EMA
EUROPEAN MEDICINES AGENCY

Product Management Service Info-Day

21 May 2025

Session 3:
From data to value – How product data flows across processes/systems

Join at Slido.com with the code #PMS-INFO-25 for Q&A and feedback

EMA
EUROPEAN MEDICINES AGENCY

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Member of Network Data Steering Group (NDSG) and Regulatory Optimization Group (ROG) PMS Operational Group

Speakers:

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PMS Product Owner

Elizabeth Scanlan
ePI Product Owner

Kristiina Puusaari
eAF Product Owner

Anna Fiodorova
Parallel Distribution and Inspections Product Owner

Madalina Duta-Mare
RPM Product Owner

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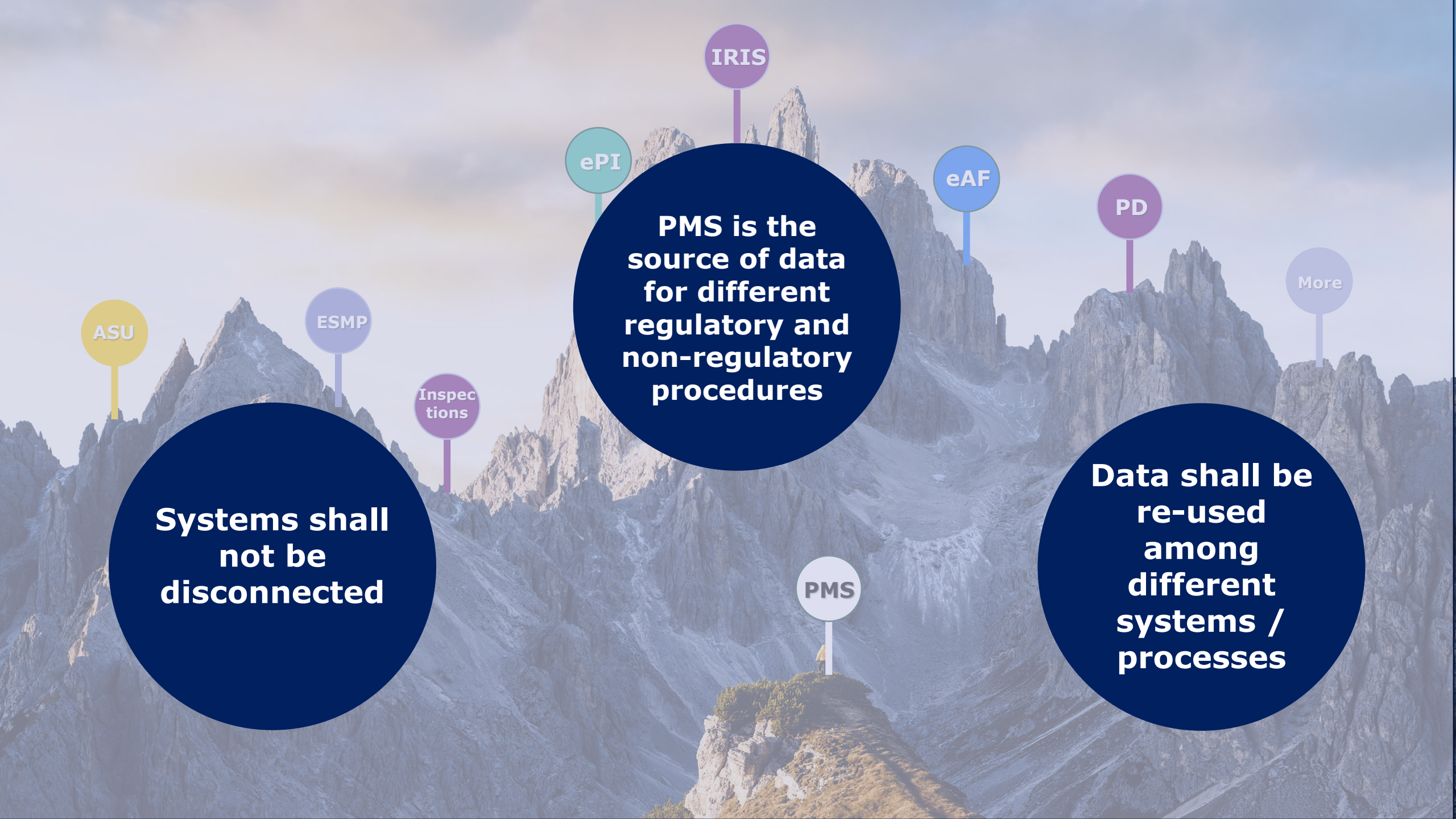
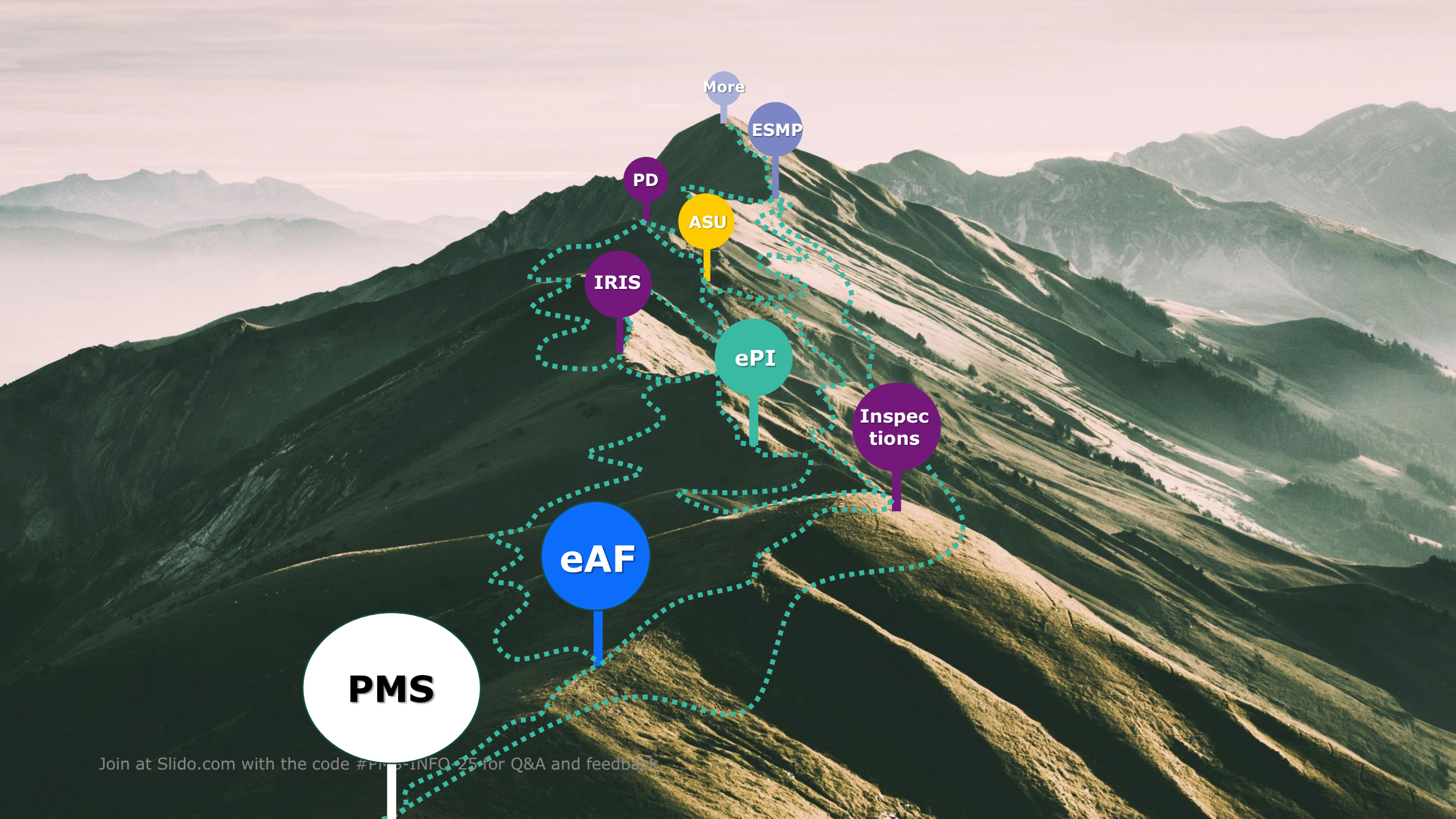
Supply and Availability of Medicines and Devices Specialist

Anastasia Pickford
ASU Product Owner


ASU
ESMP
ePI
eAF
Others
PMS


IRIS
ePI
eAF
PD
More
ASU
ESMP
Inspe
ctions
PMS


IRIS
ePI
eAF
PD
More
ASU
ESMP
Inspec tions
PMS is the source of data for different regulatory and non-regulatory procedures
Systems shall not be disconnected
Data shall be re-used among different systems / processes
PMS



eAF

The web-based variation form **replaces the interactive PDF** variation form facilitating the compliance with ISO IDMP

ePI

Authorised, statutory **product information** for medicines (including the summary of product characteristics, package leaflet and labelling) adapted for handling **in electronic format and dissemination via the web, e-platforms** and in print.

ESMP

IT platform to collect information from NCAs and MAHs on **availability, supply, and demand** of authorised medicinal products in specific circumstances to help **prevent, monitor, and manage shortages**, ensuring improved availability of medicines.

ASU

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.**

Inspections

Coordinates **GMP, GVP** and **GCP inspections** performed **by NCAs** for Centrally Authorised Products**.**

IRIS Portal

Platform used for pre and post authorisation **case management** for **EMA-led** procedures of the product lifecycle

Parallel Distribution

Management of notifications for **distribution of centrally authorised medicinal products** in parallel by companies independent from Marketing authorisation holder (MAH).

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Introduction

The aim of this presentation is to:

- Show **how data is captured** by PMS sources of data
- **How data is re-used** by the PMS consuming systems
- Explain **how different stakeholders will be handling PMS data** in the different systems and processes

CAP

Cefuroxema EMA 150 mg film-coated tablets

MAH: Fujisawa S.A.

EU/1/87/6543/001
EU/1/87/6543/002

ATC Code: J01DC02

NAP

Fidaxomicin EMA 50 mg comprimidos

MAH: Kern Pharma S.L.

3 pack sizes (091990)
Authorised in Spain

ATC Code: A07AA12

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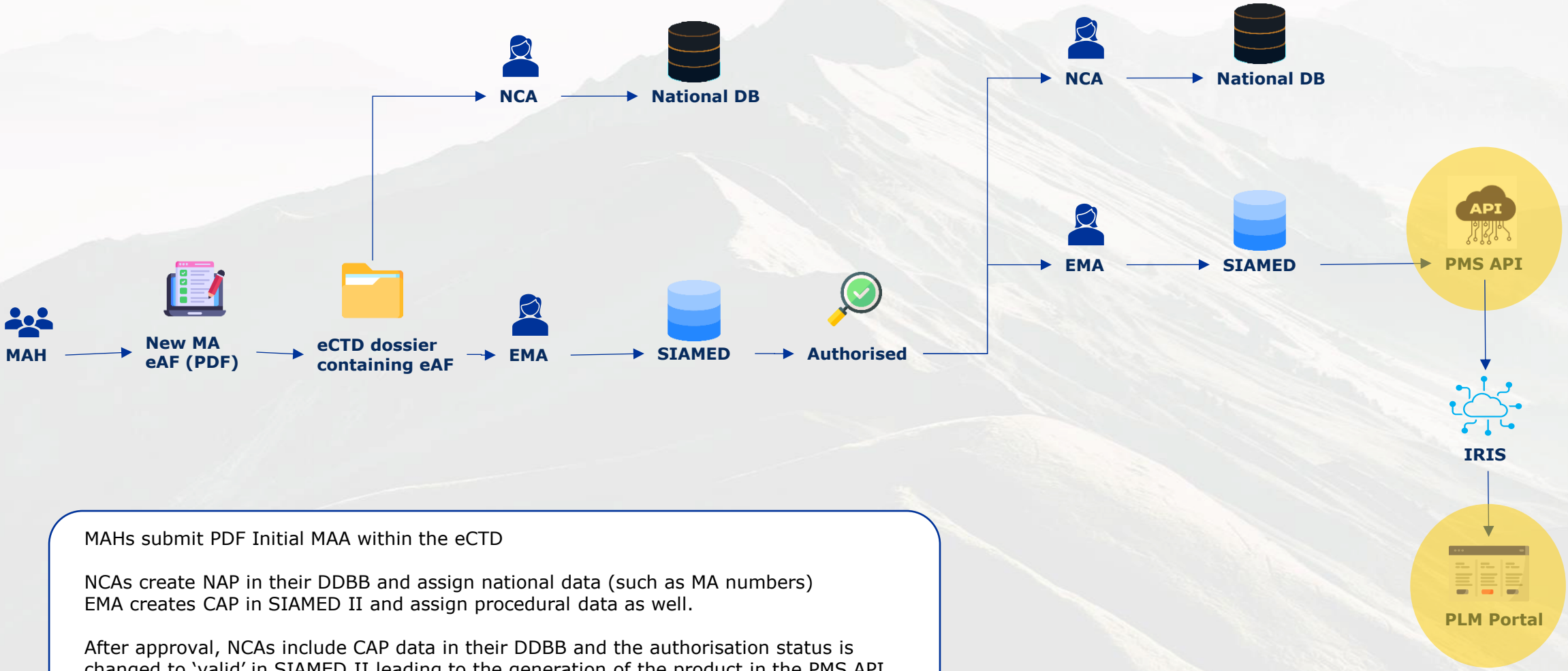
Submission and approval of initial MAA



MAHs submit PDF Initial MAA within the eCTD

NCAs create NAP in their DDBB and assign national data (such as MA numbers)
EMA creates CAP in SIAMED II and assign procedural data as well.

After approval, NCAs include CAP data in their DDBB and the authorisation status is changed to 'valid' in SIAMED II leading to the generation of the product in the PMS API and the PLM Portal

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CAP product created in the PMS API

```xml
<?xml version="1.0" encoding="utf-8"?>
<Bundle xmlns="http://hl7.org/fhir">
    <id value="700000056611" />
    <meta>
        <versionId value="1" />
        <lastUpdated value="2025-04-08T15:52:19.801+00:00" />
    </meta>
    <type value="searchset" />
    <entry>
        <fullUrl value="MedicinalProductDefinition/700000056611" />
        <resource>
            <MedicinalProductDefinition>
                <id value="700000056611" />
```

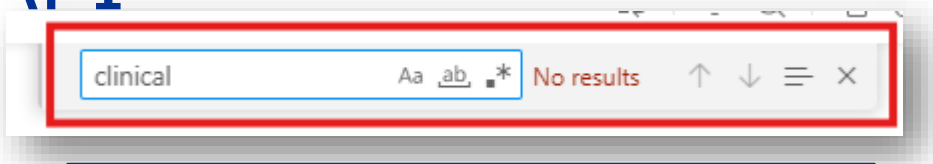
Version 1 of the medicinal product

```xml
<packagedMedicinalProduct id="7647154">
    <reference value="PackagedProductDefinition/7647154" />
</packagedMedicinalProduct>
<packagedMedicinalProduct id="7647153">
    <reference value="PackagedProductDefinition/7647153" />
</packagedMedicinalProduct>
```

Two packages are created

```xml
<name id="72203">
    <productName value="CEFUROXEMA 150 mg - Film-coated tablet" />
```

Product name as in SIAMED (not as in XEVMPD)



No indications as SIAMED does not capture them

```xml
<manufacturingBusinessOperation id="31070128">
    <type>
        <concept>
            <coding>
                <extension url="http://ema.europa.eu/fhir/extension/termVersion">
                    <valueInteger value="15" />
                </extension>
                <system value="http://spor.ema.europa.eu/v1/lists/100000160406" />
                <code value="100000160453" />
            </coding>
        </concept>
    </type>
    <effectiveDate>
        <start value="2023-08-22T22:00:00Z" />
    </effectiveDate>
    <manufacturer id="31460110">
        <reference value="http://spor.ema.europa.eu/v1/locations/LOC-100088869" />
        <display value="LOC-100088869" />
    </manufacturer>
    <confidentialityIndicator>
        <coding>
            <extension url="http://ema.europa.eu/fhir/extension/termVersion">
                <valueInteger value="2" />
            </extension>
            <system value="http://spor.ema.europa.eu/v1/lists/200000004983" />
            <code value="200000004984" />
        </coding>
    </confidentialityIndicator>
</manufacturingBusinessOperation>
```

Manufacturers from SIAMED

```xml
<paediatricUseIndicator>
    <coding>
        <system value="http://ema.europa.eu/fhir/paediatricUseIndicator" />
        <code value="False" />
    </coding>
</paediatricUseIndicator>
```

Paediatric use is false also as it is not captured in SIAMED

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CEFUROXEMA 150 mg - Film-coated tablet

PMS ID : 700000056611 | Authorisation Country : EU | MAH : ORG-100050929 | Authorisation Status : Valid | Version Number : 2 | Last updated date : 09/04/2025

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

Workspace
- History

Medicinal Product

PMS ID	700000056611	**MPID**	—
Domain	Human use	**Type**	Medicinal Product
EV Code	—		

EV codes missing as data has not yet been submitted to XEVMPD

Medicinal product name

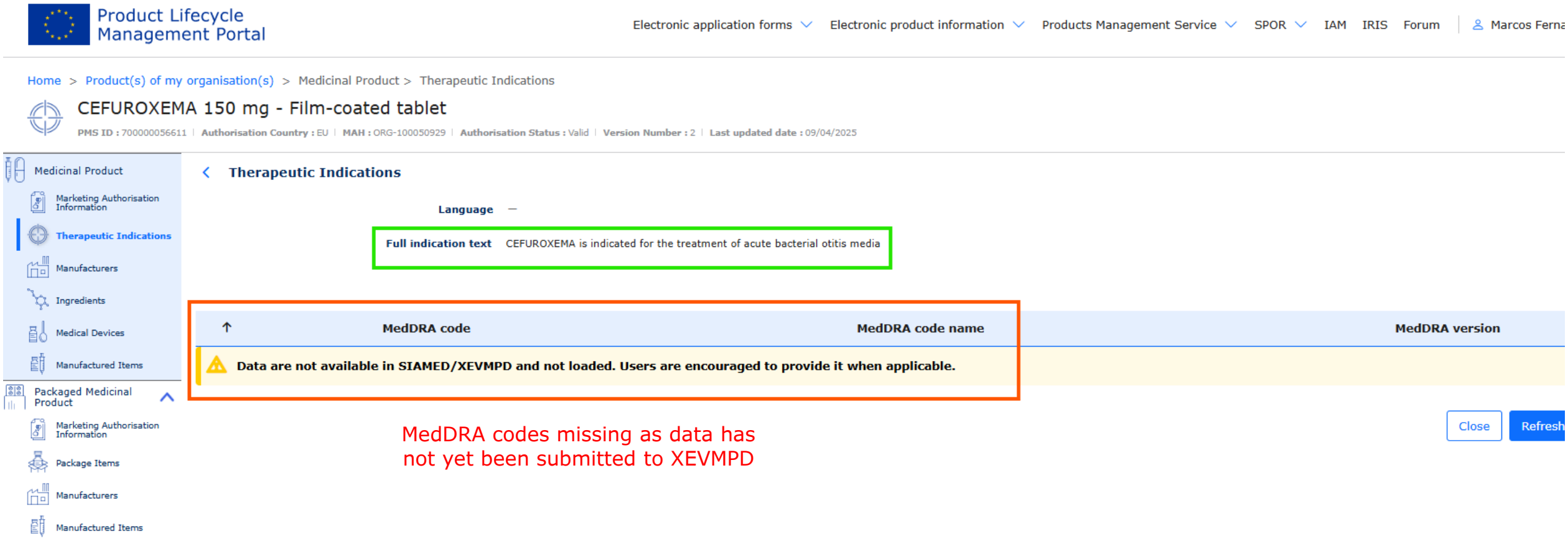
Full name	Country	Language
CEFUROXEMA 150 mg - Film-coated tablet	European Union	English

Legal status of supply	Medicinal product subject to restricted medical prescription		
(Authorised) Pharmaceutical form	Film-coated tablet		
Combined pharmaceutical dose form	—		
Paediatric use indicator	No	**Additional monitoring (Y/N)**	No
		EURD ID	—

Product Classification

ATC code	ATC code name	ATC code – Flag
J01DC02	cefuroxime	Not applicable

Legal basis	New active substance (Article 8(3) of Directive No 2001/83/EC)
Genetically modified organisms (GMOs)	No
xEVMPD product type information	—



MedDRA codes missing as data has not yet been submitted to XEVMPD

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Product Lifecycle Management Portal

Electronic application forms | Electronic product information | Products Management Service | SPOR | IAM | IRIS | Forum | Marcos Fernandez Gomez

Home > Product(s) of my organisation(s) > Medicinal Product > Manufacturers

CEFUROXEMA 150 mg - Film-coated tablet

PMS ID : 700000056611 | **Authorisation Country :** EU | **MAH :** ORG-100050929 | **Authorisation Status :** Valid | **Version Number :** 2 | **Last updated date :** 09/04/2025

- 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
- Workspace
  - History

Manufacturers

Column visibility | Download | Show 10 rows

Manufacturer	Address	Org ID	Loc ID
AB Biotek Human Nutrition & Health	Calle Escoles Pies 49 08017 Barcelona Spain	ORG-100051755	LOC-100090934
Anaxomics Biotech S.L.	Calle Balmes 89 08008 Barcelona Spain	ORG-100027558	LOC-100074350
Banc De Sang I Teixits	Passeig De La Vall D'hebron 119 08035 Barcelona Spain	ORG-100012245	LOC-100033801
Brill International S.L.	Calle Munner 8 08022 Barcelona Spain	ORG-100050841	LOC-100088869
Cebiotex S.L.	Placa De Pau Vila 1 08039 Barcelona Spain	ORG-100008503	LOC-100069866
Endor Technologies S.L.	Edificio Helix Calle Baldiri Reixac 15 Poligono Industrial Parc Cientific De Barcelona 08028 Barcelona Spain	ORG-100008492	LOC-100012863
Extendis Pharma S.L.	Carrer De Les Tres Torres 49 08017 Barcelona Spain	ORG-100052974	LOC-100093421
Freeox Biotech S.L.	Calle Del Consejo De Ciento 373-375 Piso 2 Portal 1 08009 Barcelona Spain	ORG-100013979	LOC-100019764
Gate2brain S.L.	Calle Baldiri Reixac 4-8 Poligono Industrial Parc Cientific De Barcelona 08028 Barcelona Spain	ORG-100047851	LOC-100079122
Gentec S.A.	Tramontana 3 Avinyonet Del Penedes 08793 Barcelona Spain	ORG-100008311	LOC-100054412

Showing **1** to **10** of **17** entries

< Previous 1 2 Next >

Close | Refresh | Export to XML

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EMA

Product Lifecycle Management Portal

Electronic application forms | Electronic product information | Products Management Service | SPOR | IAM | IRIS | Forum | Marcos Fernandez

Home > Product(s) of my organisation(s) > Packaged Medicinal Product

CEFUROXEMA 150 mg - Film-coated tablet

PMS ID : 700000056611 | Authorisation Country : EU | MAH : ORG-100050929 | Authorisation Status : Valid | Version Number : 2 | Last updated date : 09/04/2025

- 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
- Workspace

Packaged Medicinal Product

Download

MA number	Package size(s)	PCID	EV code	Legal status of supply	Authorisation Status
EU/1/87/6543/001	30 Tablet	–	–	Medicinal product subject to restricted medical prescription	Valid
EU/1/87/6543/002	15 Tablet	–	–	Medicinal product subject to restricted medical prescription	Valid

Showing **1** to **2** of **2** entries

Close | Refresh

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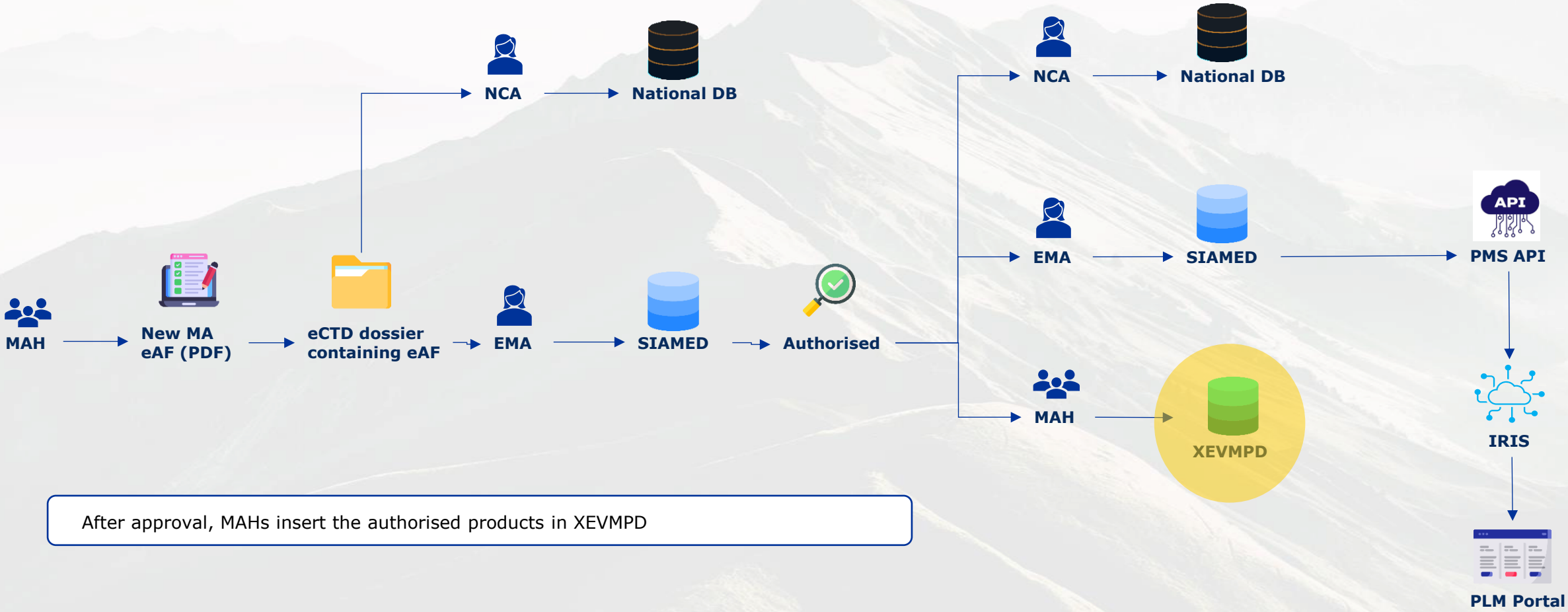
Insert of products in XEVMPD

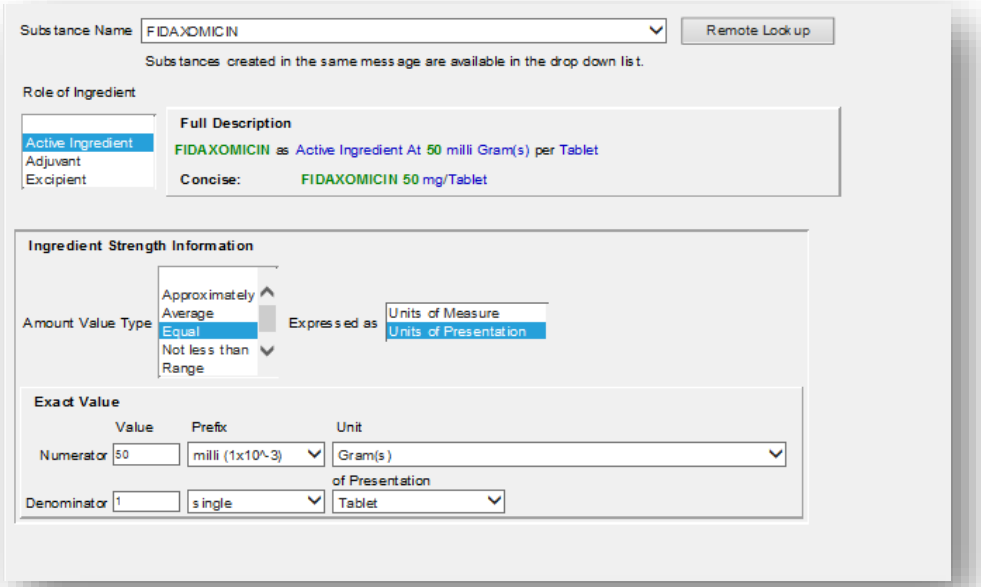


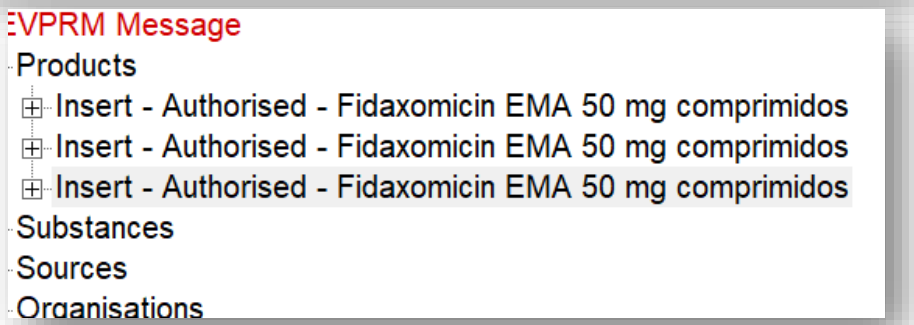
After approval, MAHs insert the authorised products in XEVMPD

Insert of products in XEVMPD

Description	Name/Value
Type	Authorised
Is EMA Owned	
Operation Type	Insert
New Owner ID	
MAH	KERN PHARMA, S.L.
QPPV	
Master File Location	
PhV enquiry email	email@email.com
PhV enquiry Phone	+31098674
Sender Local Code	
Info Date	
Authorisation Country Code	Spain
Authorisation Procedure	EU authorisation procedures - ...
Authorisation Status	Valid
Authorisation Number	091990
Authorisation/Renewal Date	07/04/2025
MRP/DCP/EMEA Number	
EU Number	
Legal Basis	Full application (Article 8(3) of ...
Orphan Drug	No
Additional Monitoring	Yes
Invalidated Date	
Full Presentation Name	Fidaxomicin EMA 50 mg compr...
Product Short Name	
Product INN/Common Name	Fidaxomicin
Product Company Name	EMA
Product Strength Name	50 MG
Product Form Name	COMPRIMIDOS
Package Description	33333 - 50 tablets
Comment	Medicinal product authorised fo...
	Medicinal Product Types (-)

Field must have a spe





Products can be submitted using EVWEB or gateway submission. CAPs and NAPs should be submitted to XEVMPD following the business rules described in Chapter 3.II of XEVMPD

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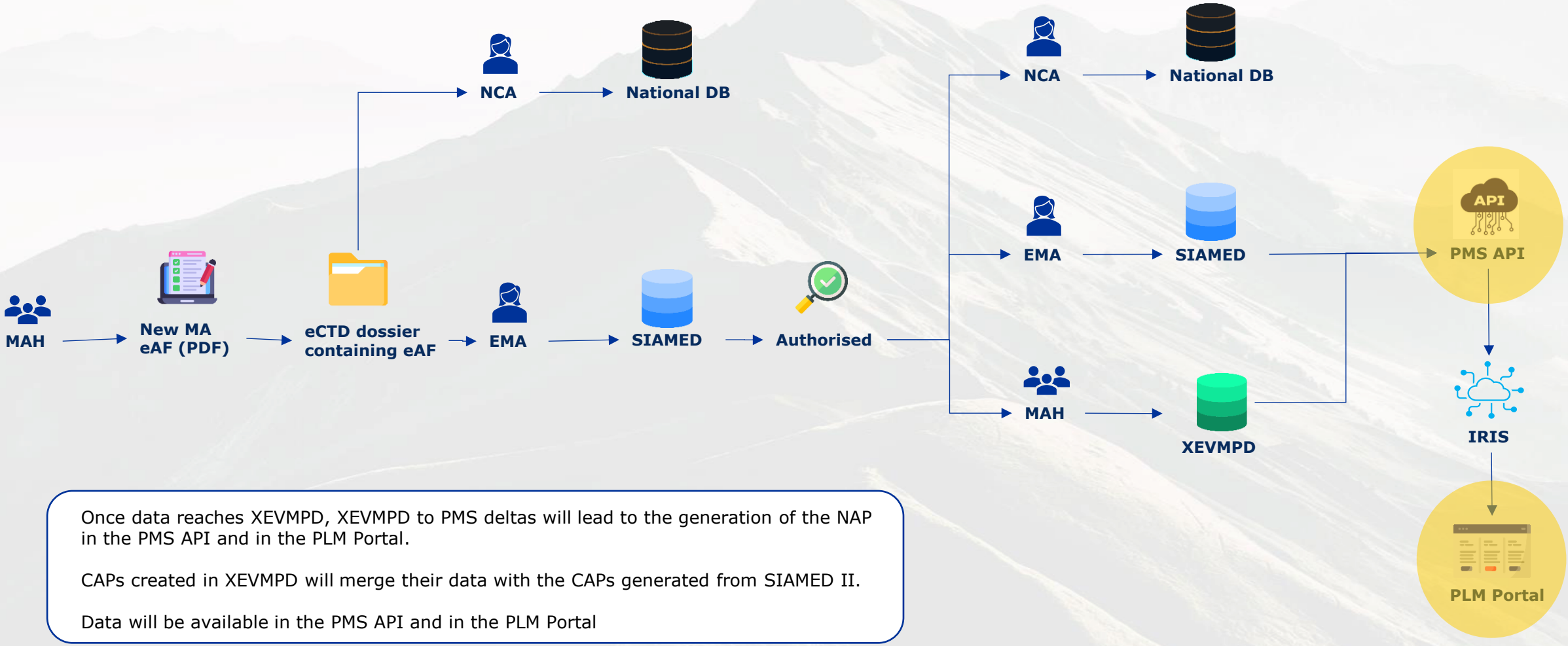
Insert of products in XEVMPD



Once data reaches XEVMPD, XEVMPD to PMS deltas will lead to the generation of the NAP in the PMS API and in the PLM Portal.

CAPs created in XEVMPD will merge their data with the CAPs generated from SIAMED II.

Data will be available in the PMS API and in the PLM Portal

CAP product is updated after XEVMPD submission

```xml
<?xml version="1.0" encoding="utf-8"?>
<Bundle xmlns="http://hl7.org/fhir">
    <id value="700000056611" />
    <meta>
        <versionId value="4" />
        <lastUpdated value="2025-04-29T08:36:57.074+00:00" />
    </meta>
    <type value="searchset" />
    <entry>
        <fullUrl value="MedicinalProductDefinition/700000056611" />
        <resource>
            <MedicinalProductDefinition>
                <id value="700000056611" />
                <contained>
```

Medicinal product is updated (new version)

```xml
<entry>
    <fullUrl value="ClinicalUseIssue/22043" />
    <resource>
        <ClinicalUseIssue>
            <id value="22043" />
            <type value="indication" />
            <subject>
                <reference value="MedicinalProductDefinition/700000056611" />
            </subject>
            <indication>
                <diseaseSymptomProcedure>
                    <coding>
                        <extension url="http://ema.europa.eu/fhir/extension/termVersion">
                            <valueInteger value="1" />
                        </extension>
                        <system value="http://spor.ema.europa.eu/v1/lists/100000000006" />
                        <code value="10065176" />
                    </coding>
                </diseaseSymptomProcedure>
            </indication>
        </ClinicalUseIssue>
```

Indications are also updated with data from XEVMPD

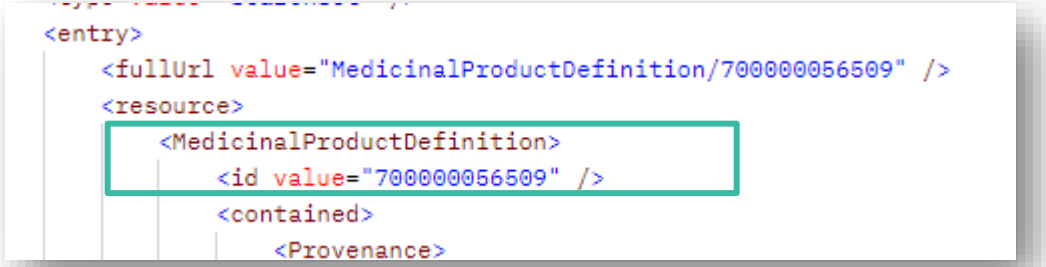
```xml
<name id="72203">
    <productName value="Cefuroxema EMA 150 mg film-coated tablets" />
```

Product name is updated with data from XEVMPD

```xml
<paediatricUseIndicator>
    <coding>
        <system value="http://ema.europa.eu/fhir/paediatricUseIndicator" />
        <code value="True" />
    </coding>
</paediatricUseIndicator>
```

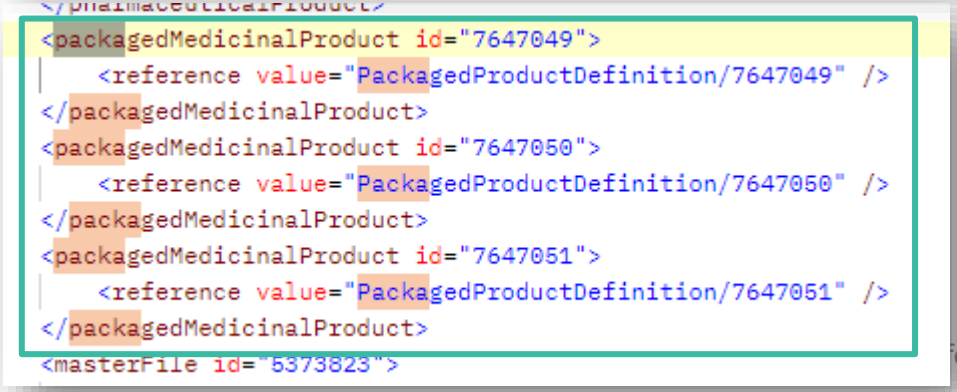
Paediatric use is updated with data from XEVMPD

NAP product is created in the PMS API



New medicinal product is created

The three EV Codes created in XEVMPD are reflected in the PMS API



Three packaged medicinal products are linked to the medicinal product (one per EV Code created)

Fidaxomicin EMA 50 mg comprimidos

PMS ID : 700000056509 | **Authorisation Country :** ES | **MAH :** ORG-100000149 | **Authorisation Status :** Valid | **Version Number :** 4 | **Last updated date :** 29/04/2025

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

Workspace
- History

Medicinal Product

PMS ID 700000056509

MPID —

Domain Human use

Type Medicinal Product

EV Code PRD11169138 | PRD11169139 | PRD11169140

Medicinal product name

Full name	Country	Language
Fidaxomicin EMA 50 mg comprimidos	Kingdom of Spain	Spanish

Legal status of supply —

(Authorised) Pharmaceutical form Tablet

Combined pharmaceutical dose form —

Paediatric use indicator Yes

Additional monitoring (Y/N) No

EURD ID —

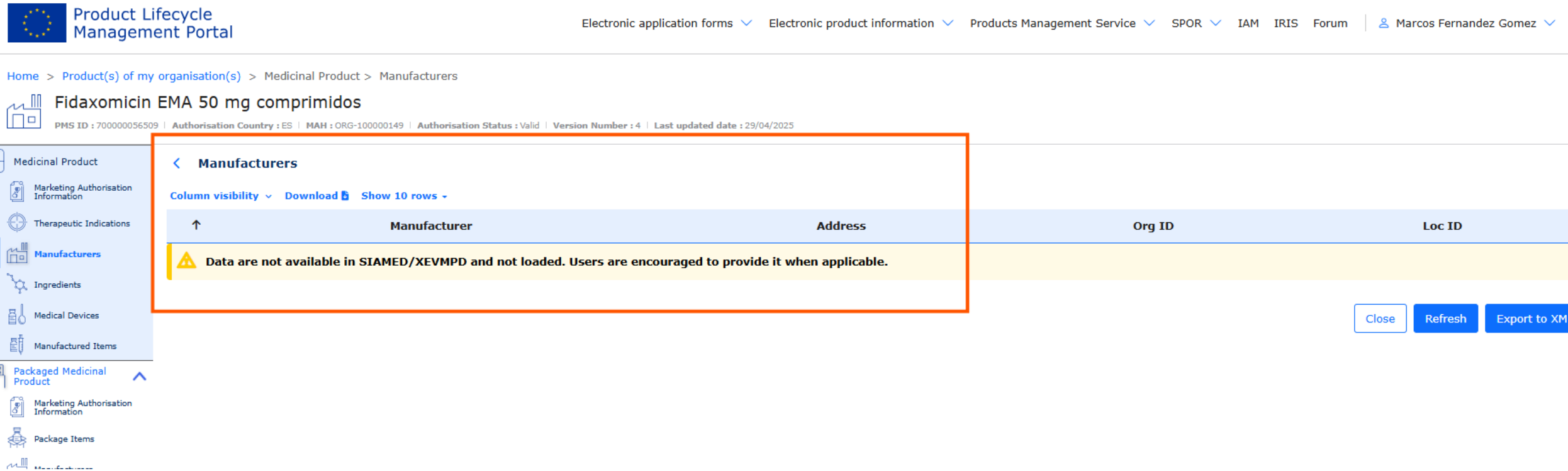
Product Classification

ATC code	ATC code name	ATC code – Flag
A07AA12	fidaxomicin	Not applicable

Legal basis Article 58 of Regulation (EC) No 726/2004

Genetically modified organisms (GMOs) —

xEVMPD product type information Other



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Product Lifecycle Management Portal

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Home > Product(s) of my organisation(s) > Packaged Medicinal Product

Fidaxomicin EMA 50 mg comprimidos

PMS ID : 700000056509 | **Authorisation Country :** ES | **MAH :** ORG-100000149 | **Authorisation Status :** Valid | **Version Number :** 4 | **Last updated date :** 29/04/2025

- 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
- Workspace
  - History

Packaged Medicinal Product

Structured pack size data is missing as this is not part of the XEVMPD data model

Download

	MA number	Package size(s)	PCID	EV code	Legal status of supply	Authorisation Status
^	091990	–	–	PRD11169140	–	Valid

Package description 33333 - 50 tablets

Language –

Open all

- Pack Size — Open
- Shelf life / Storage — Open
- Data carrier identifier(s) — Open

v	091990	–	–	PRD11169139	–	Valid
v	091990	–	–	PRD11169138	–	Valid

Showing **1** to **3** of **3** entries

Close | Refresh | Export to XML

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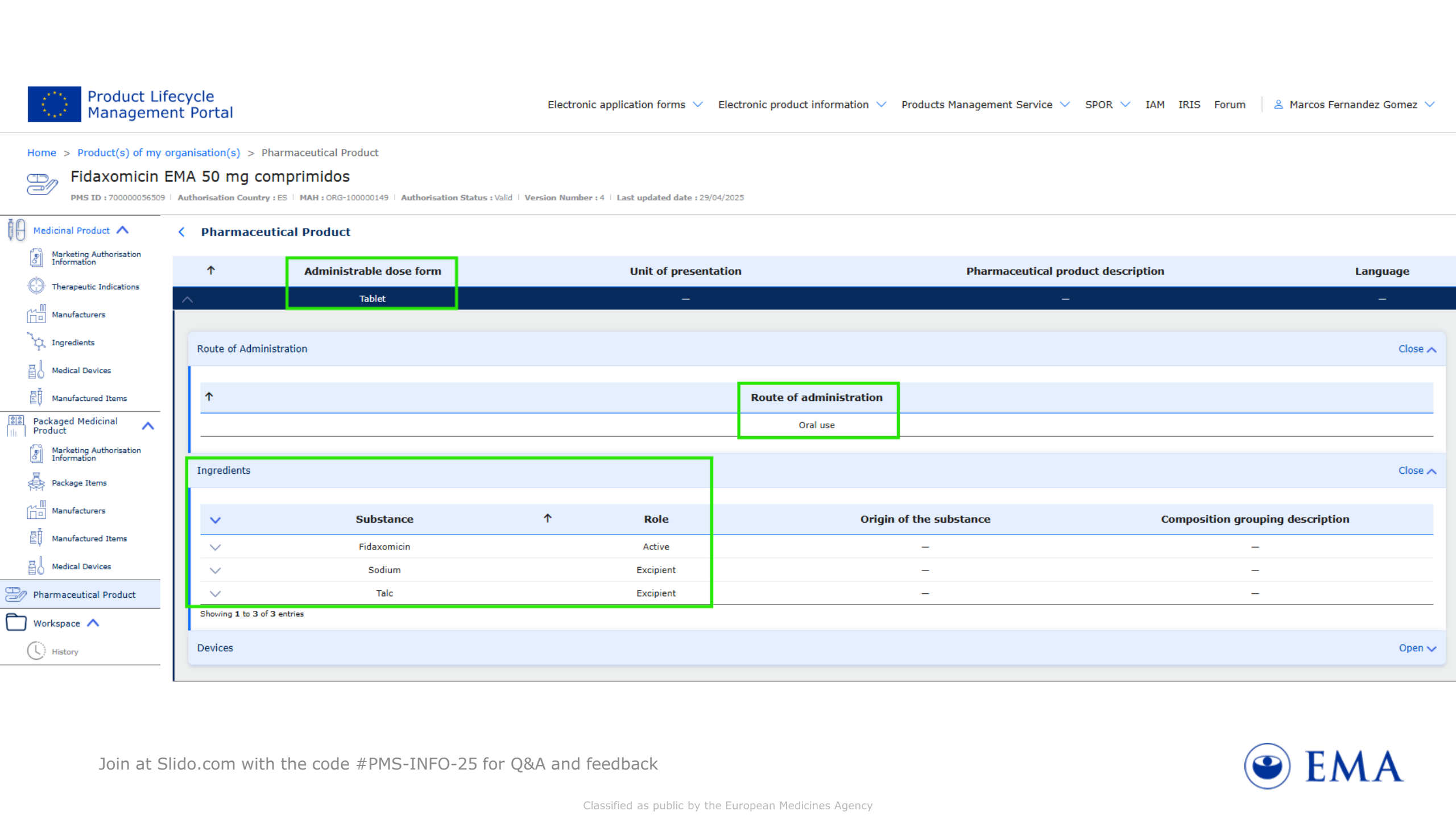
EMA



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Cefuroxema EMA 150 mg film-coated tabl...

PMS ID : 700000056611 | Authorisation Country : EU | MAH : ORG-100050929 | Authorisation Status : Valid | Version Number : 4 | Last updated date : 29/04/2025

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

Workspace
- History

Medicinal Product

PMS ID	700000056611	**MPID**	—
Domain	Human use	**Type**	Medicinal Product
EV Code	PRD11169151 | PRD11169152		

Medicinal product name

Full name	Country	Language
Cefuroxema EMA 150 mg film-coated tablets	European Union	English

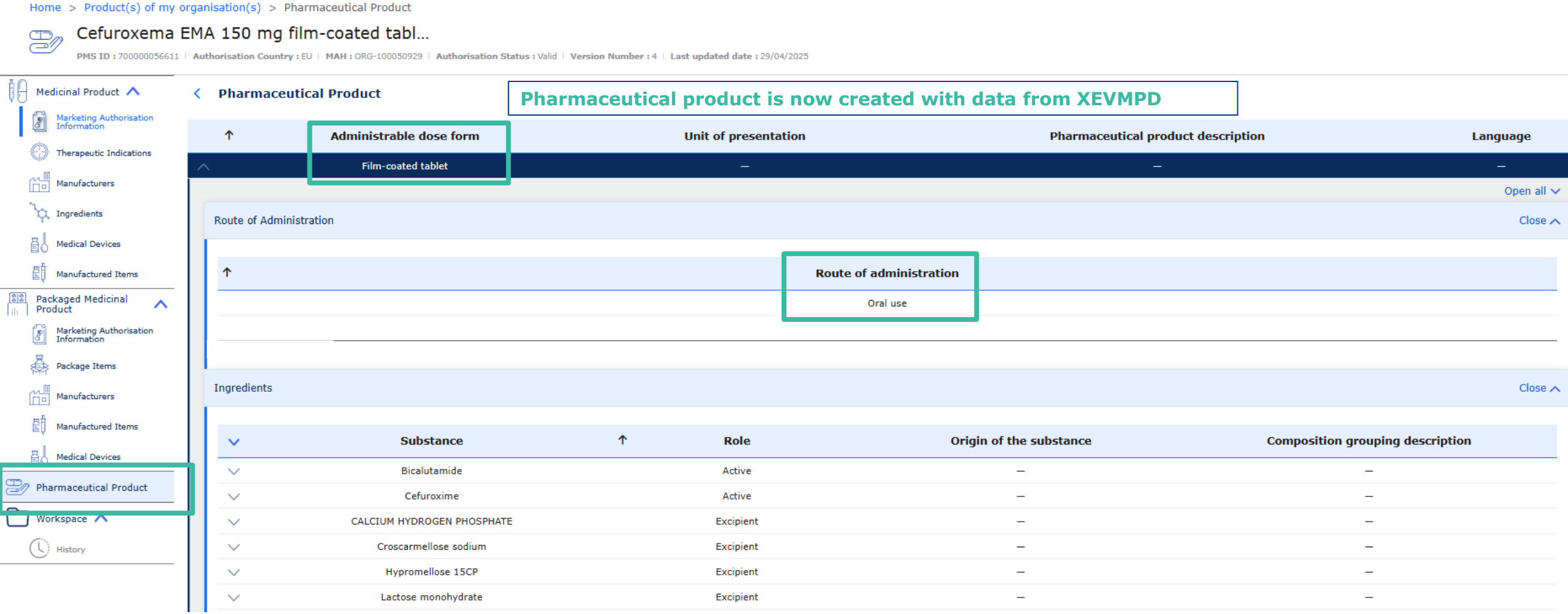
Legal status of supply	Medicinal product subject to restricted medical prescription		
(Authorised) Pharmaceutical form	Film-coated tablet		
Combined pharmaceutical dose form	—		
Paediatric use indicator	Yes	**Additional monitoring (Y/N)**	Yes
		EURD ID	—

EV Codes, name and paeditric use are updated with XEVMPD data

Product Classification

ATC code	ATC code name	ATC code – Flag
J01DC02	cefuroxime	Not applicable

Legal basis	Full application (Article 8(3) of Directive No 2001/83/EC)
Genetically modified organisms (GMOs)	No



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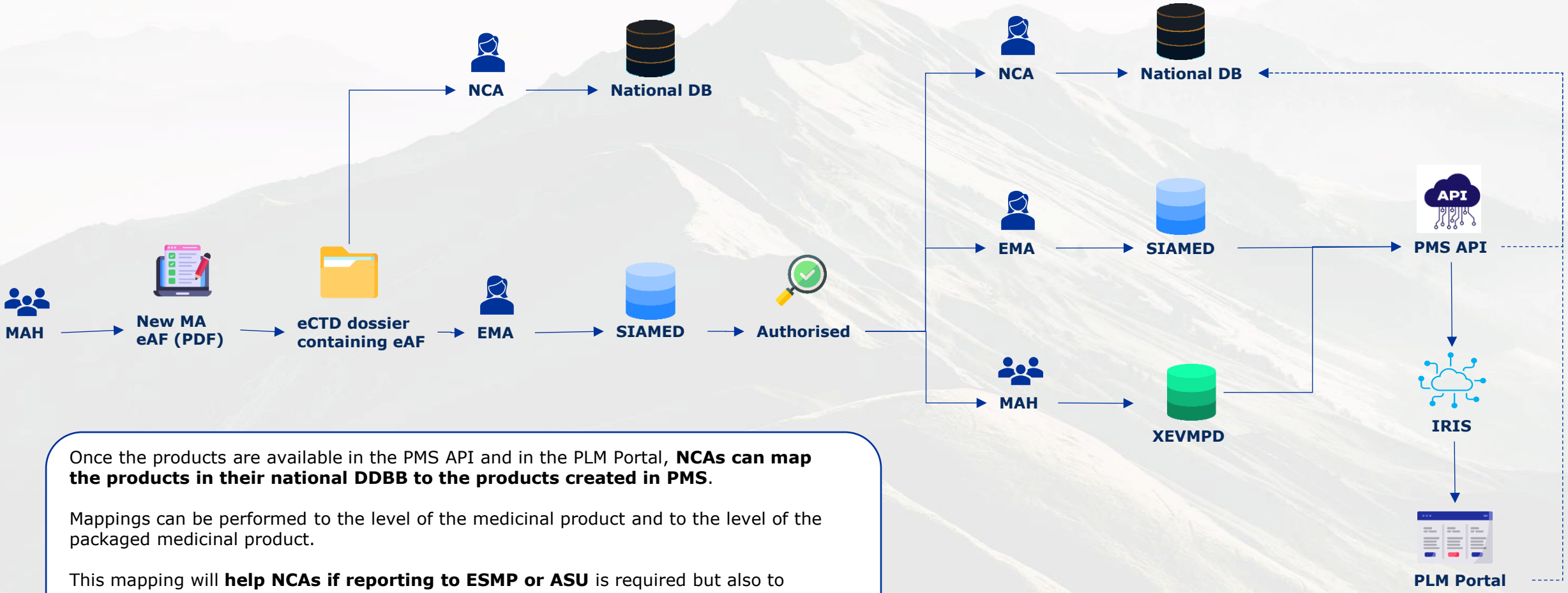
NCAs data mapping and use of PMS data



Once the products are available in the PMS API and in the PLM Portal, **NCAs can map the products in their national DDBB to the products created in PMS**.

Mappings can be performed to the level of the medicinal product and to the level of the packaged medicinal product.

This mapping will **help NCAs if reporting to ESMP or ASU** is required but also to support other regulatory procedures (such as the **use of the web-based eAF**) or non-regulatory procedures or **data verification** if performed by NCAs.

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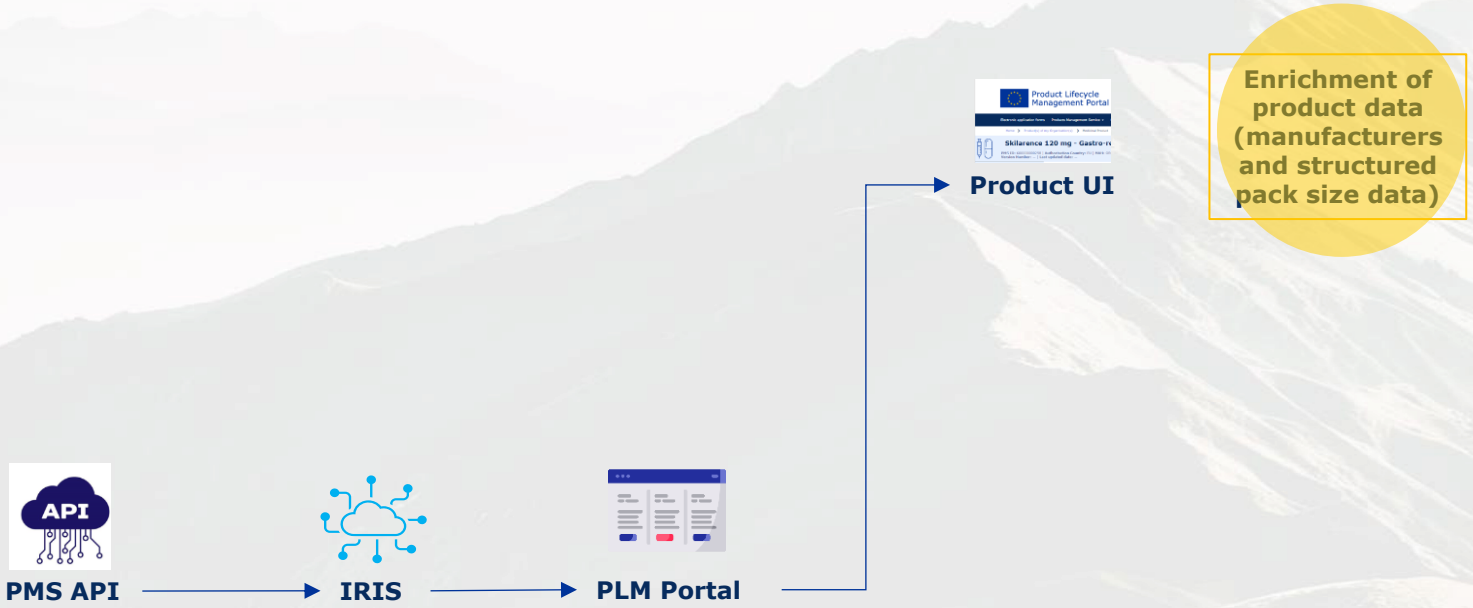
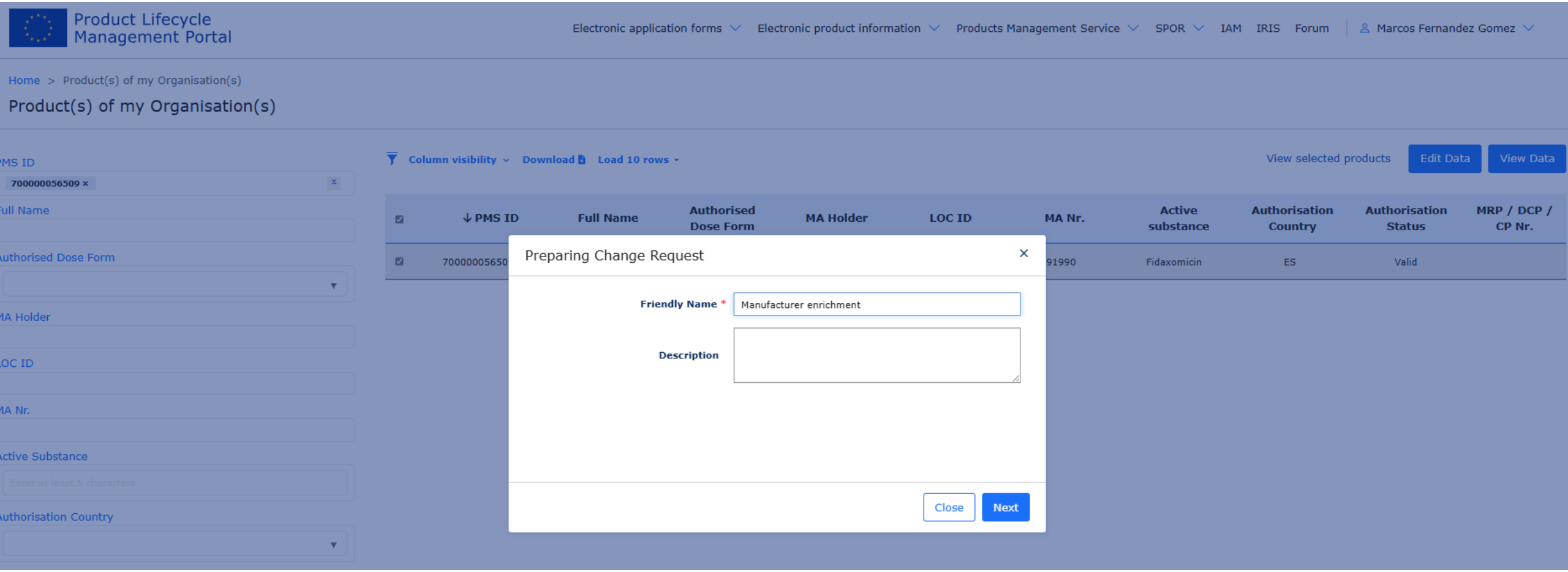
Enrichment of product data



When products belong to the Union List of Critical Medicines (ULCM) (based on ATC Code and Route of Administration), **enrichment has to be performed by MAHs**.

In this case, products belong to the ULCM and are also antibiotics, so in the scope of ASU.

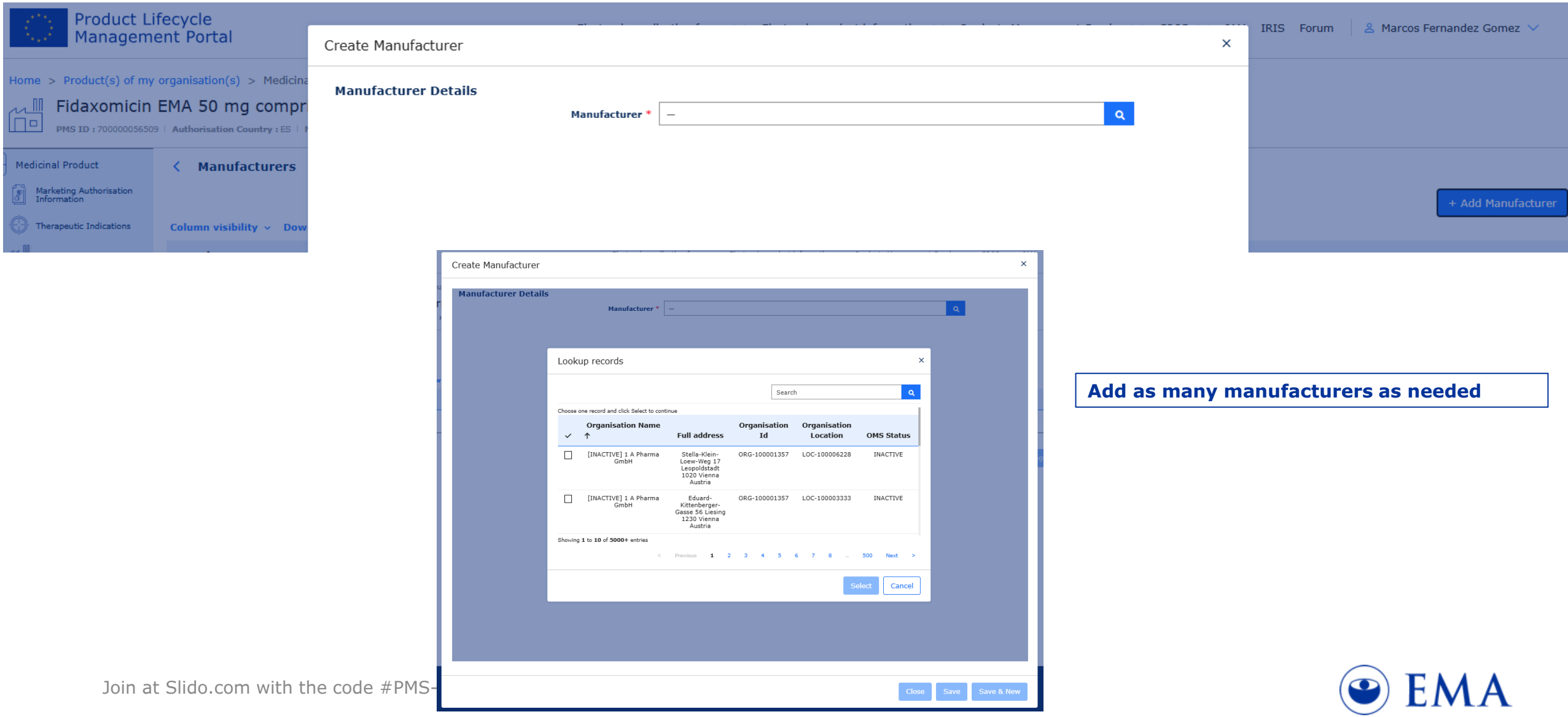
Enrichment of product data



Edit NAP product and create a change

Join at Slido.com with the code #PMS-INFO-25 for Q&A and feedback

Enrichment of product data



Add as many manufacturers as needed

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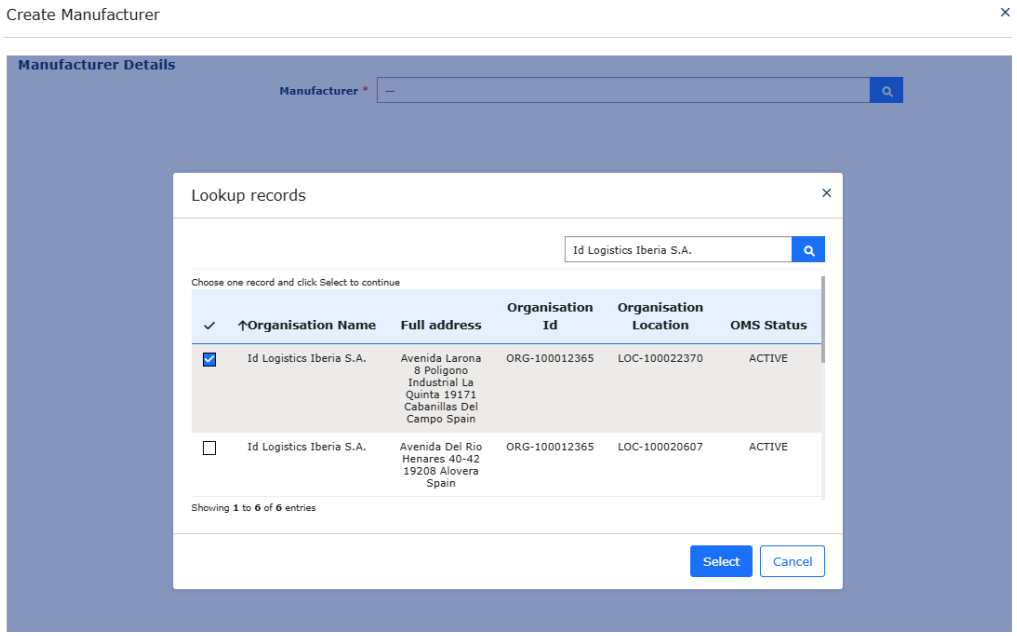
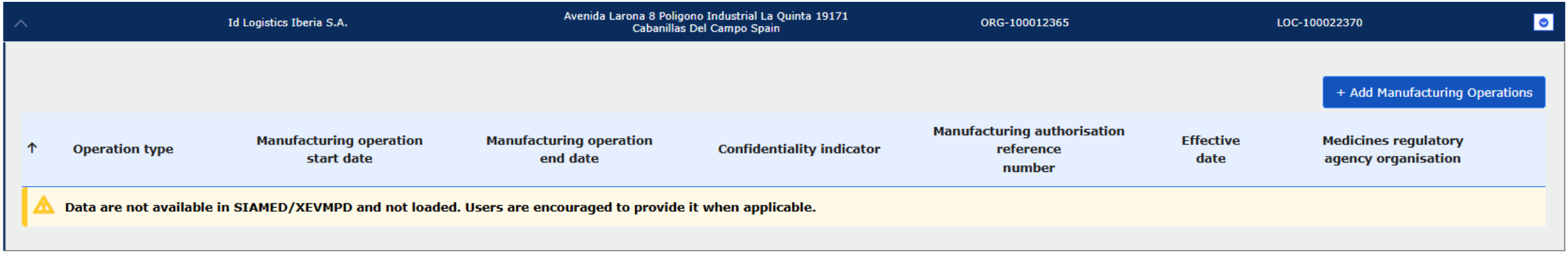
Enrichment of product data



Add as many manufacturers as needed



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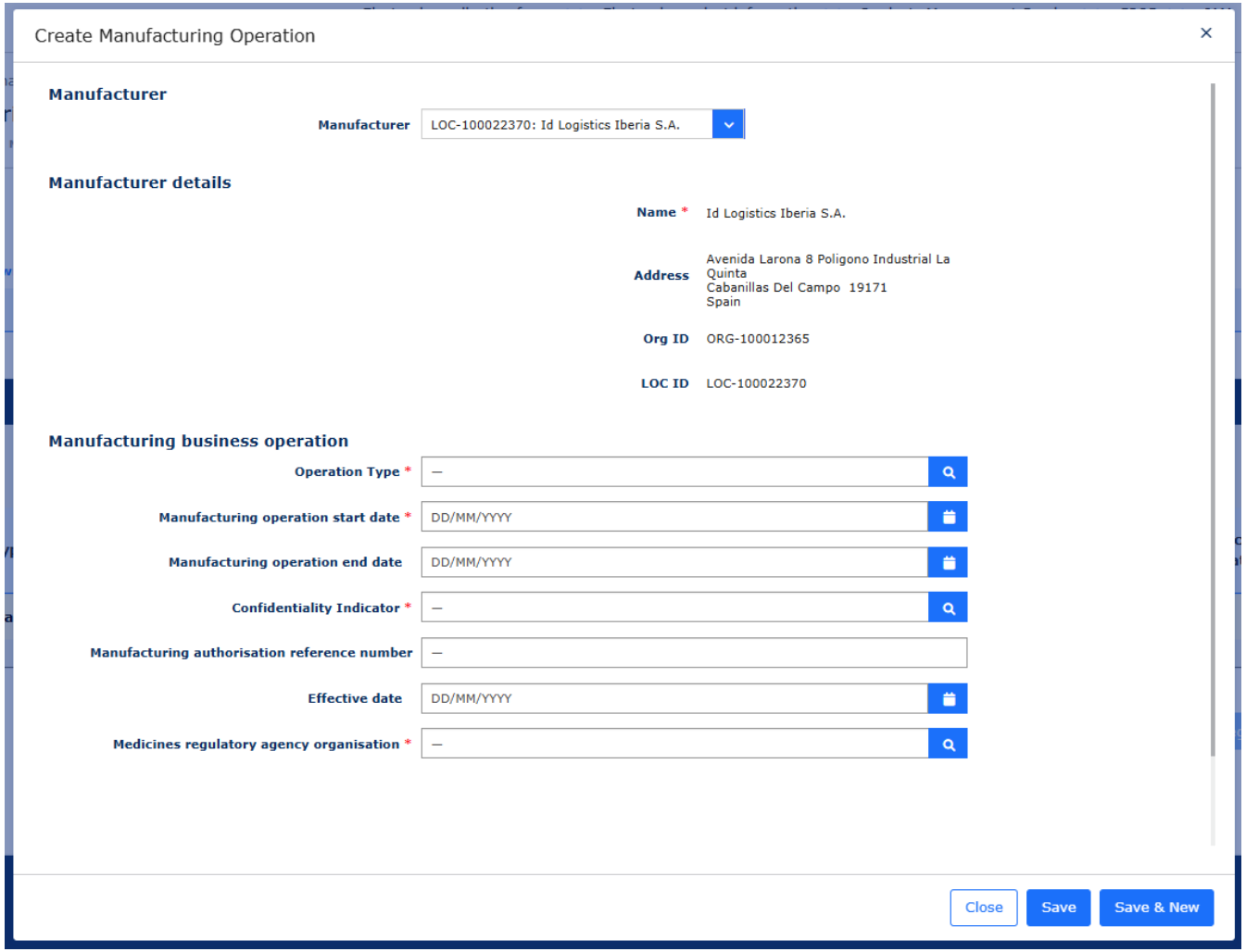
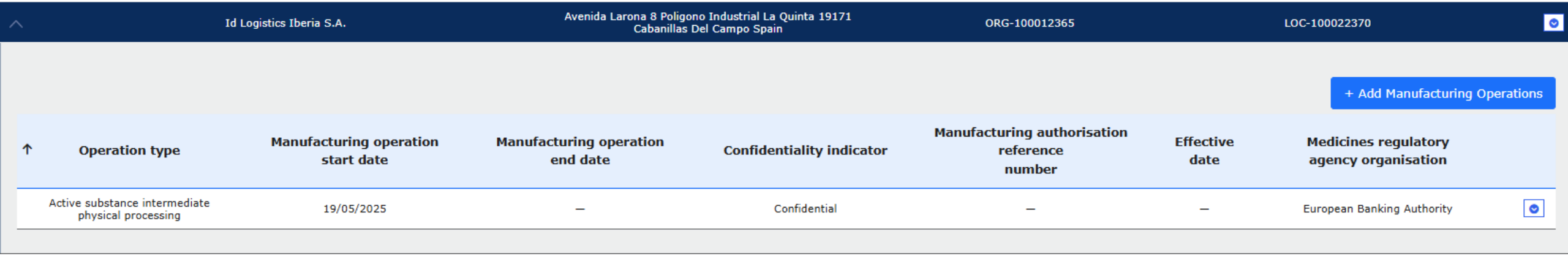
Enrichment of product data



Include additional information such as manufacturing business operations and additional data required for each manufacturer.

Enrichment of product data



Changes can be validated before they are submitted.

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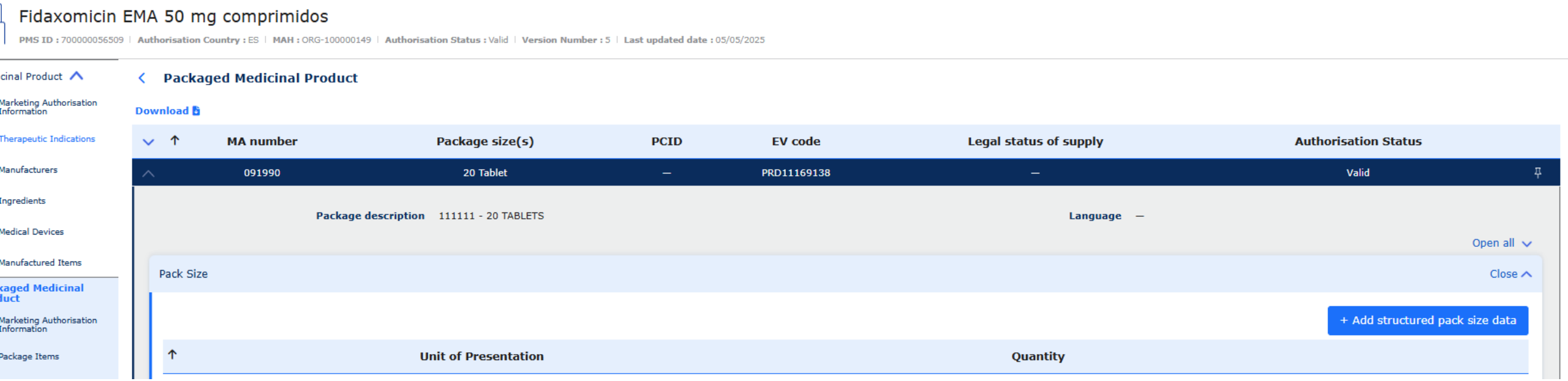
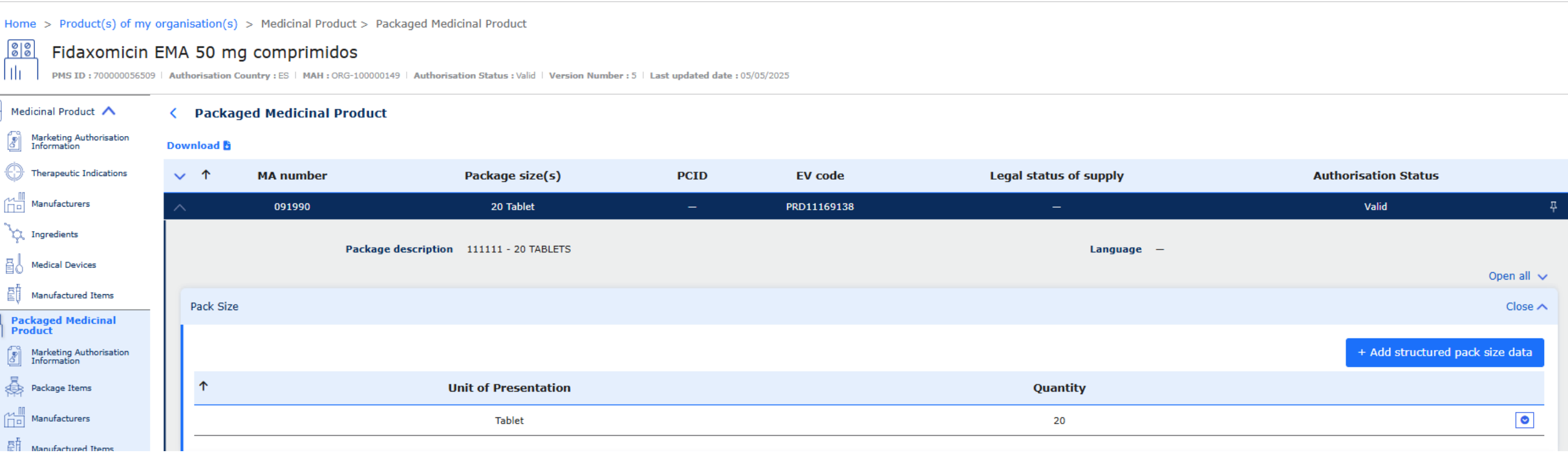


For each of the packages, add the structured pack size data.



For each of the packages, add the structured pack size data.

Home > Change Request Detail

Manufacturer enrichment

ID: CR-021432 | **Type:** Enrichment | **Status:** Modified | **Created by:** Marcos Fernandez Gomez | **Created On:** 20/5/2025 | **Last updated by:** Marcos Fernandez Gomez | **Last updated on:** 20/5/2025

Friendly Name *
Manufacturer enrichment

Type *
Enrichment

Description

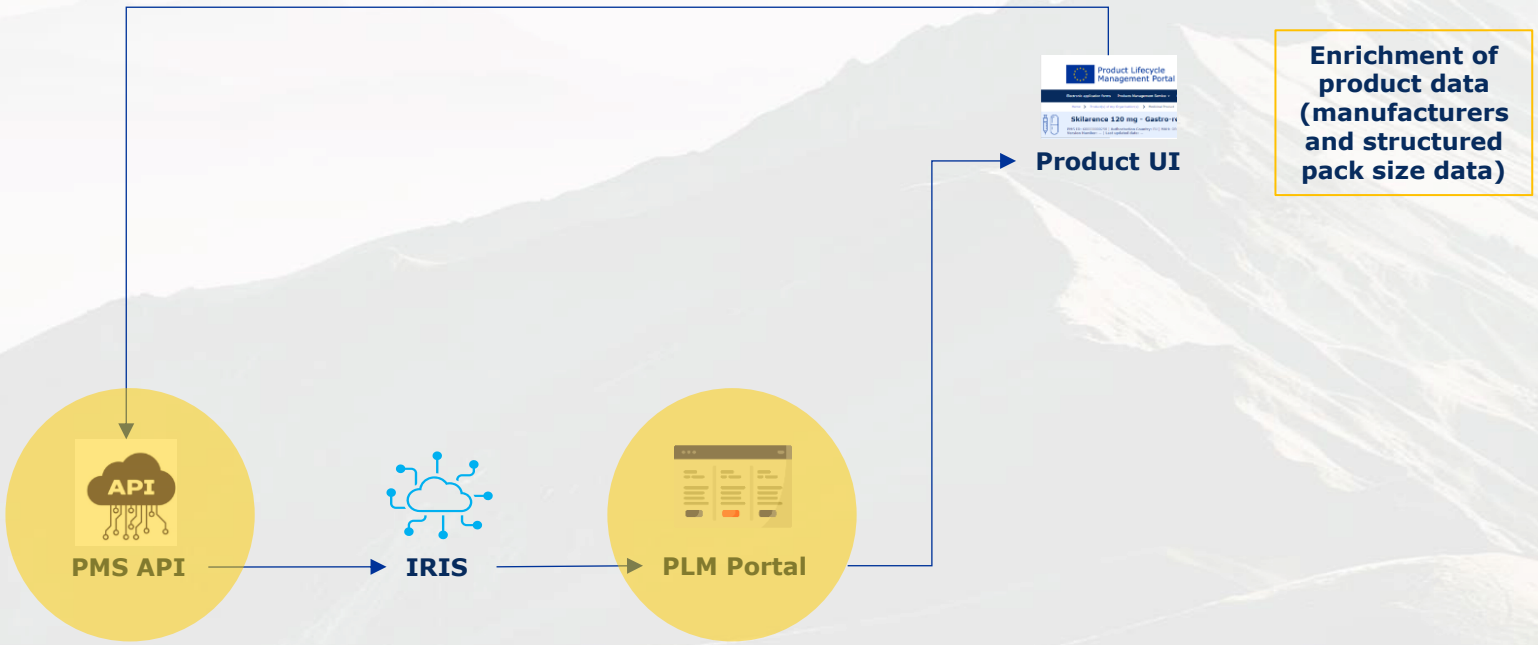
Change Request Activities — Open

Selected Products — Open

Return | Clone Change | Save | Continue to Edit | Finalisation

Change can be finalized and submitted.

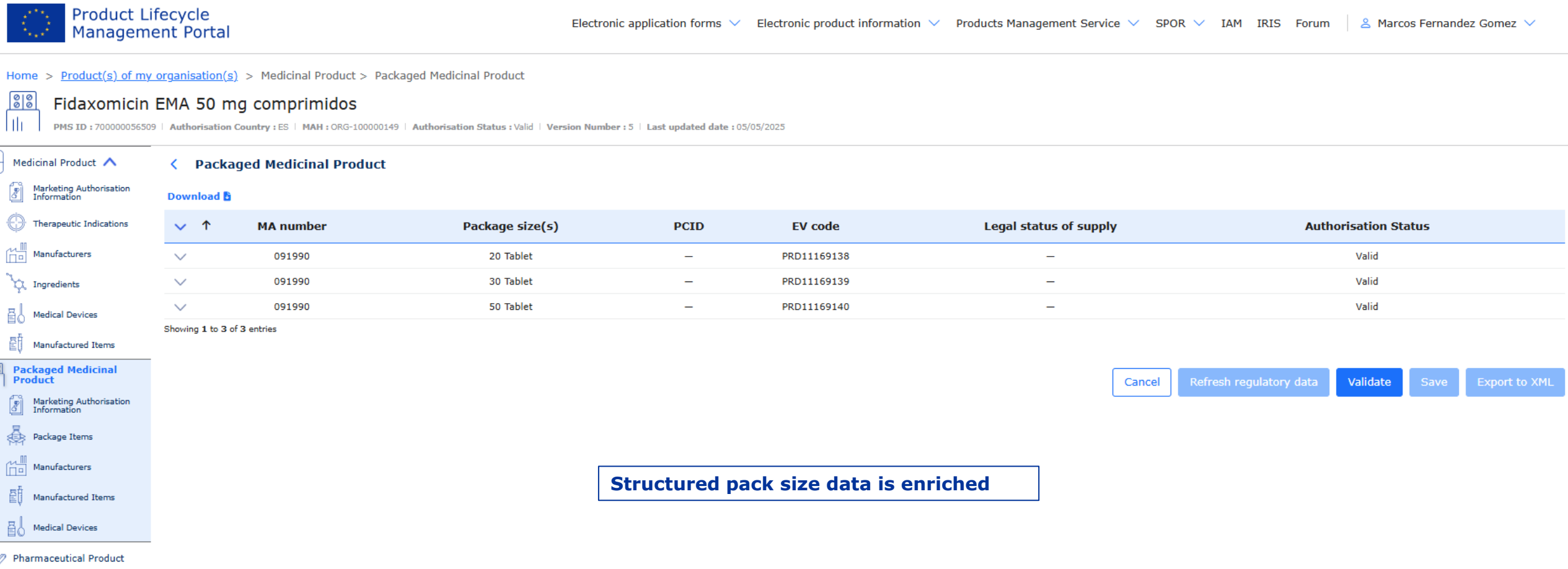
Enrichment of product data



Enriched data will be forwarded to the PMS API.

PMS API will be updated and the PLM Portal will show the updated information.

Enrichment of product data



Structured pack size data is enriched

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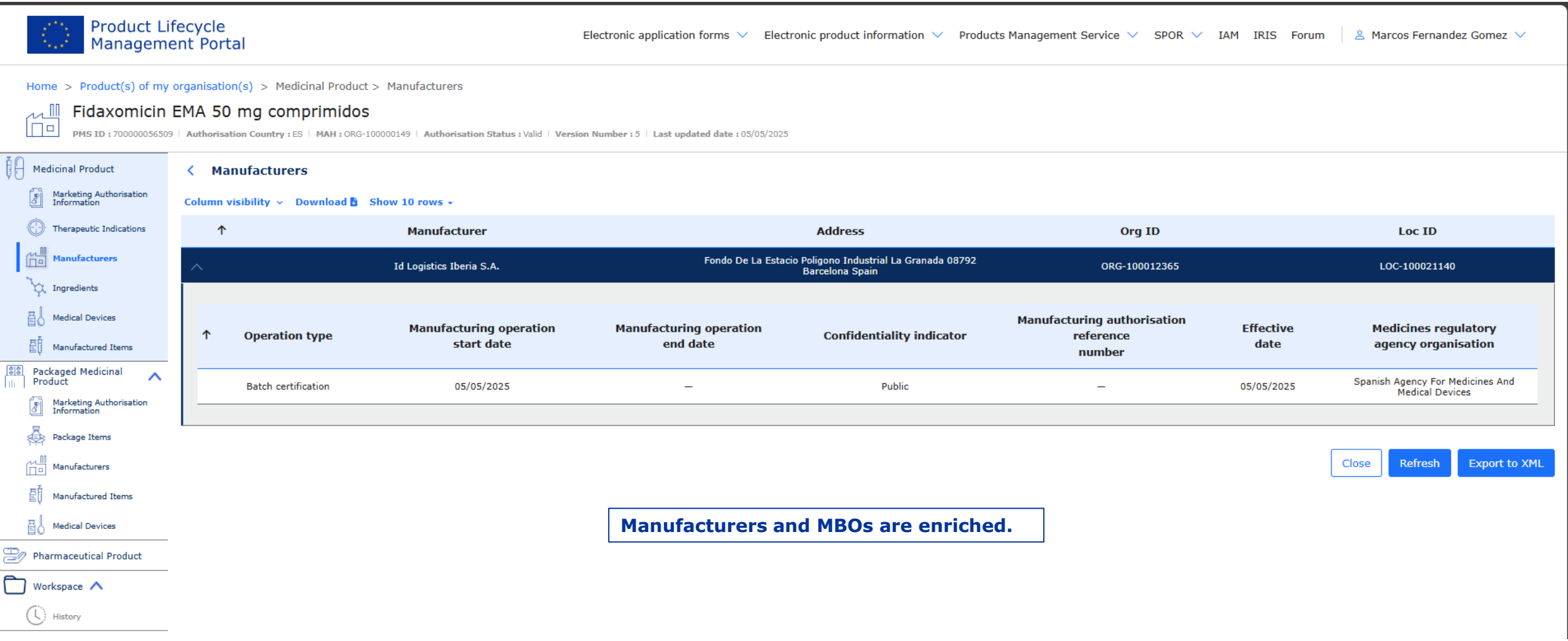
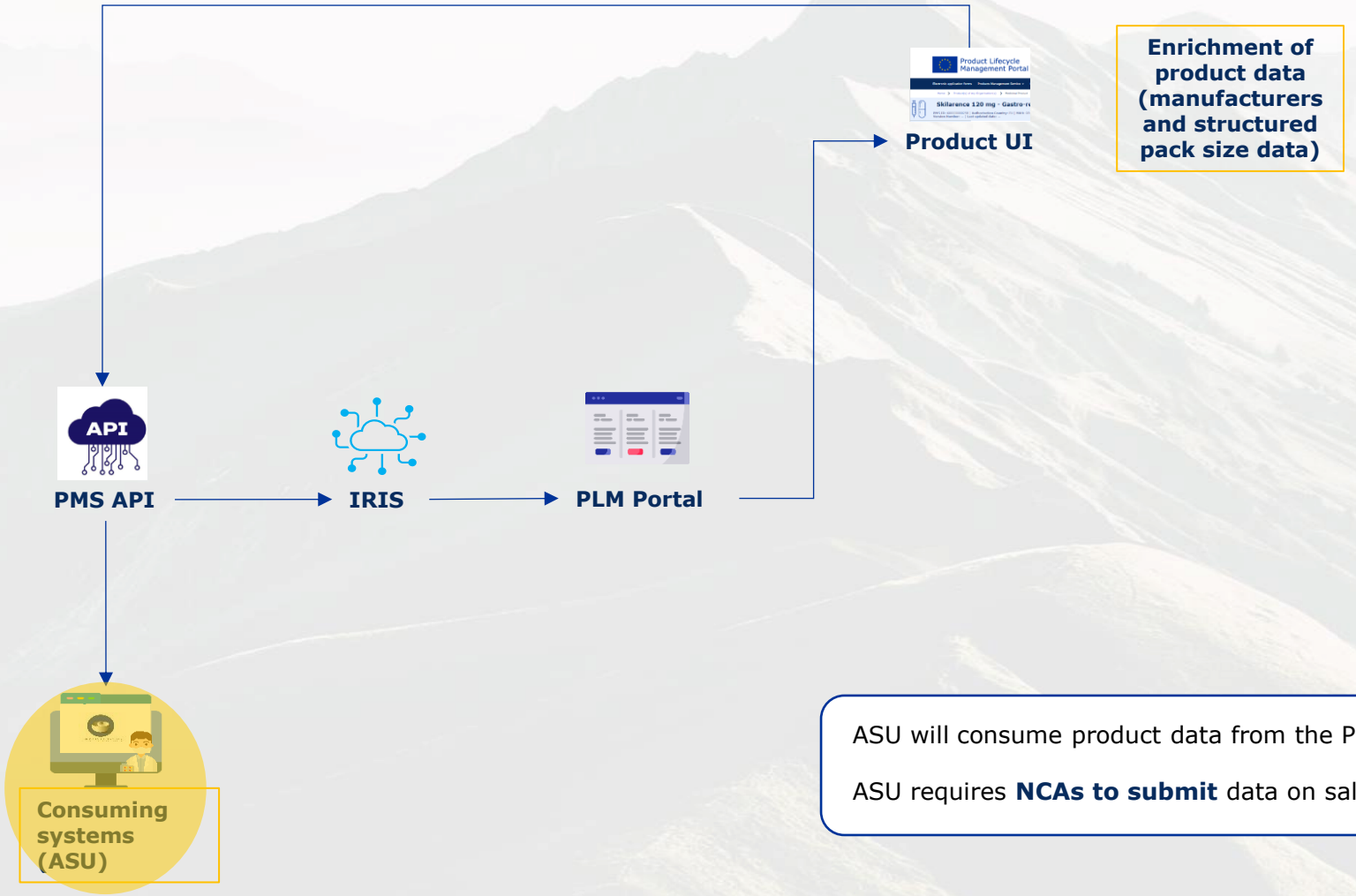
Enrichment of product data



Manufacturers and MBOs are enriched.

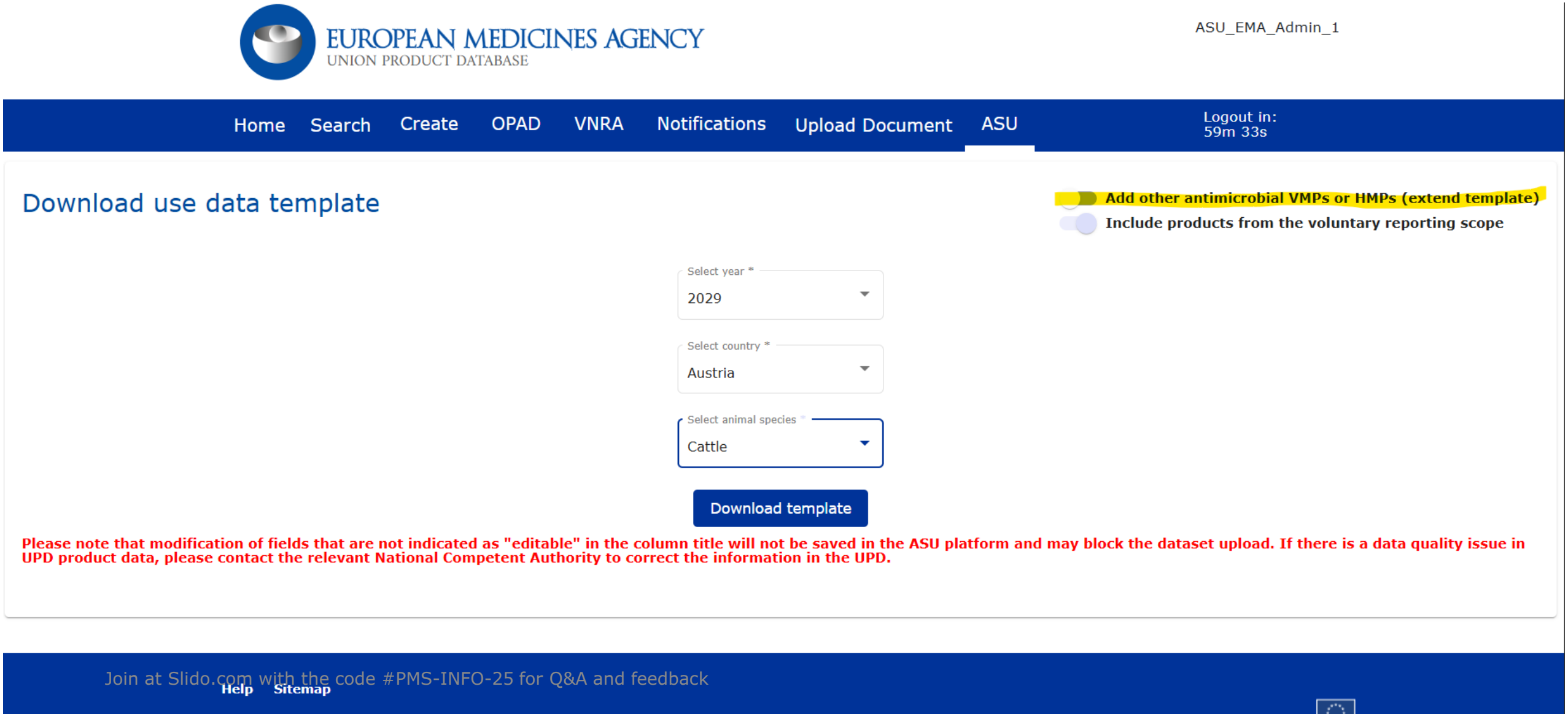
ASU use case - Monitoring of antimicrobials sales and use



ASU will consume product data from the PMS API.

ASU requires **NCAs to submit** data on sales and use of antimicrobials in animals.

1. NCA user wants to add HMPs to ASU Use data template



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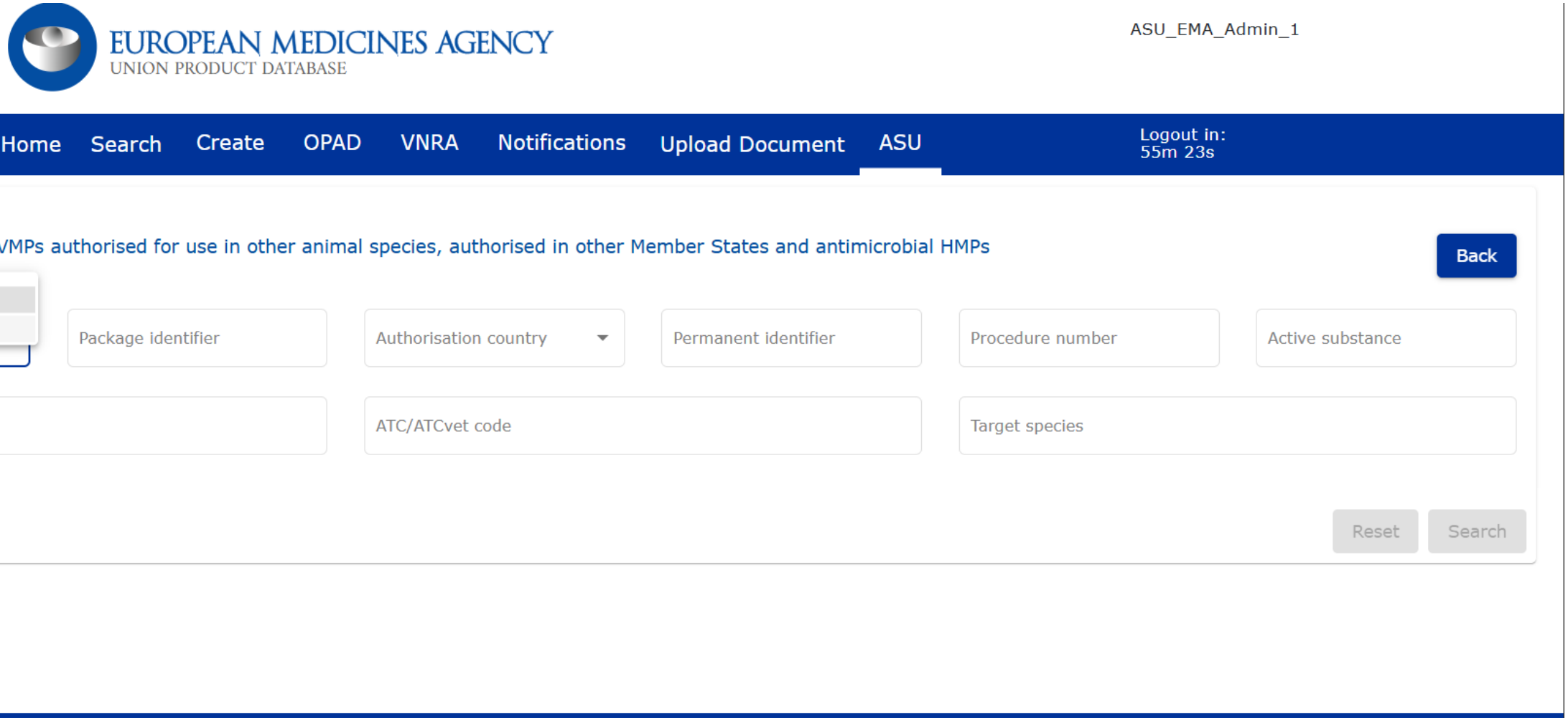
2. NCA user searches for HMP of interest with ASU search functionality



3. NCA user selects HMPs of interest to add to the template

ASU_EMA_Admin_1

Home | Search | Create | OPAD | VNRA | Notifications | Upload Document | ASU

Logout in: 53m 25s

Search for antimicrobial VMPs authorised for use in other animal species, authorised in other Member States and antimicrobial HMPs

Back

Domain: Human Products | Package identifier | Authorisation country: Austria | Permanent identifier | Procedure number | Active substance | Medicinal product name

ATC/ATCvet code | Target species

Reset | Search

Search result

Add

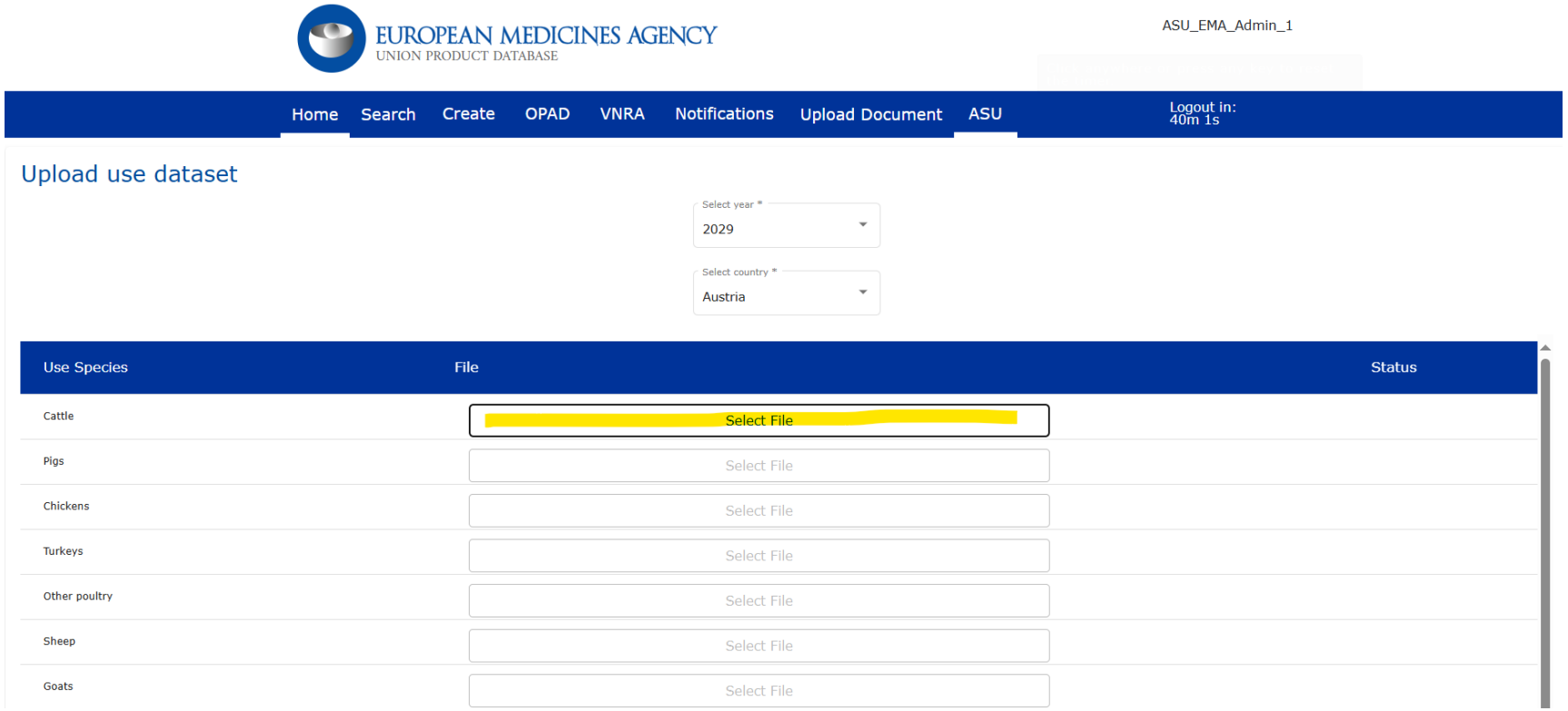
Authorisation country	Domain	Procedure number	Permanent identifier	Package identifier	Medicinal product name	Pharmaceutical composition	ASU product form	ATC/ATCvet code	Target species	Pack size description
AT	Human	EMEA/H/C/000264	600000002219	28688	Agenerase (SRD) 15 mg/ml - Oral solution	Amprenavir 15 milligram(s)/millilitre(s)	ORAL SOLU	J05AE05		240 millilitre(s)
AT	Human	EMEA/H/C/000264	600000002218	28687	Agenerase (SRD) 150 mg - Capsule, soft		TABL	J05AE05		
AT	Human	EMEA/H/C/000264	600000002217	28686	Agenerase (SRD) 150 mg - Capsule, soft		TABL	J05AE05		

4. NCA user sees HMP product information in downloaded ASU template

	A	B	C	D	E	F	G	H	J	K	L	N	O	P	Q	V	W	Z	AA
1	SPECIES	COUNTRY	YEAR	PERMANENT_IDENTIFIER	PACKAGE_	AUTH_NUM	PROCEDU	REFERENCE_MS	ADDED_AN	NAME	FORM(editable)	ASU_PACKSIZE	ASU_PACKSIZE_UNIT	ATC/ATCVI	SCOPE	SUBST_ID#1	SUBSTANCE#1	STRENGTH#1	STRENGTH_UNIT#1
29	Cattle	AT	2029	'600000002217	28687	EU/1/00/1	CP	EMA	Y_HMP	Agenerase (SRD) 150 mg - Capsule, soft	TABL			J05AE05	voluntary				
30	Cattle	AT	2029	'600000002219	28688	EU/1/00/1	CP	EMA	Y_HMP	Agenerase (SRD) 15 mg/ml - Oral solution	ORAL SOLU	240	millilitre(s)	J05AE05	voluntary	'100000089388	Amprenavir	15	milligram(s)/millilitre(s)

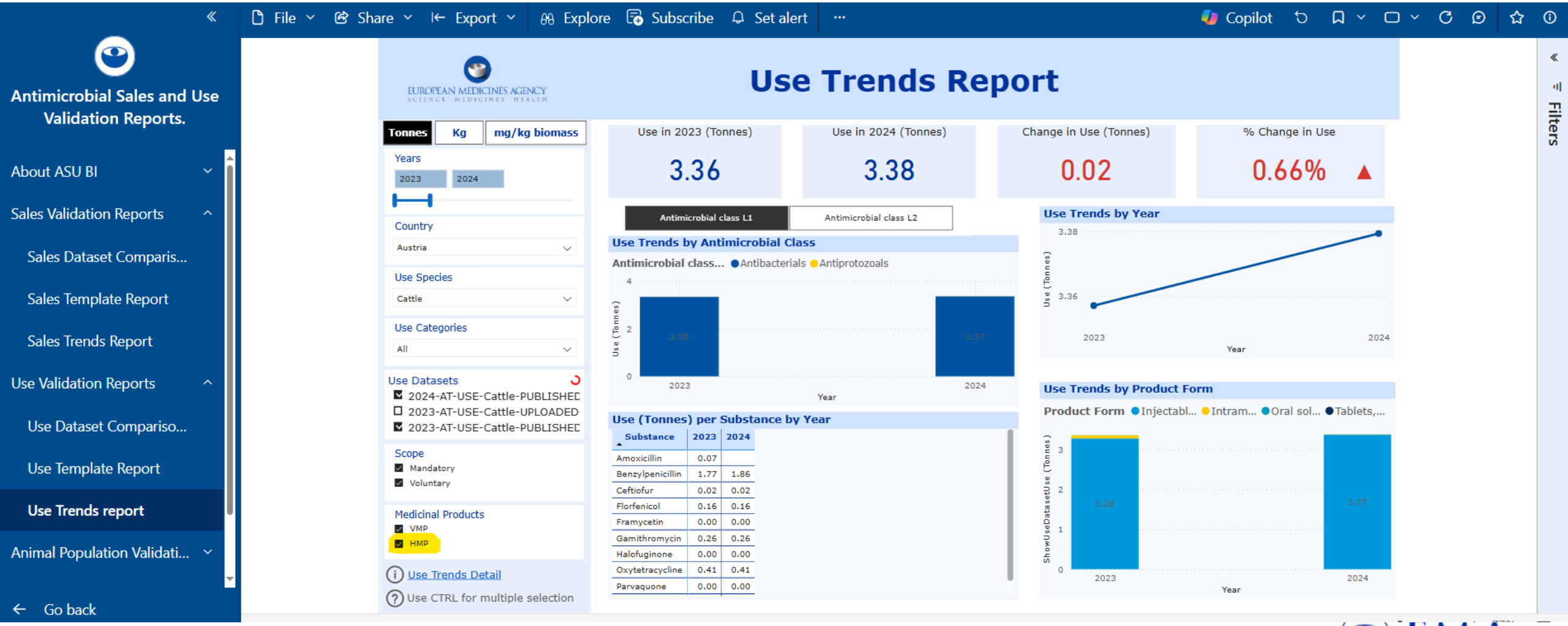
5. NCA user indicates the number of packages used per product presentation/animal category and uploads the template to the ASU Platform.

A	B	C	D	E	F	G	H	J	K	L	N	O	P	Q	R	T
SPECIES	COUNTRY	YEAR	PERMANENT_IDENTIFIER	PACKAGE_	AUTH_NUM	PROCEDU	REFERENCE_MS	ADDED_AN	NAME	FORM(editable)	ASU_PACKSIZE	ASU_PACKSIZE_UNIT	ATC/ATCVI	SCOPE	Beef cattle_NO_PACKS(editable)	Dairy cattle_NO_PACKS(editable)
Cattle	AT	2029	'600000002219	28688	EU/1/00/1	CP	EMA	Y_HMP	Agenerase (SRD) 15 mg/ml - Oral solution	ORAL SOLU	240	millilitre(s)	J05AE05	voluntary	12	5



Join at Slido.com with the code #PMS-INFO-25 for Q&A and feedback

6. NCA user can visualise their data in the ASU Power BI application and see the impact of the use of HMPs on their antimicrobial consumption trends



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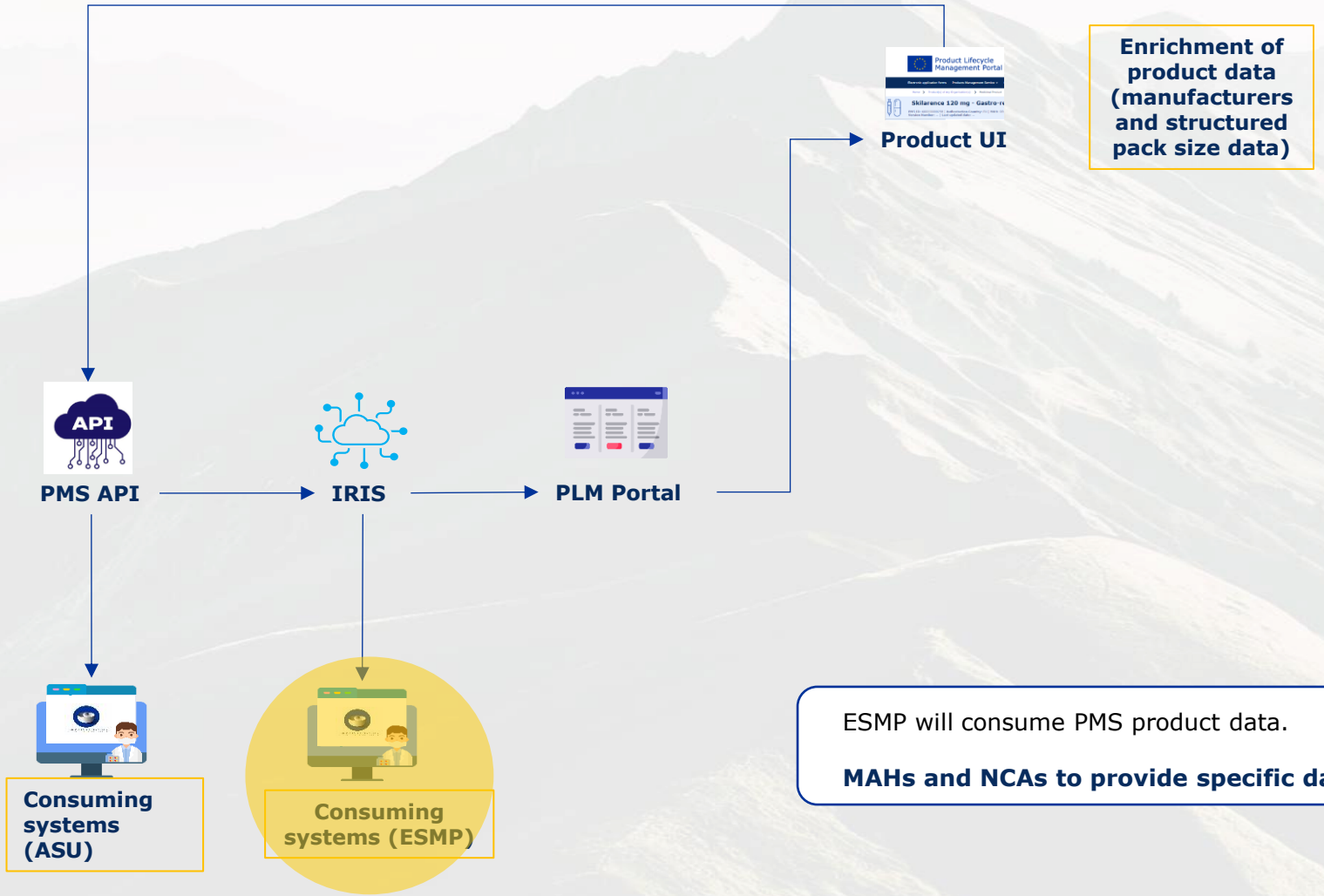
ESMP use case - Monitoring of shortages



ESMP will consume PMS product data.

MAHs and NCAs to provide specific data to support shortages management via ESMP.

Join at Slido.com with the code #PMS-INFO-25 for Q&A and feedback

How ESMP uses PMS data

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

Packaged medicinal product data (PMS)
Prefilled in ESMP templates/Machine-to-Machine

	A	B	C	D	E	F	G	H	I	J	K
1	Packaged	Medicinal product - (Full medicinal	Medicinal product	Active Substance	Strength	Pharmaceutical form	Pack Size	Packaging	PCID	Country of authorisation	Marketing Status
2	55880	Brintellix 5 mg - Film-coated tablet	Brintellix	Vortioxetine hydrobromide	5 mg	Film-coated tablet	100 tablets	Bottle		AT	Temporarily unavailable
3	55880	Brintellix 5 mg - Film-coated tablet	Brintellix	Vortioxetine hydrobromide	5 mg	Film-coated tablet	100 tablets	Bottle		BG	Marketed
4	55880	Brintellix 5 mg - Film-coated tablet	Brintellix	Vortioxetine hydrobromide	5 mg	Film-coated tablet	100 tablets	Bottle		IS	Marketed
5	55880	Brintellix 5 mg - Film-coated tablet	Brintellix	Vortioxetine hydrobromide	5 mg	Film-coated tablet	100 tablets	Bottle		LI	Temporarily unavailable
6	55880	Brintellix 5 mg - Film-coated tablet	Brintellix	Vortioxetine hydrobromide	5 mg	Film-coated tablet	100 tablets	Bottle		NO	Marketed
7	55878	Brintellix 5 mg - Film-coated tablet	Brintellix	Vortioxetine hydrobromide	5 mg	Film-coated tablet	98 x 1 tablets (unit dose)	Blister		BG	Marketed

Users **complete ESMP templates** with information per product and reupload the templates

Shortage Monitoring & Risk Analysis Tool (ESMP-SMART)

Aggregation, analysis and visualisation

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

https://euema-esmp-uat.powerappsportals.com/routine-shortage-reporting/

Update

Other favorites

EMA | ESMP

Guidance and help

Home

ROUTINE REPORTING

Routine shortage reporting

Submission history

Routine shortage reporting

Report any potential or actual shortages of centrally authorised products and update it when new information becomes available.

How to submit?

Report/update shortage | Download reporting template | Submission history

Reported active shortages

Download table

Product name

Country

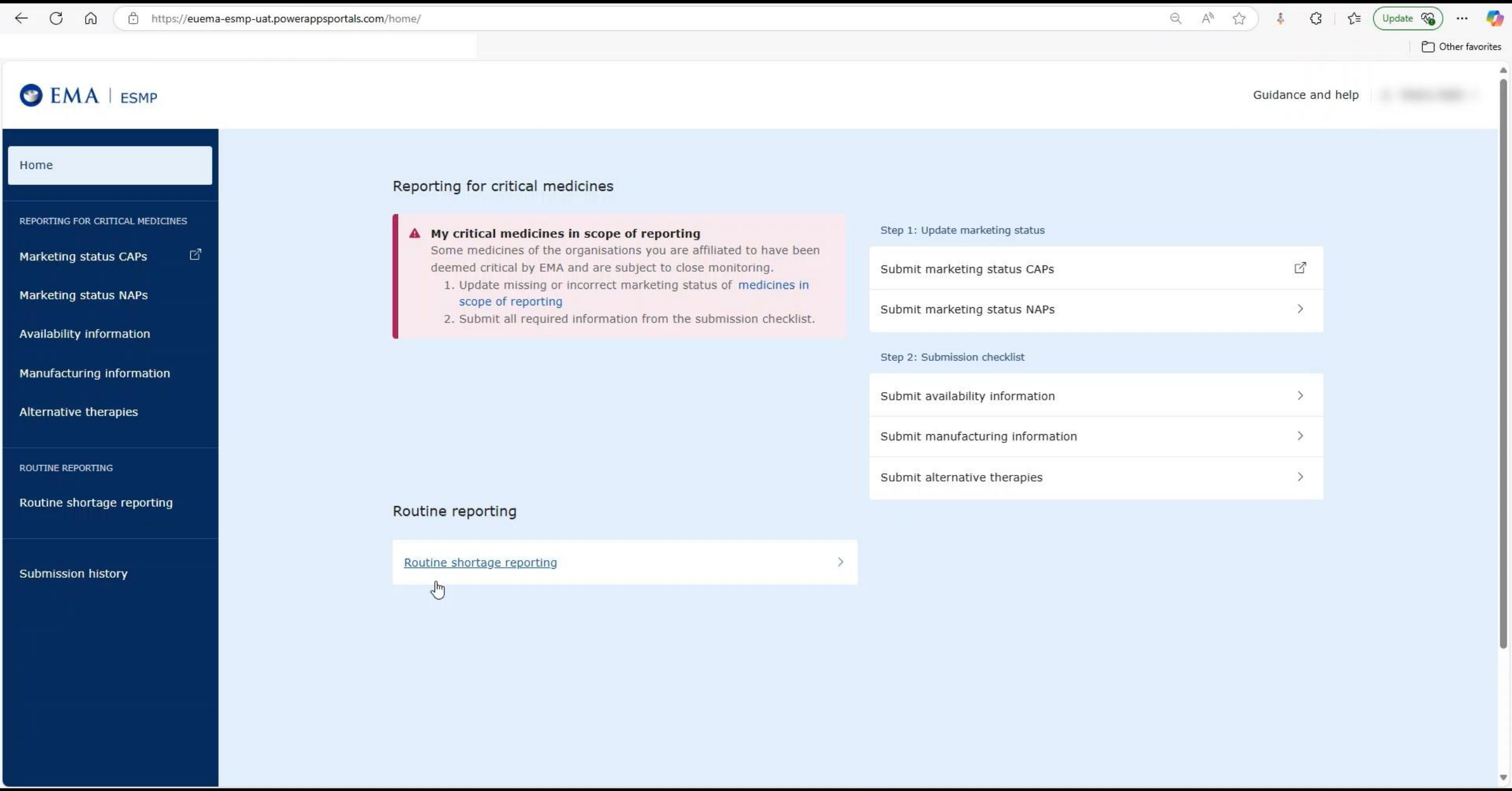
Shortage Status

- Potential
- Actual

Start date

Product name	Pack size	Country	Shortage status	(Expected) start date	(Expected) end date

There are no records to display.


https://euema-esmp-uat.powerappsportals.com/home/
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REPORTING FOR CRITICAL MEDICINES
Marketing status CAPs
Marketing status NAPs
Availability information
Manufacturing information
Alternative therapies
ROUTINE REPORTING
Routine shortage reporting
Submission history
Reporting for critical medicines
My critical medicines in scope of reporting
Some medicines of the organisations you are affiliated to have been deemed critical by EMA and are subject to close monitoring.
1. Update missing or incorrect marketing status of medicines in scope of reporting
2. Submit all required information from the submission checklist.
Step 1: Update marketing status
Submit marketing status CAPs
Submit marketing status NAPs
Step 2: Submission checklist
Submit availability information
Submit manufacturing information
Submit alternative therapies
Routine reporting
Routine shortage reporting

https://euema-esmp-uat.powerappsportals.com/home/

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REPORTING FOR CRITICAL MEDICINES

Marketing status CAPs

Marketing status NAPs

Availability information

Manufacturing information

Alternative therapies

ROUTINE REPORTING

Routine shortage reporting

Submission history

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Some medicines of the organisations you are affiliated to have been deemed critical by EMA and are subject to close monitoring.

1. Update missing or incorrect marketing status of medicines in scope of reporting
2. Submit all required information from the submission checklist.

Step 1: Update marketing status

Submit marketing status CAPs

Submit marketing status NAPs

Step 2: Submission checklist

Submit availability information

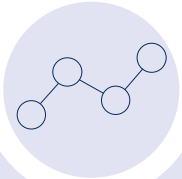
Submit manufacturing information

Submit alternative therapies

Routine reporting

Routine shortage reporting

ESMP-SMART PMS data elements use



Aggregation of similar medicinal products

- Level 1: Active substance(s)
- Level 3.1: Active substance(s) - Pharmaceutical Dose Form(s)
- Level 4.1: Active substance(s) - Pharmaceutical Dose Form(s) – Strength(s)

Automatic **conversion** to a **common unit of measurement**
(packs -> mg of active substance)

Reports with automated **aggregation, analysis** and **visualisation** of indicators

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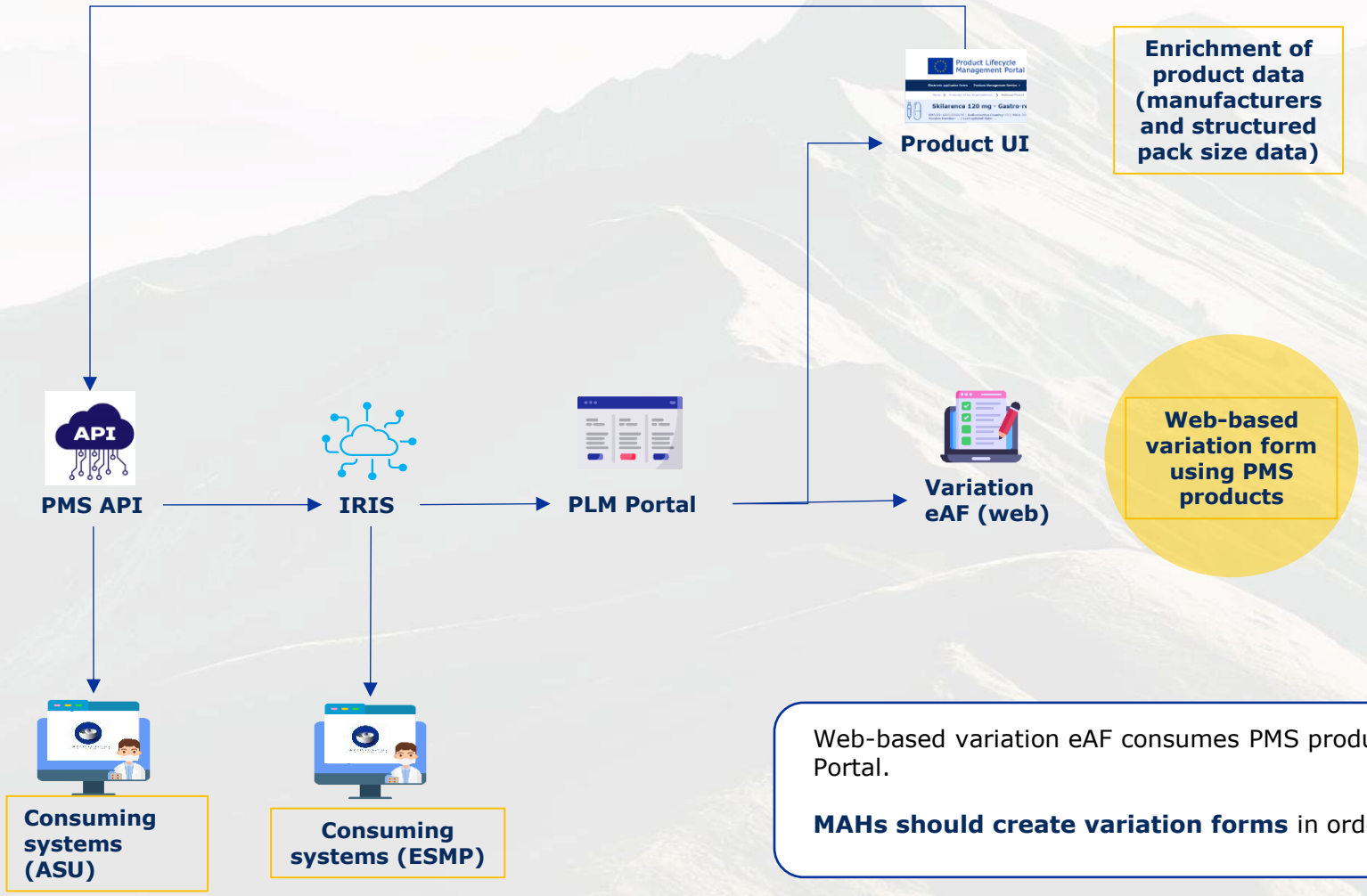
EMA

eAF use case – creation & submission of worksharing variation



Web-based variation eAF consumes PMS product data and can be accessed through the PLM Portal.

MAHs should create variation forms in order to submit their variations to EMA and/or NCAs

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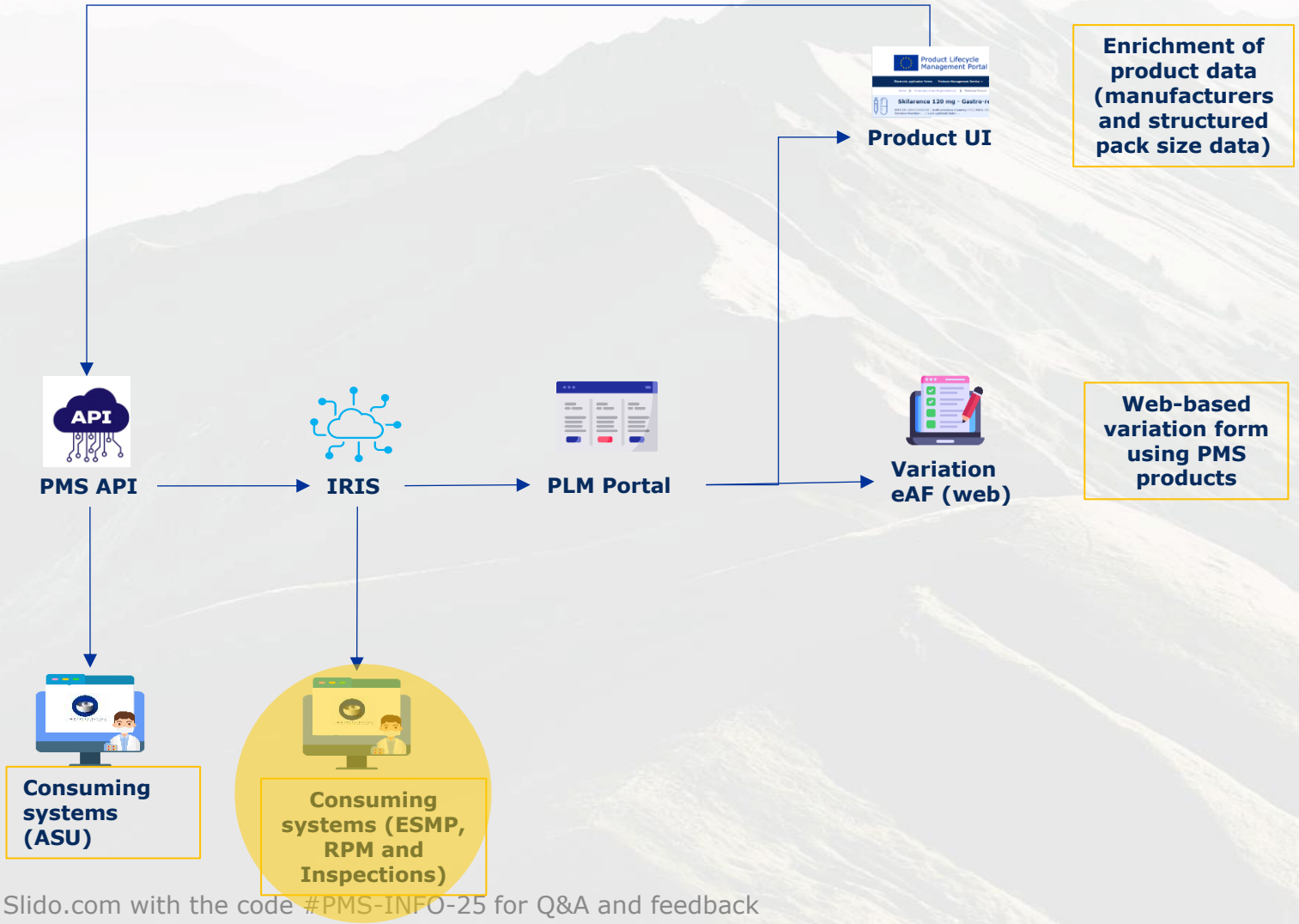
IRIS procedure management & Inspections use case

Management of CAPs variations and manufacturer's inspections for CAPs



IRIS RPM is consuming PMS data to support different EMA-led post authorisation procedures such as:

- Variations
- Parallel Distribution
- Inspections
- PSURs fee
- Article 61.3 Notifications
- MA transfers
- Post Authorisation Safety Studies (PASS)
- Post Authorisation Measures (PAM)
- Referrals

For NAPs, NCAs will be tracking the regulatory procedures in their internal systems.

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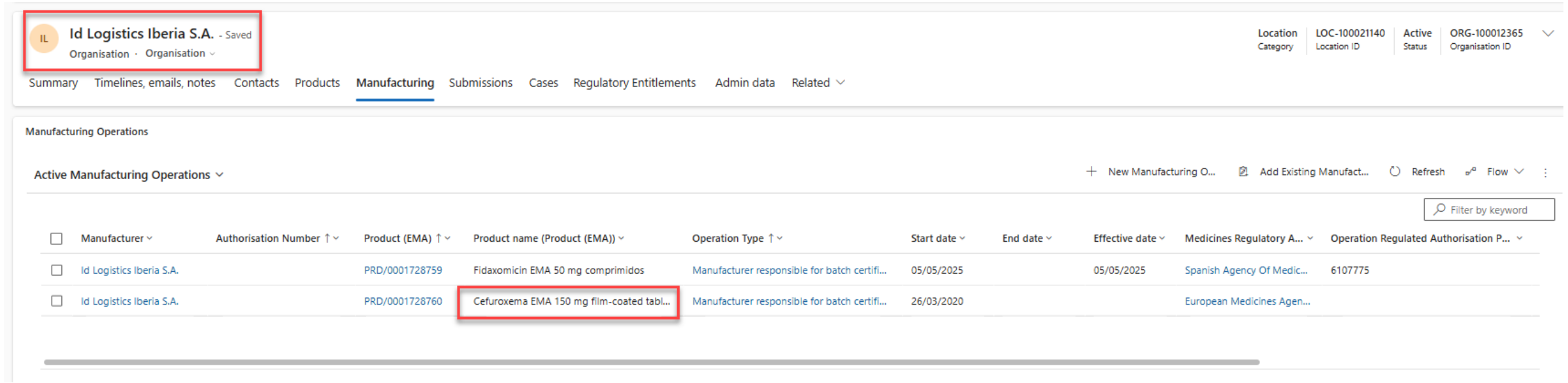
Inspections use case – creation of GMP inspection case



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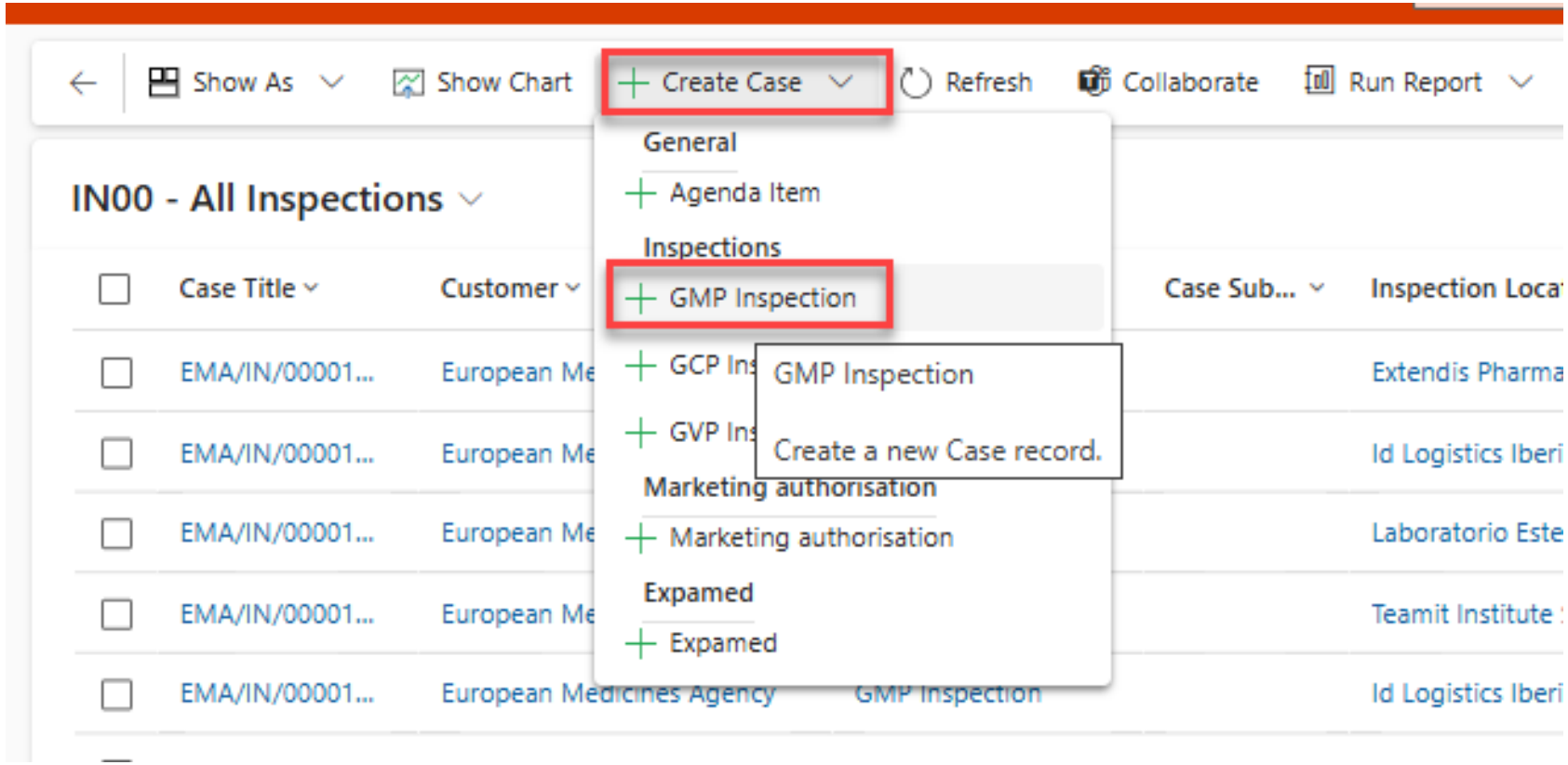
Inspections use case – creation of GMP inspection case



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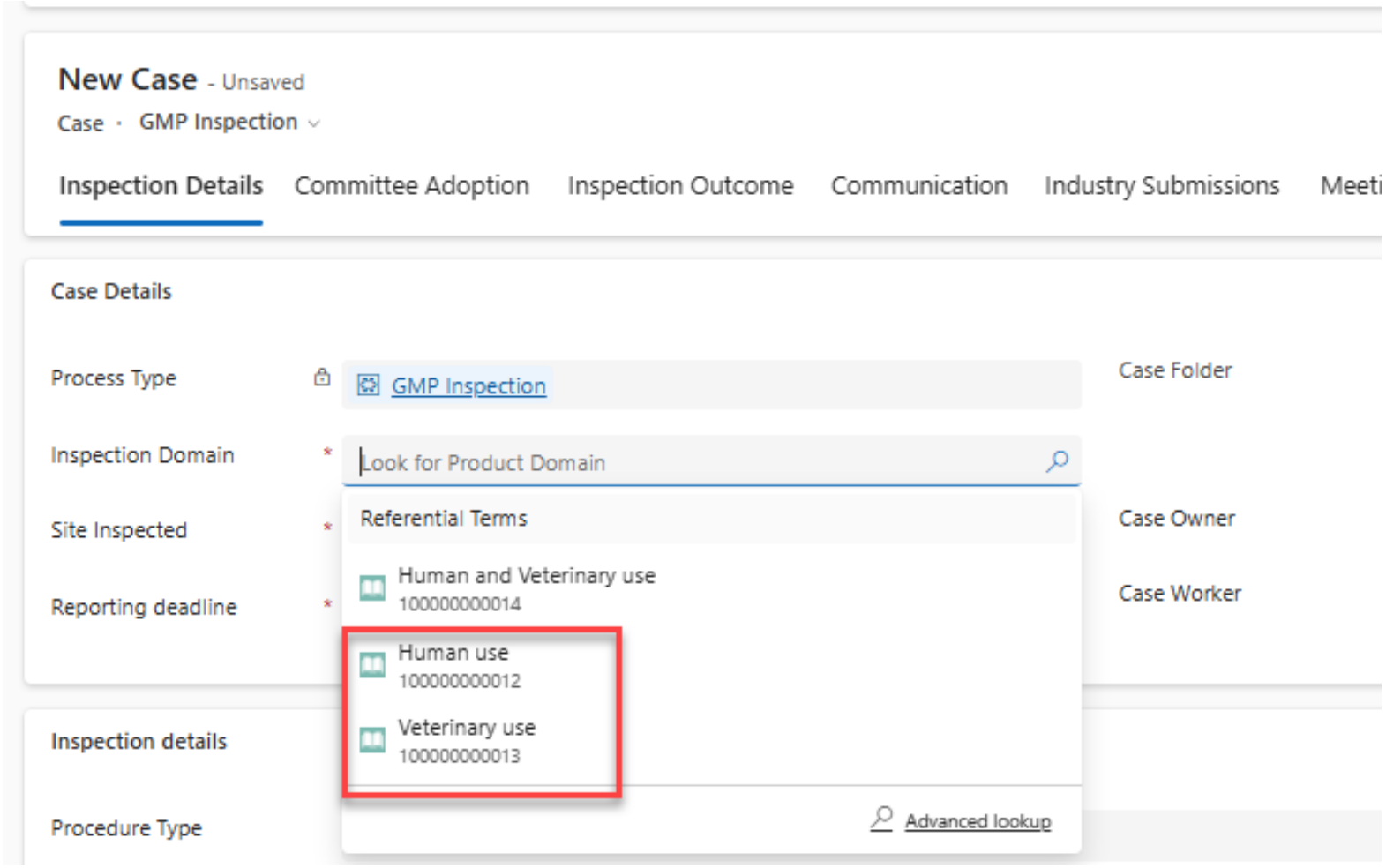
Inspections use case – creation of GMP inspection case



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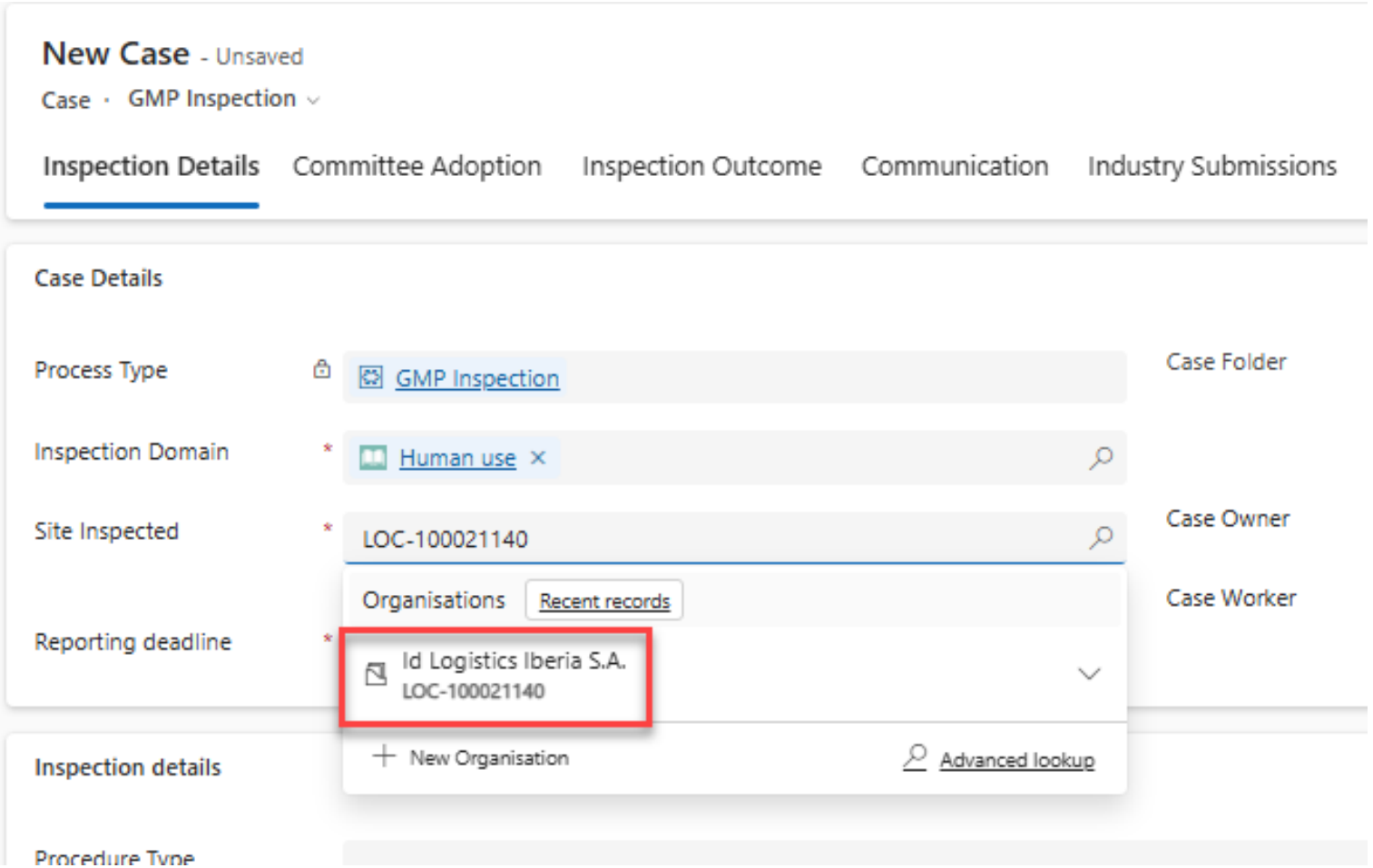
Inspections use case – creation of GMP inspection case



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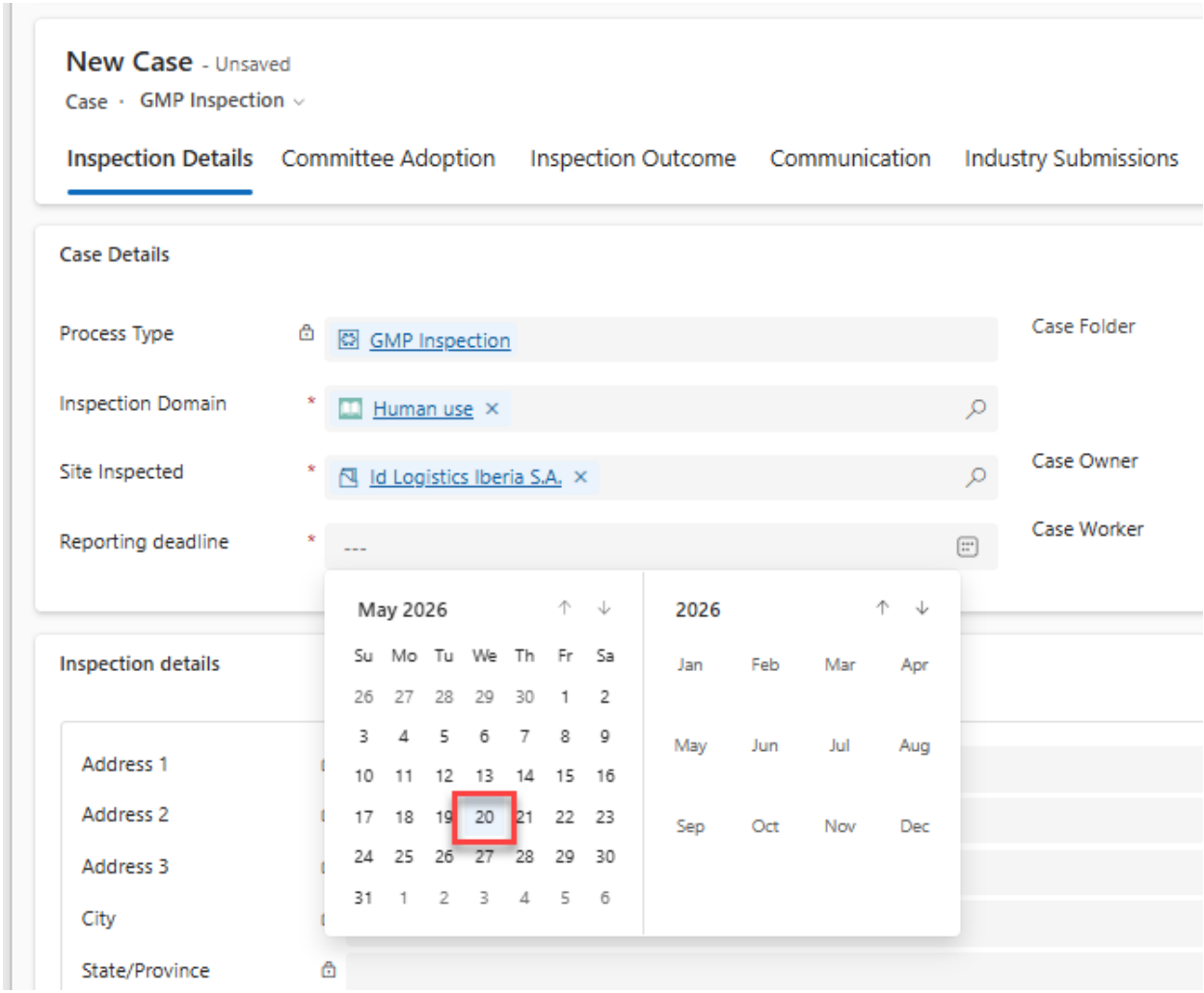
Inspections use case – creation of GMP inspection case



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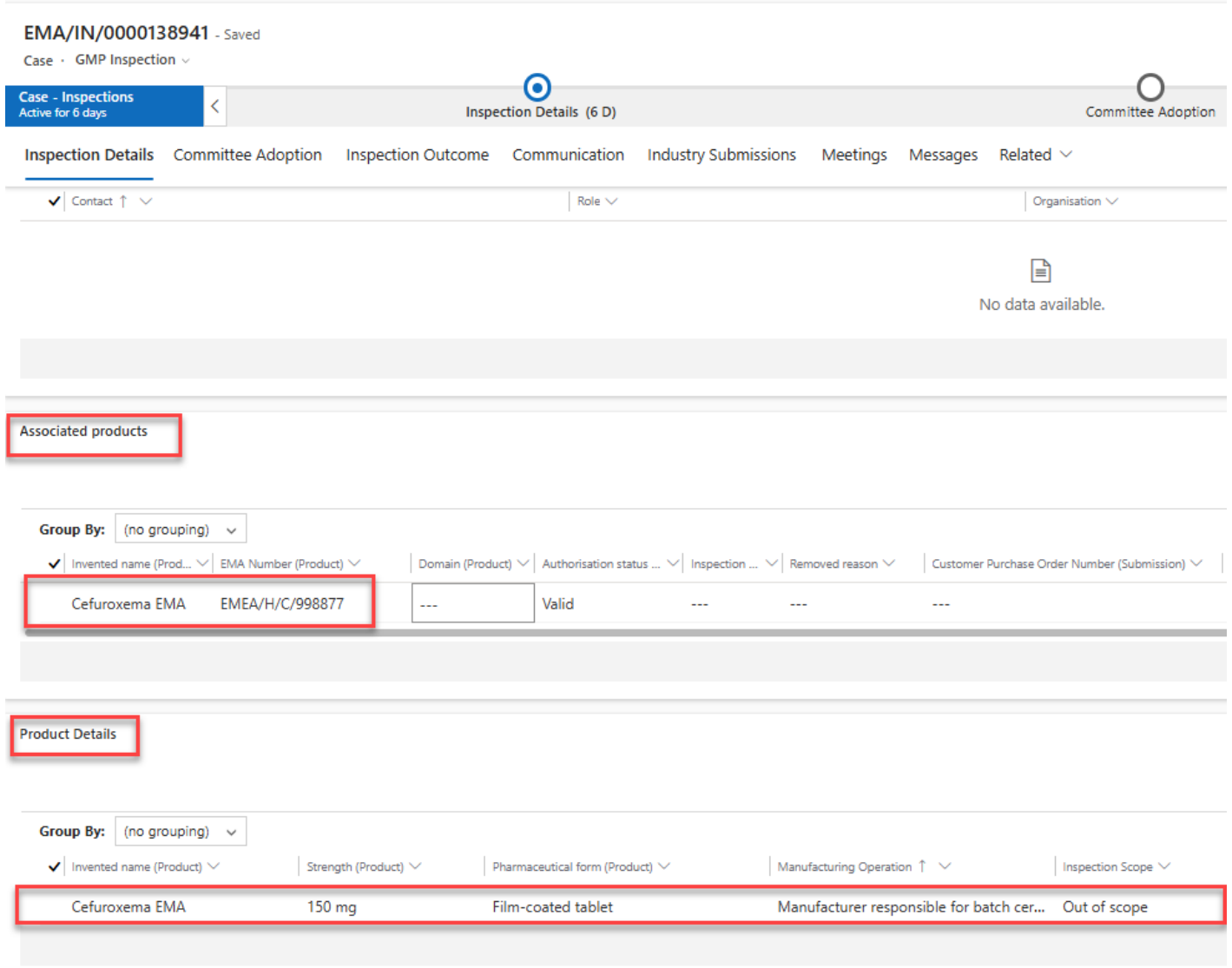
Inspections use case – creation of GMP inspection case



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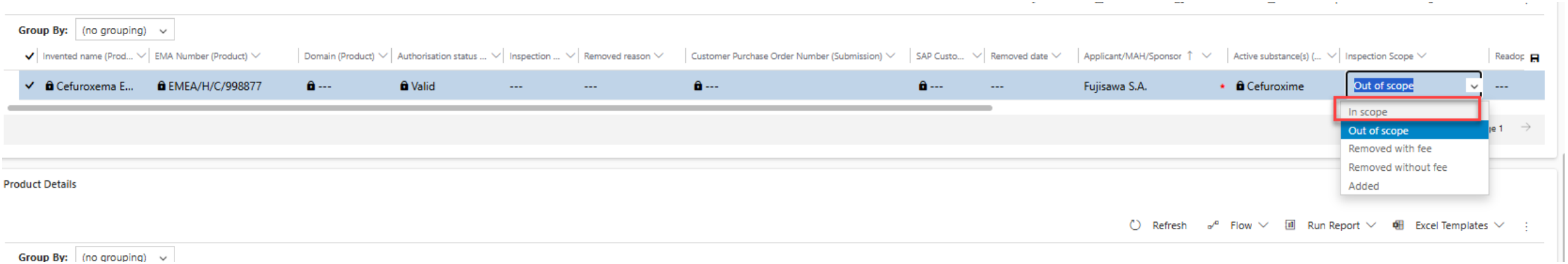
Inspections use case – creation of GMP inspection case



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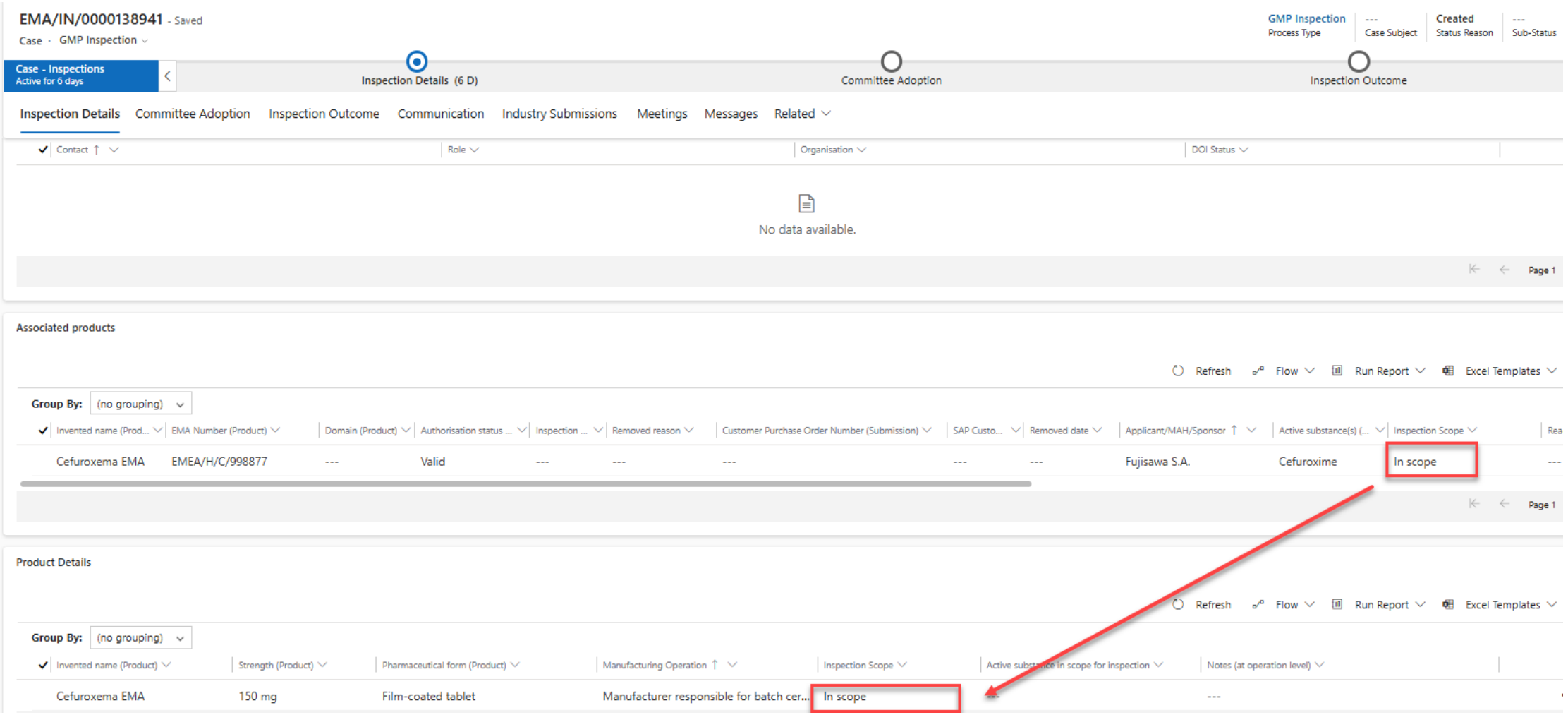

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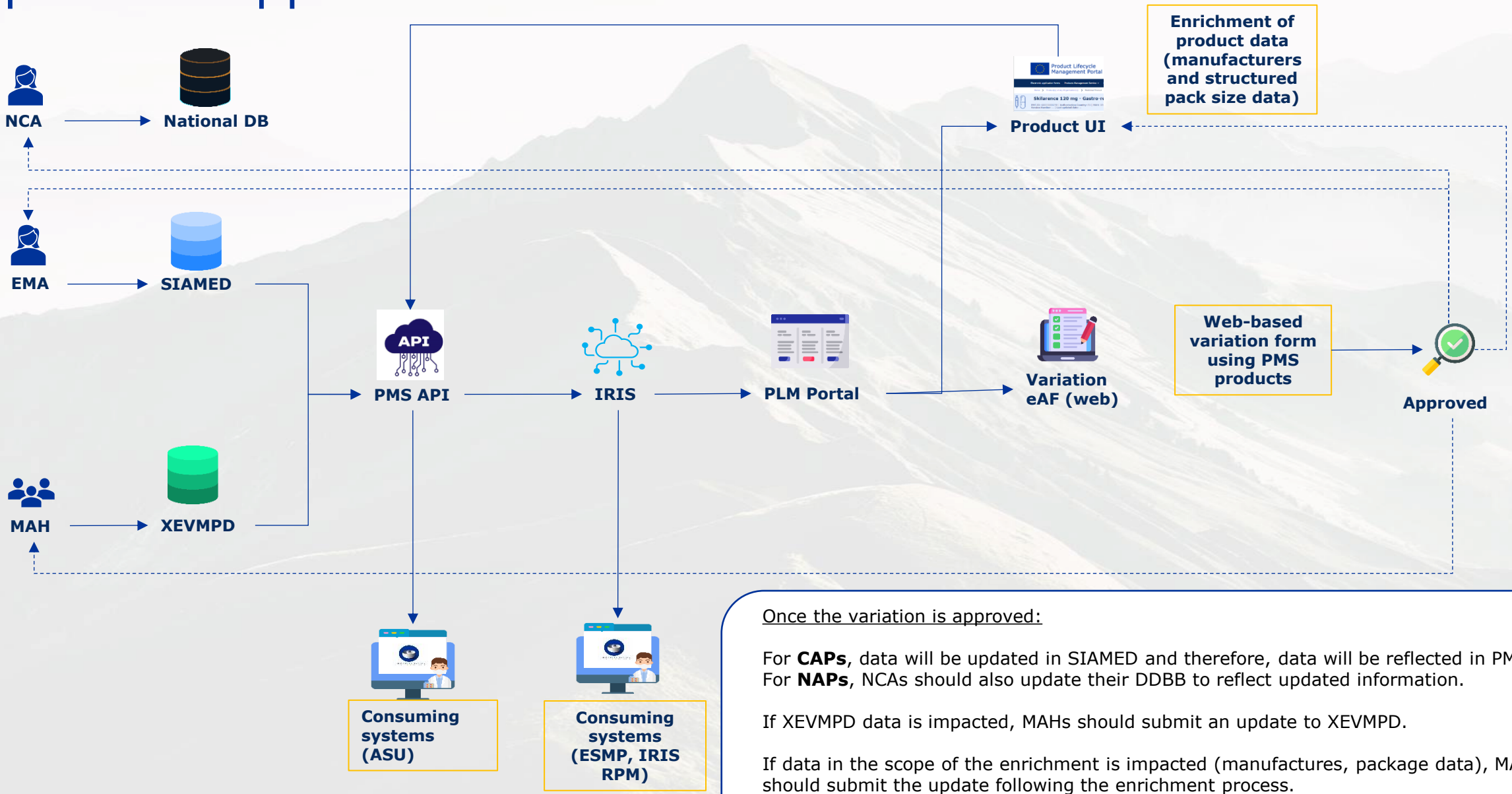
Update of approved data



Once the variation is approved:

For **CAPs**, data will be updated in SIAMED and therefore, data will be reflected in PMS.
For **NAPs**, NCAs should also update their DDBB to reflect updated information.

If XEVMPD data is impacted, MAHs should submit an update to XEVMPD.

If data in the scope of the enrichment is impacted (manufactures, package data), MAHs should submit the update following the enrichment process.

In all the cases, PMS will be updated with the most up-to-date data

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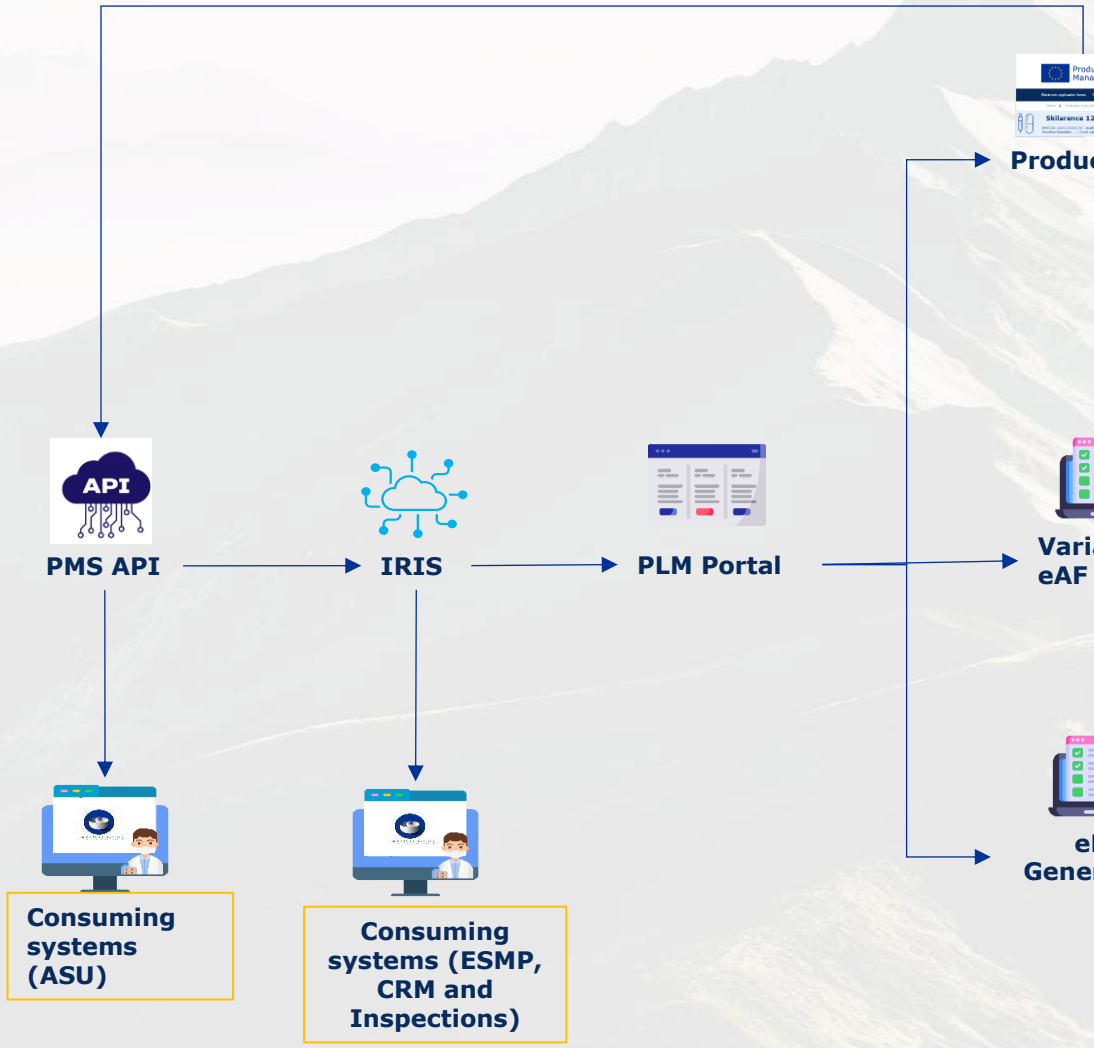
ePI use case – creation and publication of ePI



Product UI

Enrichment of product data (manufacturers and structured pack size data)

Variation eAF (web)

Web-based variation form using PMS products

In the PLM Portal, the **ePIs can be generated by MAHs** and linked to the PMS products that are already available.

ePI Generation

ePI API

Consuming systems (EMWP, NCA websites, Apps, CDSS)

Generation of ePI and link to PMS products

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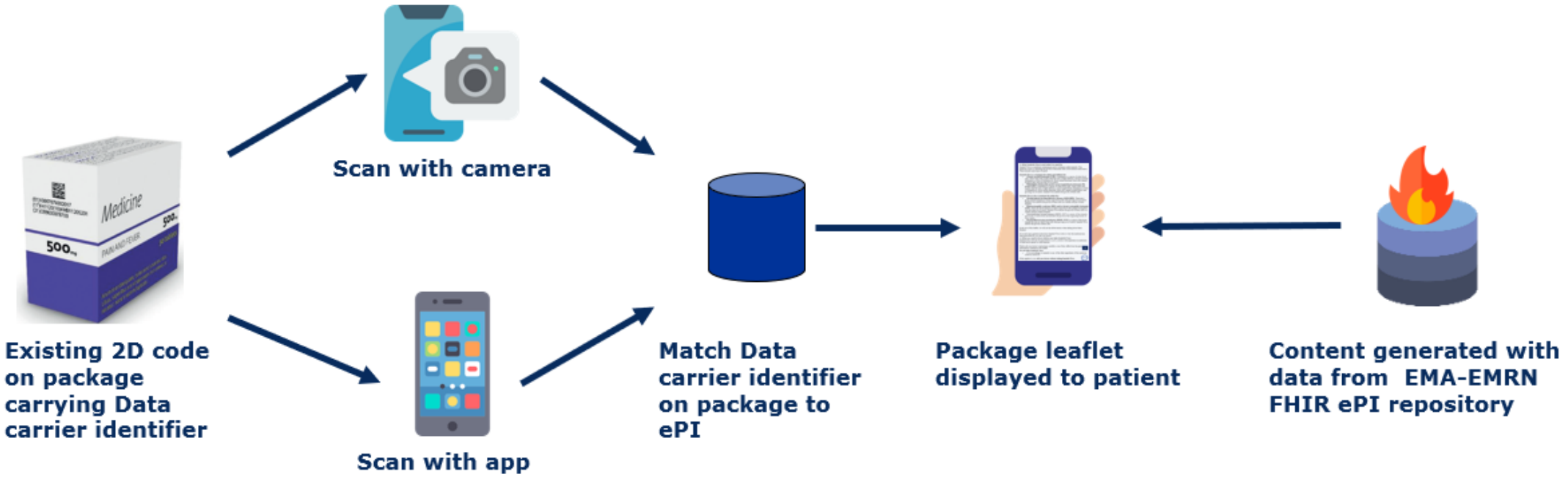
ePI use case

PMS data in ePI can:

- **Enable consumers of ePI data to leverage the 'human-friendly' ePI data together with the corresponding 'machine friendly' PMS data**
- **Give patients access to the medicines information by a simple scan of the package in their hand**



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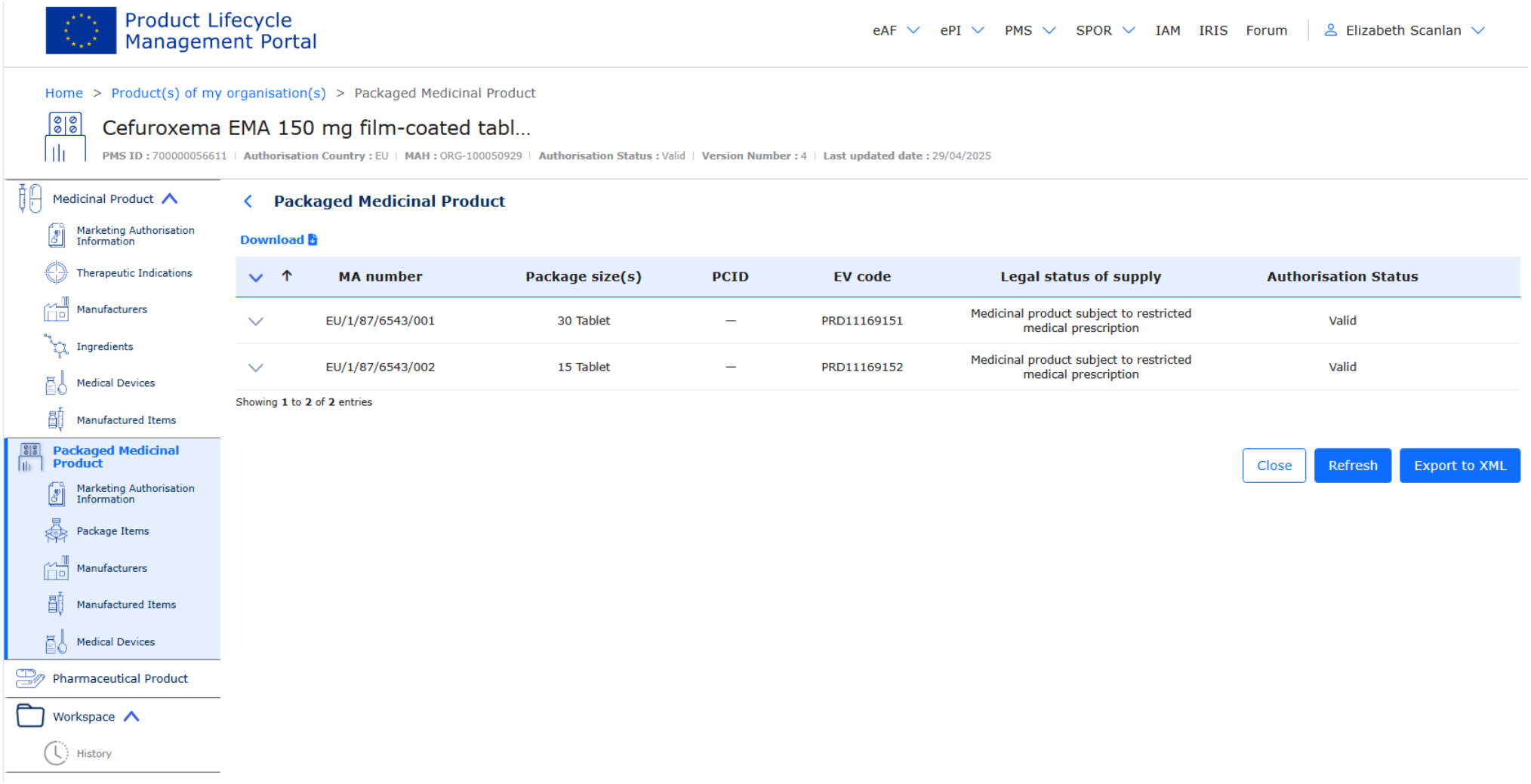
ePI use case – view from PLM: Product UI



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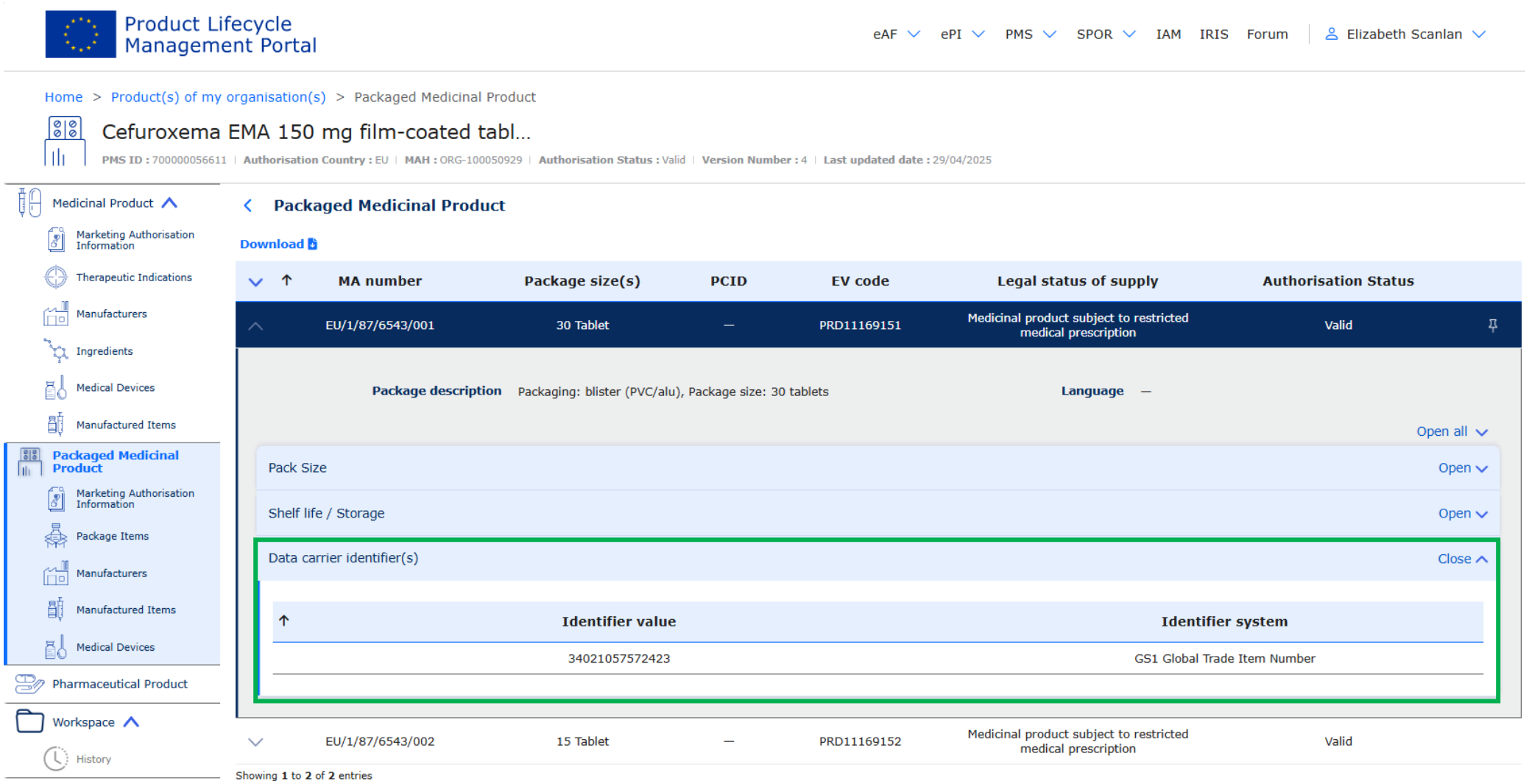
ePI use case – view from PLM: Product UI



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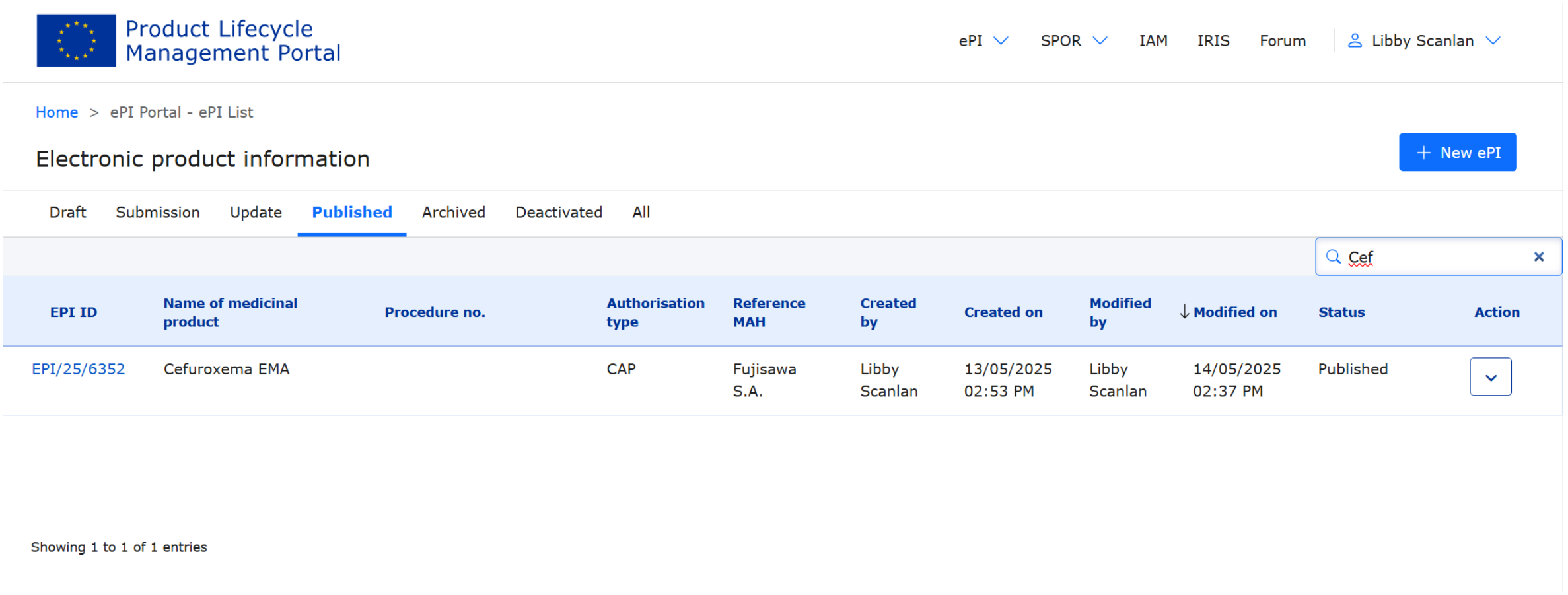
ePI use case – view from PLM: ePI



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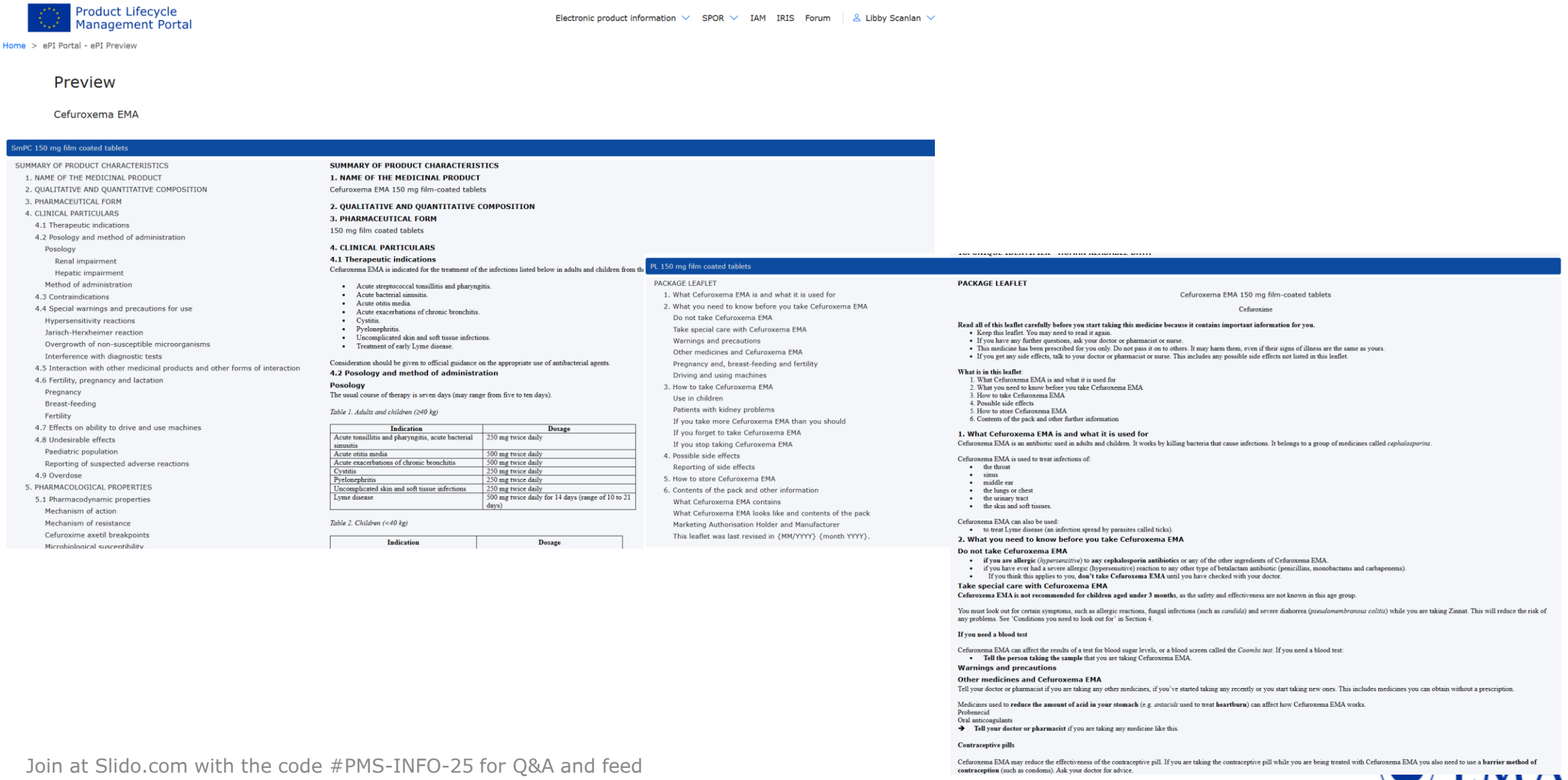
ePI use case – view from PLM: ePI



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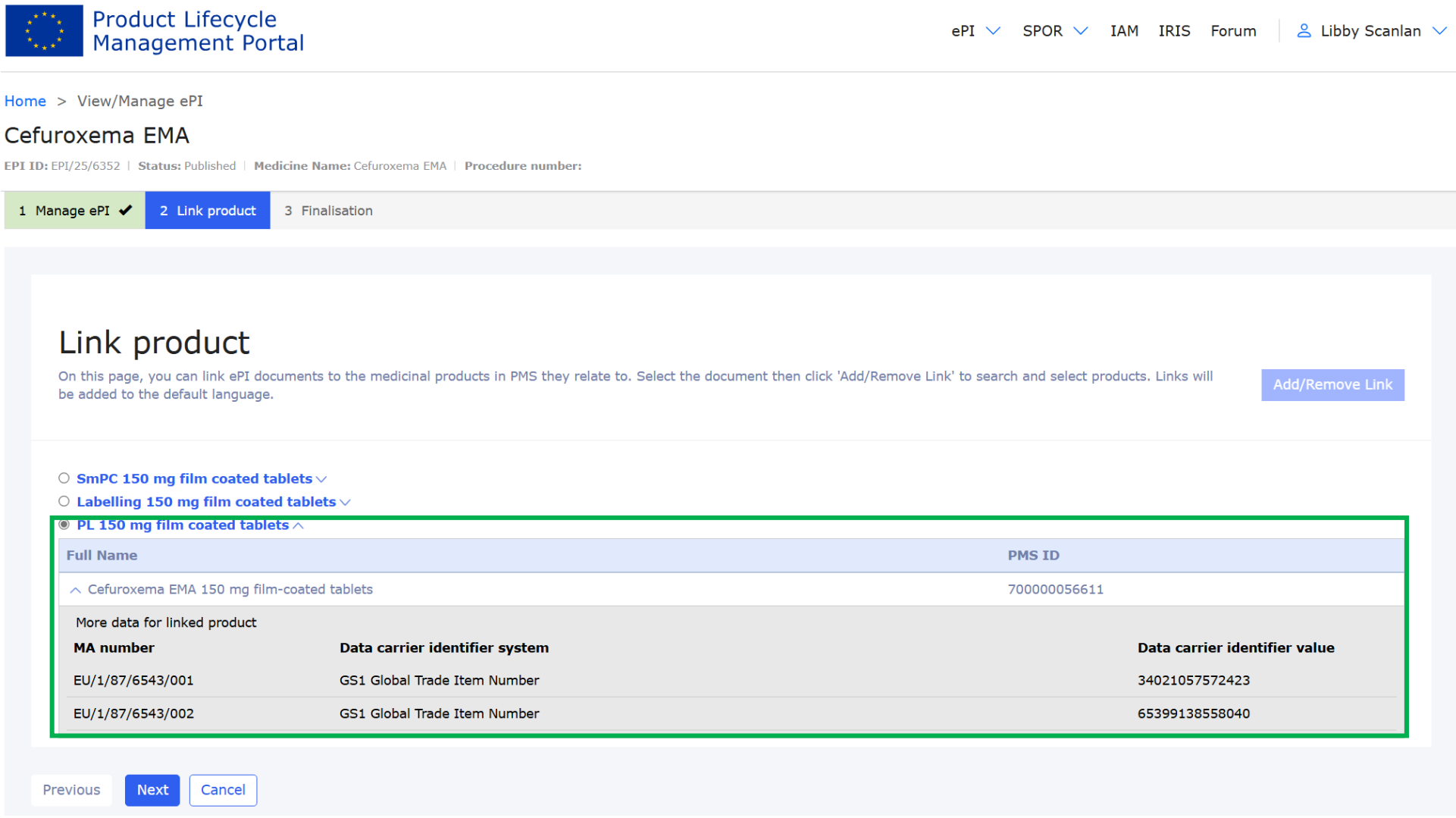
ePI use case – view from PLM: ePI



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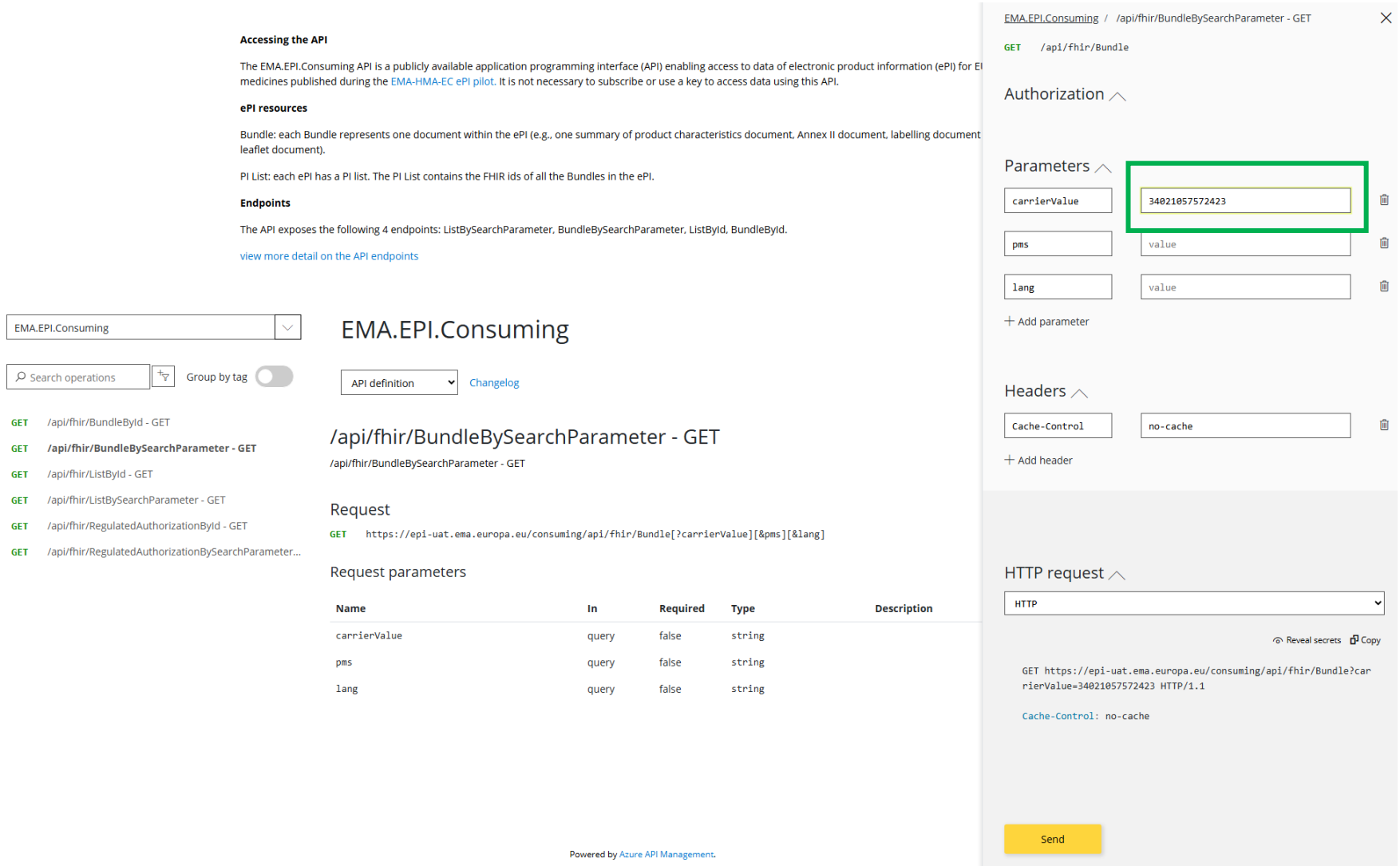
ePI use case – view from ePI API



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ePI use case – view from ePI API

Accessing the API

The EMA.EPI.Consuming API is a publicly available application programming interface (API) enabling access to data of electronic product information (ePI) for EU medicines published during the EMA-HMA-EC ePI pilot. It is not necessary to subscribe or use a key to access data using this API.

ePI resources

Bundle: each Bundle represents one document within the ePI (e.g., one summary of product characteristics document, Annex II document, labelling document, leaflet document).

PI List: each ePI has a PI list. The PI List contains the FHIR ids of all the Bundles in the ePI.

Endpoints

The API exposes the following 4 endpoints: ListBySearchParameter, BundleBySearchParameter, ListById, BundleById.

view more detail on the API endpoints

EMA.EPI.Consuming

Search operations

Group by tag

GET /api/fhir/BundleById - GET

GET **/api/fhir/BundleBySearchParameter - GET**

GET /api/fhir/ListById - GET

GET /api/fhir/ListBySearchParameter - GET

GET /api/fhir/RegulatedAuthorizationById - GET

GET /api/fhir/RegulatedAuthorizationBySearchParameter...

EMA.EPI.Consuming

API definition Changelog

/api/fhir/BundleBySearchParameter - GET

/api/fhir/BundleBySearchParameter - GET

Request

GET https://epi-uat.ema.europa.eu/consuming/api/fhir/Bundle[?carrierValue][&pms][&lang]

Request parameters

Name	In	Required	Type	Description
carrierValue	query	false	string	
pms	query	false	string	
lang	query	false	string	

Powered by Azure API Management.

p://ema.europa.eu/fhir/CodeSystem/100000155531","code":"10000
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oman', serif;\"> </p>\n<p style=\"line-height: normal; m
argin: 0cm; font-size: 11pt; font-family: 'Times New Roman',
serif;\">Read all of this leaflet carefully before yo
u start taking this medicine because it contains important in
formation for you.</p>\n<ul style=\"margin-top: 0cm;
margin-bottom: .0001pt;\">\n<li style=\"margin: 0cm -0.1pt 0.
0001pt 0px; line-height: normal; font-size: 11pt; font-famil
y: 'Times New Roman', serif;\">Keep this leaflet. You may nee
d to read it again.
\n<li style=\"margin: 0cm -0.1pt 0.00
01pt 0px; line-height: normal; font-size: 11pt; font-family:
'Times New Roman', serif;\">If you have any further question
s, ask your doctor or pharmacist or nurse.
\n<li style=
\"margin: 0cm -0.1pt 0.0001pt 0px; line-height: normal; font-
size: 11pt; font-family: 'Times New Roman', serif;\">This med
icine has been prescribed for you only. Do not pass it on to
others. It may harm them, even if their signs of illness are
the same as yours.
\n<li style=\"margin: 0cm -0.1pt 0.000
1pt 0px; line-height: normal; font-size: 11pt; font-family:
'Times New Roman', serif;\">If you get any side effects, talk
to your doctor or pharmacist or nurse. This includes any poss
ible side effects not listed in this leaflet.
\n
\n<p
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-size: 11pt; font-family: 'Times New Roman', serif;\">
</p>\n<p style=\"margin: 0cm -0.1pt 0cm 0cm; line-height: nor
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to know before you take Cefuroxema EMA
\n<li style=\"line
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\n<li style=\"line-
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\n<li style=\"li
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oman', serif;\">Contents of the pack and other further inform

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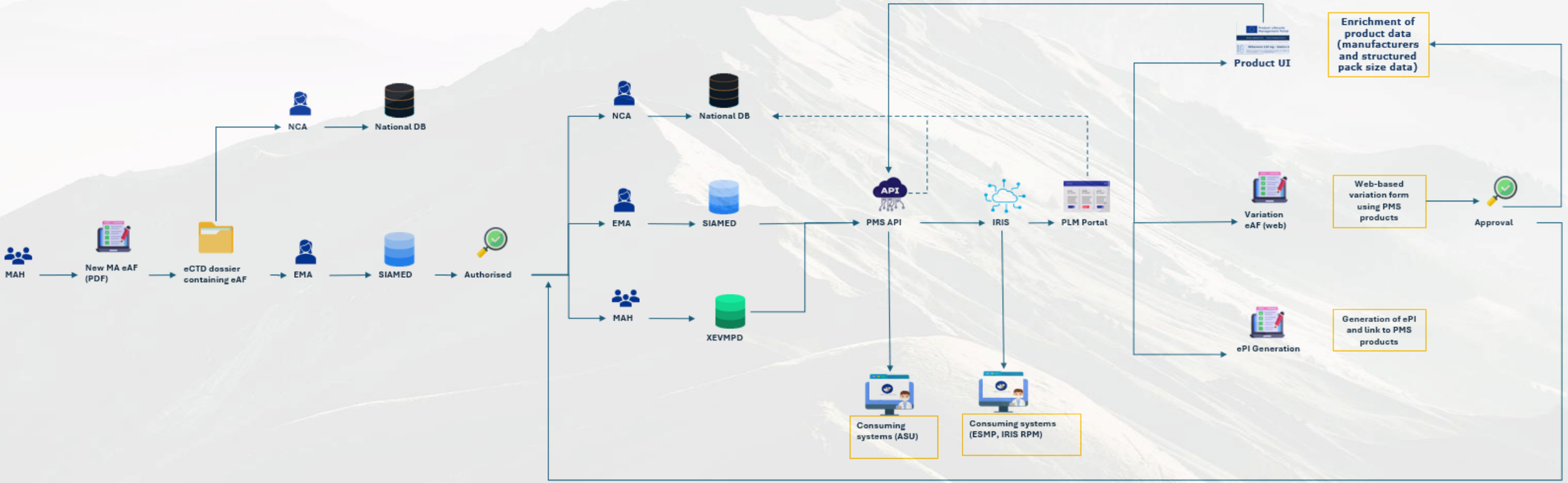
Overview of data workflow



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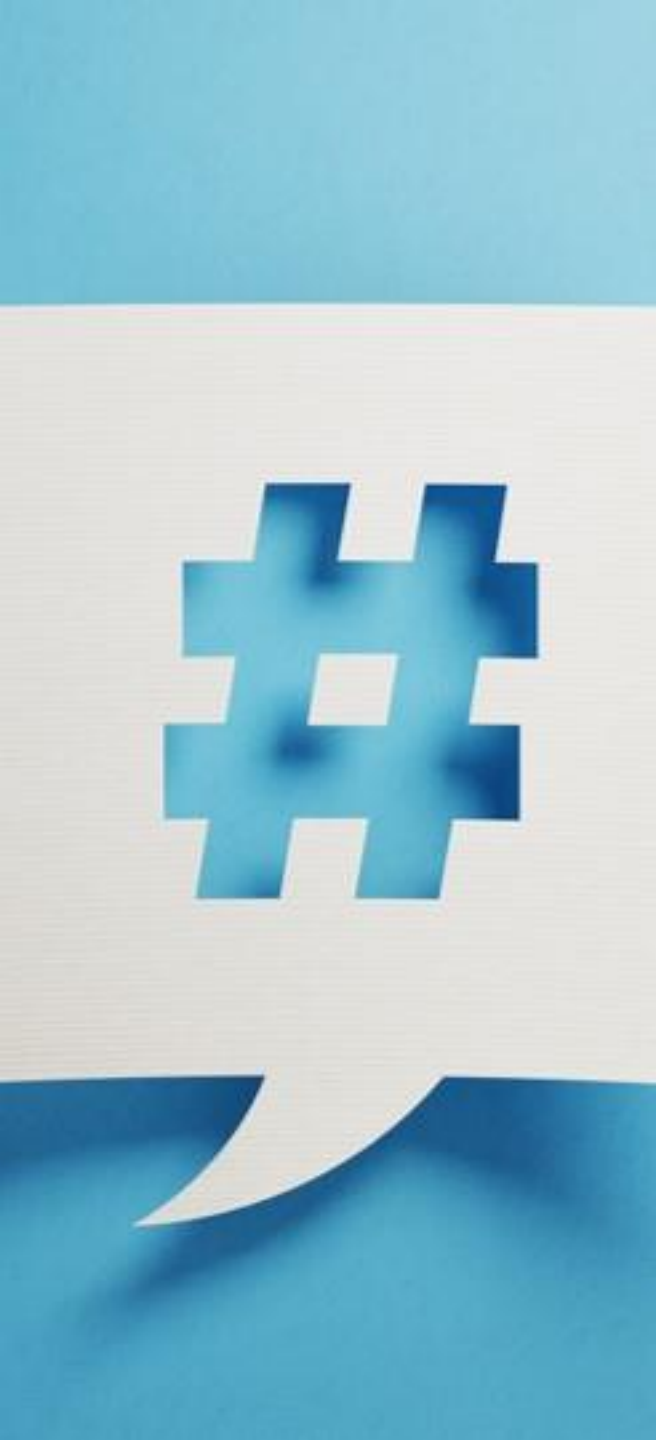


Key takeaways & conclusions

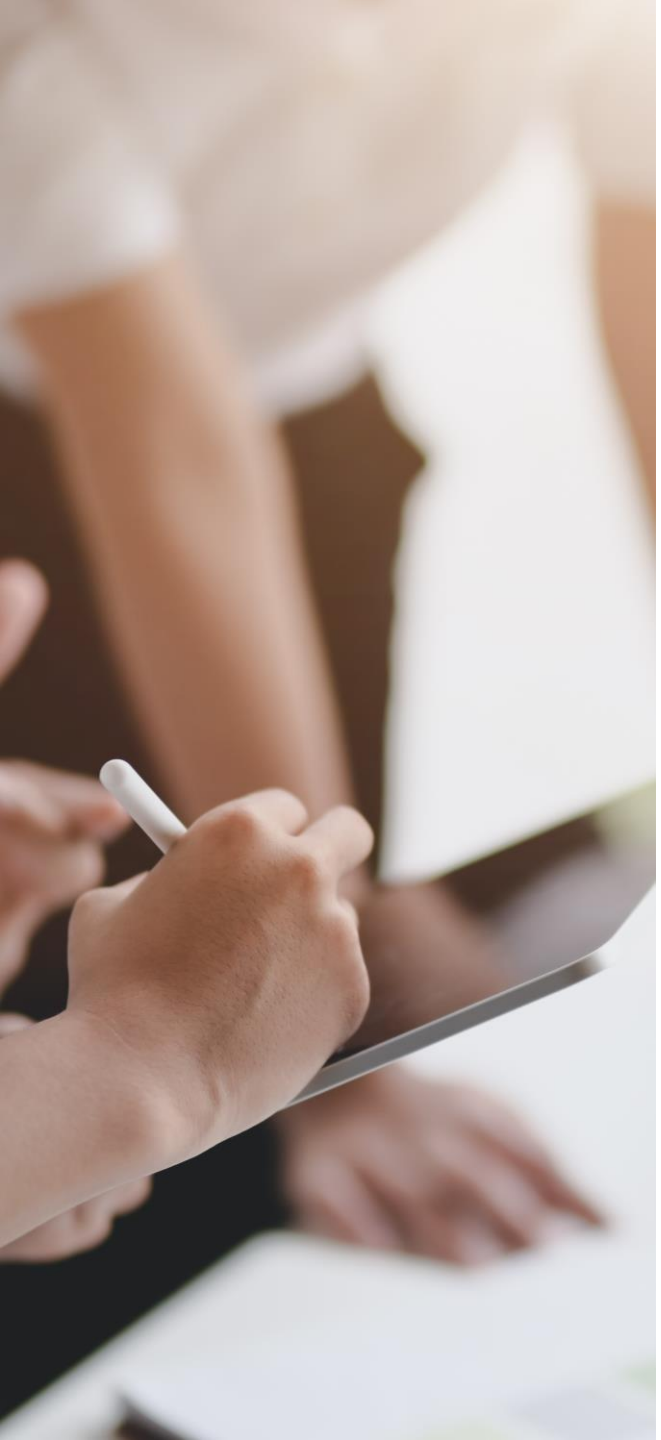
1. **Data submitted by MAHs is re-used** to feed PMS and its consuming systems (ePI, eAF, ASU, ESMP or the RPM in IRIS).

2. Regulatory and non-regulatory **processes are more efficient** now and less manual intervention is required:
   - Preparation of variation forms with already populated information
   - Evaluation of variations or management of inspections/parallel distribution
   - Data already pre-populated by systems such as ESMP or ASU to support NCAs and MAHs

3. Interconnection among systems supports the principle of **PMS being the source of product data in the EU regulatory network**. **More systems will be consuming PMS data** in the future, strengthening that principle.

4. There are discussions among different groups in the Network to **improve and expand** these business processes (NDSG, ROG, EMA, SMEs,…).

5. This session showcased the **end-to-end user journey** involving different systems and processes (regulatory and non-regulatory) all of them consuming PMS data.



Your feedback matters

- Please spare a few minutes to **complete the quick survey we just launched** in Slido, sharing **your feedback on this specific session**
- **Join Slido.com** using this code **#PMS-INFO-25** or scan this QR code

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Q&A session

Q&A housekeeping rules

- We will begin by answering a **few questions from participants in the room**, followed by **selected questions from Slido,** which will also be addressed verbally
- We will **not answer questions in writing** during the day
- The **unanswered questions** will be reviewed after the event, and the most **frequent/ relevant ones** will be added to the online **PMS FAQ document**

How to ask a question?

On-site participants

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

Online participants

- **Join Slido.com** using this code **#PMS-INFO-25** or scanning the QR code on top
- Ask your questions and vote the ones you would most like to be answered

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