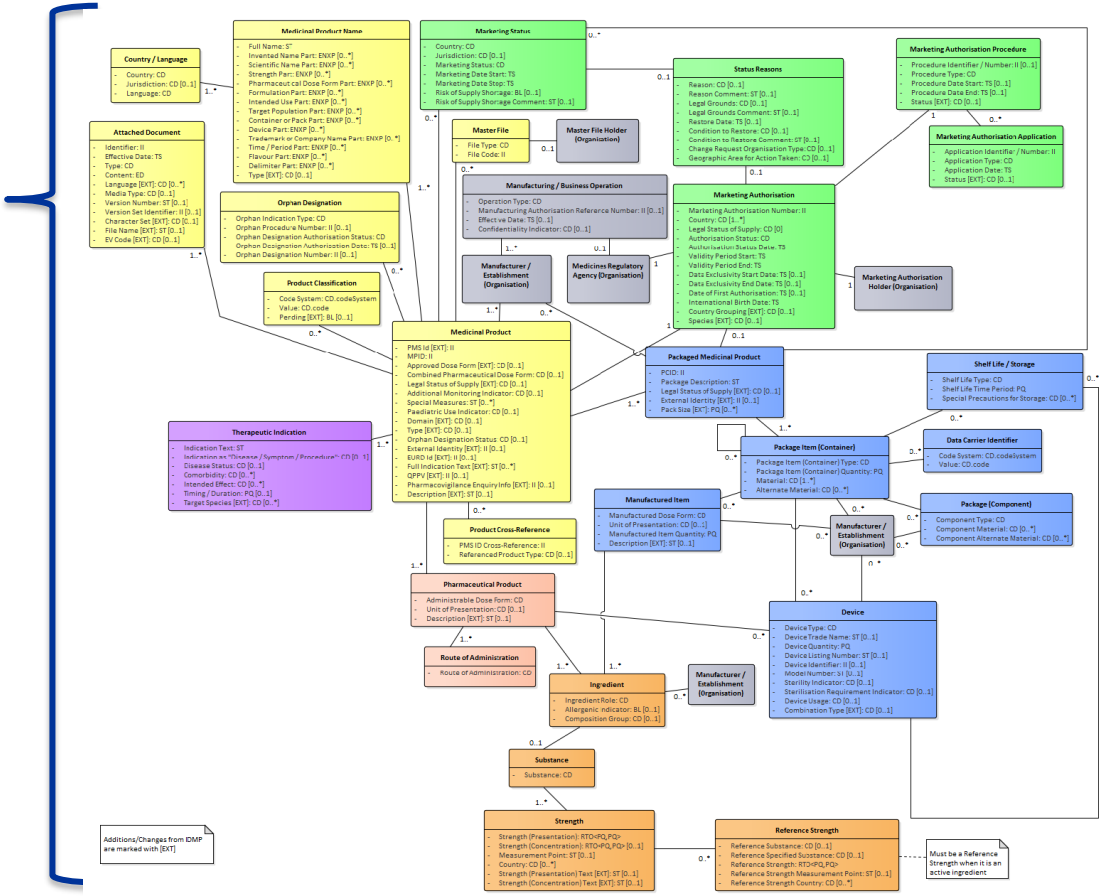
*** Note: Update to the published chapters is required to reflect the development of PMS**

# Product Management Service Data Model




## Colour legend

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

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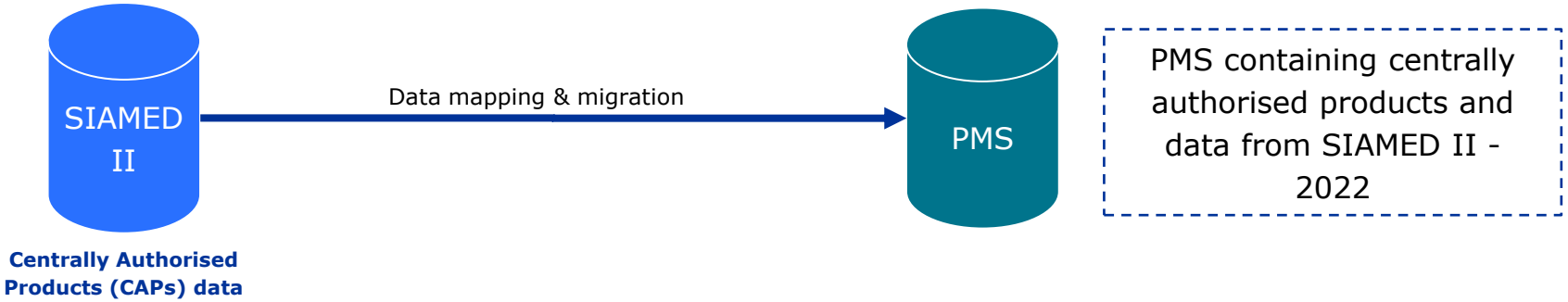
# Origin of existing product data in PMS: Initial data load

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# Migration of CAP data into PMS

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


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# Data mapping

- SIAMED contains **data** that can be **mapped to already existing terms** in other SPOR services.
- An exercise to map these terms to SPOR has been performed by EMA.

| | |
|---|---|
| Form/strength name | **120 mg - Gastro-resistant tablet** |
| Pharmaceutical form | **Gastro-resistant tablet** |
| Route of administration | Oral use, |

Composition/ingredients

| Substance | Role |
|---|---|
| Dimethyl fumarate | Active |

Applicant **Almirall S.A**

**R**

| | |
|---|---|
| Identifier | 100000110655 |

**Source Of Information:** SIAMED - EMA CP management system
**Source Term ID:** milligram(s)
**Main Source?:** no

| | | |
|---|---|---|
| Identifier | 100000073667 | |
| Operational Attributes | | |
| Term Name | en | Gastro-resistant tablet |

**Source Of Information:** SIAMED - EMA CP management system
**Source Term ID:** Gastro-resistant tablet
**Main Source?:** no

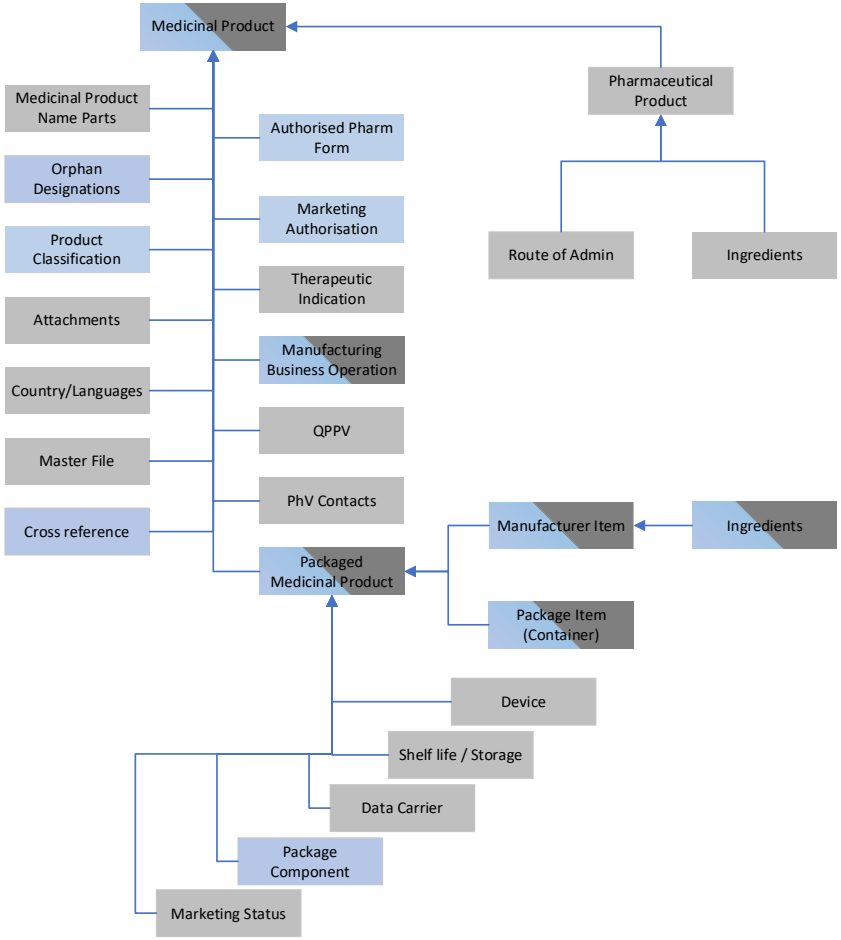
**S**

| | |
|---|---|
| **Term** | Dimethyl fumarate |
| **Identifier** | 100000079228 |
| **Status** | Current |

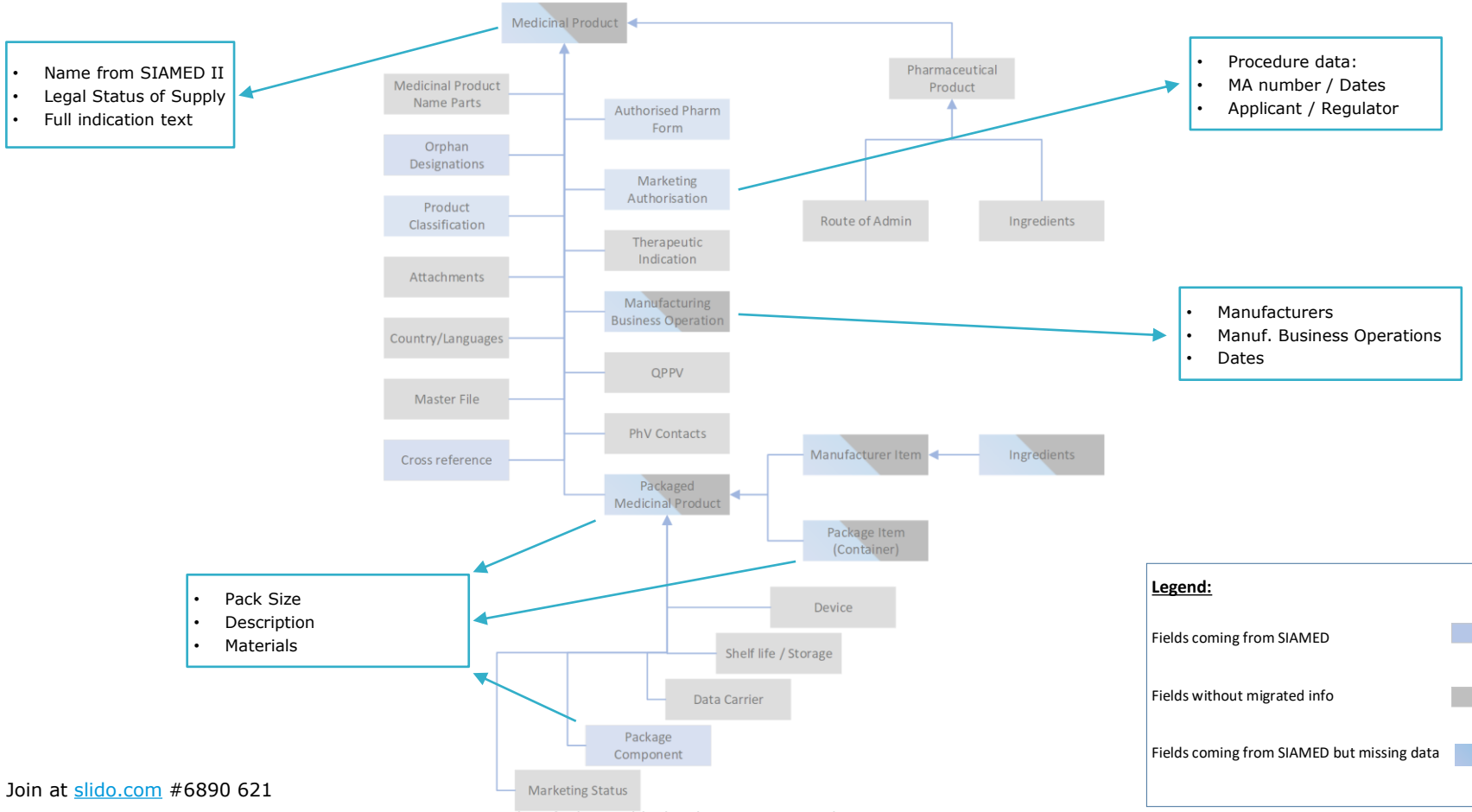
**O**

| | |
|---|---|
| ORG-100000571 | Almirall S.A. |

# Data migrated from SIAMED II



# Data migrated from SIAMED II



# CAPs data in Product Lifecycle Management (PLM) Portal

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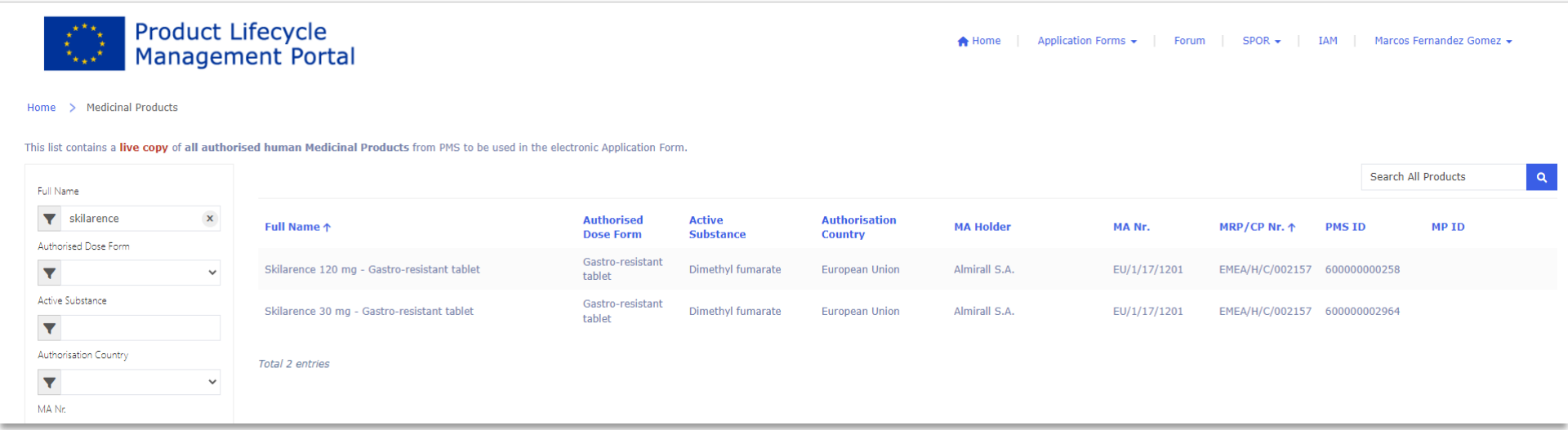


- PMS contains CAP data as described before while PLM portal only shows specific data elements for the time being
- More than **3,000 CAP medicinal products** in the PLM portal
- PMS products and data already in use by Inspections team and web-based electronic Application Form (eAF)

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# PMS API

- PMS API aligned with Chapter 2 of the EU IG
- Only to be used internally at EMA


```
"fullUrl": "MedicinalProductDefinition/600000000258",
"resource": {
    "resourceType": "MedicinalProductDefinition",
    "id": "600000000258",
    "contained": [ ···
    ],
    "extension": [ ···
    ],
    "identifier": [ ···
    ],
    "domain": { ···
    },
    "version":
    "status": { ···
    },
    "indication": "Skilarence is indicated for the treatment of moderate to severe plaque psoriasis in adults in need of systemic medicinal therapy.",
    "_indication": { ···
    },
    "legalStatusOfSupply": { ···
    },
    "additionalMonitoringIndicator": { ···
    },
    "paediatricUseIndicator": { ···
    },
    "productClassification": [ ···
    ],
    "characteristic": [ ···
    ],
    "packagedMedicinalProduct": [ ···
    ],
    "name": [
        {
            "id": "       ,
            "productName": "Skilarence 120 mg - Gastro-resistant tablet",
            "type": {
```


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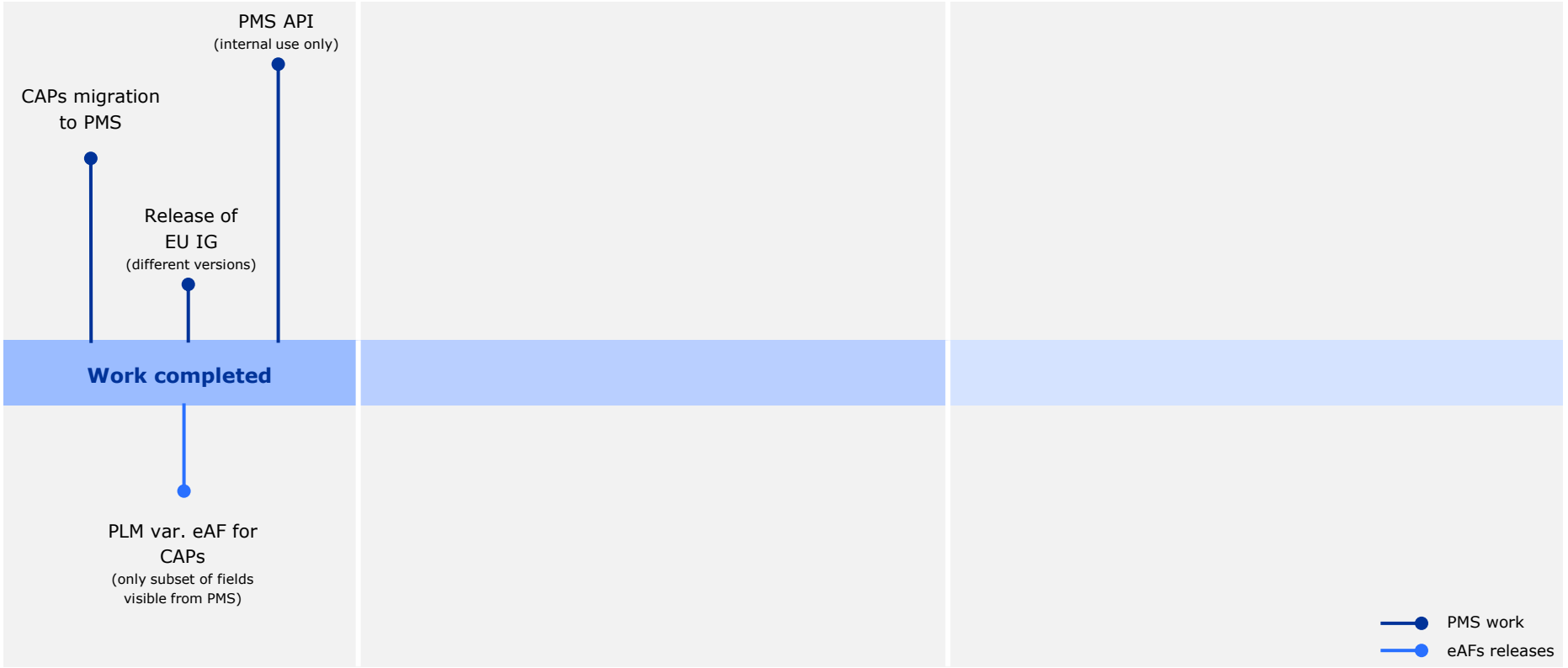
# Summary




**IMPORTANT**: this slide **DOES NOT represent timelines or sequencing of release** but pieces of work or events to be delivered and the impact on users.

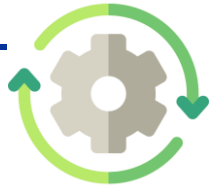
# Ongoing PMS Work

**Marcos Fernandez Gomez**, *PMS Product Co-owner, EMA*

**Veronica Lipucci Di Paola**, *PMS Product Co-owner, EMA*

# Ongoing work with Industry and Network SMEs





- Providing expert input on EPIC/Feature related topics for prioritisation:
  - Development of **Product User Interface design** and graphic
  - Support the development of **Product UI VIEW** and **EDIT** functionalities
  - Support the set up of **user access and security management in PLM**
  - Refinement of **EU Implementation Guide** and **PMS Data Model**
- Support the product owners with insights and identification of technical and business solution
- Provision of input in support of the prioritization of PMS user stories and features

# Split of products from SIAMED II

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- There are some specific products in SIAMED II which are **not following the IDMP structure**
  - **PMS** defines a medicinal product based on the name as authorised in section 1 of the SmPC
  - **SIAMED II** does not capture the full name as authorised
- That situation leads to a case where in SIAMED II we only have one medicinal product but in PMS, more than one MP should be created
- A logic has been implemented to **split these products** before the match and merge protocol
- As advised by **eAF team**, these products should not be used until they have been split to avoid issues

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# Split of products from SIAMED II

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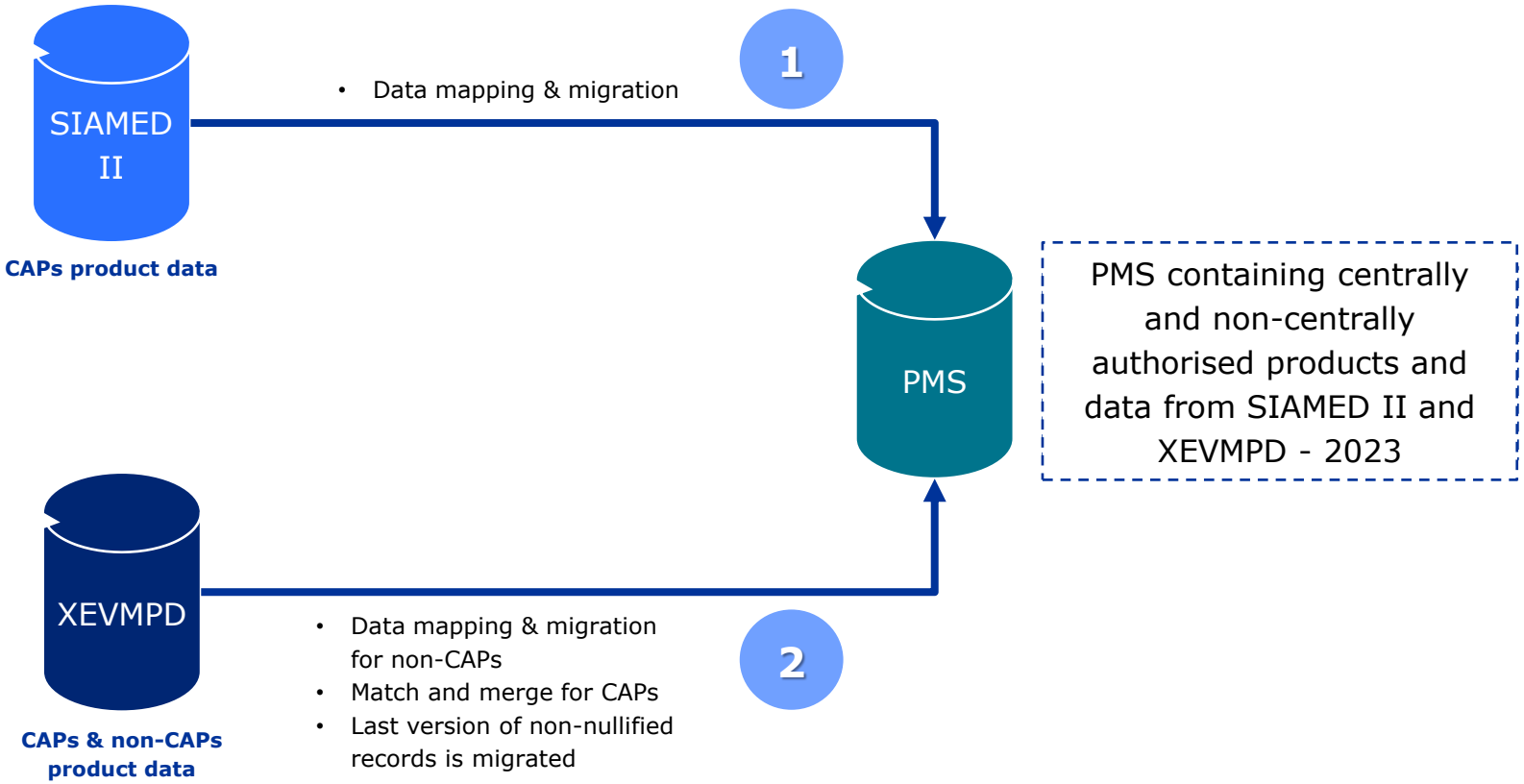
| SIAMED STRUCTURE | | PMS STRUCTURE | |
|---|---|---|---|
| Aimovig - 70 mg – solution for injection | EU/1/18/1293/001 | Aimovig 70 mg solution for injection in pre-filled pen | EU/1/18/1293/001 |
| | EU/1/18/1293/002 | | EU/1/18/1293/002 |
| | EU/1/18/1293/003 | Aimovig 70 mg solution for injection in pre-filled syringe | EU/1/18/1293/003 |
| Aimovig - 140 mg – solution for injection | EU/1/18/1293/004 | Aimovig 140 mg solution for injection in pre-filled pen | EU/1/18/1293/004 |
| | EU/1/18/1293/005 | | EU/1/18/1293/005 |
| | EU/1/18/1293/006 | Aimovig 140 mg solution for injection in pre-filled syringe | EU/1/18/1293/006 |
| **2 products each of them with 3 presentations** | | **4 products each of the with different number of presentations** | |

*As a general rule, if, for the same strength and dose form, there are **different full names authorised,** these products will be split in PMS.*

# Data migrated from XEVMPD

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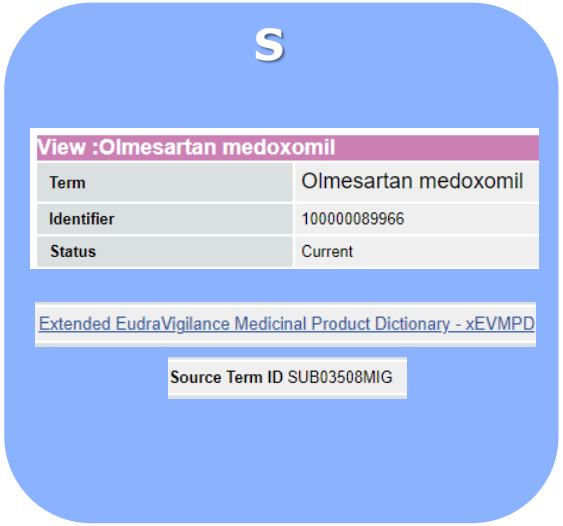
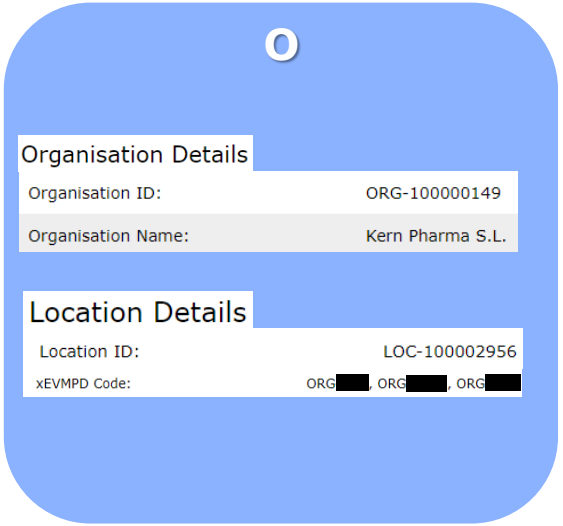
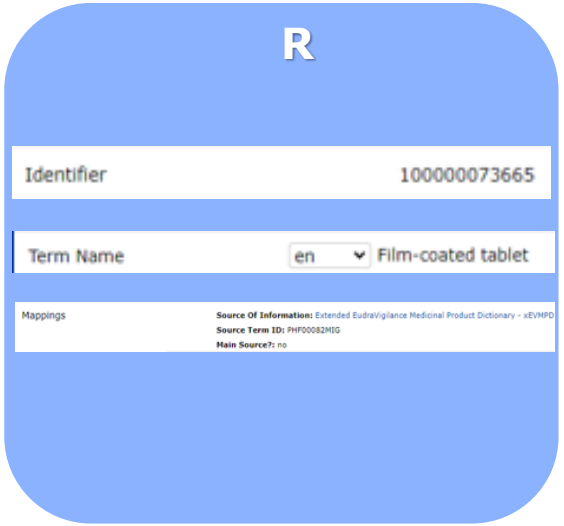
# Data mapping

- SIAMED and XEVMPD contain **data** that can be **mapped to already existing terms** in other SPOR services.
- An exercise to map the terms in both databases to SPOR has been performed by EMA.

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# Origin of existing product data in PMS: Initial data load

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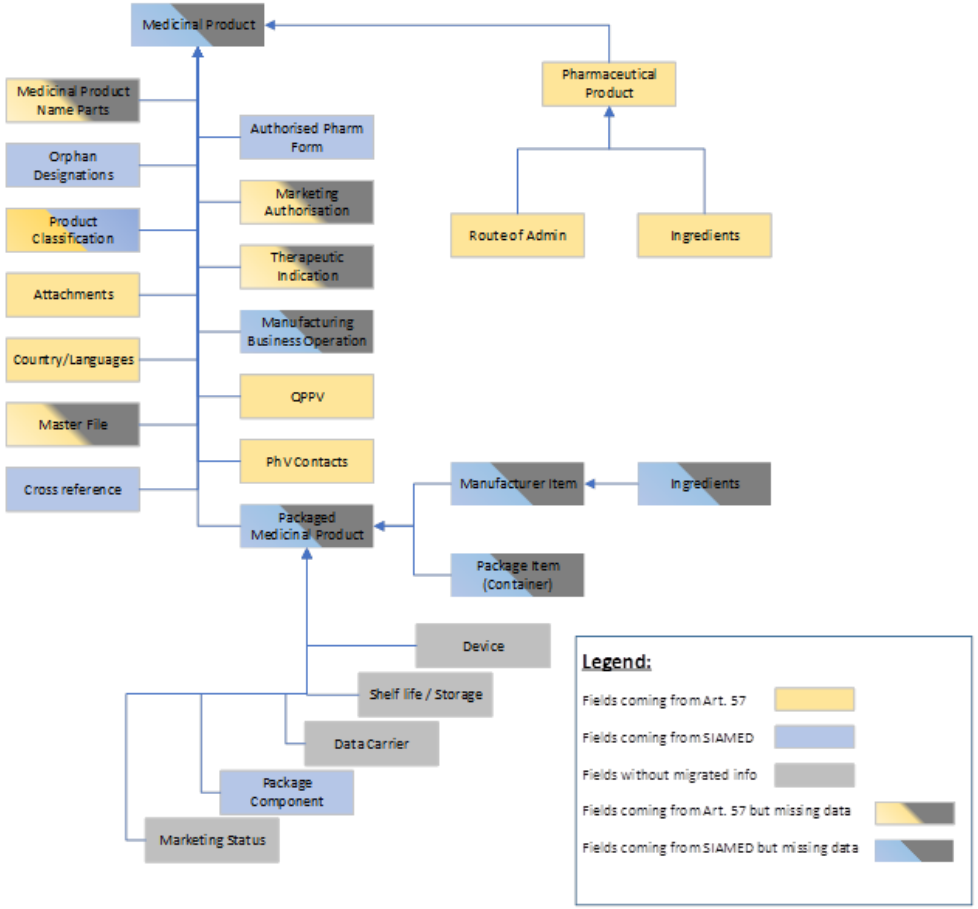
- **CAPs**: data sourced from SIAMED and XEVMPD
- **Non-CAPs**: limited data sourced only from XEVMPD
- Despite the initial data load from SIAMED and XEVMPD some PMS definitions & resources **will be missing** (e.g. non-CAP MBO, data carrier, device etc.)

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# Migration of XEVMPD data into PMS

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- XEVMPD contains **CAPs** data:
  - At presentation level (i.e. one EV code per presentation)
  - 4 records per presentation (i.e. 4 countries: EU, LI, NO, IS)

- The **match and merge protocol** consists in the identification of:
  - a product in PMS migrated from SIAMED II with their respective presentation
  - the same presentation in XEVMPD and merge them

| PMS | SIAMED II | MA number | XEVMPD |
|---|---|---|---|
| 600000000258 | Skilarence 120 mg **-** **G**astro-resistant tablet | EU/1/17/1201/002<br>EU/1/17/1201/003<br>EU/1/17/1201/004<br>EU/1/17/1201/005<br>EU/1/17/1201/006<br>EU/1/17/1201/007<br>EU/1/17/1201/008 | Skilarence 120 mg **g**astro-resistant tablet**s** |
| 600000002964 | Skilarence 30 mg **-** **G**astro-resistant tablet | EU/1/17/1201/001<br>EU/1/17/1201/013<br>EU/1/17/1201/014 | Skilarence 30 mg **g**astro-resistant tablet**s** |

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# Merge business rules

Once a record from SIAMED II *(now in PMS)* and a record from XEVMPD match, there are several **business rules** defined for the merge and are described in EU IG Chapter 7.

*Depending on the data field, the final source of data might be different.*

| Is this field in SIAMED? | Is this field in XEVMPD? | Business rule | Example |
|---|---|---|---|
| NO | NO | This field will be empty | Storage conditions |
| YES | NO | Keep the data migrated from SIAMED | Manufacturers |
| NO | YES | Migrate the data from XEVMPD | MedDRA Codes |
| YES | YES | Define the source of data | Full name - overwritten by XEVMPD data |

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# Migration of XEVMPD data into PMS

XEVMPD contains **non-CAPs** data:

- At presentation level (i.e. one EV code per presentation)
- At medicinal product level (i.e. no presentations are submitted to XEVMPD)
- BE, FI and LU authorised products are submitted in each official language

EV codes with the same data in the following **XEVMPD fields** are grouped under the same PMS Medicinal Product


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

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# Examples

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## Example 1

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

**3 EV codes** in XEVMPD
(1 per presentation)

→

**1 Medicinal product** with
**3 Package medicinal products**

## Example 2

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

**3 EV codes** in XEVMPD
(1 per product)

→

**3 Medicinal product** with
**1 Package medicinal product each**

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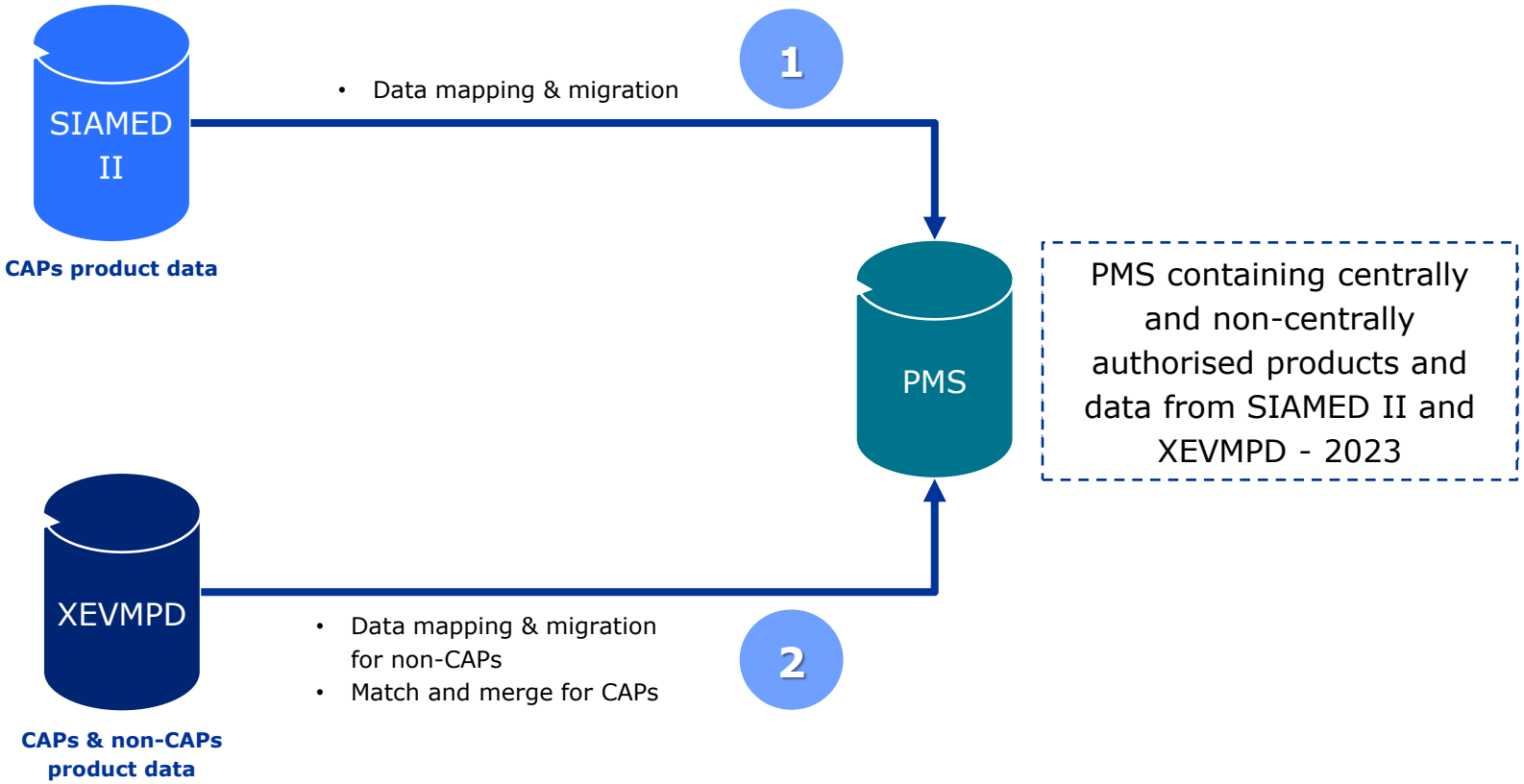
# Data migrated from XEVMPD

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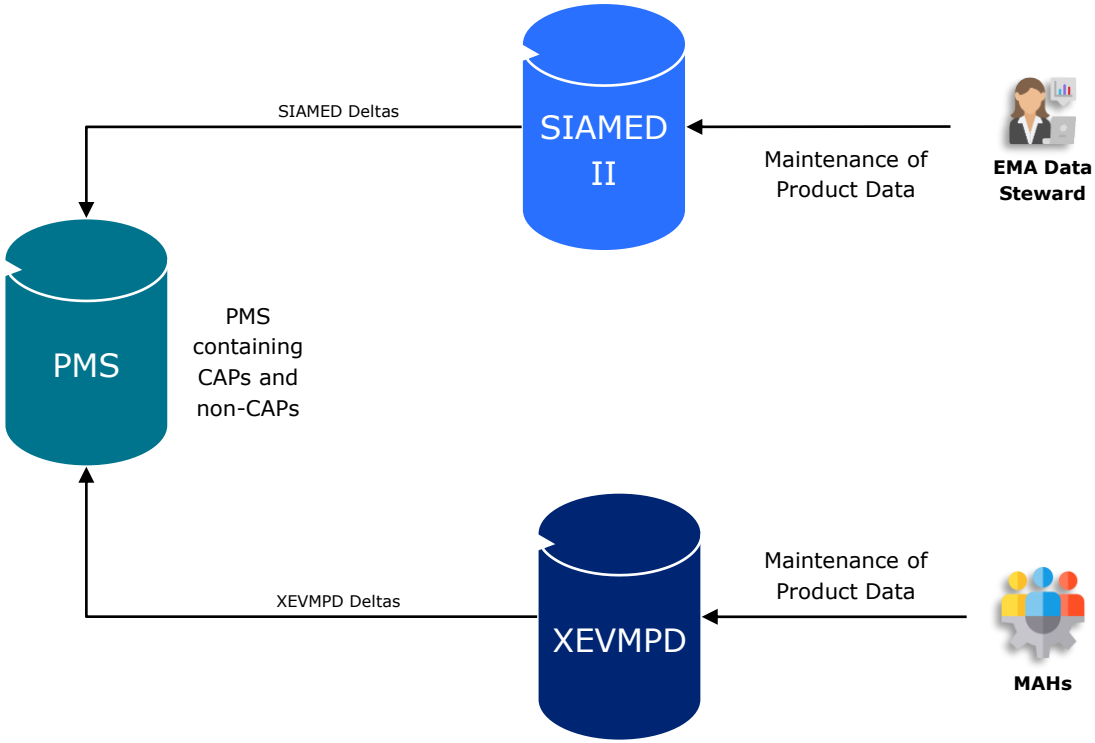
# Deltas to PMS




## XEVMPD deltas

- Changes done in XEVMPD are propagated to PMS
- Messages from XEVMPD stay in a queue and are processed in PMS (performance of deltas will increase over time)
- Same logics as initial load are used in the deltas

# Product UI – view pages

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PMS team is working in a **Product User Interface** that will allow users to:

- See medicinal products data
- Maintain product data

*Product UI will be located in the PLM Portal*

Points also under discussion:

- User roles (Industry and NCAs)
- Security and Access Management

# Product UI – view pages

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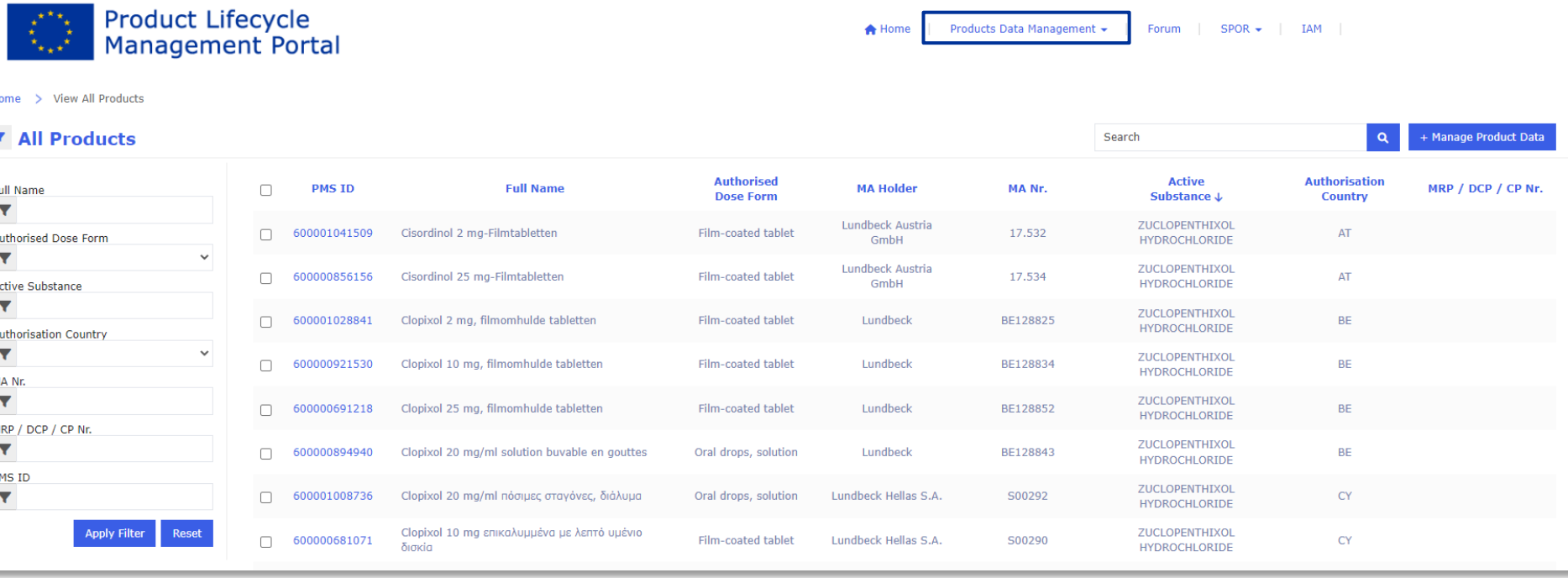


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# Product UI – view pages

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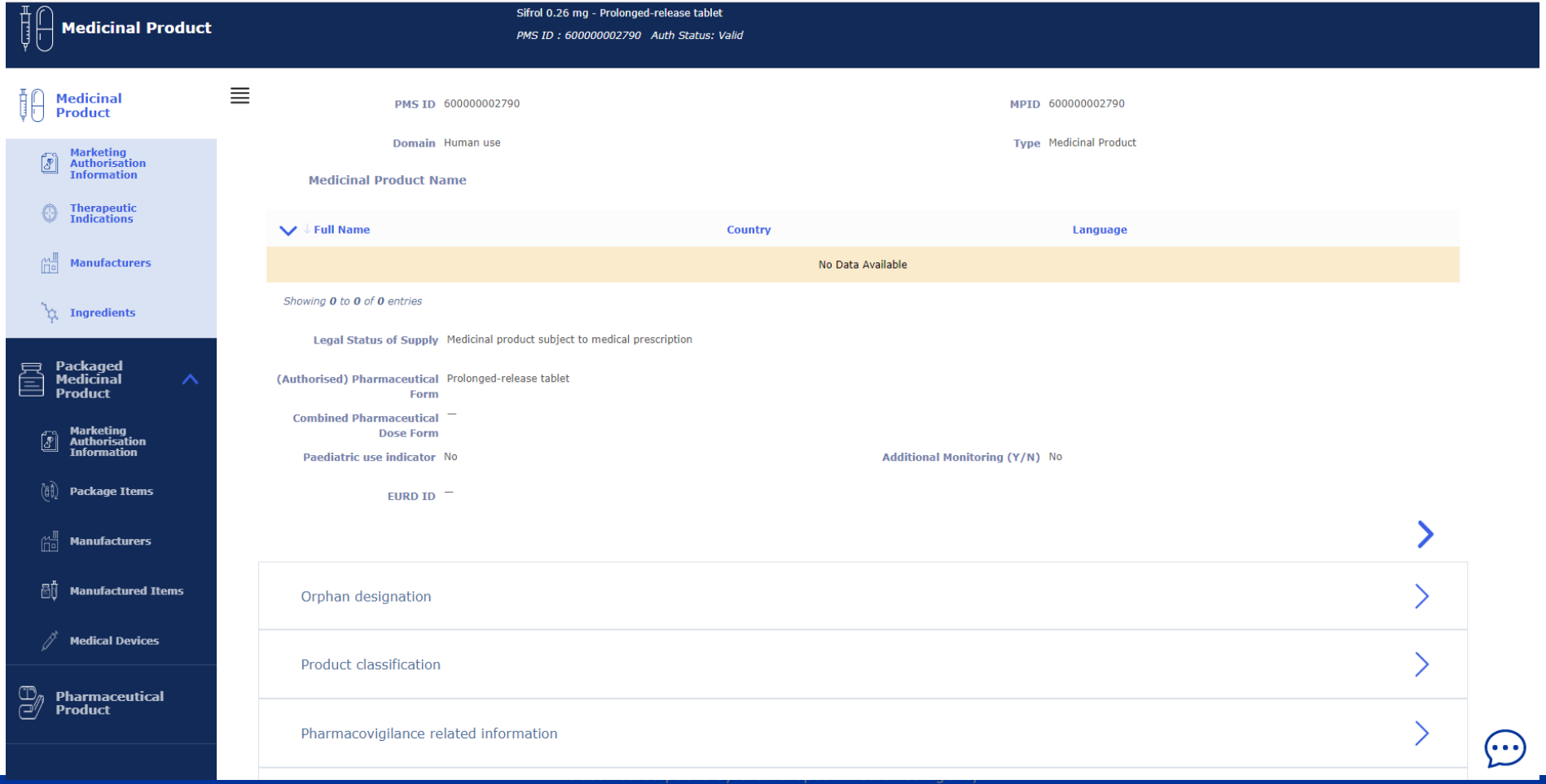

# PMS API

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PMS is working on the **Security and Access Management of the PMS API** (read access only) for Industry and NCAs.

➡ Users will be able to see medicinal product data through the API or the product UI

```
<?xml version="1.0" encoding="utf-8"?>
<Bundle xmlns="http://hl7.org/fhir">
    <id value="600000001280" />
    <meta>
        <versionId value="1" />
        <lastUpdated value="2023-05-09T13:08:11.932+00:00" />
    </meta>
    <type value="searchset" />
    <entry>
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                    PNH: - in patients with haemolysis with clinical symptom(s) indicative of high disease activity.  - in patients who are clinically stable after having been treated with
                    eculizumab for at least the past 6 months (see section 5.1).  Atypical haemolytic uremic syndrome (aHUS) Ultomiris is indicated in the treatment of patients with a body
                    weight of 10 kg or above with aHUS who are complement inhibitor treatment-naive or have received eculizumab for at least 3 months and have evidence of response to eculizumab
                    (see section 5.1).  Generalized myasthenia gravis (gMG) Ultomiris is indicated as an add-on to standard therapy for the treatment of adult patients with gMG who are
                    anti-acetylcholine receptor (AChR) antibody-positive.  Neuromyelitis Optica Spectrum Disorder (NMOSD) Ultomiris is indicated in the treatment of adult patients with NMOSD
                    who are anti-aquaporin 4 (AQP4) antibody-positive (see section 5.1)." id="1793">…
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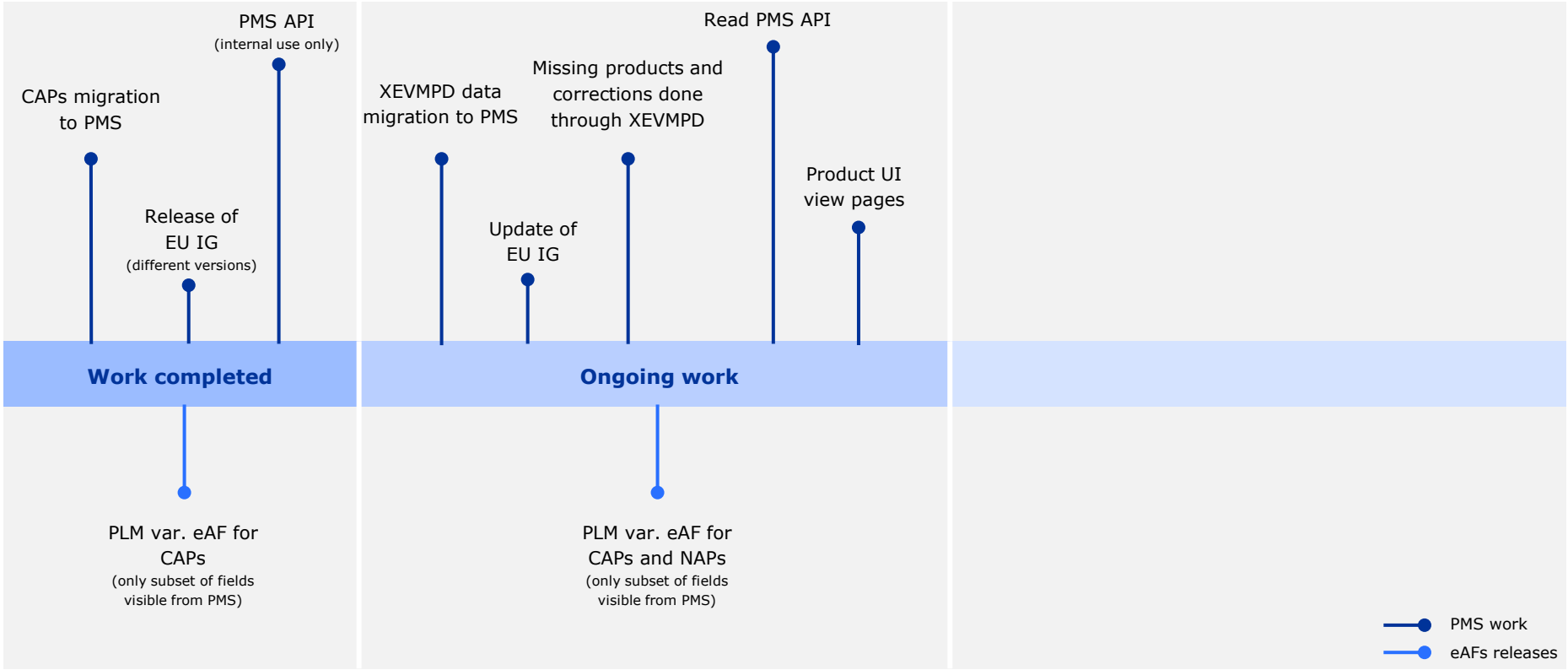
# Summary




**IMPORTANT**: this slide **DOES NOT represent timelines or sequencing of release** but pieces of work or events to be delivered and the impact on users.

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# Future PMS Work

**Marcos Fernandez Gomez**, *PMS Product Co-owner, EMA*

**Veronica Lipucci Di Paola**, *PMS Product Co-owner, EMA*

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# Product User Interface

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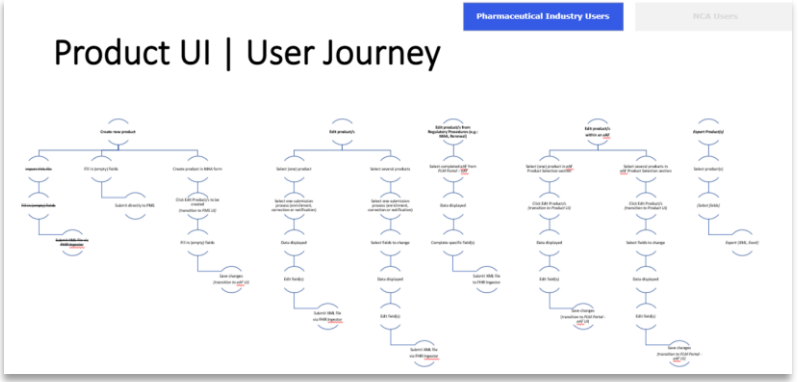
*PMS will be working on:*

- Improve **view pages** of the product user interface
- Create the **edit pages** that will allow users to **modify data directly in PMS** through the product UI
- Build all the **necessary processes** behind the user interface to support:
  - ✓ Enrichments
  - ✓ Corrections
  - ✓ Notifications
  - ✓ Updates

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# PMS API Work

In order to **support machine to machine connections** to PMS, additional work will be done in the PMS API.

This will allow to view the data in PMS and **submit changes** to it

**FHIR profiles** will be generated and made them public.

# PMS EPICs and Features

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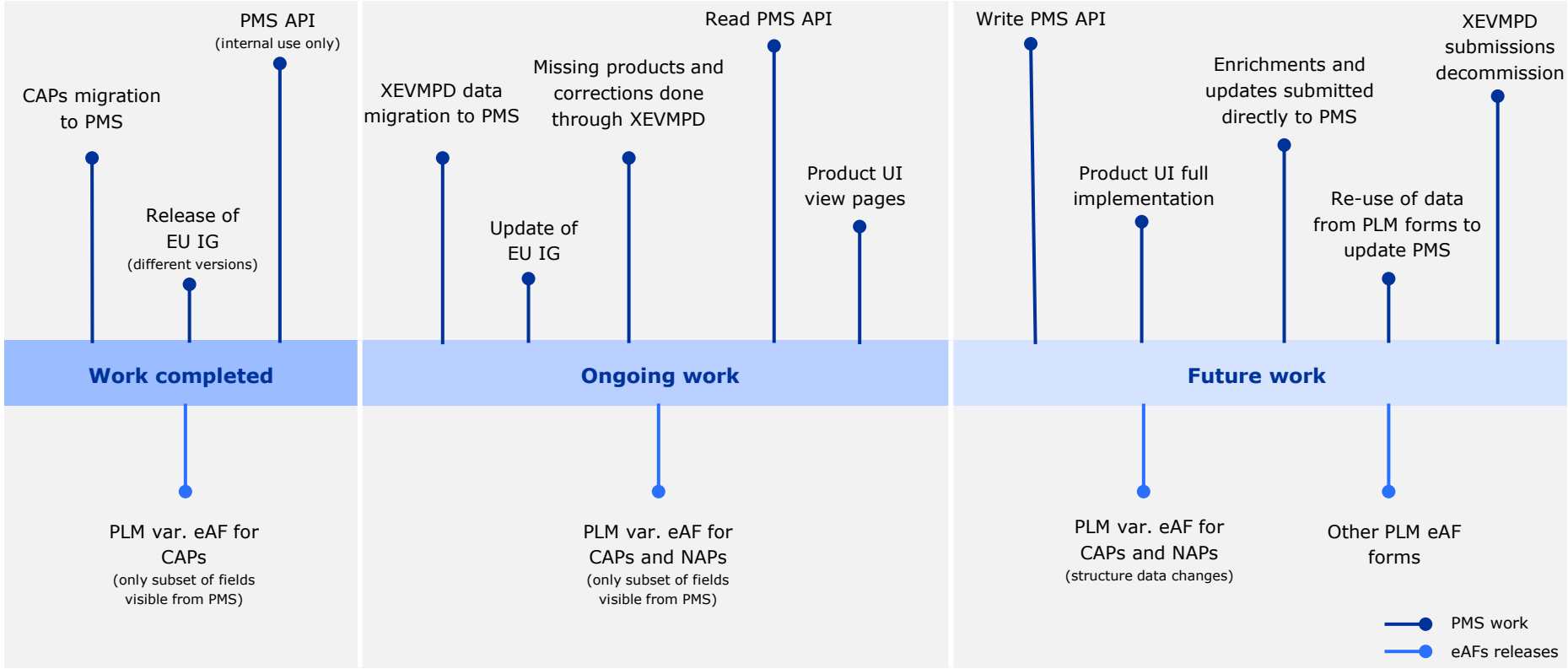
| | | | |
|---|---|---|---|
| **Product Data Management Services** | **Product Management Service (PMS)** | SIAMED Integration | Migration and deltas from SIAMED II |
| | | XEVMPD Integration | Migration and deltas from XEVMPD |
| | **Data Quality, Exchange and Sync. Services** | ISO IDMP Implementation (including API) | PMS API (read and write capabilities) |
| | | FHIR Adaptor Implementation | Re-use of other FHIR messages to update PMS. (eAF FHIR message for example) |
| | | PMS to XEVMPD Sync | To be able to decommission XEVMPD submissions, a synchronisation between PMS and XEVMPD should be in place. |
| | **Product UI** | View Pages | Read access to the Product User Interface |
| | | Edit Pages | These pages will be used to edit medicinal product data |
| | | PMS Processes | Different business processes will use the edit pages. Those processes should be implemented in the UI. |
| | | IDMP Compliance | Capability to make sure that the data received in PMS is IDMP compliance – data profiling, AcKs, etc |

Already started | Work to be done

# Summary




**IMPORTANT**: this slide **DOES NOT represent timelines or sequencing of release** but pieces of work or events to be delivered and the impact on users.

# Q&A Session

**Marcos Fernandez Gomez**, *PMS Product Co-owner, EMA*

**Veronica Lipucci Di Paola**, *PMS Product Co-owner, EMA*

**Moderator: Caterina Scarpati,** *PMS Change Management Team*

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# Send your questions via Slido

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**1. Join via the QR code or link**


**2. Send or upvote the questions you want to hear answered**


**3. Questions will be shown on the screen and managed live in the Q&A session**

# Closing

**Veronica Lipucci Di Paola**, *PMS Product Co-owner, EMA*

**Marcos Fernandez Gomez**, *PMS Product Co-owner, EMA*