



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PMS Deep-Dive Webinar

Presented by Marcos Fernández Gómez on 22 February 2024
PMS Co-product Owner

An agency of the European Union





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- 2 Background**
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- 4 What is happening in 2024**
- 5 Recommendations to applicants – what you can do now**
- 6 What will happen next (still in 2024)**
- 7 What will happen later (end of 2024 & beginning of 2025)**
- 8 Recommendations to applicants – Heads up**
- 9 Summary of activities and impacts to Industry**
- 10 Q&A Session**



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](#).

Join at
slido.com
#PMSDIVE



- Join via **QR code** or **slido.com** - *please provide your questions and comments in Slido only*
- **Send or upvote the questions** you want to hear answered – *before raising a question check whether its has been raised already and vote for it*



Q&A Management

- Questions will be shown on the screen and managed live in the Q&A session
- EMA colleagues will attempt to **address questions in writing throughout the session**
- EMA colleagues will **verbally address (unanswered) top voted questions** at the end in the live Q&A session.



Unanswered questions

- This can be due to high volume of questions or assistance of a specific colleague not available today is required.
- Unanswered questions will be reviewed, and the **most relevant ones may be addressed** in other webinars or in a FAQ document.
- We may request that you ask **Questions on specific issues/cases** in Service Desk to be tracked, investigated and adequately assigned.



Today's webinar aims at sharing:

- What PMS has delivered until now (i.e. before 2024)
- What PMS is delivering in the short term (i.e. during 2024)
- Provide MAHs and applicants information and recommendations on how to prepare for PMS go-live and use of its data in 2024

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.

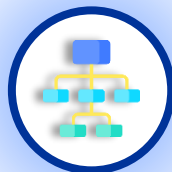
PMS data will be used by regulators and industry in **regulatory and non-regulatory procedures** as well for the general benefit of European citizens.



Key changes



**Product data storage
in PMS database**



**Delivery of ISO IDMP-
compliant structured data**

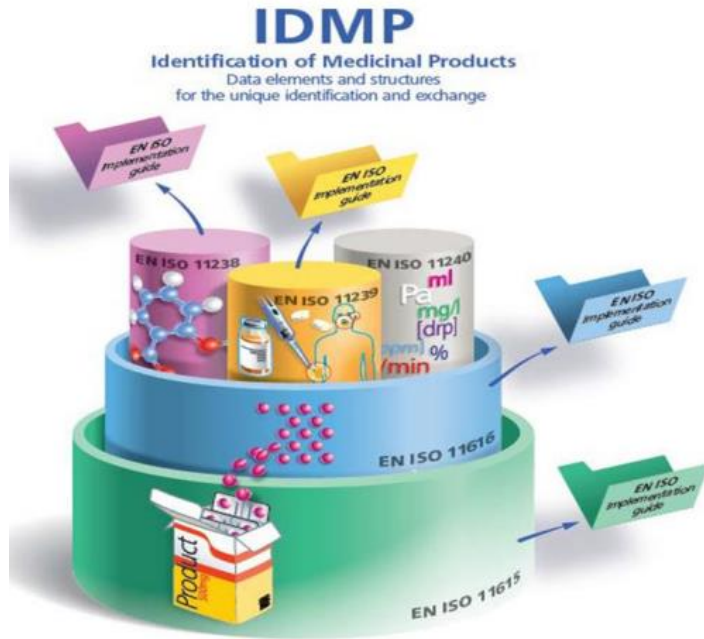


**User interface/ API
to access data in PMS**

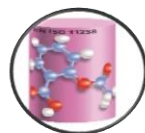


Background

ISO IDMP and PMS data Model



- **ISO IDMP** is a set of 5 standards developed by the International Organization for Standardization (ISO) for the identification of medicinal products (IDMP)
- These standards are developed to **uniquely identify medicinal products based on different data elements.**
- EMA is implementing these standards in the EU in a step wise approach



SMS

Ibuprofen



RMS

Tablet
Oral Use
Blister



RMS

200 mg



PMS

Tablet of 200 mg of ibuprofen

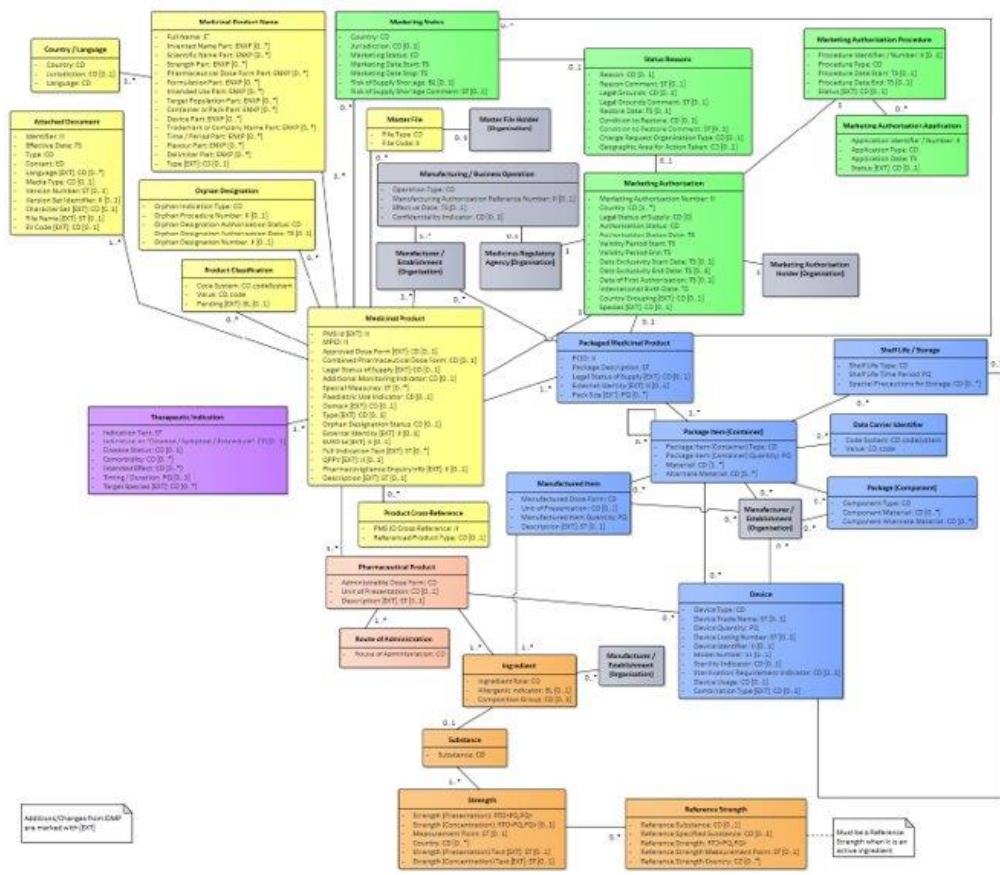


PMS

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



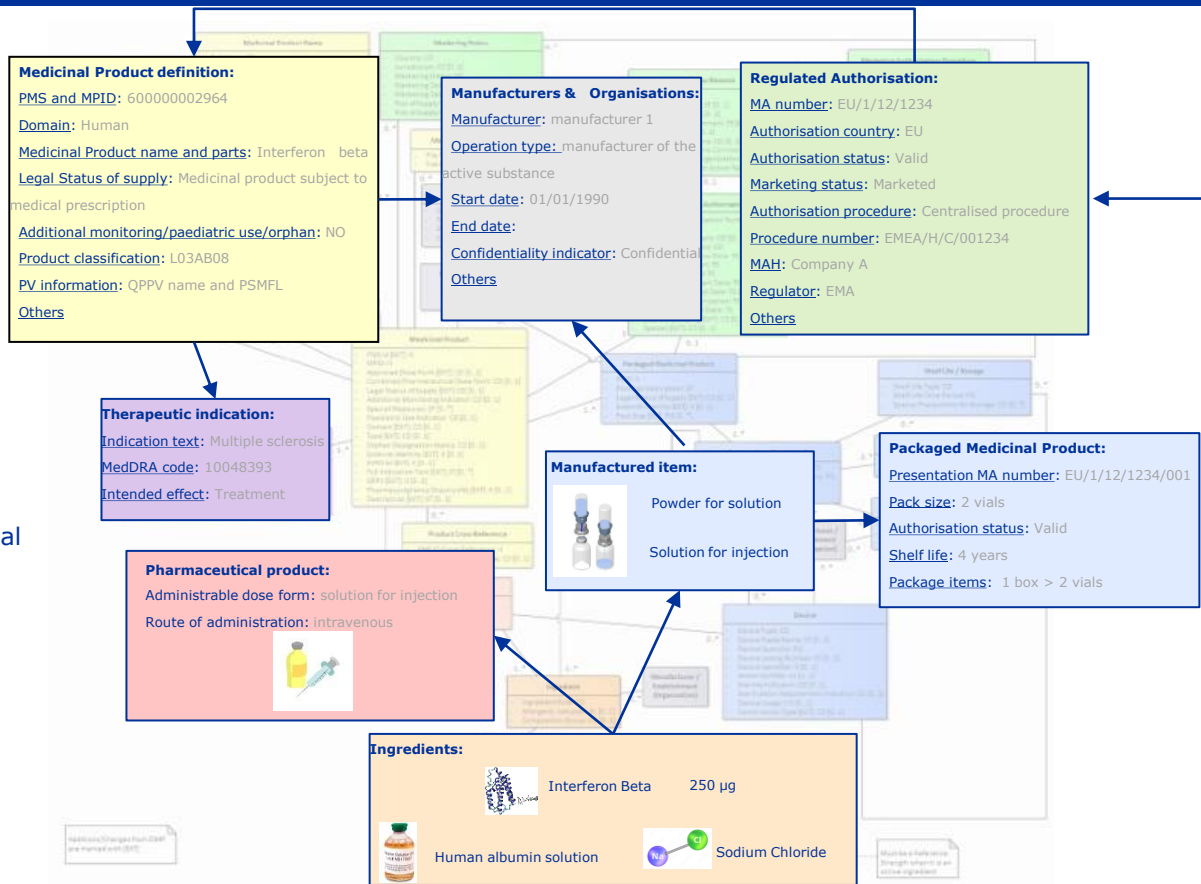
PMS will be consuming master data from the other three domains (**S, O & R**) to be able to uniquely identify medicinal products



- The PMS data model contains more than 150 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

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



Colour legend

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

Ch. 2: full list of data elements from the PMS data model

Ch. 8: specific and detailed examples of real medicinal products



What has been done until 2024

Data mappings to S,O & R

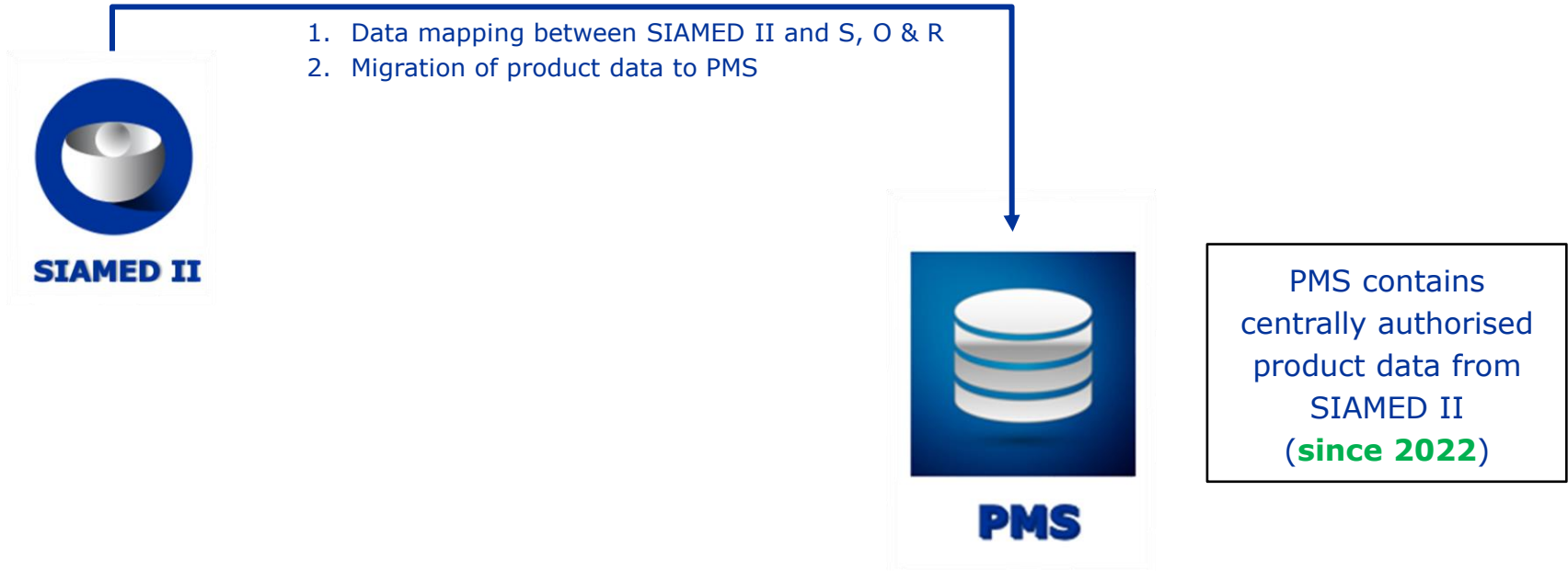
Data migration from SIAMED



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

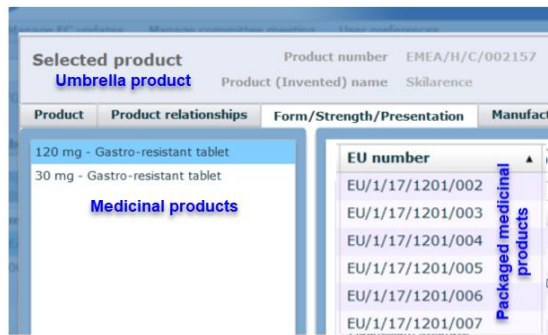
In SIAMED II, a “product” is an umbrella term which can contain several IDMP medicinal products, and each medicinal product can contain multiple presentations.

Product	Product relationships	Form/Strength/Presentation	Manufacturers
Selected product Umbrella product		Product number: EMEA/H/C/002157	Product (Invented) name: Skilarence
120 mg - Gastro-resistant tablet			
30 mg - Gastro-resistant tablet			
Medicinal products			
		EU number	Packaged medicinal products
		EU/1/17/1201/002	
		EU/1/17/1201/003	
		EU/1/17/1201/004	
		EU/1/17/1201/005	
		EU/1/17/1201/006	
		EU/1/17/1201/007	





The umbrella product as stored in SIAMED II is split into medicinal products following the rules established in Chapter 2 of the EU IG.

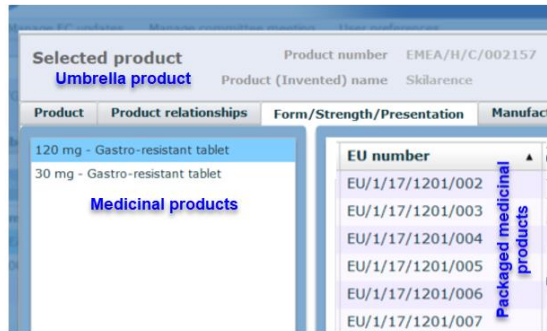


PMS ID	Medicinal product name	Packaged medicinal product
600000001234	Skilarence - 30 mg – Gastro-resistant tablet	EU/1/17/1201/001 EU/1/17/1201/013 EU/1/17/1201/014
600000005678	Skilarence - 120 mg – Gastro-resistant tablet	EU/1/17/1201/005 EU/1/17/1201/006 EU/1/17/1201/007

Medicinal product name is a concatenation of:
Invented name – strength – authorised dose form

Presentations were migrated as Packaged medicinal products

SIAMED contains some data from the PMS data model but not all of it (e.g.: pharmaceutical products or indications are not in SIAMED)



As stated in Chapter 7 of the EU IG, only medicinal products with the following authorization statuses were migrated to PMS:

- **Valid**: Application for Marketing Authorisation approved.
- **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.
- **Revoked**: Withdrawn after Marketing Authorisation by the Regulatory Authority.
- **Expired**: Renewal application not received.

(i.e. products for which there is/was a valid Marketing authorisation)

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

Updates performed in SIAMED II (by EMA) on authorised products are directly propagated to PMS.

Each MAH can see their own list of CAPs in the PLM portal.

- PLM portal is used for the generation of the web-based eAF
- PLM portal will host the Product User Interface to manage medicinal product data from PMS
- PLM portal will also host the ePIs



Please, check [eSubmission: Projects \(europa.eu\)](#) for additional information on how access to PLM portal is granted to support web-based eAF

Home > Medicinal Products

This list contains a **live copy** of all **authorised human Medicinal Products** from PMS to be used in the electronic Application Form.

The access to the content of this page is being reviewed and during the revision and potential re-design of the page, the Medicinal Products will not be available for anonymous visitors, but only for eAF users.

Authorised Dose Form

Active Substance

Authorisation Country

MA Nr.

MRP/CP Nr.

PMS ID

MP ID

Full Name ↑	Authorised Dose Form	Active Substance	Authorisation Country	MA Holder	MA Nr.	MRP/CP Nr. ↑	PMS ID	MP ID
Skilarence 120 mg - Gastro-resistant tablet	Gastro-resistant tablet	Dimethyl fumarate	European Union	Almirall S.A.	EU/1/17/120 1	EMA/H/C/00 2157	60000000025 8	
Skilarence 30 mg - Gastro-resistant tablet	Gastro-resistant tablet	Dimethyl fumarate	European Union	Almirall S.A.	EU/1/17/120 1	EMA/H/C/00 2157	60000000296 4	

Total 2 entries

For the moment, only these fields from PMS are shown in the PLM portal

Seeing CAPs product from PMS



Full Name: Skilarence 30 mg - Gastro-resistant tablet

Full Name	Authorised Dose Form	Active Substance	Authorisation Country	MA Holder	MA Nr. ①	MRP / CP Nr.	PMS ID	MP ID	MRP Variation Nr.	Nr. of Selected Packages
Skilarence 30 mg - Gastro-resistant tablet	Gastro-resistant tablet	Dimethyl fumarate	European Union	Almirall S.A.	EU/1/17/1201	EMEA/H/C/002157	600000002964			0/3

Selected Packaged Medicinal Product(s)

Full Name	Pack Size	MA Number	PMS ID	Authorisation Status
<input type="checkbox"/> Skilarence 30 mg - Gastro-resistant tablet	210 tablets	EU/1/17/1201/014	76252	Valid
<input type="checkbox"/> Skilarence 30 mg - Gastro-resistant tablet	70 tablets	EU/1/17/1201/013	76253	Valid
<input type="checkbox"/> Skilarence 30 mg - Gastro-resistant tablet	42 tablets	EU/1/17/1201/001	76251	Valid

Showing 1 of 3 entries

Different pack sizes, coming to PMS from SIAMED II are also shown when creating an eAF

Full Name: Skilarence 120 mg - Gastro-resistant tablet

Full Name	Authorised Dose Form	Active Substance	Authorisation Country	MA Holder	MA Nr. ①	MRP / CP Nr.	PMS ID	MP ID	MRP Variation Nr.	Nr. of Selected Packages
Skilarence 120 mg - Gastro-resistant tablet	Gastro-resistant tablet	Dimethyl fumarate	European Union	Almirall S.A.	EU/1/17/1201	EMEA/H/C/002157	60000000258			0/11

Selected Packaged Medicinal Product(s)

Full Name	Pack Size	MA Number	PMS ID	Authorisation Status
<input type="checkbox"/> Skilarence 120 mg - Gastro-resistant tablet	90 tablets	EU/1/17/1201/004	76259	Valid
<input type="checkbox"/> Skilarence 120 mg - Gastro-resistant tablet	180 tablets	EU/1/17/1201/007	76265	Valid
<input type="checkbox"/> Skilarence 120 mg - Gastro-resistant tablet	240 tablets	EU/1/17/1201/009	76266	Valid
<input type="checkbox"/> Skilarence 120 mg - Gastro-resistant tablet	400 tablets	EU/1/17/1201/011	76263	Valid
<input type="checkbox"/> Skilarence 120 mg - Gastro-resistant tablet	200 tablets	EU/1/17/1201/008	76261	Valid
<input type="checkbox"/> Skilarence 120 mg - Gastro-resistant tablet	100 tablets	EU/1/17/1201/005	76264	Valid
<input type="checkbox"/> Skilarence 120 mg - Gastro-resistant tablet	120 tablets	EU/1/17/1201/006	76260	Valid
<input type="checkbox"/> Skilarence 120 mg - Gastro-resistant tablet	360 tablets	EU/1/17/1201/010	76262	Valid
<input type="checkbox"/> Skilarence 120 mg - Gastro-resistant tablet	70 tablets	EU/1/17/1201/003	76258	Valid
<input type="checkbox"/> Skilarence 120 mg - Gastro-resistant tablet	40 tablets	EU/1/17/1201/002	76257	Valid
<input type="checkbox"/> Skilarence 120 mg - Gastro-resistant tablet	300 tablets	EU/1/17/1201/012	76267	Valid

Seeing CAPs product from PMS



Full Name | Authorised Dose Form | Active Substance | Authorisation Country | MA Holder | MA Nr. | MRP / CP Nr. | PMS ID | MP ID | MRP Variation Nr. | Nr. of Selected Packages

Skilarence 30 mg - Gastro-resistant tablet | Gastro-resistant tablet | Dimethyl fumarate | European Union | Almirall S.A. | EU/1/17/1201 | EMEA/H/C/002157 | 600000002964 | | | | 0/3

Selected Packaged Medicinal Product(s)

Full Name	Pack Size	MA Number	PMS ID	Authorisation Status
<input type="checkbox"/> Skilarence 30 mg - Gastro-resistant tablet	210 tablets	EU/1/17/1201/014	76252	Valid
<input type="checkbox"/> Skilarence 30 mg - Gastro-resistant tablet	70 tablets	EU/1/17/1201/013	76253	Valid
<input type="checkbox"/> Skilarence 30 mg - Gastro-resistant tablet	42 tablets	EU/1/17/1201/001	76251	Valid

Showing 1 to 3 of 3 entries

Only by using the variation eAF, this information can be seen for the moment.

Skilarence 120 mg - Gastro-resistant tablet | Gastro-resistant tablet | Dimethyl fumarate | European Union | Almirall S.A. | EU/1/17/1201 | EMEA/H/C/002157 | 60000000258 | | | | 0/11

Selected Packaged Medicinal Product(s)

Full Name	Pack Size	MA Number	PMS ID	Authorisation Status
<input type="checkbox"/> Skilarence 120 mg - Gastro-resistant tablet	90 tablets	EU/1/17/1201/004	76259	Valid
<input type="checkbox"/> Skilarence 120 mg - Gastro-resistant tablet	180 tablets	EU/1/17/1201/007	76265	Valid
<input type="checkbox"/> Skilarence 120 mg - Gastro-resistant tablet	240 tablets	EU/1/17/1201/009	76266	Valid
<input type="checkbox"/> Skilarence 120 mg - Gastro-resistant tablet	400 tablets	EU/1/17/1201/011	76263	Valid
<input type="checkbox"/> Skilarence 120 mg - Gastro-resistant tablet	200 tablets	EU/1/17/1201/008	76261	Valid
<input type="checkbox"/> Skilarence 120 mg - Gastro-resistant tablet	100 tablets	EU/1/17/1201/005	76264	Valid
<input type="checkbox"/> Skilarence 120 mg - Gastro-resistant tablet	120 tablets	EU/1/17/1201/006	76260	Valid
<input type="checkbox"/> Skilarence 120 mg - Gastro-resistant tablet	360 tablets	EU/1/17/1201/010	76262	Valid
<input type="checkbox"/> Skilarence 120 mg - Gastro-resistant tablet	70 tablets	EU/1/17/1201/003	76258	Valid
<input type="checkbox"/> Skilarence 120 mg - Gastro-resistant tablet	40 tablets	EU/1/17/1201/002	76257	Valid
<input type="checkbox"/> Skilarence 120 mg - Gastro-resistant tablet	300 tablets	EU/1/17/1201/012	76267	Valid

- [PMS](#) contains medicinal products migrated from SIAMED II, i.e. only [CAPs](#).
- The data of these medicinal products has been [mapped to S,O and R](#).
- Medicinal product data from SIAMED II does [not cover the full PMS data model](#).
- CAPs medicinal product data can be seen in the [PLM portal](#) (after login in); only a subset of fields can be seen at the moment.
- Review [EU IG](#) for additional information:
 - Data Migration rules can be found in [Chapter 7](#) of the EU IG.
 - The Data elements and business rules for the PMS data model can be found in [Chapter 2](#) of the EU IG.
 - Complete examples of products can be found in [Chapter 8](#) of the EU IG.

EU IDMP Implementation Guide



Product Management Services (PMS) - Implementation of International Organization for Standardization (ISO) standards for the identification of medicinal products (IDMP) in Europe - Chapter 2

First published: 11/02/2020
Last updated: 27/07/2022
Reference Number: EMA/285848/2020 Version 2.1.1

English (EN) (5.66 MB - PDF)

[View](#)



Products Management Services (PMS) - Implementation of International Organization for Standardization (ISO) standards for the identification of medicinal products (IDMP) in Europe - Chapter 7

First published: 11/02/2020
Last updated: 18/01/2023
Reference Number: EMA/676106/2019

English (EN) (603.74 KB - PDF)

[View](#)



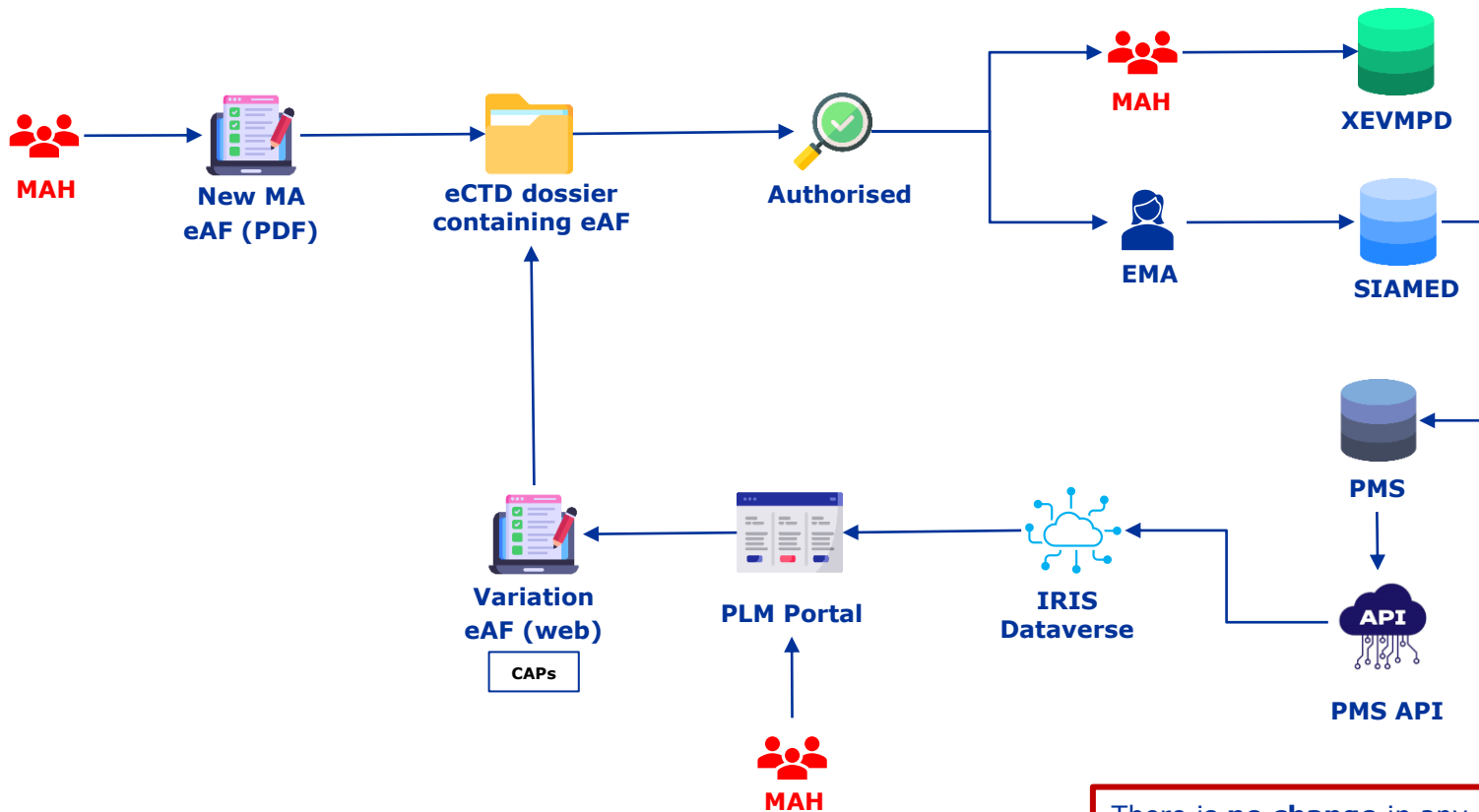
Product Management Service (PMS) - Implementation of International Organization for Standardization (ISO) standards for the identification of medicinal products (IDMP) in Europe - Chapter 8

First published: 22/02/2021
Last updated: 27/07/2022
Reference Number: EMA/285849/2020 Version 2.1.1

English (EN) (4.05 MB - PDF)

[View](#)

What is the current process (CAPs)?



There is **no change** in any current process



What is happening in 2024

XEVMPD data mappings to S,O & R and initial migration

Match and merge of CAP products across SIAMED and XEVMPD

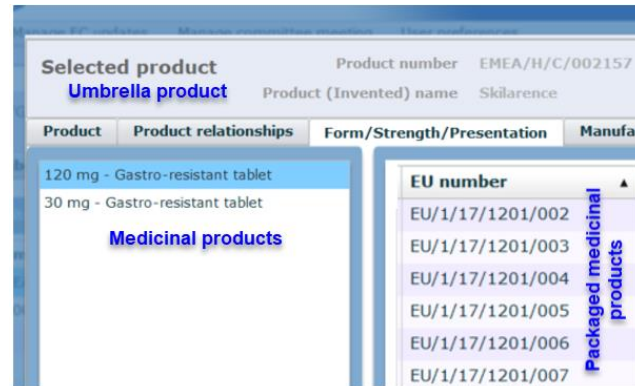
Split CAP/SIAMED products

XEVMPD deltas



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.



Product	Product relationships	Form/Strength/Presentation	Manufact
Selected product		Product number	EMEA/H/C/002157
Umbrella product		Product (Invented) name	Skilarence
120 mg - Gastro-resistant tablet		EU number	Packaged medicinal products
30 mg - Gastro-resistant tablet			
Medicinal products		EU/1/17/1201/002	
		EU/1/17/1201/003	
		EU/1/17/1201/004	
		EU/1/17/1201/005	
		EU/1/17/1201/006	
		EU/1/17/1201/007	

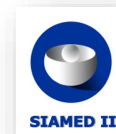


XEVMPD is a database maintained by marketing authorization holders and contains central and national medicinal products authorised in the EU and EEA.

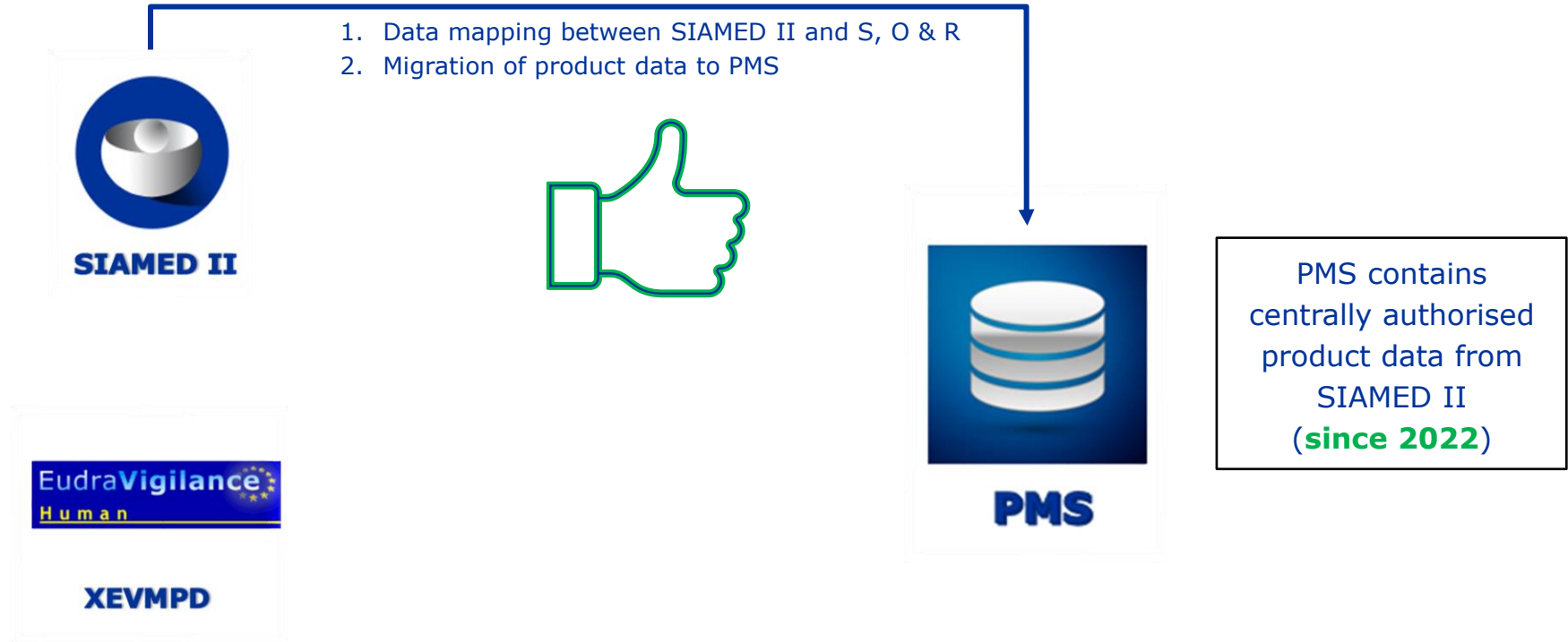
This database is maintained following the Art. 57 legal obligation and medicinal products can be submitted following different strategies and business rules explained in Chapter 3.II: XEVPRM User Guidance

Authorisation Country	Substance names	Pharmaceutical Form	Full Presentation Name	Authorisation Number
Romania	CROSPVOIDONE, LACTOSE MONOHYDRATE, MAGNESIUM STEARATE, SILICA, CO	TABLET	Flamexin, 20 mg, comprimato	7146/2006/03
Romania	CROSPVOIDONE, LACTOSE MONOHYDRATE, MAGNESIUM STEARATE, SILICA, CO	TABLET	Flamexin, 20 mg, comprimato	7146/2006/01
Romania	CROSPVOIDONE, LACTOSE MONOHYDRATE, MAGNESIUM STEARATE, SILICA, CO	TABLET	Flamexin, 20 mg, comprimato	7146/2006/02

Authorisation Country	Substance names	Pharmaceutical Form	Full Presentation Name	Authorisation Number
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



What is happening now?





- SIAMED and xEVMPD contain **data** that can be **mapped to existing terms** in S, O & R services.
- An exercise to map the terms in both databases to S, O & R has been performed by EMA.

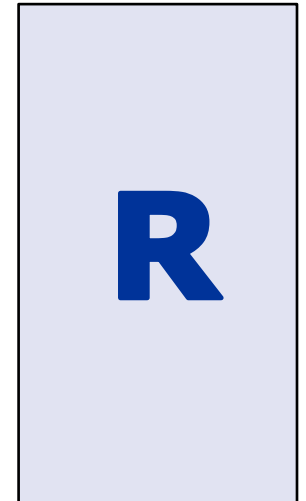
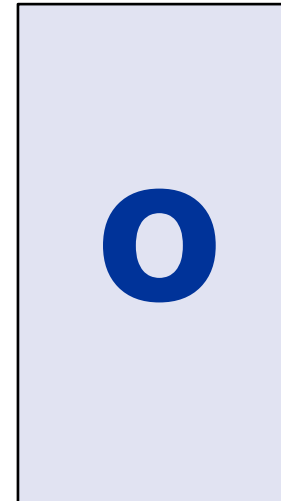
S

View :Dimethyl fumarate

Term	Dimethyl fumarate
Identifier	100000079228
Status	Current

[Extended EudraVigilance Medicinal Product Dictionary - xEVMPD](#)

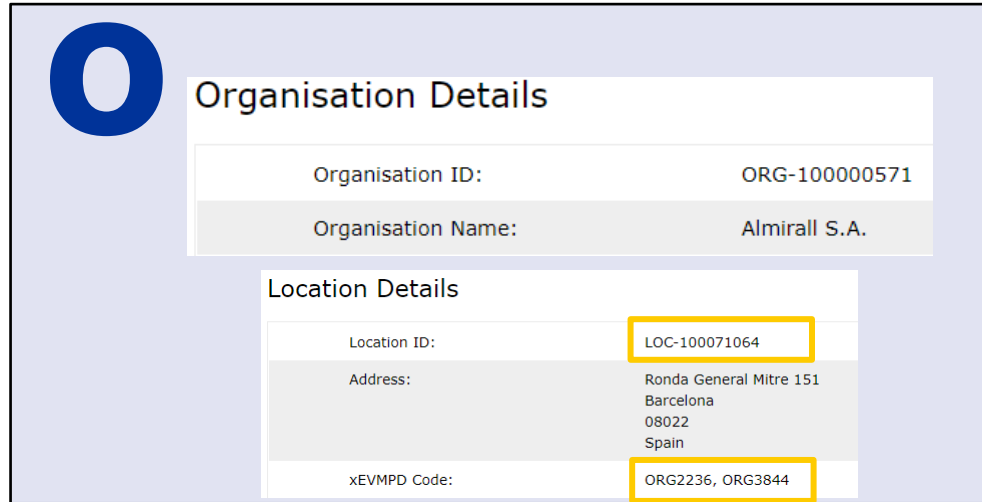
Source Term ID SUB13608MIG



All the information related to the mappings can be found in [Chapter 7](#) of the EU IG



- SIAMED and xEVMPD contain **data** that can be **mapped to existing terms** in S, O & R services.
- An exercise to map the terms in both databases to S, O & R has been performed by EMA.



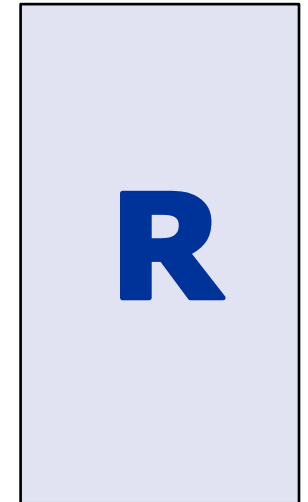
A screenshot of a web interface showing 'Organisation Details' and 'Location Details'. The 'Organisation Details' section includes:

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

The 'Location Details' section includes:

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

Yellow boxes highlight the Location ID, the Address, and the xEVMPD Code fields.



All the information related to the mappings can be found in [Chapter 7](#) of the EU IG



- SIAMED and xEVMPD contain **data** that can be **mapped to existing terms** in S, O & R services.
- An exercise to map the terms in both databases to S, O & R has been performed by EMA.

S

O

- OMS team is reviewing all MAHs in XEVMPD to ensure they exist and are correctly mapped and synchronized from XEVMPD into OMS

R

All the information related to the mappings can be found in [Chapter 7](#) of the EU IG



- SIAMED and xEVMPD contain **data** that can be **mapped to existing terms** in S, O & R services.
- An exercise to map the terms in both databases to S, O & R has been performed by EMA.

S

O

R

Terms in xEVMPD were mapped to 11 RMS lists

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

All the information related to the mappings can be found in [Chapter 7](#) of the EU IG

Scenario	Impact to Industry						
<p>Exact match or new “valid” standard term</p> <table border="1" data-bbox="258 233 962 361"> <thead> <tr> <th>XEVMPD</th> <th>RMS</th> </tr> </thead> <tbody> <tr> <td>Tablet</td> <td>Tablet</td> </tr> <tr> <td>Prolonged-release pessary</td> <td>Prolonged-release pessary (new ST)</td> </tr> </tbody> </table>	XEVMPD	RMS	Tablet	Tablet	Prolonged-release pessary	Prolonged-release pessary (new ST)	<p>None Mapping to the standard term was done in RMS</p>
XEVMPD	RMS						
Tablet	Tablet						
Prolonged-release pessary	Prolonged-release pessary (new ST)						
<p>Typo and/or close match</p> <table border="1" data-bbox="291 430 950 558"> <thead> <tr> <th>XEVMPD</th> <th>RMS</th> </tr> </thead> <tbody> <tr> <td>Scored Film-coated Tablet</td> <td>Film-coated tablet</td> </tr> <tr> <td>Tablets</td> <td>Tablet</td> </tr> </tbody> </table>	XEVMPD	RMS	Scored Film-coated Tablet	Film-coated tablet	Tablets	Tablet	<p>Product could be updated in XEVMPD by selecting correct term</p>
XEVMPD	RMS						
Scored Film-coated Tablet	Film-coated tablet						
Tablets	Tablet						
<p>New legacy term in RMS</p> <table border="1" data-bbox="253 618 993 745"> <thead> <tr> <th>XEVMPD</th> <th>RMS</th> </tr> </thead> <tbody> <tr> <td>Solution for infusion (RoA)</td> <td>Solution for infusion (non-current)</td> </tr> <tr> <td>Oromucosal spray</td> <td>Oromucosal spray (non-current)</td> </tr> </tbody> </table>	XEVMPD	RMS	Solution for infusion (RoA)	Solution for infusion (non-current)	Oromucosal spray	Oromucosal spray (non-current)	<p>Product should be updated in XEVMPD to use approved standard term when possible</p>
XEVMPD	RMS						
Solution for infusion (RoA)	Solution for infusion (non-current)						
Oromucosal spray	Oromucosal spray (non-current)						
<p>Split terms</p> <table border="1" data-bbox="200 817 1000 926"> <thead> <tr> <th>XEVMPD</th> <th>RMS</th> </tr> </thead> <tbody> <tr> <td>Powder for solution for injection/infusion/inhalation</td> <td> <ul style="list-style-type: none"> • Powder for solution for injection/infusion • Inhalation powder </td> </tr> </tbody> </table>	XEVMPD	RMS	Powder for solution for injection/infusion/inhalation	<ul style="list-style-type: none"> • Powder for solution for injection/infusion • Inhalation powder 	<p>Product MUST be corrected in XEVMPD to refer to more than one term</p> <p>XEVMPD team already contacted some QPPVs requesting the update of the data</p>		
XEVMPD	RMS						
Powder for solution for injection/infusion/inhalation	<ul style="list-style-type: none"> • Powder for solution for injection/infusion • Inhalation powder 						

All the information related to the mappings can be found in [Chapter 7](#) of the EU IG



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

XEVMPD can capture records at pack size level or only at medicinal product level (depending at which level the MA number is granted or how the MAH is submitting the data).

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)
- 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



XEVMPD



The following XEVMPD fields are used to group records under the same PMS medicinal product for NAPs.



XEVMPD

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



*All countries except BE, FI and LU

EV Code	MA number	Full Presentation Name	Pack size	Authorised dose form	Active substance and strength	Authorisation country	MAH
PRD111111	9472150	Fosfomicina Reddy Bambini 2 g granulato per soluzione orale	12 sachets	Granules for oral solution	Fosfomicin – 2 g	IT	LABIANA PHARMACEUTICALS S.L.U.
PRD222222	9472151		24 sachets				

For this medicinal product, XEVMPD captures **two EV codes = two pack sizes**

Grouping elements contain the same information so in PMS this product is migrated as:

- 1 Medicinal Product**
- 2 Package medicinal products (PRD111111 & PRD222222)**



*All countries except BE, FI and LU

EV Code	MA number	Full Presentation Name	Pack size	Authorised dose form	Active substance and strength	Authorisation country	MAH
PRD111111	630123	Alprazolam Kern Pharma 1 mg comprimidos	1,3 and 5 tablets	Capsules	Alprazolam – 1 mg	ES	KERN PHARMA, S.L.
PRD222222	630124	Alprazolam Kern Pharma 2 mg comprimidos	1,3 and 5 tablets		Alprazolam – 2 mg		
PRD333333	630125	Alprazolam Kern Pharma 0,5 mg comprimidos	1,3 and 5 tablets		Alprazolam – 3 mg		
PRD444444	630126	Alprazolam Kern Pharma 0,25 mg comprimidos	1,3 and 5 tablets		Alprazolam – 0,25 mg		

In this case, XEVMPD contains one EV code per medicinal product. No pack sizes are submitted.

Grouping elements contain different information (name and strength) so it is migrated as:

4 Medicinal Products



**FI and LU

EV Code	MA number	Full Presentation Name	Pack size	Authorised dose form	Active substance and strength	Authorisation country	MAH
PRD111111	138115	Diamox 250 mg Tabletten	1,3 and 5 tablets	Tablet	Acetazolamide – 250 mg	LU	MENARINI INTERNATIONAL
PRD222222	138115	Diamox 250 mg Comprimés	1,3 and 5 tablets				

FI and LU medicinal products contain 2 records in XEVMPD (one per each official language). Therefore, the full presentation name is not used as grouping element.

As the authorisation number is the same in both records, this is used as grouping element.

In this case where I have two EV codes in XEVMPD, they are migrated to PMS as:

- 1 Medicinal Product**
- 2 pack sizes (one per EV Code)**

Initial migration handles data in this way as we need to migrate all EV codes from XEVMPD



***BE

EV Code	MA number	Full Presentation Name	Pack size	Authorised dose form	MRP/DCP number	Active substance and strength	Authorisation country	MAH
PRD111111	630123	Gabapentine 600 mg comprimés pelliculés - French	20 tablets – Alu/Alu blister	Capsules	DE/H/2852/004	Gabapentine – 600 mg	BE	BOEHRINGER INGELHEIM INTERNATIONAL GMBH
PRD333333		Gabapentine 600 mg filmomhulde tablet - Dutch	20 tablets – Alu/Alu blister					
PRD222222	630456	Gabapentine 600 mg comprimés pelliculés - French	20 tablets – PVC/Alu blister					
PRD444444		Gabapentine 600 mg filmomhulde tablet - Dutch	20 tablets – PVC/Alu blister					

In BE, different MA numbers can be granted to different pack sizes belonging to the same medicinal product.

There is also more than one official language.

Therefore, the MRP/DCP number is used as grouping element

In this case, these 4 EV codes are migrated as:

1 Medicinal Product
4 pack sizes (one per EV Code)



***BE

EV Code	MA number	Full Presentation Name	Pack size	Authorised dose form	MRP/DCP number	Active substance and strength	Authorisation country	MAH
PRD111111	630123	Gabapentine 600 mg comprimés pelliculés - French	20 tablets – Alu/Alu blister	Capsules	Ø	Gabapentine – 600 mg	BE	BOEHRINGER INGELHEIM INTERNATIONAL GMBH
PRD333333		Gabapentine 600 mg filmomhulde tablet - Dutch	20 tablets – Alu/Alu blister					
PRD222222	630456	Gabapentine 600 mg comprimés pelliculés - French	20 tablets – PVC/Alu blister					
PRD444444		Gabapentine 600 mg filmomhulde tablet - Dutch	20 tablets – PVC/Alu blister					

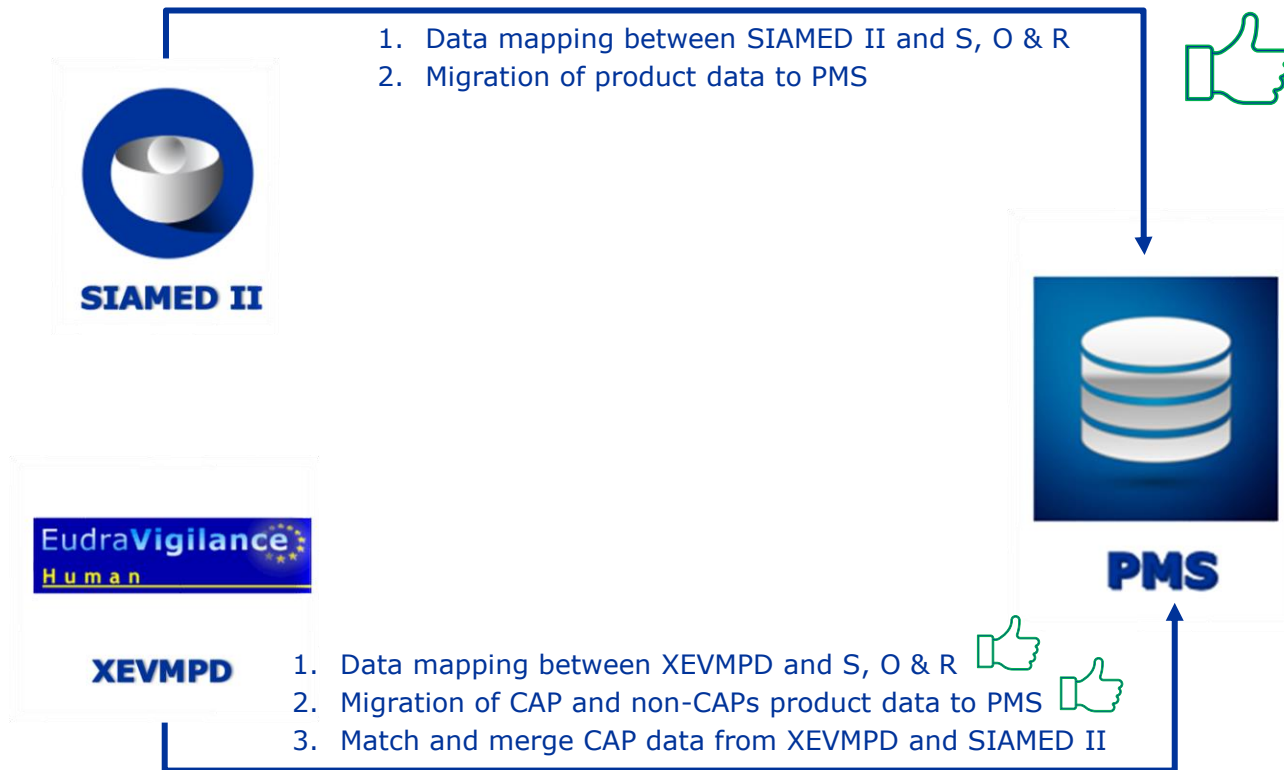
In BE, different MA numbers can be granted to different pack sizes belonging to the same medicinal product.

There is also more than one official language.

Pure nationals don't have the MRP/DCP number.

In this case, these 4 EV codes are migrated as:

1 Medicinal Product
4 pack sizes (one per EV Code)





Two medicinal products will be matched when the following conditions are all met:

- All presentations in XEVMPD must match the presentations from SIAMED II
- MAH (LOC ID) in SIAMED II and XEVMPD are the same
- Only EU records from XEVMPD will be matched (CAPs with authorisation country LI, NO and IS are considered different records)

Business rules of the match and merge

If the match happens, the next step is the merge, when the two medicinal products are merged into one and the data between them is consolidated:

- Full presentation name from XEVMPD will survive
- Authorised dose form from SIAMED will survive
- ...

Business rules on which source survives after the match and merge can be found in Chapter 7 of the EU IG

Match and merge CAP products



Selected product Product number EMEA/H/C/002157
Umbrella product Product (Invented) name Skilarence

Product	Product relationships	Form/Strength/Presentation	Manufact
120 mg - Gastro-resistant tablet			
30 mg - Gastro-resistant tablet			

Medicinal products

EU number
EU/1/17/1201/002
EU/1/17/1201/003
EU/1/17/1201/004
EU/1/17/1201/005
EU/1/17/1201/006
EU/1/17/1201/007

Packaged medicinal products

PMS ID	Medicinal product name	Packaged medicinal product
600000003227	Skilarence - 30 mg – Gastro-resistant tablet	EU/1/17/1201/001 EU/1/17/1201/013 EU/1/17/1201/014
600000001121	Skilarence - 120 mg – Gastro-resistant tablet	EU/1/17/1201/005 EU/1/17/1201/006 EU/1/17/1201/007

Match and merge of this pair of products



EV Code	Full Presentation Name	Authorisation Number	EU Number
PRD513	Skilarence 120 mg gastro-resistant tablets	EU/1/17/1201/002	EU/1/17/1201/002
PRD513	Skilarence 120 mg gastro-resistant tablets	EU/1/17/1201/003	EU/1/17/1201/003
PRD513	Skilarence 120 mg gastro-resistant tablets	EU/1/17/1201/004	EU/1/17/1201/004
PRD513	Skilarence 120 mg gastro-resistant tablets	EU/1/17/1201/005	EU/1/17/1201/005
PRD513	Skilarence 120 mg gastro-resistant tablets	EU/1/17/1201/006	EU/1/17/1201/006
PRD513	Skilarence 120 mg gastro-resistant tablets	EU/1/17/1201/007	EU/1/17/1201/007
PRD513	Skilarence 120 mg gastro-resistant tablets	EU/1/17/1201/008	EU/1/17/1201/008

Medicinal product name	Packaged medicinal product
Skilarence 30 mg gastro-resistant tablets	EU/1/17/1201/001 EU/1/17/1201/013 EU/1/17/1201/014
Skilarence 120 mg gastro-resistant tablets	EU/1/17/1201/005 EU/1/17/1201/006 EU/1/17/1201/007

Match and merge CAP products



PMS ID	Medicinal product name	Packaged medicinal product
600000003227	Skilarence - 30 mg – Gastro-resistant tablet	EU/1/17/1201/001 EU/1/17/1201/013 EU/1/17/1201/014
600000001121	Skilarence - 120 mg – Gastro-resistant tablet	EU/1/17/1201/005 EU/1/17/1201/006 EU/1/17/1201/007

Match and merge of this pair of products

↓ PMS ID	Full Name	Authorised Dose Form	MA Holder
600000001121	Skilarence 120 mg gastro-resistant tablets	Gastro-resistant tablet	Almirall S.A.
600000003227	Skilarence 30 mg gastro-resistant tablets	Gastro-resistant tablet	Almirall S.A.

Medicinal product name	Packaged medicinal product
Skilarence 30 mg gastro-resistant tablets	EU/1/17/1201/001 EU/1/17/1201/013 EU/1/17/1201/014
Skilarence 120 mg gastro-resistant tablets	EU/1/17/1201/005 EU/1/17/1201/006 EU/1/17/1201/007

Split of products from SIAMED II



Selected product Product number EMEA/H/C/00444

Product (Invented) name **Aimovig**

Product	Product relationships	Form/Strength/Presentation	Manu
140 mg - Solution for injection			
70 mg - Solution for injection			

Presentations

No.	EU number
7	EU/1/18/1293/004
8	EU/1/18/1293/005
9	EU/1/18/1293/006

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

Match and merge can't happen as there are two products coming from XEVMPD and one from SIAMED II



EV Code	Full Presentation Name	Authorisation Number
PRD7257406	Aimovig 140 mg solution for injection in pre-filled pen	EU/1/18/1293/004
PRD7257410	Aimovia 140 mg solution for injection in pre-filled pen	EU/1/18/1293/005
PRD7257414	Aimovig 140 mg solution for injection in pre-filled syringe	EU/1/18/1293/006

PMS ID	Medicinal product name	Packaged medicinal product
600000001234	Aimovig 140 mg solution for injection in pre-filled pen	EU/1/18/1239/004 EU/1/18/1239/005
600000005678	Aimovig 140 mg solution for injection in pre-filled syringe	EU/1/18/1239/006

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

- Product from SIAMED II (already in PMS) is split to contain the same presentations as in XEVMPD.
- Two medicinal products are created out of the former one already existing.

↓ PMS ID	Full Name	Authorised Dose Form
600000252661	Aimovig 140 mg solution for injection in pre-filled syringe	Solution for injection
600000252662	Aimovig 140 mg solution for injection in pre-filled pen	Solution for injection
600000252718	Aimovig 70 mg solution for injection in pre-filled syringe	Solution for injection
600000252719	Aimovig 70 mg solution for injection in pre-filled pen	Solution for injection

There is a perfect match now and therefore merge can happen

PMS ID	Medicinal product name	Packaged medicinal product
600000001234	Aimovig 140 mg solution for injection in pre-filled pen	EU/1/18/1239/004 EU/1/18/1239/005
600000005678	Aimovig 140 mg solution for injection in pre-filled syringe	EU/1/18/1239/006

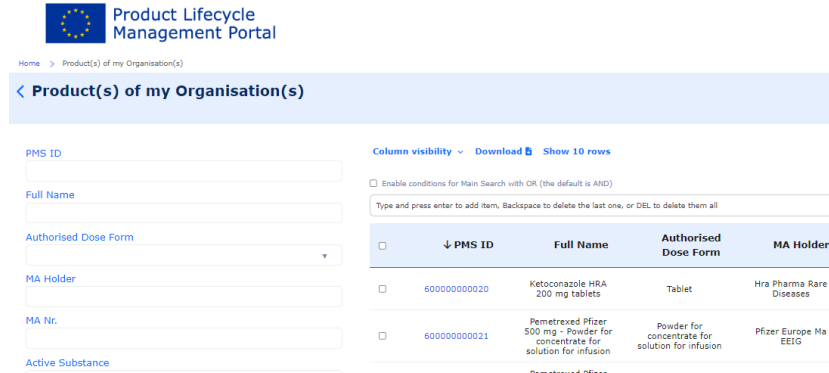
- Full presentation name is taken from XEVMPD
- Authorised dose form is kept from SIAMED II

Products to be split, shall not be used in the web-based eAF until the split is completed.



- As stated in the legislation MAHs are responsible to maintain XEVMPD data up to date.
- Inserts, updates, invalidations and nullifications submitted to XEVMPD will be pushed to PMS.
- EMA intends to process the updates/deltas almost in real time.
- The updates/deltas are sent to a queue and are processed in that order.
- Only XEVPRMs with a positive 2nd acknowledgement are processed.
- Updates performed by EMA data stewards during the validation are also propagated to PMS.
- EMA encourages MAHs to review Chapter 9 of the EU IG where updates/deltas are explained.

- Medicinal product data will be migrated from XEVMPD to PMS and maintained with the XEVMPD to PMS Deltas.
- The data of these medicinal products has been mapped to S,O and R.
- Specific CAP records will be split to be compliant with IDMP business rules
- CAPs medicinal product data from SIAMED II and XEVMPD will be matched and merged into a single medicinal product record.
- The PMS data model will be enriched/completed with data from both SIAMED and XEVMPD.
- PMS team will allow access to products data via the PMS API and the Product User Interface



Product Lifecycle Management Portal

Home > Product(s) of my Organisation(s)

< Product(s) of my Organisation(s)

PMS ID:

Full Name:

Authorised Dose Form:

MA Holder:

MA Nr.:

Active Substance:

Column visibility Download Show 10 rows

Enable conditions for Main Search with OR (the default is AND)

Type and press enter to add item, Backspace to delete the last one, or DEL to delete them all

<input type="checkbox"/>	↓ PMS ID	Full Name	Authorised Dose Form	MA Holder
<input type="checkbox"/>	600000000020	Ketoconazole HRA 200 mg tablets	Tablet	Hra Pharma Rare Diseases
<input type="checkbox"/>	600000000021	Pemetrexed Pfizer 500 mg - Powder for concentrate for solution for infusion	Powder for concentrate for solution for infusion	Pfizer Europe Ma EEG



Recommendations to applicants

What you can do now

Check your XEVMPD data to avoid Data Quality issues

Check the following fields to avoid migration/consolidation issues

- Legal basis - cannot be null/empty
- Product Full name – check that product full name is consistent (no spaces, typos etc) across similar/grouped EV codes
- Auth number – for CP ensure it aligns with Annex A.
- EU number – for CAPs is the same as the Authorisation number
- MRP/CP number – for CP ensure it aligns with Annex A and for BE products is consistent across grouped EV codes
- Authorised Dose Form – Check mapping across EV and RMS
- Administrable Dose Form – refers to the dose form administered to the patient (might not be the same as the authorised dose form)
- Active substance – check mapping to SMS, If SVG flag = 0 select another substance for the product
- Strength – is consistent among EV codes to be grouped
- MAH – check mapping to OMS (LOC ID) (if missing/wrong → open a request in Service now to correct the mappings)
- Packages – ensure all packages for CAPs are entered separately (one EV code per package), even if they were withdrawn/surrendered...
- Auth Status – check it is the correct one not only for valid but also withdrawn,...

IMPORTANT: transferred records shall have the status “non valid – superseded by MA transfer”

Nullified records shall not be reviewed as they are out of the scope of the migration

Tip: XEVMPD or the export tool can be used to extract full list of EV codes in Excel or CSV and work with this information

This is not a comprehensive list of business rules and verifications applicants can do, for further information consult Chapter 3.II

EV Code	MA number	Full Presentation Name	Pack size	Authorised dose form	Active substance and strength	Authorisation country	MAH
PRD111111	9472150	Fosfomicina Reddy Bambini 2 g granulato per soluzione orale	12 sachets	Granules for oral solution	Fosfomicin – 2 g	IT	LABIANA PHARMACEUTICALS S.L.U.
PRD222222	9472151	Fosfomicina Reddy Bambini 2 g granulato per soluzione	24 sachets				

Two medicinal products will be created in PMS as there are two different names.

For records **grouped by name**, check that EV codes belonging to the same medicinal product has the same name and same active substance and strength

EV Code	MA number	Full Presentation Name	Pack size	Authorised dose form	Active substance and strength	Authorisation country	MAH
PRD111111	138115	Diamox 250 mg Tabletten	1,3 and 5 tablets	Tablet	Acetazolamide – 250 mg	LU	MENARINI INTERNATIONAL
PRD222222	138115-2	Diamox 250 mg Comprimés	1,3 and 5 tablets				

Two medicinal products will be created in PMS as there are two different MA number.

For records **grouped by MA number**, check that EV codes belonging to the same medicinal product has the same MA number and same active substance and strength

Data quality issues shall be handled in XEVMPD.
 Any change to XEVMPD will be propagated to PMS and the business rules from the initial migration will apply.
 → **XEVMPD to PMS deltas**

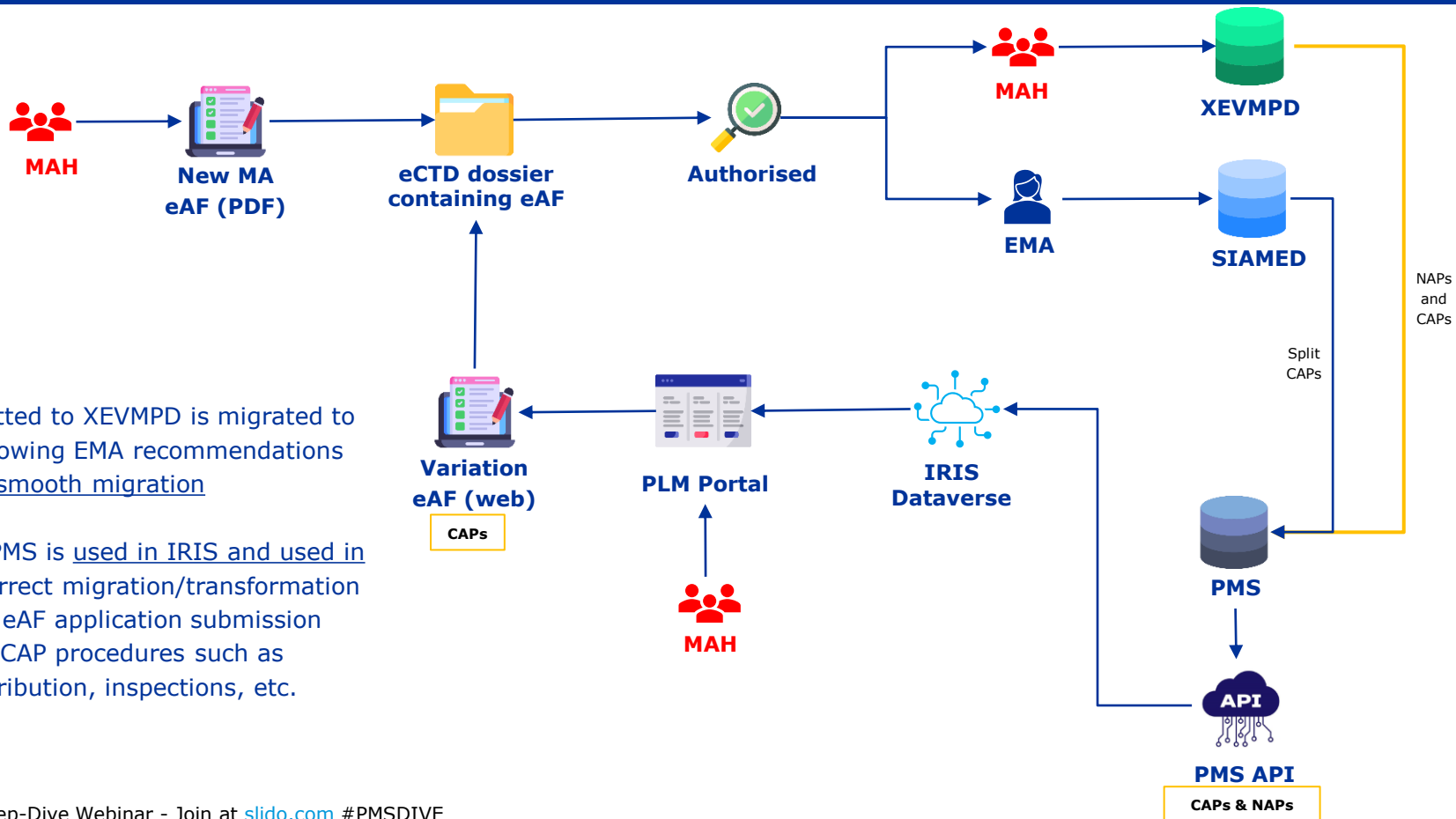
Ensure any Data Quality findings are permanently solved

- EMA is monitoring and identifying Data Quality issues.
- EMA is/will contact QPPVs requesting the update of XEVMPD to solve data quality issues
- Please ensure QPPV/company email is monitored and that data is corrected in YOUR systems so that it does not get overwritten
- Make sure you don't send emails from Art57-QC@ema.europa.eu to the spam folder
- Review 3rd AcK after EMA perform validations and if needed, update your systems, if don't agree with the change: raise a ticket to Service Now
- For records 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.
- These activities will reduce the amount of **data quality issues** leading to a better initial migration of product data.

To support web-based eAF

- xEVMPD can also have 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
- If needed, pack sizes for medicinal products where the MA number is assigned at medicinal product level can be submitted as well. Package description in XEVMPD should be populated correctly.
- Pending MRPs and DCPs will be able to be submitted to XEVMPD when eAF allows NAPs variations.

Why should you care?



- Data submitted to XEVMPD is migrated to PMS -> following EMA recommendations will ensure smooth migration
- Data from PMS is used in IRIS and used in eAF -> incorrect migration/transformation could delay eAF application submission and impact CAP procedures such as Parallel distribution, inspections, etc.

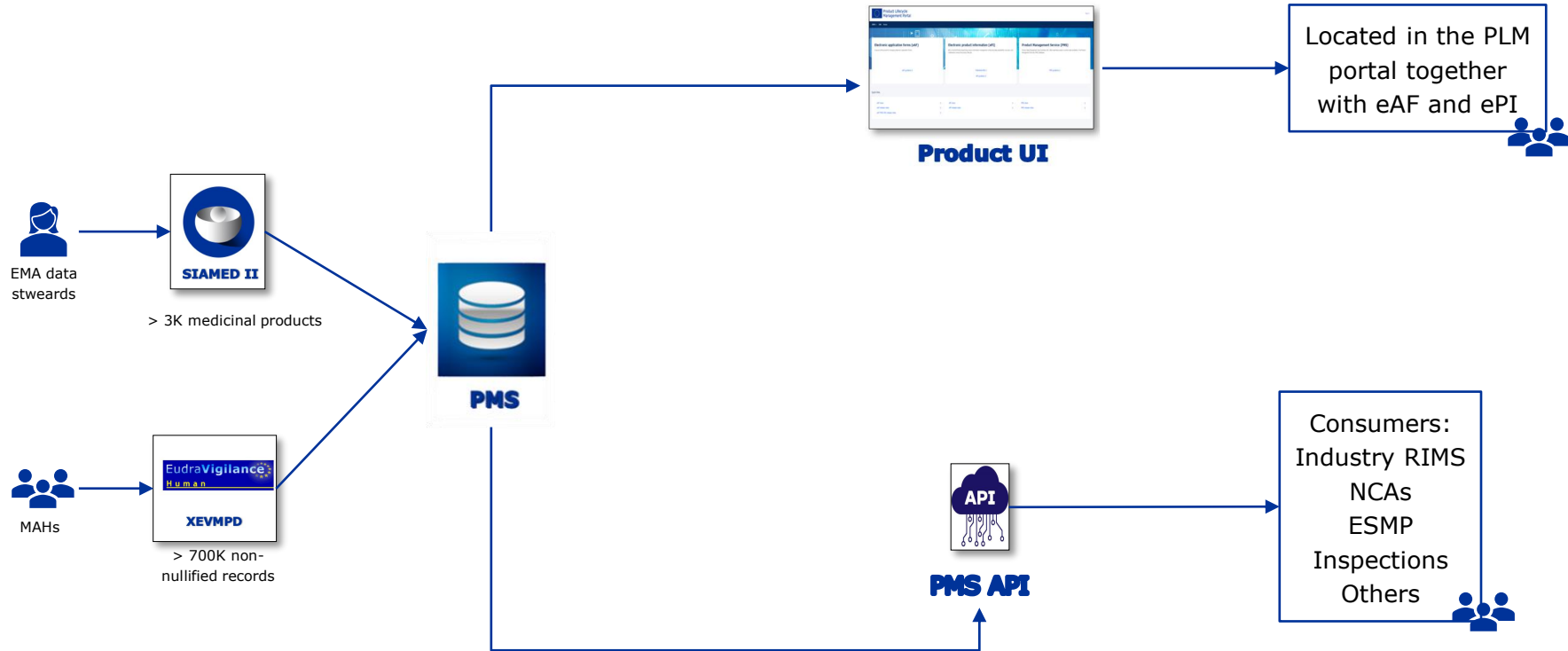


What will happen next (still in 2024)

Product UI - view pages – CAPs only

PMS API – read only – CAPs and NAPs

PMS user roles and how to request access





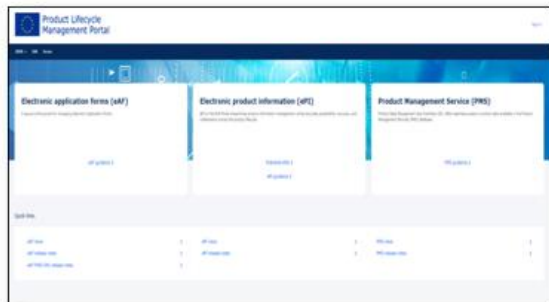
PMS API

- API = Application Programming Interface
- MAHs/NCAs can connect to the PMS API to query the FHIR messages in XML or JSON format
- Useful for MAHs with a RIMS in place
- **At go-live it will contain CAPs and NAPs and only view access**
- **Expected go-live: Q2 2024**
- Process to request API credentials will be updated soon
- Access for Industry and NCAs

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7   </meta>
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27                  <system value="http://terminology.hl7.org/CodeSystem" />
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35    </resource>
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37 </Bundle>
```



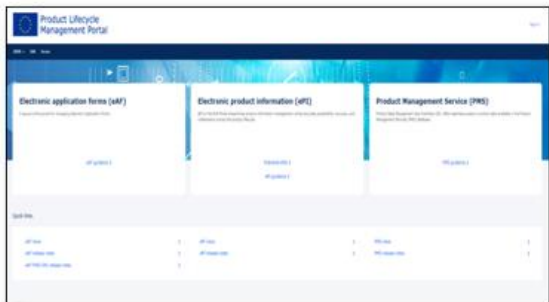
Product UI



Product UI

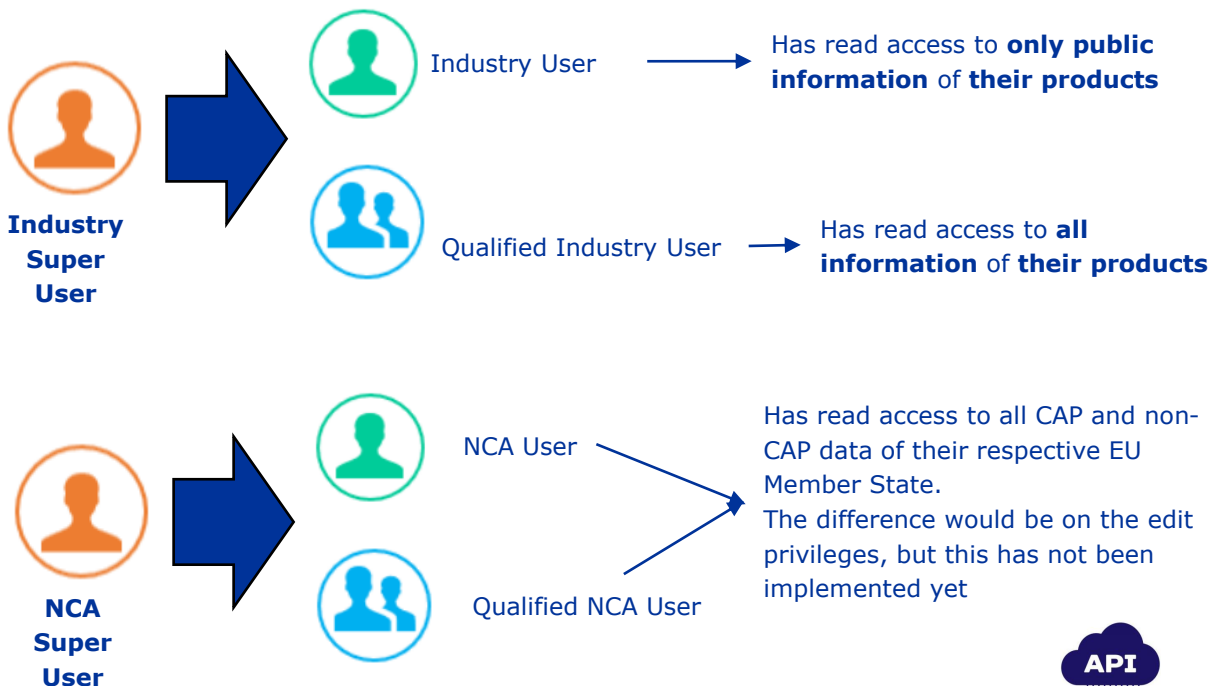
- PLM portal will host the **Product UI**
- The user interface will provide a visual representation of the FHIR message
- Useful for MAHs without a RIMS in place
- **At go-live it will contain only CAPs and only view access**
- **Expected go-live: Q2 2024**
- Process to request Product UI access and roles will be updated soon
- Please, review System Demos' recordings at EMA YouTube Channel to see how the Product UI looks like





Product UI

Roles of Product UI in PLM Portal



PMS API

Skilarence 120 mg - Gastro-resistant tablet

PMS ID: 600000000258 | Authorisation Country: EU | MAH: ORG-100000571 | Authorisation Status: Valid
Version Number: — | Last updated date: —

< Medicinal Product

PMS ID 600000000258

MPID —

Domain Human use

Type Medicinal Product

EV Code

Medicinal product name

↑	Full name	Country	Language
↓	Skilarence 120 mg - Gastro-resistant tablet	European Union	English

Legal status of supply Medicinal product subject to medical prescription

(Authorised) Pharmaceutical form Gastro-resistant tablet

Combined pharmaceutical dose form —

Paediatric use indicator No

Additional monitoring (Y/N) No

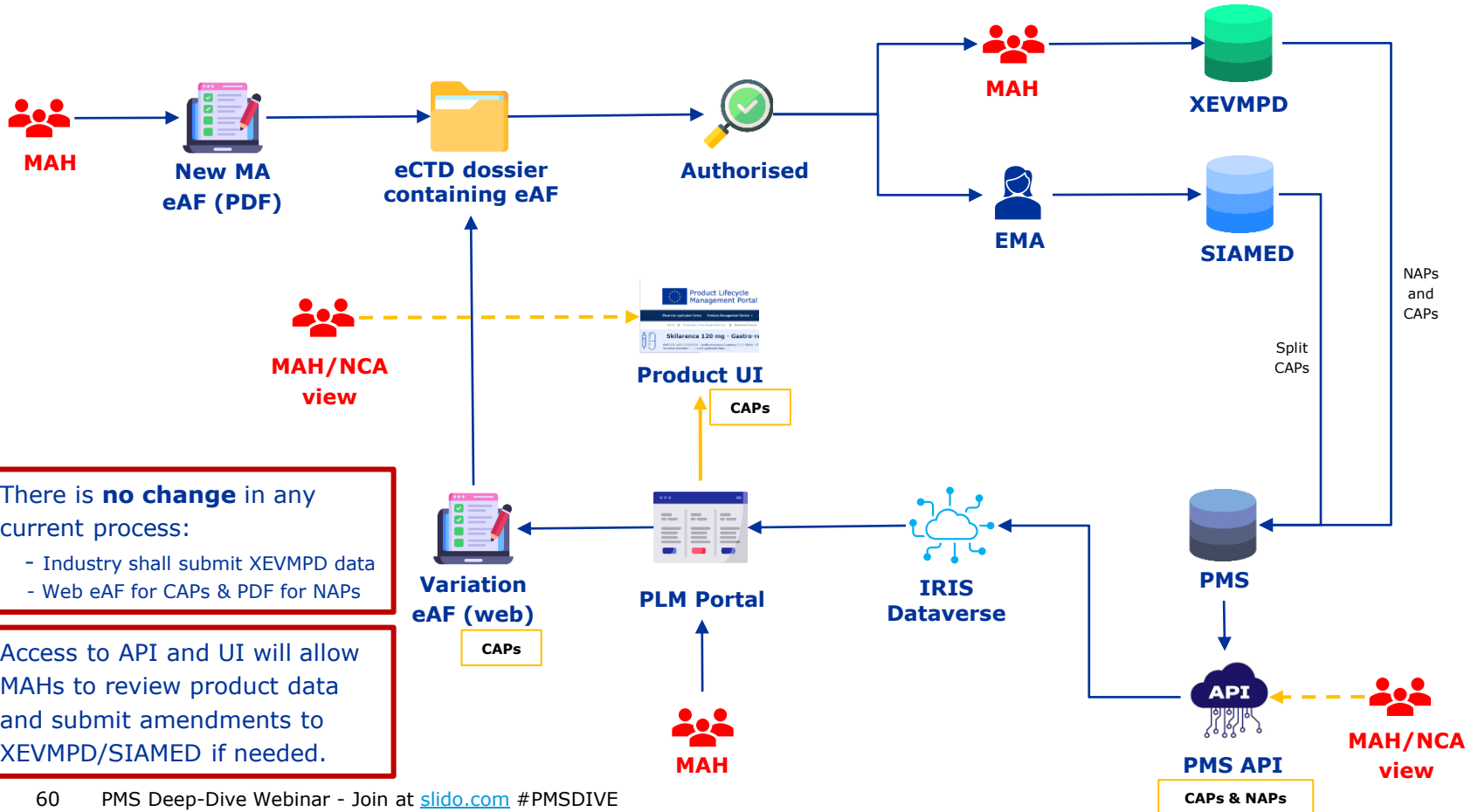
Language —

EURD ID —

Full indication text Skilarence is indicated for the treatment of moderate to severe plaque psoriasis in adults in need of systemic medicinal therapy.

- Medicinal Product
- Marketing Authorisation Information
- Therapeutic Indications
- Manufacturers
- Ingredients
- Medical Devices
- Manufactured Items
- Packaged Medicinal Product
- Marketing Authorisation Information
- Package Items
- Manufacturers
- Manufactured Items
- Medical Devices
- Pharmaceutical Product

What is the short-term process?





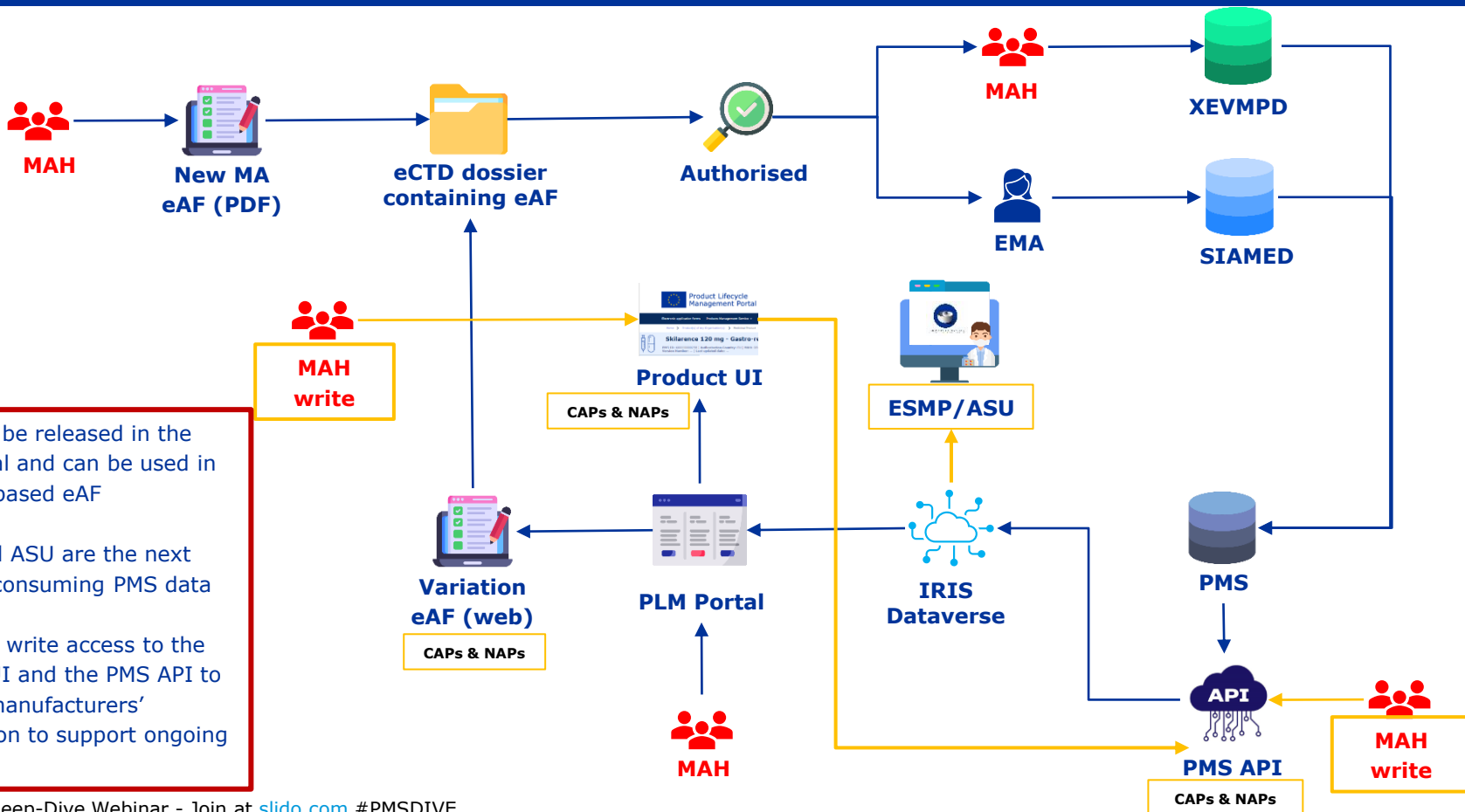
What will happen later (end of 2024 & beginning of 2025)

NAPs release in PLM portal

CAP/NAP PMS data in product UI (& eAF)

First edit process in Product UI & PMS API (manufacturers)

What is the medium-term (end 2024) process?



- 1) NAPs will be released in the PLM Portal and can be used in the web-based eAF
- 2) ESMP and ASU are the next projects consuming PMS data
- 3) MAHs get write access to the Product UI and the PMS API to provide manufacturers' information to support ongoing projects



Recommendations to applicants

Heads up!

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) and that 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.

Additional information on the different requests to Service Desk and how to use them will be released and explained shortly.

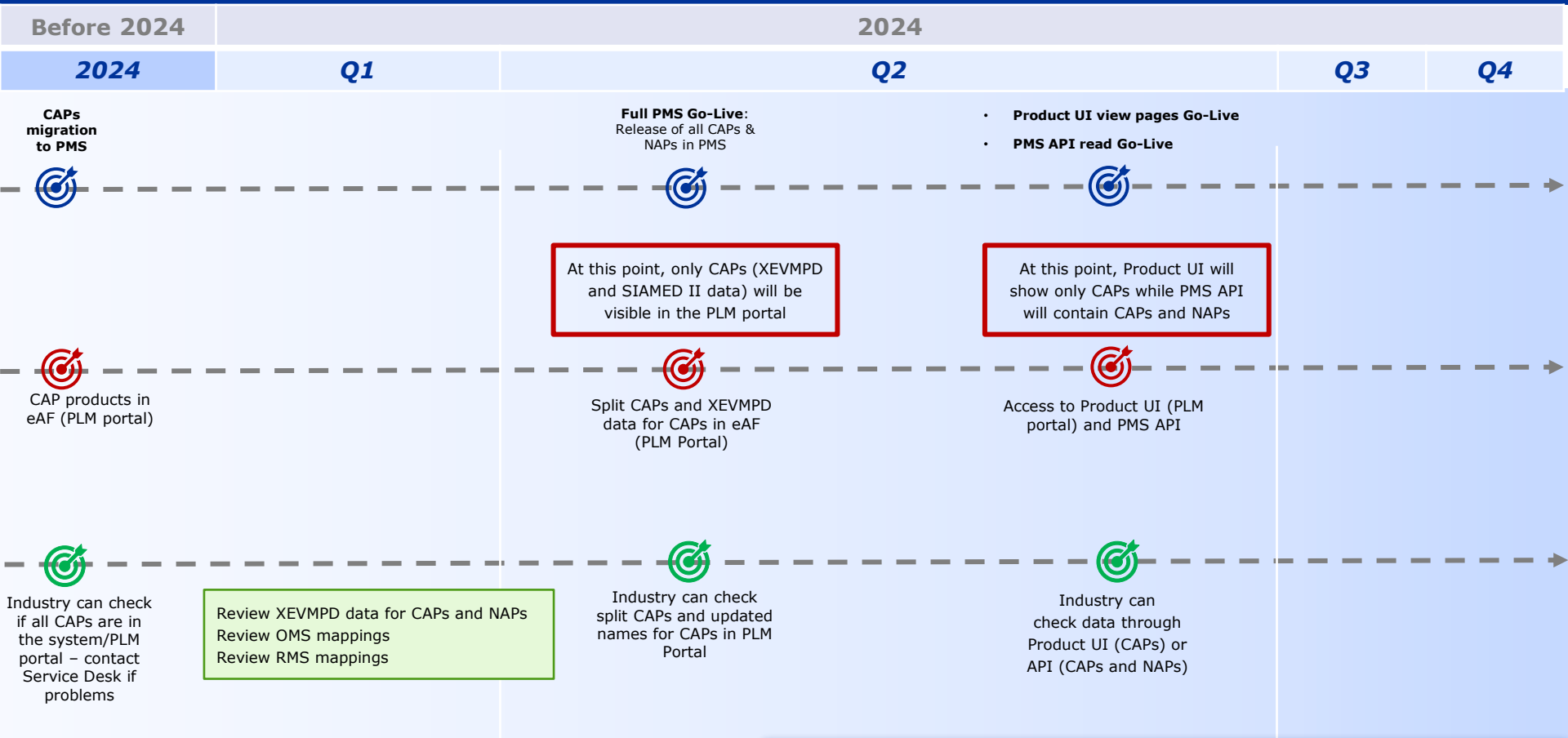
What can you do to support the needs of ongoing/future projects?

- PMS data will be used to prepare web application forms, support ESMP submissions, ASU and support other CAP procedures.
- Applicants should prepare to submit and maintain manufacturers data and pack sizes
- Things to consider:
 - Focus on critical medicines first
 - Map manufacturing operations to the terms in the RMS list
 - Map your manufacturers to OMS
 - Start compiling your authorised pack sizes to be submitted to XEVMPD

Additional information and the requirements and timelines to support specific use cases will be announced on the PMS Info Day taking place on April 16th.



Summary of activities and impacts to Industry





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

PMS Info-Day (16 April 2024)



This event aims to offer further insights into the **implications of PMS for key stakeholders** and present the **connection of PMS to other EMA digital solutions** (i.e. eAF, SPOR, ESMP, ePI, etc.)

The event will be available **online for live broadcast** on the dedicated **web page** and **EMA YouTube Channel**.

Details will be published soon on EMA Website.



Q&A



Thank you for your interest!

Further information

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