

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



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*Co-chair of Network
ICT Advisory
Committee (NICTAC)
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*Member of Network
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Optimization Group
(ROG) PMS
Operational Group*

Speakers:



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Gomez**
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



Pieter Jan Desiere
*Supply and Availability of
Medicines and Devices
Specialist*



Anastasia Pickford
ASU Product Owner



ASU

ESMP

ePI

eAF

Others

PMS



ASU

ESMP

Inspe
ctions

ePI

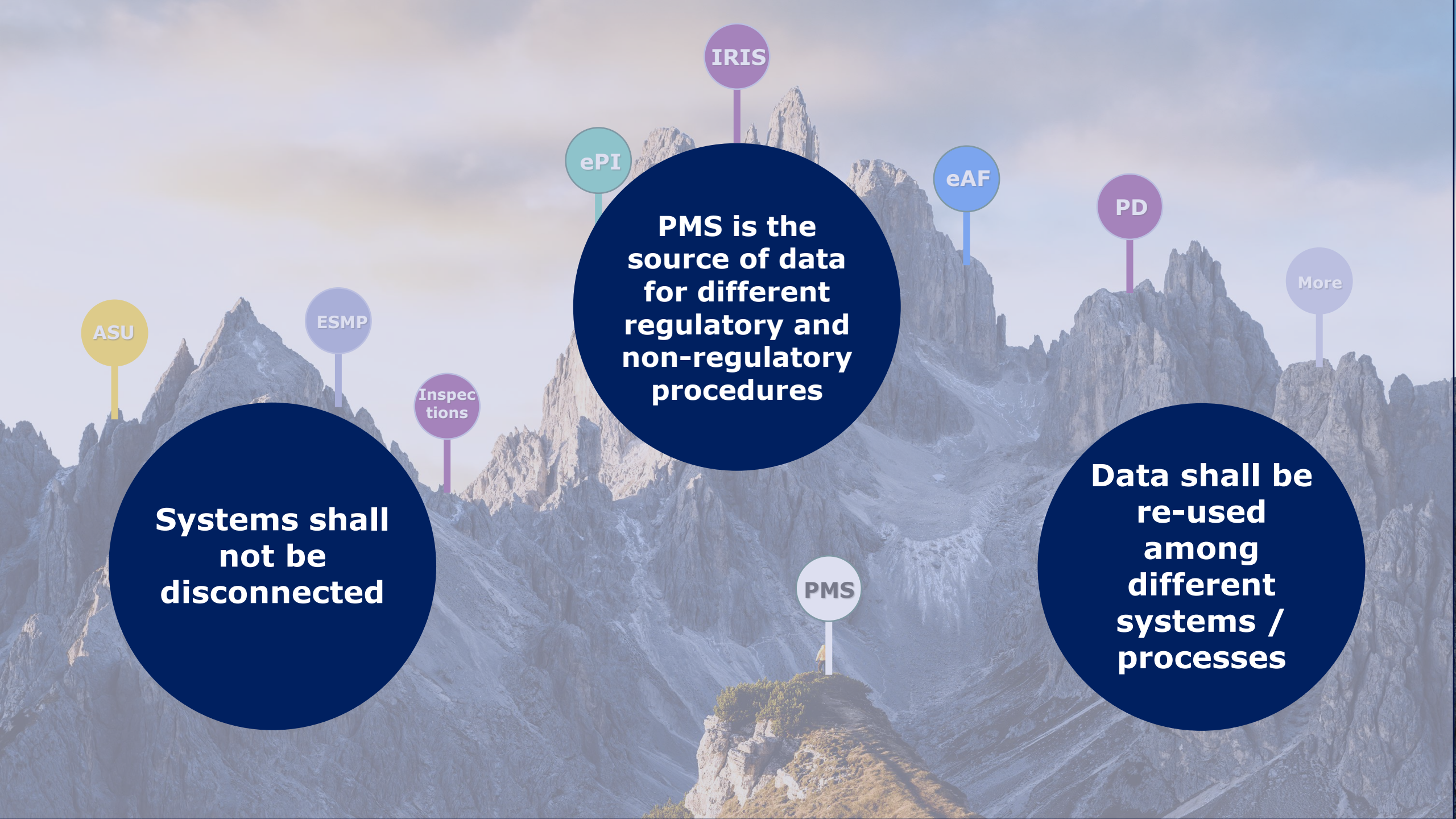
IRIS

eAF

PD

More

PMS



IRIS

ePI

eAF

PD

More

ASU

ESMP

Inspections

**PMS is the
source of data
for different
regulatory and
non-regulatory
procedures**

PMS

**Systems shall
not be
disconnected**

**Data shall be
re-used
among
different
systems /
processes**

PMS

eAF

Inspections

ePI

IRIS

ASU

PD

ESMP

More

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

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

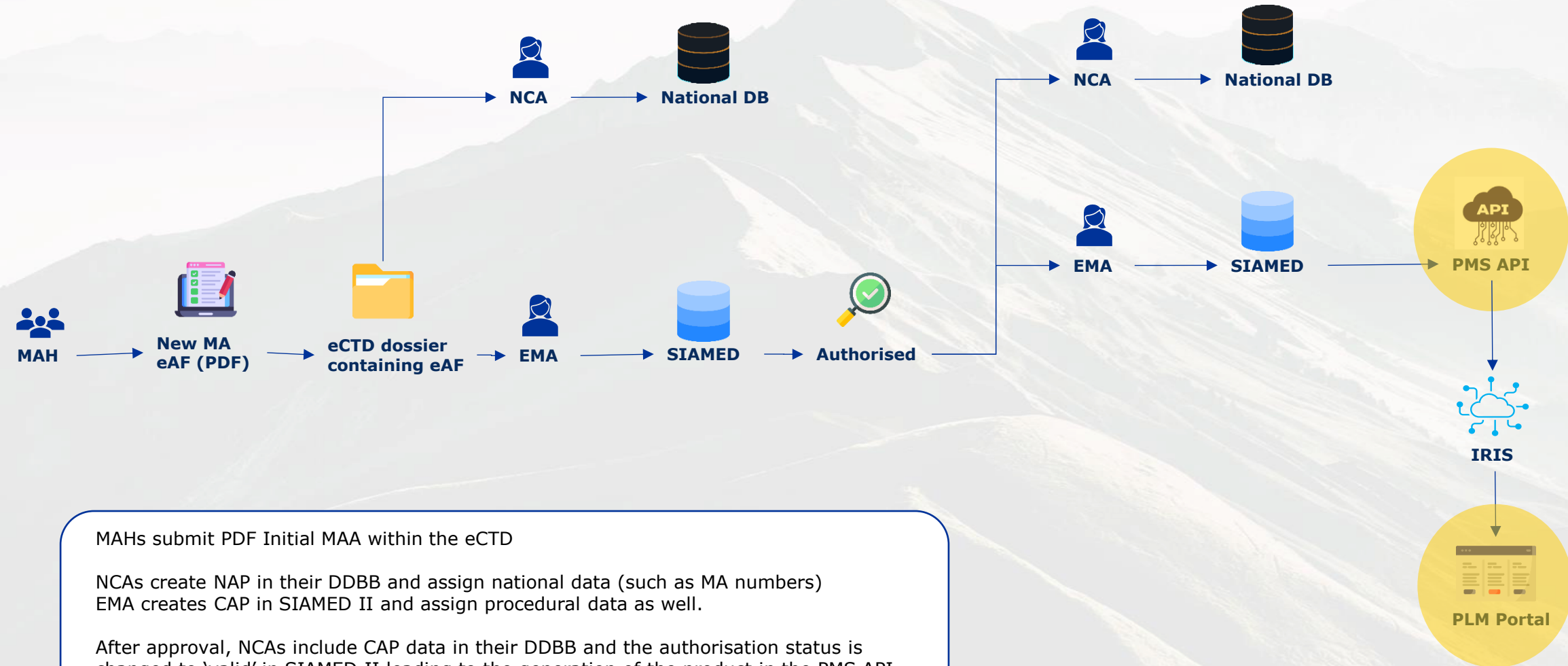
MAH: Kern Pharma S.L.

3 pack sizes (091990)

Authorised in Spain

ATC Code: A07AA12

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

```
1 <?xml version="1.0" encoding="utf-8"?>
2 <Bundle xmlns="http://hl7.org/fhir">
3   <id value="700000056611" />
4   <meta>
5     <versionId value="1" />
6     <lastUpdated value="2025-04-08T15:52:19.801+00:00" />
7   </meta>
8   <type value="searchset" />
9   <entry>
10    <fullUrl value="MedicinalProductDefinition/700000056611" />
11    <resource>
12      <MedicinalProductDefinition>
13        <id value="700000056611" />
```

Version 1 of the medicinal product

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

Two packages are created

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

Product name as in SIAMED (not as in XEVMPD)

clinical

Aa ab *

No results

No indications as SIAMED does not capture them

```
<manufacturingBusinessOperation id="31070120">
  <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="100000160406" />
      </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-1000000809" />
    <display value="LOC-1000000809" />
  </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

```
<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

[Home](#) > [Product\(s\) of my organisation\(s\)](#) > 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
 - 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 —

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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

Therapeutic Indications

Language —

Full indication text CEFUROXEMA is indicated for the treatment of acute bacterial otitis media

↑	MedDRA code	MedDRA code name	MedDRA version
⚠ Data are not available in SIAMED/XEVMPD and not loaded. Users are encouraged to provide it when applicable.			

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

Close Refresh

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

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

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

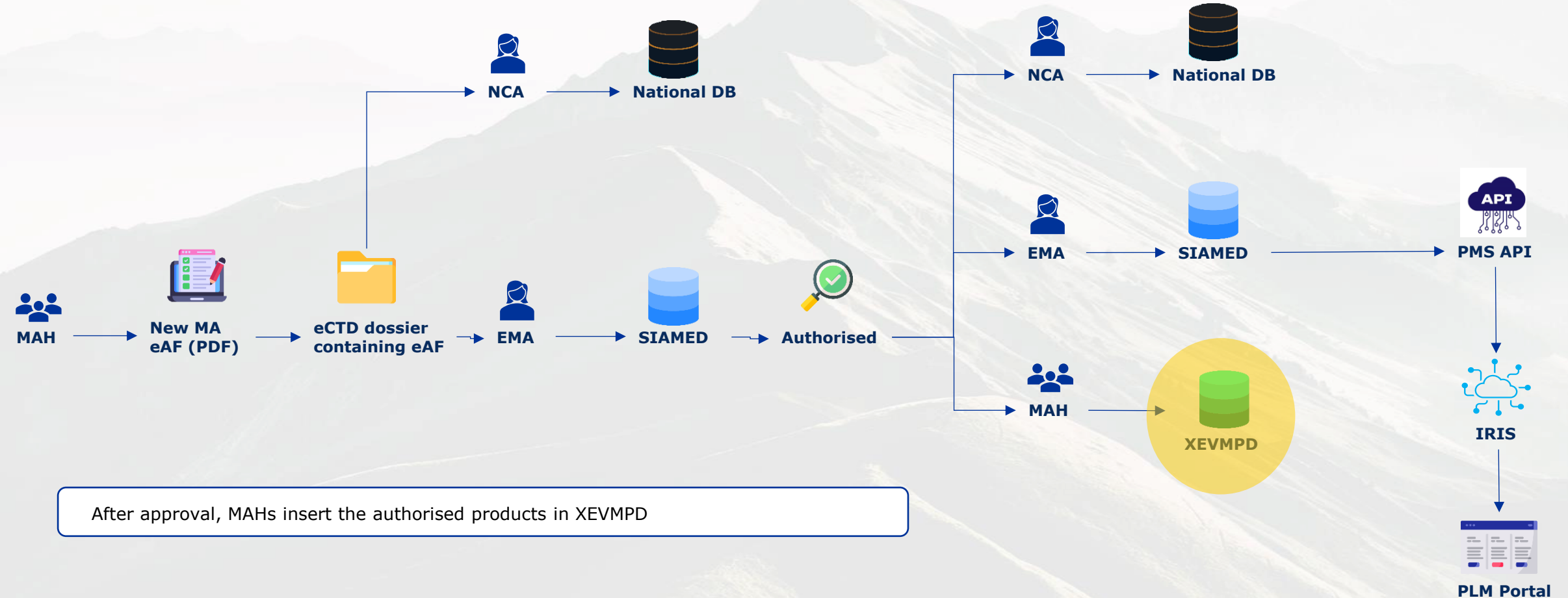
[Download](#)

	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

CloseRefresh

Insert of products in XEVMPD



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

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/EMA 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 (-)

Substance Name:

Substances created in the same message are available in the drop down list.

Role of Ingredient

Full Description

Active Ingredient: FIDAXOMICIN as Active Ingredient At 50 milli Gram(s) per Tablet

Concise: FIDAXOMICIN 50 mg/Tablet

Ingredient Strength Information

Amount Value Type:

Expressed as:

Exact Value

Value	Prefix	Unit
Numerator: 50	milli (1x10 ⁻³)	Gram(s)
Denominator: 1	single	Tablet

EVPRM Message

Products

- + Insert - Authorised - Fidaxomicin EMA 50 mg comprimidos
- + Insert - Authorised - Fidaxomicin EMA 50 mg comprimidos
- + Insert - Authorised - Fidaxomicin EMA 50 mg comprimidos

Substances

Sources

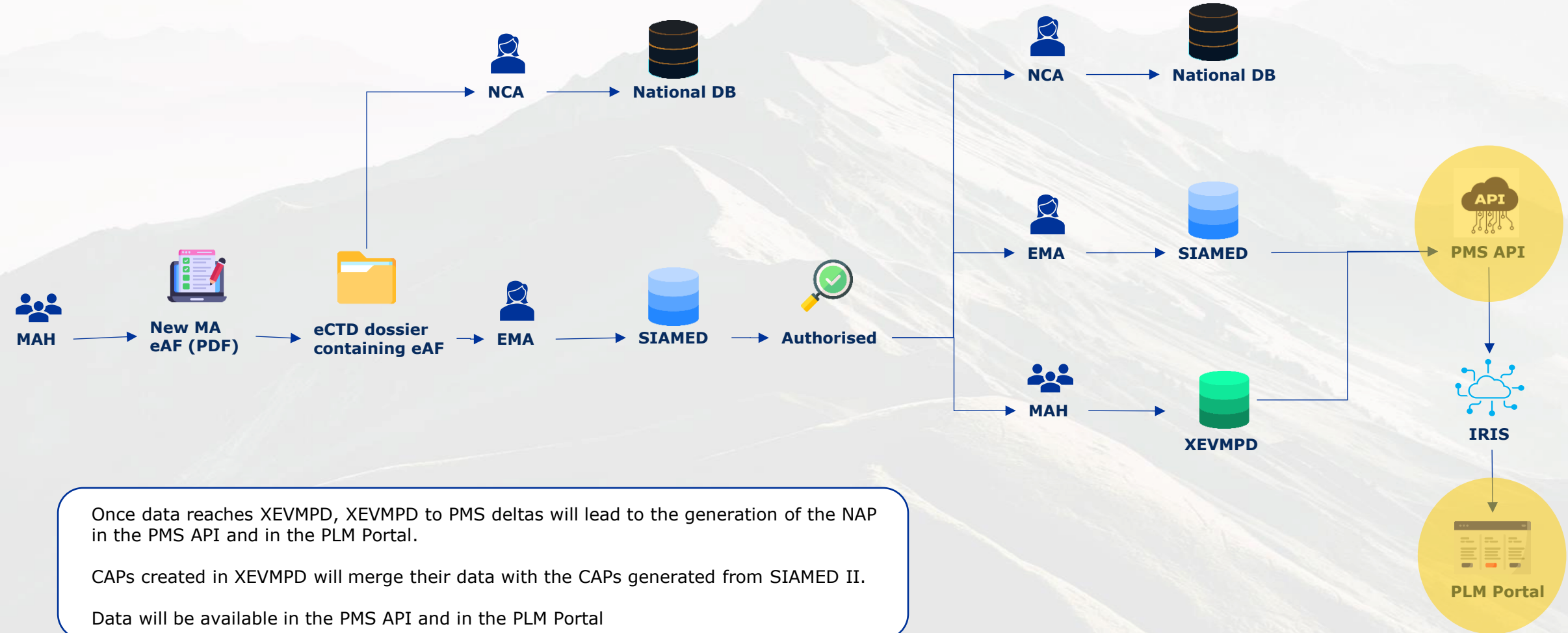
Organisations

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

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



Insert of products in XEVMPD



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

CAP product is updated after XEVMPD submission

```
1 <?xml version="1.0" encoding="utf-8"?>
2 <Bundle xmlns="http://hl7.org/fhir">
3   <id value="700000056611" />
4   <meta>
5     <versionId value="4" />
6     <lastUpdated value="2025-04-29T08:36:57.074+00:00" />
7   </meta>
8   <type value="searchset" />
9   <entry>
10    <fullUrl value="MedicinalProductDefinition/700000056611" />
11    <resource>
12      <MedicinalProductDefinition>
13        <id value="700000056611" />
14        <contained>
```

Medicinal product is updated (new version)

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

Product name is updated with data from XEVMPD

```
<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

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

Paediatric use is updated with data from XEVMPD

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

NAP product is created in the PMS API

```
<entry>
  <fullUrl value="MedicinalProductDefinition/700000056509" />
  <resource>
    <MedicinalProductDefinition>
      <id value="700000056509" />
      <contained>
        <Provenance>
```

New medicinal product is created

```
<identifier id="20420">
  <system value="http://spor.ema.europa.eu/v1/lists/100000000009/terms/100000075665" />
  <value value="PRD11169138" />
</identifier>
<identifier id="20421">
  <system value="http://spor.ema.europa.eu/v1/lists/100000000009/terms/100000075665" />
  <value value="PRD11169139" />
</identifier>
<identifier id="20422">
  <system value="http://spor.ema.europa.eu/v1/lists/100000000009/terms/100000075665" />
  <value value="PRD11169140" />
</identifier>
```

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

```
</PharmaceuticalProduct>
<packagedMedicinalProduct id="7647049">
  <reference value="PackagedProductDefinition/7647049" />
</packagedMedicinalProduct>
<packagedMedicinalProduct id="7647050">
  <reference value="PackagedProductDefinition/7647050" />
</packagedMedicinalProduct>
<packagedMedicinalProduct id="7647051">
  <reference value="PackagedProductDefinition/7647051" />
</packagedMedicinalProduct>
<masterFile id="5373823">
```

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

Feedback

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

Medicinal Product

PMS ID 700000056509 MPID —
Domain Human use Type Medicinal Product
EV Code PRD111169138 | PRD111169139 | PRD111169140

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

[Home](#) > [Product\(s\) of my organisation\(s\)](#) > [Medicinal Product](#) > [Manufacturers](#)



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

< Manufacturers

Column visibility [Download](#) [Show 10 rows](#)

↑	Manufacturer	Address	Org ID	Loc ID
⚠ Data are not available in SIAMED/XEVMPD and not loaded. Users are encouraged to provide it when applicable.				

Close

Refresh

Export to XML

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

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

Download

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

MA number	Package size(s)	PCID	EV code	Legal status of supply	Authorisation Status
091990	—	—	PRD11169140	—	Valid
Package description33333 - 50 tablets Language — Pack SizeOpen Shelf life / StorageOpen Data carrier identifier(s)Open					
091990	—	—	PRD11169139	—	Valid
091990	—	—	PRD11169138	—	Valid

Showing 1 to 3 of 3 entries

Close

Refresh

Export to XML

Home > Product(s) of my organisation(s) > Pharmaceutical 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

Pharmaceutical Product

↑	Administrable dose form	Unit of presentation	Pharmaceutical product description	Language
↑	Tablet	—	—	—

Route of Administration

Close

↑	Route of administration
	Oral use

Ingredients

Close

↓	Substance	↑	Role	Origin of the substance	Composition grouping description
↓	Fidaxomicin		Active	—	—
↓	Sodium		Excipient	—	—
↓	Talc		Excipient	—	—

Showing 1 to 3 of 3 entries

Devices

Open

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



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
Domain Human use
MPID —
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 paediatric 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

Join at [ema.europa.eu](#) with the code #1115 111 0 23 for XEVMPD data feedback





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
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- Manufacturers
- Manufactured Items
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- Pharmaceutical Product
- Workspace
- History

Pharmaceutical Product

Pharmaceutical product is now created with data from XEVMPD

↑	Administrable dose form	Unit of presentation	Pharmaceutical product description	Language
↑	Film-coated tablet	—	—	—

Route of Administration

↑

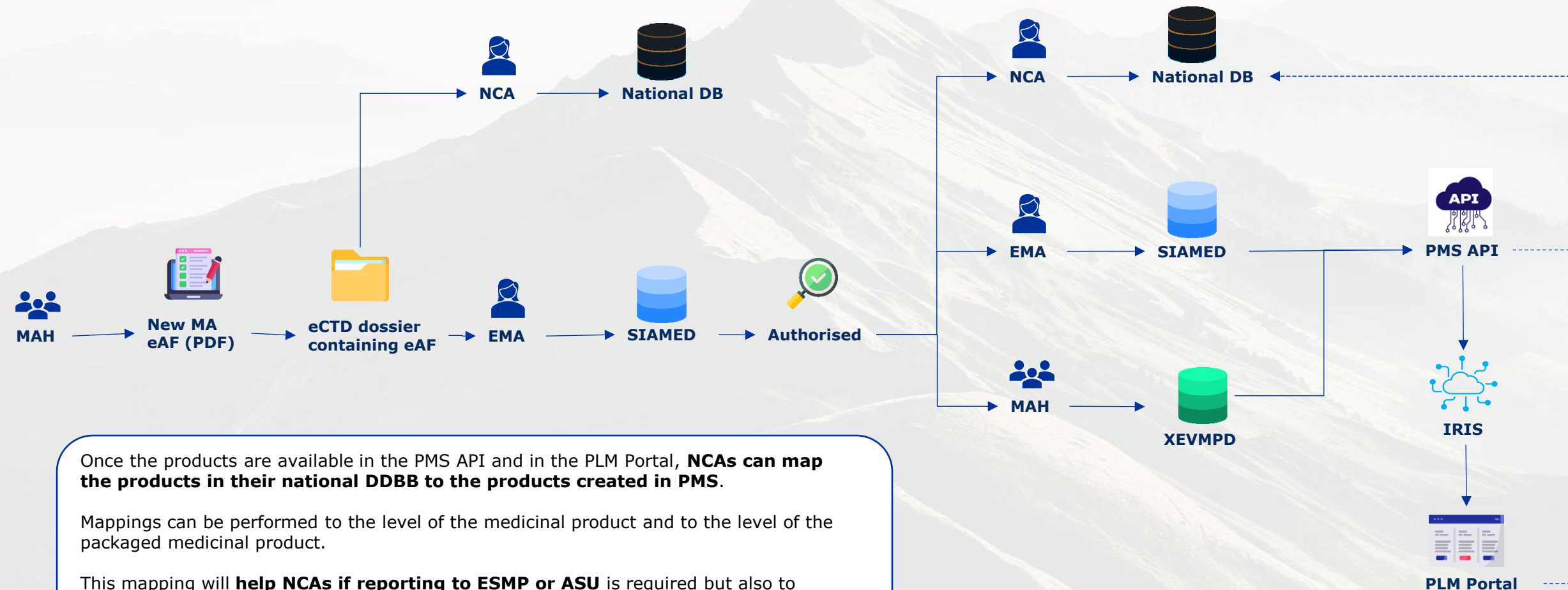
Route of administration

Oral use

Ingredients

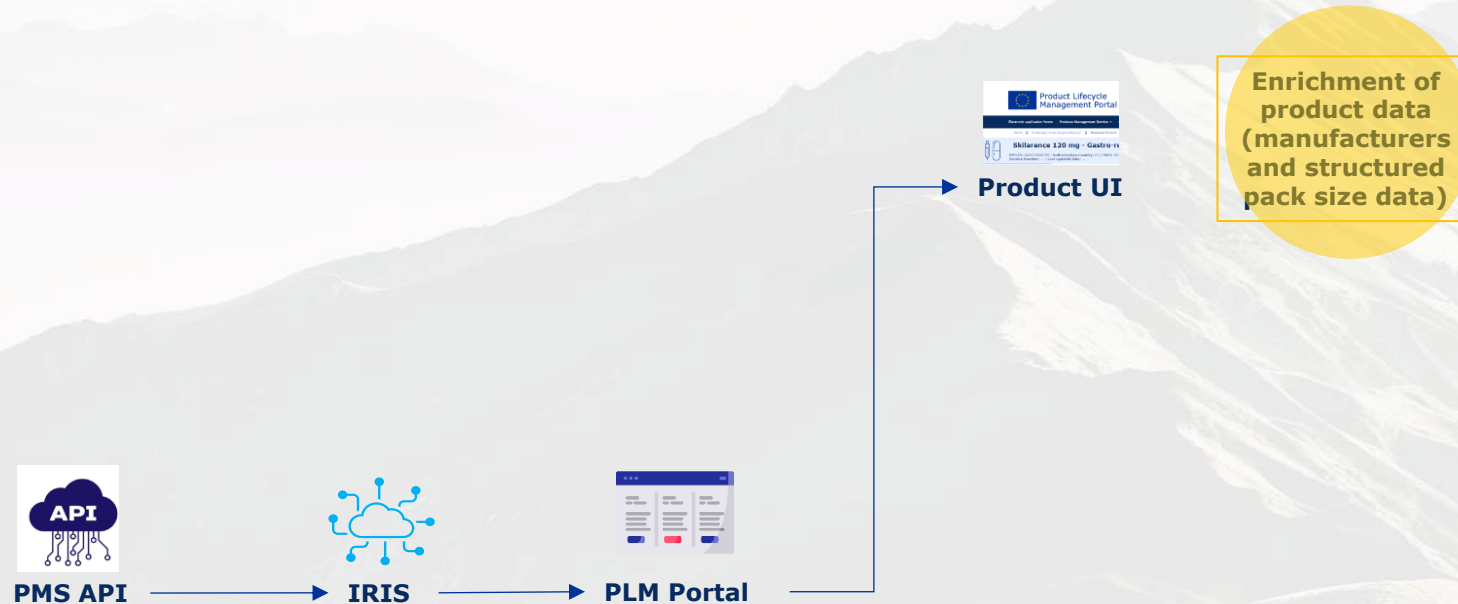
↓	Substance	↑	Role	Origin of the substance	Composition grouping description
↓	Bicalutamide		Active	—	—
↓	Cefuroxime		Active	—	—
↓	CALCIUM HYDROGEN PHOSPHATE		Excipient	—	—
↓	Croscarmellose sodium		Excipient	—	—
↓	Hypromellose 15CP		Excipient	—	—
↓	Lactose monohydrate		Excipient	—	—

NCAs data mapping and use of PMS data



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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.

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Enrichment of product data

**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\(s\)](#)

Product(s) of my Organisation(s)

PMS ID

700000056509 x

Full Name

Authorised Dose Form

MA Holder

LOC ID

MA Nr.

Active Substance

Enter at least 5 characters

Authorisation Country

Column visibility ▾ Download  Load 10 rows ▾

[View selected products](#) [Edit Data](#) [View Data](#)

☒	↓ PMS ID	Full Name	Authorised Dose Form	MA Holder	LOC ID	MA Nr.	Active substance	Authorisation Country	Authorisation Status	MRP / DCP / CP Nr.
☒	70000005650					91990	Fidaxomicin	ES	Valid	

Preparing Change Request

Friendly Name *

Manufacturer enrichment

Description

Close

Next

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

Product Lifecycle Management Portal

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

Fidaxomicin EMA 50 mg comprimés

PMS ID : 700000056509 | Authorisation Country : ES

Medicinal Product < Manufacturers

Marketing Authorisation Information

Therapeutic Indications

Column visibility ▾ Download

IRIS Forum Marcos Fernandez Gomez ▾

+ Add Manufacturer

Create Manufacturer

Manufacturer Details

Manufacturer * —

Lookup records

Search

Choose one record and click Select to continue

✓	Organisation Name	Full address	Organisation Id	Organisation Location	OMS Status
☐	[INACTIVE] 1 A Pharma GmbH	Stella-Klein-Loew-Weg 17 Leopoldstadt 1020 Vienna Austria	ORG-100001357	LOC-100006228	INACTIVE
☐	[INACTIVE] 1 A Pharma GmbH	Eduard-Kittenberger-Gasse 56 Liesing 1230 Vienna Austria	ORG-100001357	LOC-100003333	INACTIVE

Showing 1 to 10 of 5000+ entries

< Previous 1 2 3 4 5 6 7 8 ... 500 Next >

Select Cancel

Close Save Save & New

Add as many manufacturers as needed

Join at Slido.com with the code #PMS-

Enrichment of product data

Create Manufacturer ×

Manufacturer Details

Manufacturer * 🔍

Lookup records

🔍

Choose one record and click Select to continue

✓	↑ Organisation Name	Full address	Organisation Id	Organisation Location	OMS Status
☒	Id Logistics Iberia S.A.	Avenida Larona 8 Poligono Industrial La Quinta 19171 Cabanillas Del Campo Spain	ORG-100012365	LOC-100022370	ACTIVE
☐	Id Logistics Iberia S.A.	Avenida Del Rio Henares 40-42 19208 Alovera Spain	ORG-100012365	LOC-100020607	ACTIVE

Showing 1 to 6 of 6 entries

Select Cancel

Add as many manufacturers as needed

Id Logistics Iberia S.A.		Avenida Larona 8 Poligono Industrial La Quinta 19171 Cabanillas Del Campo Spain		ORG-100012365	LOC-100022370	+ Add Manufacturing Operations	
↑	Operation type	Manufacturing operation start date	Manufacturing operation end date	Confidentiality indicator	Manufacturing authorisation reference number	Effective date	Medicines regulatory agency organisation
⚠ Data are not available in SIAMED/XEVMPD and not loaded. Users are encouraged to provide it when applicable.							

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Enrichment of product data

Create Manufacturing Operation

Manufacturer

Manufacturer

LOC-100022370: Id Logistics Iberia S.A.

Manufacturer details

Name *

Id Logistics Iberia S.A.

Address

Avenida Larona 8 Poligono Industrial La Quinta
Cabanillas Del Campo 19171
Spain

Org ID

ORG-100012365

LOC ID

LOC-100022370

Manufacturing business operation

Operation Type *

—

Manufacturing operation start date *

DD/MM/YYYY

Manufacturing operation end date

DD/MM/YYYY

Confidentiality Indicator *

—

Manufacturing authorisation reference number

—

Effective date

DD/MM/YYYY

Medicines regulatory agency organisation *

—

Close

Save

Save & New

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

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The logo of the European Medicines Agency (EMA), featuring a stylized eye icon and the letters "EMA".

Classified as public by the European Medicines Agency

Enrichment of product data

Id Logistics Iberia S.A.

Avenida Larona 8 Poligono Industrial La Quinta 19171
Cabanillas Del Campo Spain

ORG-100012365

LOC-100022370

+ Add Manufacturing Operations

↑	Operation type	Manufacturing operation start date	Manufacturing operation end date	Confidentiality indicator	Manufacturing authorisation reference number	Effective date	Medicines regulatory agency organisation	
	Active substance intermediate physical processing	19/05/2025	—	Confidential	—	—	European Banking Authority	

[Home](#) > [Product\(s\) of my organisation\(s\)](#) > [Medicinal Product](#) > [Manufacturers](#)

 **Fidaxomicin EMA 50 mg comprimidos**
PMS ID : 700000056509 | Authorisation Country : ES | MAH : ORG-100000149 | Authorisation Status : Valid | Version Number : 5 | Last updated date : 05/05/2025

Medicinal Product

Marketing Authorisation Information

Therapeutic Indications

Manufacturers

Ingredients

Medical Devices

Manufactured Items

Packaged Medicinal Product

Marketing Authorisation Information

Package Items

Manufacturers

Manufactured Items

< Manufacturers

Validation successful

Close

+ Add Manufacturer

Column visibility Download Show 10 rows

↑	Manufacturer	Address	Org ID	Loc ID	
▼	Id Logistics Iberia S.A.	Fondo De La Estacio Poligono Industrial La Granada 08792 Barcelona Spain	ORG-100012365	LOC-100021140	
▼	Id Logistics Iberia S.A.	Avenida Larona 8 Poligono Industrial La Quinta 19171 Cabanillas Del Campo Spain	ORG-100012365	LOC-100022370	

Showing 1 to 2 of 2 entries

Cancel Refresh regulatory data Validate Save Export to XML

Changes can be validated before they are submitted.

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



Fidaxomicin EMA 50 mg comprimidos

PMS ID : 700000056509 | Authorisation Country : ES | MAH : ORG-100000149 | Authorisation Status : Valid | Version Number : 5 | Last updated date : 05/05/2025

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

Packaged Medicinal Product

Download

MA number	Package size(s)	PCID	EV code	Legal status of supply	Authorisation Status
091990	20 Tablet	—	PRD11169138	—	Valid
Package description111111 - 20 TABLETS Language — Pack Size + Add structured pack size data Unit of Presentation Quantity					

Add Pack Size

Unit of Presentation *

Tablet

Quantity *

20

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

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



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

Fidaxomicin EMA 50 mg comprimidos

PMS ID : 700000056509 | Authorisation Country : ES | MAH : ORG-100000149 | Authorisation Status : Valid | Version Number : 5 | Last updated date : 05/05/2025

Medicinal Product

Marketing Authorisation Information

Therapeutic Indications

Manufacturers

Ingredients

Medical Devices

Manufactured Items

Packaged Medicinal Product

Marketing Authorisation Information

Package Items

Manufacturers

Manufactured Items

< Packaged Medicinal Product

Download

MA number	Package size(s)	PCID	EV code	Legal status of supply	Authorisation Status
091990	20 Tablet	—	PRD11169138	—	Valid

Package description 111111 - 20 TABLETS

Language —

Open all

Pack Size

Close

+ Add structured pack size data

Unit of Presentation	Quantity
Tablet	20

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

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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

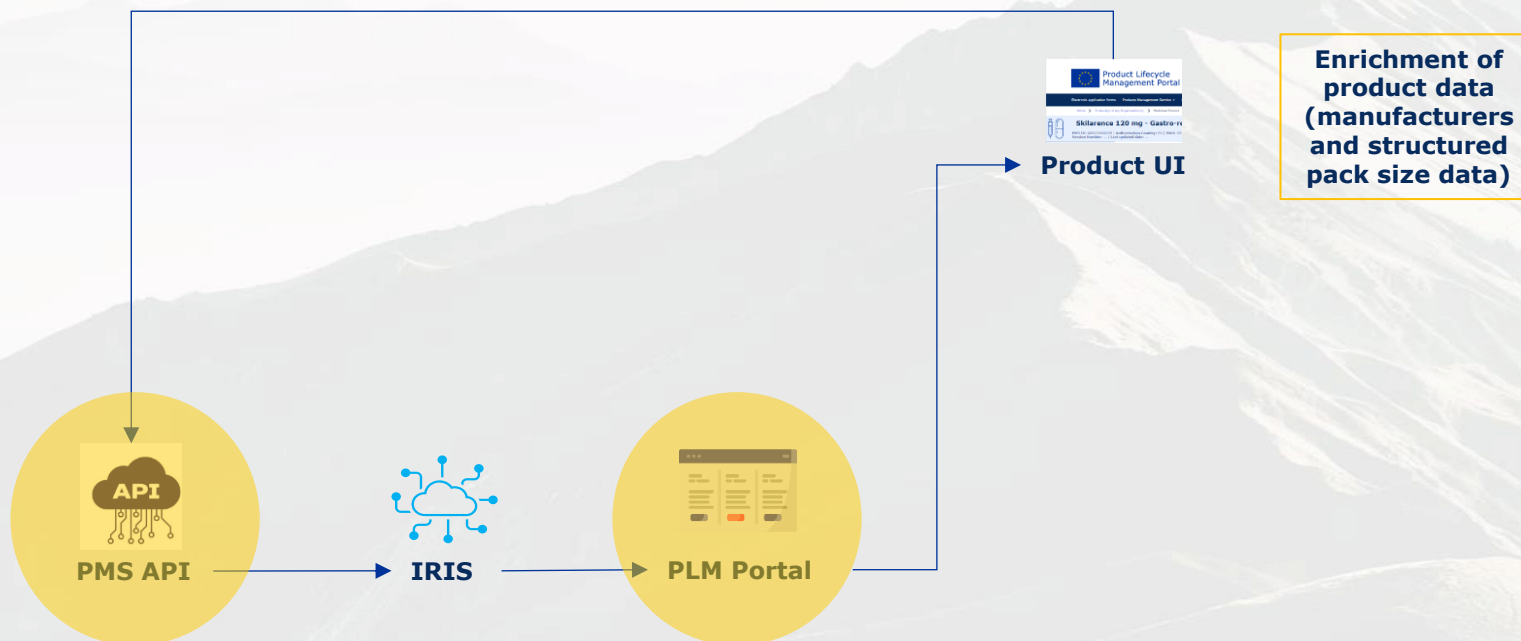
Save

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.

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Enrichment of product data

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



Fidaxomicin EMA 50 mg comprimidos

PMS ID : 700000056509 | Authorisation Country : ES | MAH : ORG-100000149 | Authorisation Status : Valid | Version Number : 5 | Last updated date : 05/05/2025

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

Packaged Medicinal Product

Download

	MA number	Package size(s)	PCID	EV code	Legal status of supply	Authorisation Status
▼	091990	20 Tablet	—	PRD11169138	—	Valid
▼	091990	30 Tablet	—	PRD11169139	—	Valid
▼	091990	50 Tablet	—	PRD11169140	—	Valid

Showing 1 to 3 of 3 entries

Cancel Refresh regulatory data Validate Save Export to XML

Structured pack size data is enriched

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Enrichment of product data

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

 **Fidaxomicin EMA 50 mg comprimidos**
PMS ID : 700000056509 | Authorisation Country : ES | MAH : ORG-100000149 | Authorisation Status : Valid | Version Number : 5 | Last updated date : 05/05/2025

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
^	Id Logistics Iberia S.A.	Fondo De La Estacio Poligono Industrial La Granada 08792 Barcelona Spain	ORG-100012365	LOC-100021140

↑	Operation type	Manufacturing operation start date	Manufacturing operation end date	Confidentiality indicator	Manufacturing authorisation reference number	Effective date	Medicines regulatory agency organisation
	Batch certification	05/05/2025	—	Public	—	05/05/2025	Spanish Agency For Medicines And Medical Devices

Close

Refresh

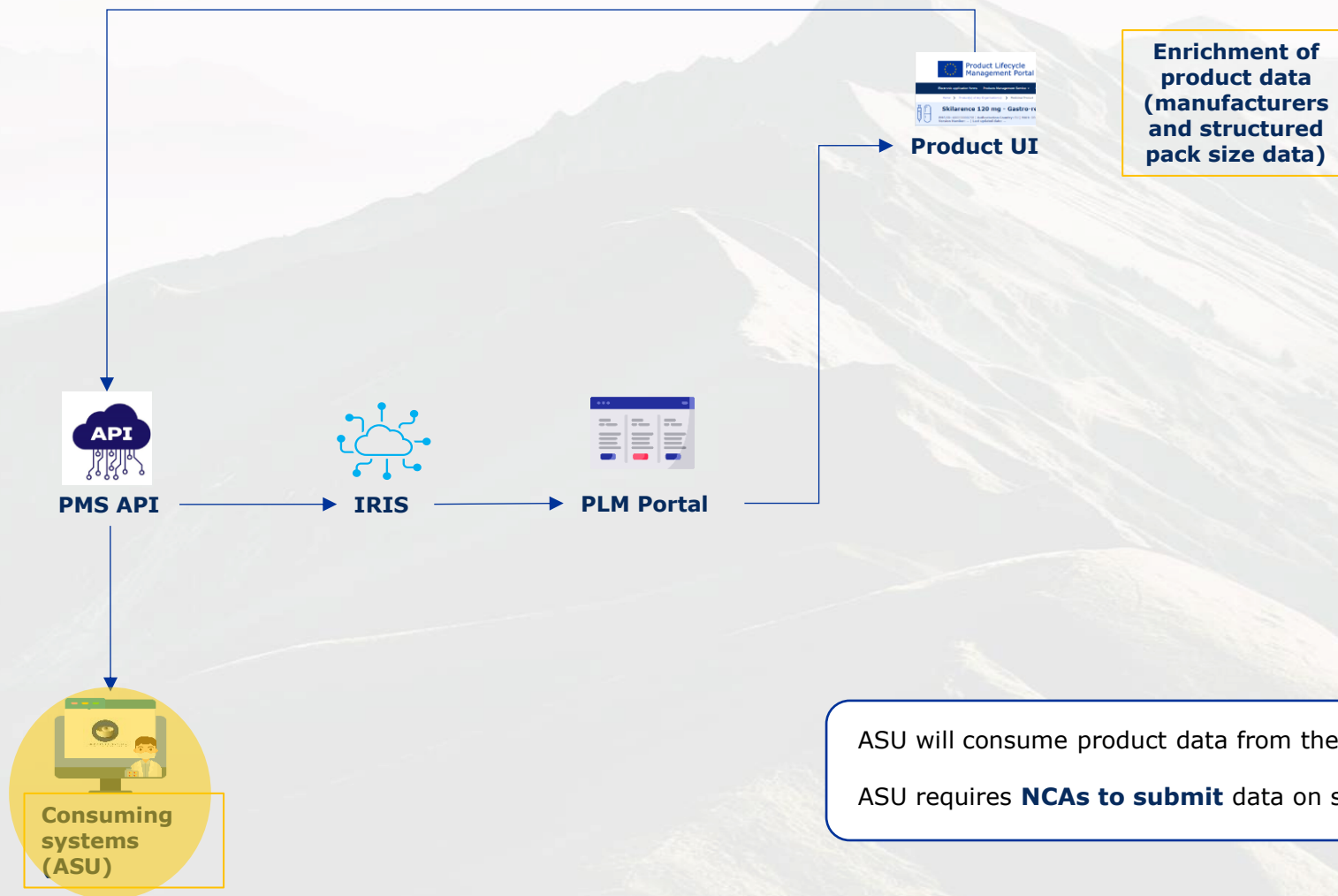
Export to XML

Manufacturers and MBOs are enriched.

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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.

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

Download use data template

- ☒ Add other antimicrobial VMPs or HMPs (extend template)
- ☐ Include products from the voluntary reporting scope

Select year *
2029

Select country *
Austria

Select animal species *
Cattle

Download template

Please note that modification of fields that are not indicated as "editable" in the column title will not be saved in the ASU platform and may block the dataset upload. If there is a data quality issue in UPD product data, please contact the relevant National Competent Authority to correct the information in the UPD.

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



ASU_EMA_Admin_1

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

Logout in:
55m 23s

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

Back

Veterinary Products

Human Products

Package identifier

Authorisation country ▼

Permanent identifier

Procedure number

Active substance

Medicinal product name

ATC/ATCvet code

Target species

Reset

Search

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



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



ASU_EMA_Admin_1

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	600000002217	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	
	SPECIES	COUNTRY	YEAR	PERMANENT_IDENTIFIER	PACKAGE	AUTH_NUM	PROCEDU	REFERENCE_MS	ADDED_A	NAME	FORM(editable)	ASU_PACKSIZE	ASU_PACKSIZE_UNIT	ATC/ATCVI	SCOPE	SUBST_ID#1	SUBSTANCE#1	STRENGTH#1	STRENGTH_UNIT#1	S
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)	

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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	PROCEДУ	REFERENCE_MS	ADDED_A	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	



EUROPEAN MEDICINES AGENCY
UNION PRODUCT DATABASE

ASU_EMA_Admin_1

HomeSearchCreateOPADVNRANotificationsUpload DocumentASU

Logout in:
40m 1s

Upload use dataset

Select year *
2029

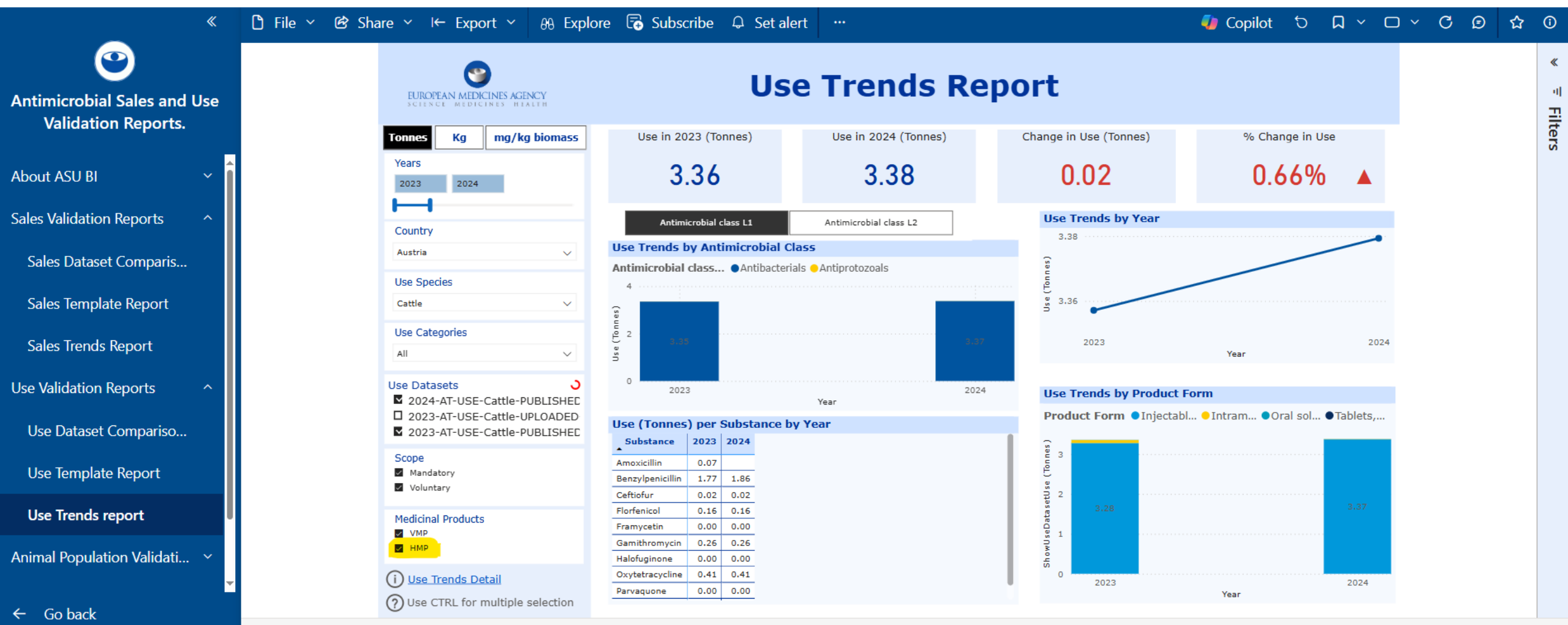
Select country *
Austria

Use Species	File	Status
Cattle	Select File	
Pigs	Select File	
Chickens	Select File	
Turkeys	Select File	
Other poultry	Select File	
Sheep	Select File	
Goats	Select File	

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



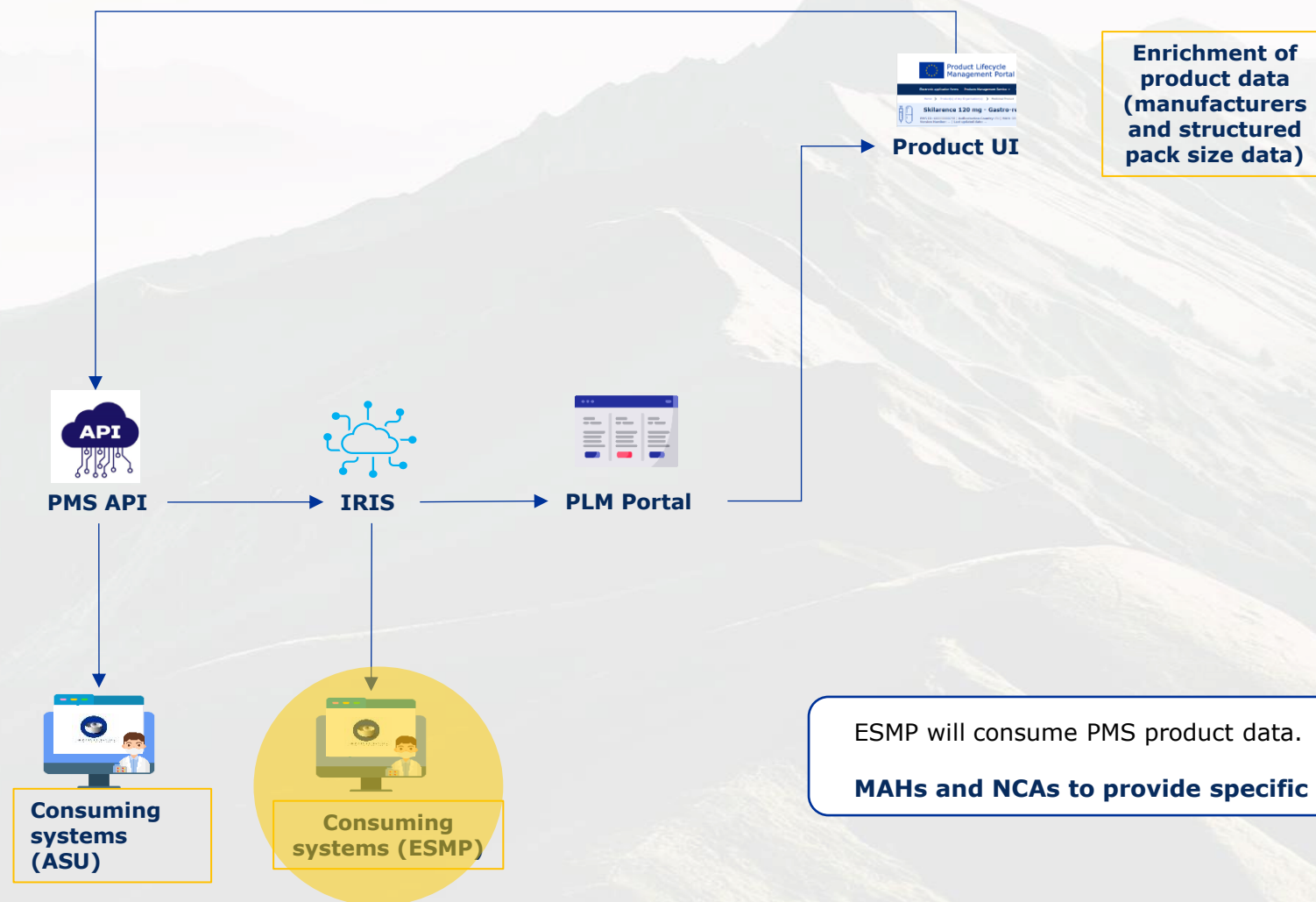
6. NCA user can visualise their data in the ASU Power BI application and see the impact of the use of HMPs on their antimicrobial consumption trends



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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.

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How ESMP uses PMS data

Member State data systems

NCA's 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



Users access ESMP and download reporting templates

ESMP

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

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

Shortage Monitoring & Risk Analysis Tool (ESMP-SMART)



Aggregation, analysis and visualisation



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.

Home

- 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](#)

Home

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 [➤](#)

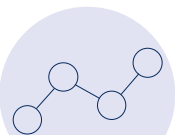
Submit manufacturing information [➤](#)

Submit alternative therapies [➤](#)

Routine reporting

Routine shortage reporting [➤](#)

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**

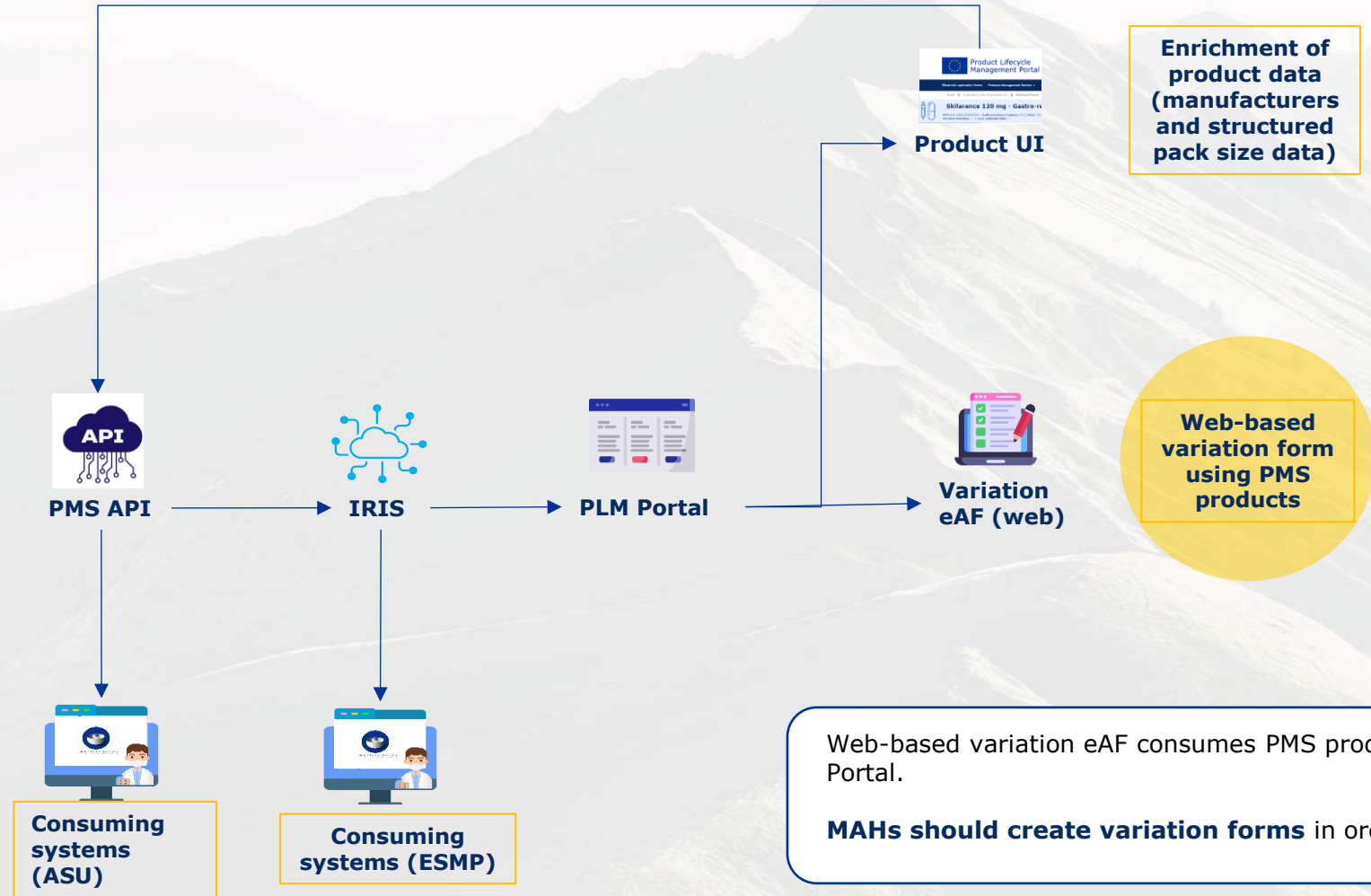
(packs -> mg of active substance)



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

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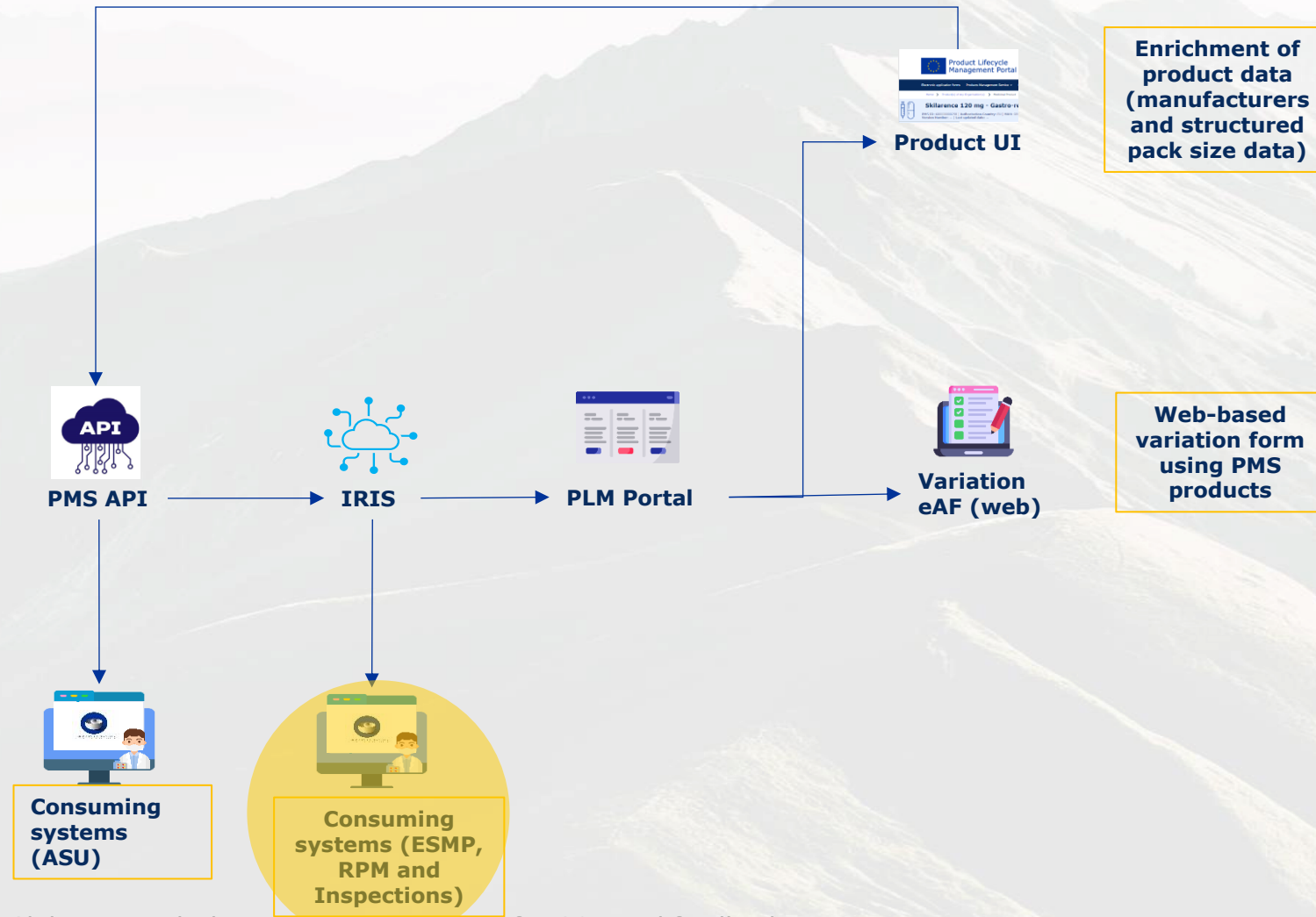
eAF use case – creation & submission of worksharing variation



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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

IL

Id Logistics Iberia S.A. - Saved
Organisation · Organisation ▾

Location Category

LOC-100021140
Location ID

Active Status

ORG-100012365
Organisation ID

▾

Summary

Timelines, emails, notes

Contacts

Products

Manufacturing

Submissions

Cases

Regulatory Entitlements

Admin data

Related ▾

Manufacturing Operations

Active Manufacturing Operations ▾

+ New Manufacturing O...

Add Existing Manufact...

Refresh

Flow ▾

Filter by keyword

☐	Manufacturer ▾	Authorisation Number ↑ ▾	Product (EMA) ↑ ▾	Product name (Product (EMA)) ▾	Operation Type ↑ ▾	Start date ▾	End date ▾	Effective date ▾	Medicines Regulatory A... ▾	Operation Regulated Authorisation P... ▾
☐	Id Logistics Iberia S.A.		PRD/0001728759	Fidaxomicin EMA 50 mg comprimidos	Manufacturer responsible for batch certifi...	05/05/2025		05/05/2025	Spanish Agency Of Medic...	6107775
☐	Id Logistics Iberia S.A.		PRD/0001728760	Cefuroxema EMA 150 mg film-coated tabl...	Manufacturer responsible for batch certifi...	26/03/2020			European Medicines Agen...	

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

Inspections use case – creation of GMP inspection case

The screenshot displays the EMA PMS interface. At the top, a navigation bar includes a back arrow, 'Show As' dropdown, 'Show Chart' icon, a red-outlined '+ Create Case' dropdown, 'Refresh' icon, 'Collaborate' icon, and 'Run Report' dropdown. Below this, the main content area is titled 'IN00 - All Inspections' with a dropdown arrow. A table lists inspection cases with columns for 'Case Title', 'Customer', 'Case Sub...', and 'Inspection Location'. The first row shows 'EMA/IN/00001...' for 'European Medicines Agency' at 'Extendis Pharma'. The second row shows 'EMA/IN/00001...' for 'European Medicines Agency' at 'Id Logistics Iberi'. The third row shows 'EMA/IN/00001...' for 'European Medicines Agency' at 'Laboratorio Este'. The fourth row shows 'EMA/IN/00001...' for 'European Medicines Agency' at 'Teamit Institute'. The fifth row shows 'EMA/IN/00001...' for 'European Medicines Agency' at 'Id Logistics Iberi'. A dropdown menu is open from the '+ Create Case' button, showing categories: 'General' (with '+ Agenda Item'), 'Inspections' (with a red-outlined '+ GMP Inspection'), 'Marketing authorisation' (with '+ Marketing authorisation'), and 'Expamed' (with '+ Expamed'). A tooltip for '+ GMP Inspection' reads 'GMP Inspection' and 'Create a new Case record.'.

Case Title	Customer	Case Sub...	Inspection Location
EMA/IN/00001...	European Medicines Agency		Extendis Pharma
EMA/IN/00001...	European Medicines Agency		Id Logistics Iberi
EMA/IN/00001...	European Medicines Agency		Laboratorio Este
EMA/IN/00001...	European Medicines Agency		Teamit Institute
EMA/IN/00001...	European Medicines Agency		Id Logistics Iberi

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Inspections use case – creation of GMP inspection case

New Case - Unsaved
Case · GMP Inspection ▾

Inspection Details Committee Adoption Inspection Outcome Communication Industry Submissions Meeting

Case Details

Process Type	  GMP Inspection	Case Folder
Inspection Domain	* Look for Product Domain 	
Site Inspected	* Referential Terms	Case Owner
Reporting deadline	*  Human and Veterinary use 100000000014	Case Worker
	 Human use 100000000012	
	 Veterinary use 100000000013	

Inspection details

Procedure Type  [Advanced lookup](#)

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

Inspections use case – creation of GMP inspection case

New Case - Unsaved
Case · GMP Inspection ▾

Inspection Details Committee Adoption Inspection Outcome Communication Industry Submissions

Case Details

Process Type	  <u>GMP Inspection</u>	Case Folder
Inspection Domain	*  <u>Human use</u> × 	
Site Inspected	* <u>LOC-100021140</u> 	Case Owner
Reporting deadline	* Organisations <u>Recent records</u>  Id Logistics Iberia S.A. LOC-100021140   New Organisation  <u>Advanced lookup</u>	Case Worker
Inspection details		
Procedure Type		

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

Inspections use case – creation of GMP inspection case

New Case - Unsaved
Case · GMP Inspection ▾

Inspection Details Committee Adoption Inspection Outcome Communication Industry Submissions

Case Details

Process Type  GMP Inspection Case Folder

Inspection Domain *  Human use × 

Site Inspected *  Id Logistics Iberia S.A. × 

Reporting deadline * --- 

Inspection details

Address 1

Address 2

Address 3

City

State/Province 

May 2026 ↑ ↓

Su	Mo	Tu	We	Th	Fr	Sa
26	27	28	29	30	1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31	1	2	3	4	5	6

2026 ↑ ↓

Jan	Feb	Mar	Apr
May	Jun	Jul	Aug
Sep	Oct	Nov	Dec

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

Inspections use case – creation of GMP inspection case

EMA/IN/0000138941 - Saved
Case · GMP Inspection ▾

Case - Inspections
Active for 6 days

Inspection Details (6 D)

Committee Adoption

Inspection Details Committee Adoption Inspection Outcome Communication Industry Submissions Meetings Messages Related ▾

✓ Contact ↑ ▾ Role ▾ Organisation ▾

No data available.

Associated products

Group By: (no grouping) ▾

✓ Invented name (Prod... ▾	EMA Number (Product) ▾	Domain (Product) ▾	Authorisation status ... ▾	Inspection ... ▾	Removed reason ▾	Customer Purchase Order Number (Submission) ▾
Cefuroxema EMA	EMA/H/C/998877	---	Valid	---	---	---

Product Details

Group By: (no grouping) ▾

✓ Invented name (Product) ▾	Strength (Product) ▾	Pharmaceutical form (Product) ▾	Manufacturing Operation ↑ ▾	Inspection Scope ▾
Cefuroxema EMA	150 mg	Film-coated tablet	Manufacturer responsible for batch cer...	Out of scope

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

Inspections use case – creation of GMP inspection case

Group By: (no grouping) ▾

✓ Invented name (Prod...	EMA Number (Product) ▾	Domain (Product) ▾	Authorisation status ... ▾	Inspection ... ▾	Removed reason ▾	Customer Purchase Order Number (Submission) ▾	SAP Custo... ▾	Removed date ▾	Applicant/MAH/Sponsor ↑ ▾	Active substance(s) (...) ▾	Inspection Scope ▾	Readop: 📄
✓ Cefuroxema E...	EMA/H/C/998877	---	Valid	---	---	---	---	---	Fujisawa S.A.	Cefuroxime	Out of scope ▾	---

Product Details

Group By: (no grouping) ▾

Refresh Flow Run Report Excel Templates

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

Inspections use case – creation of GMP inspection case

EMA/IN/0000138941 - Saved
Case · GMP Inspection

GMP Inspection Process Type --- Case Subject Created Status Reason --- Sub-Status

Case - Inspections Active for 6 days

Inspection Details (6 D) Committee Adoption Inspection Outcome

Inspection Details Committee Adoption Inspection Outcome Communication Industry Submissions Meetings Messages Related

✓ Contact ↑ Role Organisation DOI Status

No data available.

Page 1

Associated products

Refresh Flow Run Report Excel Templates

Group By: (no grouping)

✓ Invented name (Prod...)	EMA Number (Product)	Domain (Product)	Authorisation status ...	Inspection ...	Removed reason	Customer Purchase Order Number (Submission)	SAP Custo...	Removed date	Applicant/MAH/Sponsor ↑	Active substance(s) [...]	Inspection Scope	Rea
Cefuroxema EMA	EMA/H/C/998877	---	Valid	---	---	---	---	---	Fujisawa S.A.	Cefuroxime	In scope	---

Page 1

Product Details

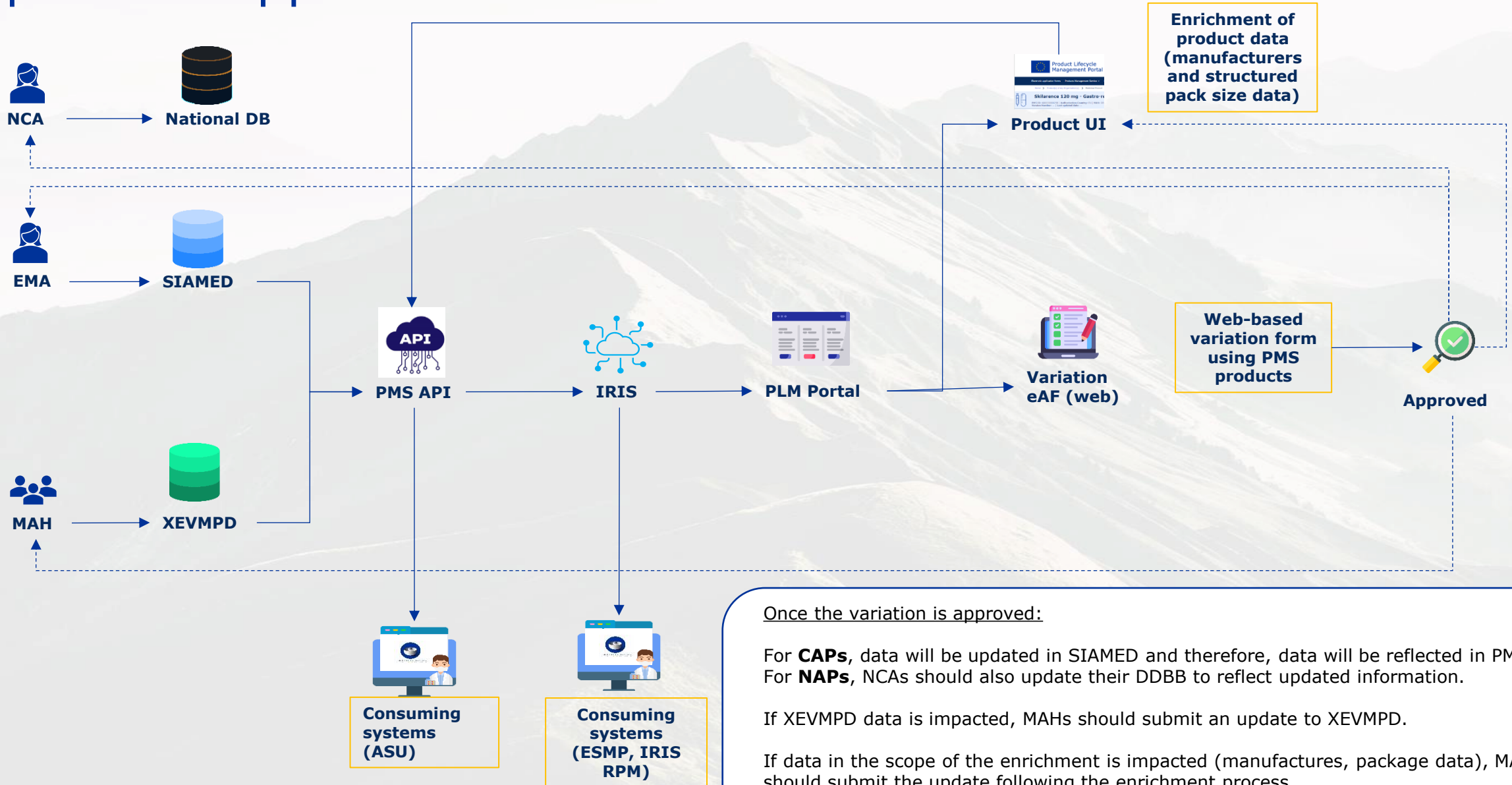
Refresh Flow Run Report Excel Templates

Group By: (no grouping)

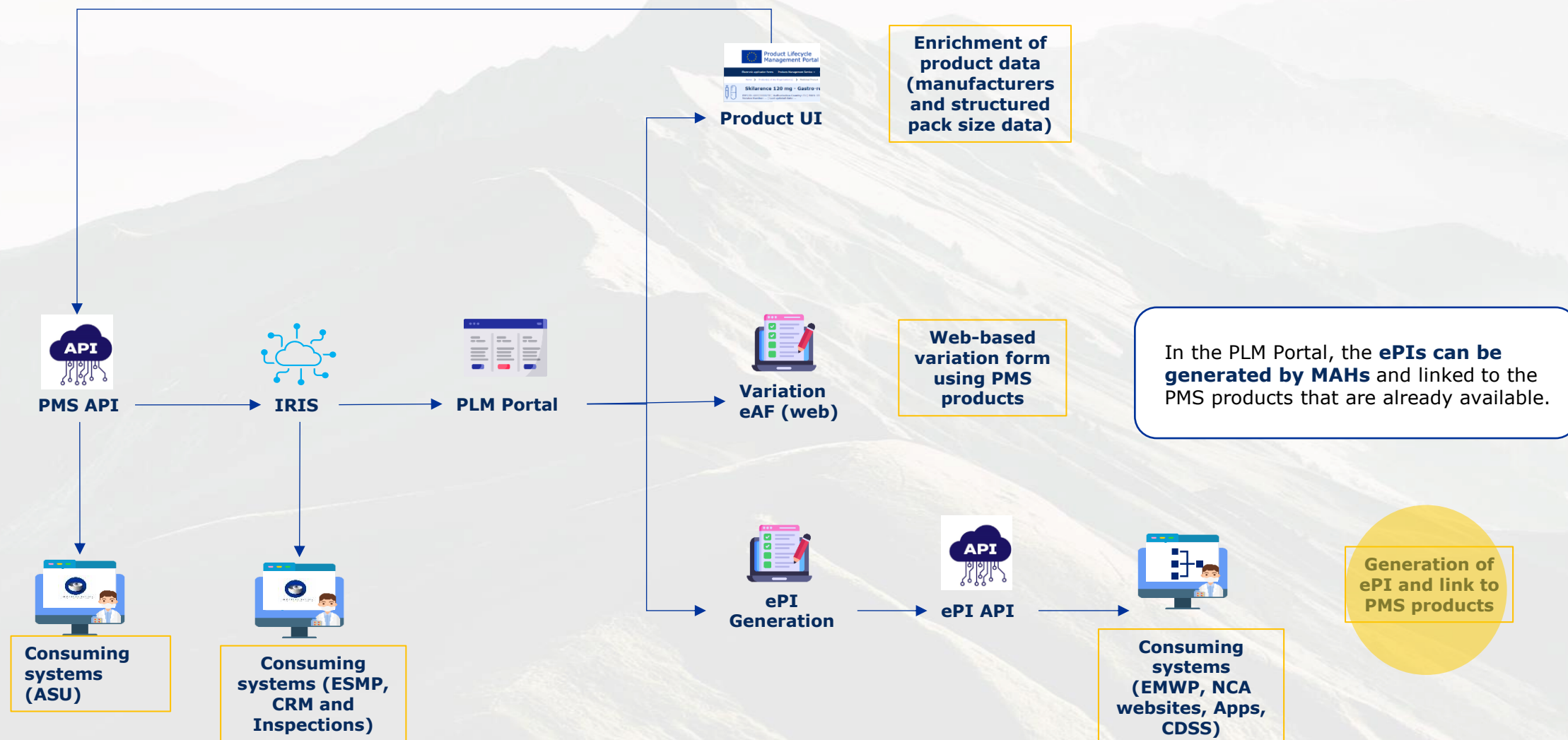
✓ Invented name (Product)	Strength (Product)	Pharmaceutical form (Product)	Manufacturing Operation ↑	Inspection Scope	Active substance in scope for inspection	Notes (at operation level)
Cefuroxema EMA	150 mg	Film-coated tablet	Manufacturer responsible for batch cer...	In scope	---	---

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

Update of approved data



ePI use case – creation and publication of ePI

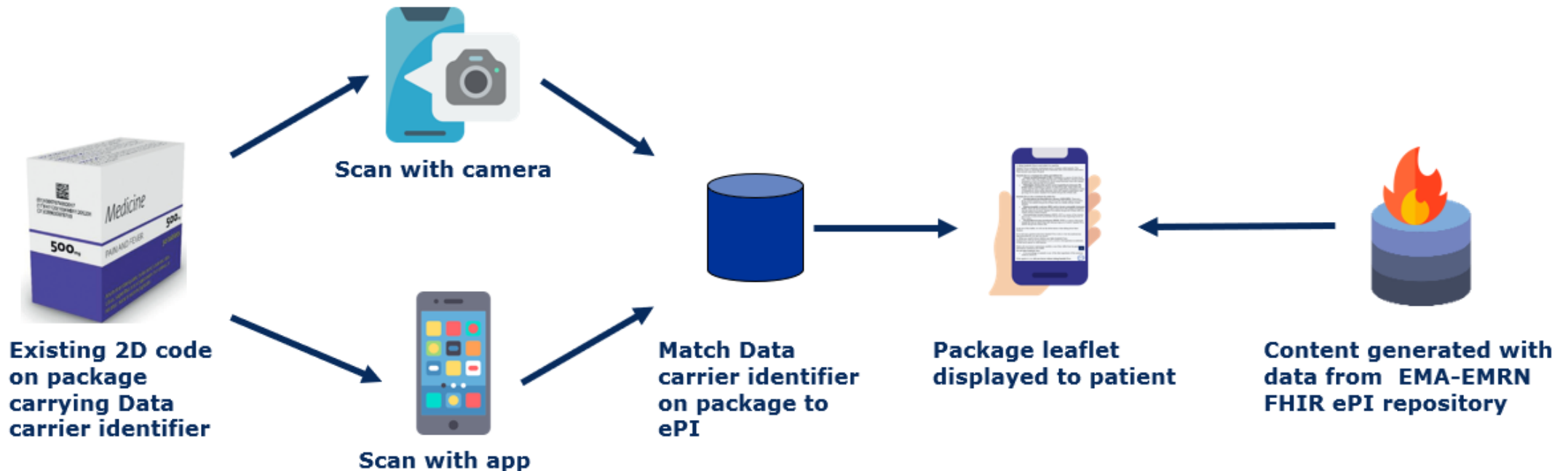


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ePI use case

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

 **Product Lifecycle Management Portal**

eAF ▾ ePI ▾ PMS ▾ SPOR ▾ IAM IRIS Forum |  Elizabeth Scanlan ▾

[Home](#) > [Product\(s\) of my organisation\(s\)](#) > [Packaged Medicinal Product](#)

 **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

< 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	—	PRD11169151	Medicinal product subject to restricted medical prescription	Valid
▾	EU/1/87/6543/002	15 Tablet	—	PRD11169152	Medicinal product subject to restricted medical prescription	Valid

Showing 1 to 2 of 2 entries

[Close](#) [Refresh](#) [Export to XML](#)

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

ePI use case – view from PLM: Product UI

**Product Lifecycle Management Portal**

eAF ▾ ePI ▾ PMS ▾ SPOR ▾ IAM IRIS Forum |  Elizabeth Scanlan ▾

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

**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

< 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	—	PRD11169151	Medicinal product subject to restricted medical prescription	Valid							
Package description Packaging: blister (PVC/alu), Package size: 30 tablets Language — Open all ▼ Pack Size Open ▼ Shelf life / Storage Open ▼ Data carrier identifier(s) Close ▲ <table><thead><tr><th>↑</th><th>Identifier value</th><th>Identifier system</th></tr></thead><tbody><tr><td></td><td>34021057572423</td><td>GS1 Global Trade Item Number</td></tr></tbody></table>								↑	Identifier value	Identifier system		34021057572423	GS1 Global Trade Item Number
↑	Identifier value	Identifier system											
	34021057572423	GS1 Global Trade Item Number											
▼	EU/1/87/6543/002	15 Tablet	—	PRD11169152	Medicinal product subject to restricted medical prescription	Valid							

Showing 1 to 2 of 2 entries

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

ePI use case – view from PLM: ePI



[Home](#) > ePI Portal - ePI List

Electronic product information

+ New ePI

Draft Submission Update **Published** Archived Deactivated All

🔍 Cef ×

EPI ID	Name of medicinal product	Procedure no.	Authorisation type	Reference MAH	Created by	Created on	Modified by	↓ Modified on	Status	Action
EPI/25/6352	Cefuroxema EMA		CAP	Fujisawa S.A.	Libby Scanlan	13/05/2025 02:53 PM	Libby Scanlan	14/05/2025 02:37 PM	Published	▾

Showing 1 to 1 of 1 entries

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ePI use case – view from PLM: ePI

Preview

Cefuroxema EMA

SmPC 150 mg film coated tablets

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

3. PHARMACEUTICAL FORM

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

4.2 Posology and method of administration

Posology

Renal impairment

Hepatic impairment

Method of administration

4.3 Contraindications

4.4 Special warnings and precautions for use

Hypersensitivity reactions

Jarisch-Herxheimer reaction

Overgrowth of non-susceptible microorganisms

Interference with diagnostic tests

4.5 Interaction with other medicinal products and other forms of interaction

4.6 Fertility, pregnancy and lactation

Pregnancy

Breast-feeding

Fertility

4.7 Effects on ability to drive and use machines

4.8 Undesirable effects

Paediatric population

Reporting of suspected adverse reactions

4.9 Overdose

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mechanism of action

Mechanism of resistance

Cefuroxime axetil breakpoints

Microbiological susceptibility

PL 150 mg film coated tablets

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Cefuroxema EMA 150 mg film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

3. PHARMACEUTICAL FORM

150 mg film coated tablets

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Cefuroxema EMA is indicated for the treatment of the infections listed below in adults and children from the

Acute streptococcal tonsillitis and pharyngitis.

Acute bacterial sinusitis.

Acute otitis media.

Acute exacerbations of chronic bronchitis.

Cystitis.

Pyelonephritis.

Uncomplicated skin and soft tissue infections.

Treatment of early Lyme disease.

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

4.2 Posology and method of administration

Posology

The usual course of therapy is seven days (may range from five to ten days).

Table 1. Adults and children (≥40 kg)

Indication	Dosage
Acute tonsillitis and pharyngitis, acute bacterial sinusitis	250 mg twice daily
Acute otitis media	500 mg twice daily
Acute exacerbations of chronic bronchitis	500 mg twice daily
Cystitis	250 mg twice daily
Pyelonephritis	250 mg twice daily
Uncomplicated skin and soft tissue infections	250 mg twice daily
Lyme disease	500 mg twice daily for 14 days (range of 10 to 21 days)

Table 2. Children (<40 kg)

Indication	Dosage
------------	--------

PL 150 mg film coated tablets

PACKAGE LEAFLET

1. What Cefuroxema EMA is and what it is used for

2. What you need to know before you take Cefuroxema EMA

Do not take Cefuroxema EMA

Take special care with Cefuroxema EMA

Warnings and precautions

Other medicines and Cefuroxema EMA

Pregnancy and, breast-feeding and fertility

Driving and using machines

3. How to take Cefuroxema EMA

Use in children

Patients with kidney problems

If you take more Cefuroxema EMA than you should

If you forget to take Cefuroxema EMA

If you stop taking Cefuroxema EMA

4. Possible side effects

Reporting of side effects

5. How to store Cefuroxema EMA

6. Contents of the pack and other information

What Cefuroxema EMA contains

What Cefuroxema EMA looks like and contents of the pack

Marketing Authorisation Holder and Manufacturer

This leaflet was last revised in {MM/YYYY} {month YYYY}.

PACKAGE LEAFLET

Cefuroxema EMA 150 mg film-coated tablets

Cefuroxime

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your doctor or pharmacist or nurse.

This medicine 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.

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Cefuroxema EMA is and what it is used for

2. What you need to know before you take Cefuroxema EMA

3. How to take Cefuroxema EMA

4. Possible side effects

5. How to store Cefuroxema EMA

6. Contents of the pack and other further information

1. What Cefuroxema EMA is and what it is used for

Cefuroxema EMA is an antibiotic used in adults and children. It works by killing bacteria that cause infections. It belongs to a group of medicines called *cephalosporins*.

Cefuroxema EMA is used to treat infections of:

the throat

sinus

middle ear

the lungs or chest

the urinary tract

the skin and soft tissues.

Cefuroxema EMA can also be used:

to treat Lyme disease (an infection spread by parasites called ticks).

2. What you need to know before you take Cefuroxema EMA

Do not take Cefuroxema EMA

If you are allergic (*hypersensitive*) to any **cephalosporin** antibiotics or any of the other ingredients of Cefuroxema EMA.

if you have ever had a severe allergic (hypersensitive) reaction to any other type of betalactam antibiotic (penicillins, monobactams and carbapenems).

If you think this applies to you, **don't take Cefuroxema EMA** until you have checked with your doctor.

Take special care with Cefuroxema EMA

Cefuroxema EMA is **not recommended for children aged under 3 months**, as the safety and effectiveness are not known in this age group.

You must look out for certain symptoms, such as allergic reactions, fungal infections (such as *candida*) and severe diarrhoea (*pseudomembranous colitis*) while you are taking Zinnat. This will reduce the risk of any problems. See 'Conditions you need to look out for' in Section 4.

If you need a blood test

Cefuroxema EMA can affect the results of a test for blood sugar levels, or a blood screen called the *Coombs test*. If you need a blood test:

Tell the person taking the sample that you are taking Cefuroxema EMA.

Warnings and precautions

Other medicines and Cefuroxema EMA

Tell your doctor or pharmacist if you are taking any other medicines, if you've started taking any recently or you start taking new ones. This includes medicines you can obtain without a prescription.

Medicines used to **reduce the amount of acid in your stomach** (e.g. *antacids* used to treat **heartburn**) can affect how Cefuroxema EMA works.

Probenecid

Oral anticoagulants

→ Tell your doctor or pharmacist if you are taking any medicine like this.

Contraceptive pills

Cefuroxema EMA may reduce the effectiveness of the contraceptive pill. If you are taking the contraceptive pill while you are being treated with Cefuroxema EMA you also need to use a **barrier method of contraception** (such as condoms). Ask your doctor for advice.

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

ePI use case – view from PLM: ePI

[Home](#) > View/Manage ePI

Cefuroxema EMA

EPI ID: EPI/25/6352 | Status: Published | Medicine Name: Cefuroxema EMA | Procedure number:

1 Manage ePI ✓ 2 Link product 3 Finalisation

Link product

On this page, you can link ePI documents to the medicinal products in PMS they relate to. Select the document then click 'Add/Remove Link' to search and select products. Links will be added to the default language.

Add/Remove Link

- ☐ SmPC 150 mg film coated tablets ▾
- ☐ Labelling 150 mg film coated tablets ▾

☒ PL 150 mg film coated tablets ^

Full Name		PMS ID
^ Cefuroxema EMA 150 mg film-coated tablets		700000056611
More data for linked product		
MA number	Data carrier identifier system	Data carrier identifier value
EU/1/87/6543/001	GS1 Global Trade Item Number	34021057572423
EU/1/87/6543/002	GS1 Global Trade Item Number	65399138558040

Previous Next Cancel

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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 API definition Changelog

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/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](#).

EMA.EPI.Consuming /api/fhir/BundleBySearchParameter - GET

GET /api/fhir/Bundle

Authorization

Parameters

carrierValue

34021057572423

pms

value

lang

value

+ Add parameter

Headers

Cache-Control

no-cache

+ Add header

HTTP request

HTTP

Reveal secrets Copy

GET https://epi-uat.ema.europa.eu/consuming/api/fhir/Bundle?carrierValue=34021057572423 HTTP/1.1

Cache-Control: no-cache

Send

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ePI use case – view from ePI API

Accessing the API

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[view more detail on the API endpoints](#)

EMA.EPI.Consuming	▼
-------------------	---

EMA.EPI.Consuming

Search operations Group by tag

API definition Changelog

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GET /api/fhir/ListBySearchParameter - GET

GET /api/fhir/RegulatedAuthorizationById - GET

GET /api/fhir/RegulatedAuthorizationBySearchParameter...

/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](#).

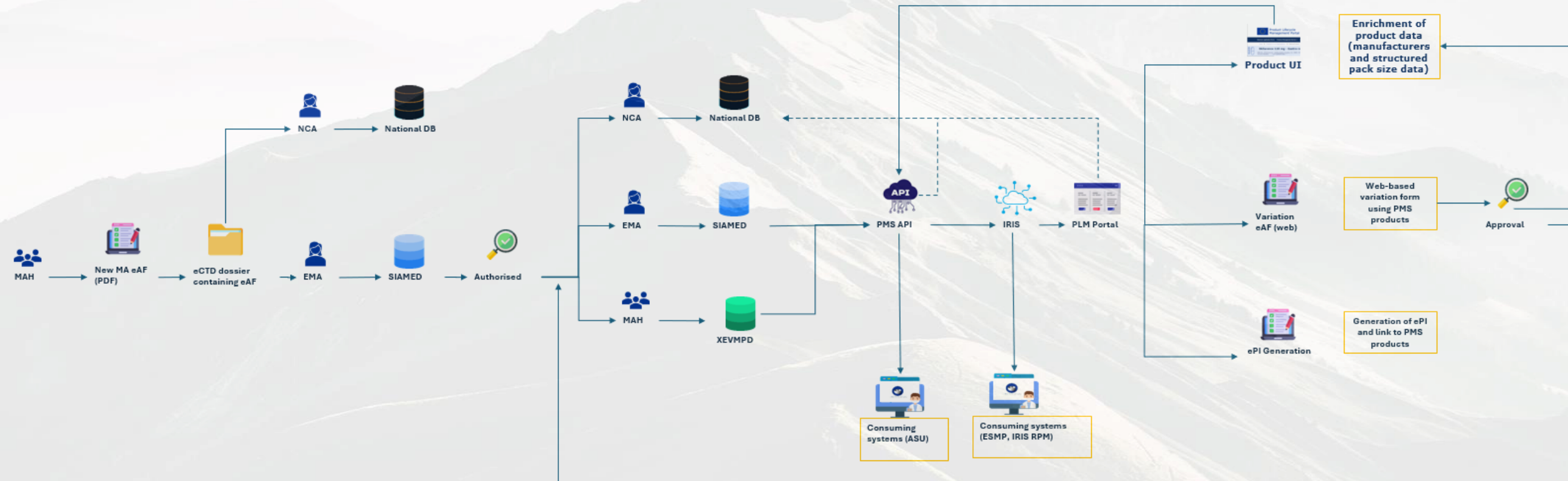
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```

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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



*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 with the code #PMS-INFO-25 for Q&A and feedback



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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