EMA
EUROPEAN MEDICINES AGENCY

Product Management Service Info-Day

21 May 2025

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Welcome

Chairs:

Peter Arlett, *Co-chair of the Network Data Steering Group (NDSG) and Head of Data Analytics and Methods Task Force*

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

Zaide Frias, *Co-chair of Regulatory Optimization Group (ROG), Chair of Portfolio Board (PB) and Head of Digital Business Transformation Task Force*

Hilmar Hamann, *Co-chair of Network ICT Advisory Committee (NICTAC) and Head of Information Management Division*

Alexis Nolte, *PMS Business Sponsor and Head of Human Medicines Division*

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Housekeeping

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

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

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

Join Slido.com using the code #PMS-INFO-25 or scanning the **QR code** here

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

- We will answer **a couple of questions** from **onsite participants**, followed by **a couple from Slido**
- We will **not be answering Slido in written** during the event. Questions raised will be evaluated post-event and organised/distributed via the PMS FAQs accordingly

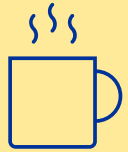
* If you choose to use Slido, you consent to the processing of your personal data as explained in the EMA Data Protection Notice for Webex (europa.eu).

Housekeeping for on-site participants

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

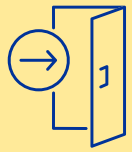
Join the Network **'Guest Wi-Fi'**

Password: W!rel3ss@3m@!2022



Coffee break will be set up at the **Industry Lounge** (located on the ground floor)

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



If you are an **Industry representative** and need to **leave the room**, please reach out to the **reception staff** outside. They will accompany you to your destination

Lunch for **Industry representatives** will be at the Industry lounge, while **Network participants** will be able to also access the canteen

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

What do we want to achieve today?

Today’s Info-Day aims at…

Shape the future of PMS

Enable stakeholders to engage directly with senior leaders and opinion setters on the future of PMS and its role in the Network strategy

Explore the Digital user journey

Showcase EMRN digital transformation and the end-to-end user journey for a seamless interaction with product data across the different EMRN solutions

Enable PMS success

Knowledge sharing and alignment towards a successful EU implementation of PMS

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Agenda

1. **Welcome and opening remarks**
   9:00 – 9:20

2. **Session 1: PMS a strategic Network data asset**
   9:20 – 10:20

Coffee break (*20 min*)

3. **Session 2: From strategy to reality – PMS in the Network Portfolio**
   10:40 – 12:00

Lunch (*60 min*)

4. **Session 3: From data to value – How product data flows across processes/systems**
   13:00 – 15:00

Coffee break (*20 min*)

5. **Session 4: PMS, our shared journey**
   15:20 – 17:00

6. **Conclusions and closing remarks**
   17:00 – 17:20

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Opening remarks

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Opening Remarks

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Co-chair of the Network Data Steering Group (NDSG) and Head of Data Analytics and Methods Task Force

Hilmar Hamann
Co-chair of Network ICT Advisory Committee (NICTAC) and Head of Information Division

Speakers:

Emer Cooke
Executive Director of the European Medicines Agency

Karl Broich
Co-chair of the Network Data Steering Group (NDSG) and Executive Director of the Federal Institute for Drugs and Medical Devices (BfArM)

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Opening Remarks

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Alexis Nolte
PMS Business Sponsor and Head of Human Medicines Division

Session 1: PMS a strategic Network data asset

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

Speakers:

Aimad Torqui
Member of Network Portfolio Advisory Group (NPAG), Network Data Steering Group (NDSG) and Regulatory Optimization Group (ROG)

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

Pelle Persson
Member of Network ICT Advisory Committee (NICTAC) and Network Data Steering Group (NDSG)

Jerome De Barros
European Commission representative (DG SANTE)

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Speakers:

Aimad Torqui
Member of Network Portfolio Advisory Group (NPAG), Network Data Steering Group (NDSG) and Regulatory Optimization Group (ROG)

Topic:

The European medicines agencies network strategy 2028

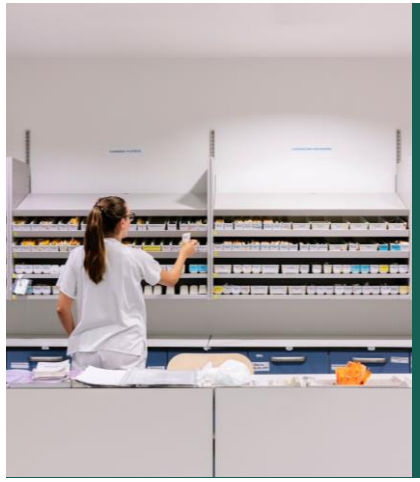
EMANS to 2028
Strategic Focus Areas (themes)

Theme 1: Accessibility

Theme 2: Leveraging data, digitalisation and artificial intelligence

Theme 3: Regulatory science, innovation and competitiveness

Theme 4: Antimicrobial resistance and other health threats



Theme 5: Availability and supply

Theme 6: Sustainability of the network

[The European medicines agencies network strategy 2028]

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HMA Heads of Medicines Agencies EMA

EMANS 2028
Driving digital transformation and sustainability

Theme 2
Leveraging data, digitalisation and AI

- Data driven network
- Experimentation / innovation
- Technology modernization and cybersecurity

Theme 6
Sustainability of the network

- Capabilities
- Shared operating model
- Technology modernization and pharma legislation

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Product vision, main objectives and benefits

Product Management Service (PMS) will make available, for human and machine interaction, **structured, standardised and consistent human authorised medicinal product data** from across the European Medicines Regulatory Network. PMS data will be used by regulators and industry in **regulatory and non-regulatory procedures** as well for the general benefit of European citizens.

Objectives	**Shared centralized repository of human medicinal product information** (for CAPs and non-CAP) accessible via a dedicated **interfaces**	**Harmonised set of rules**/ messaging standards/ technology to exchange human medicinal product data	**ISO IDMP-compatible** product data available for both CAPs and non-CAPs
Benefits	Avoidance of data inconsistencies, easier retrieval & exchange of data	Easier reuse of data by different stakeholders and streamlined regulatory processes	Standardised, trustworthy, high-quality and consistent product data

Objectives of theme 2: Leveraging data, digitalisation and artificial intelligence

Goal 2.1 (data for decision making)

2.1.1: **Embed the use of EU healthcare data** from diverse populations in the network's processes, including in support of the EHDS implementation, and pilot the use of novel types of data (e.g. synthetic data, patient experience data or data for personalised medicine, e.g. genomic data)

2.1.2: Ensure a **high level of interoperability** (including through the use of master data), **standardisation and quality of data**, addressing potential biases and ethical considerations, and ensure that the network data assets are appropriately managed

"Shared Source of Truth" *

PMS API | **eAF** | **Product UI**

Goal 2.1 (digitalisation, experimentation and innovation)

2.2.1 **Reinforce the network's digital infrastructure in line with the Network Portfolio Vision to drive the digital transformation of the network's scientific and regulatory processes**

Information Security

Legacy Modernisation*

2.2.2: Foster a culture of **continuous experimentation and innovation** across the network

Data Analytics & AI | **ePI**

Goal 2.3 (artificial intelligence)

2.3.1: **Leverage experimentation and technological advances in AI** to support the digital business transformation of the EU network

Data Analytics & AI

2.3.2: Harness the potential of **AI throughout the medicines' lifecycle**

** – also Theme 6*

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Speakers:

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

Topic:

EMRN Data Strategy and Network Data Steering Group (NDSG) Workplan

From Vision to Implementation

Business Strategy → **Data strategy** → **Data Planning** → **Implementation**

[The European medicines agencies network strategy 2028]

EMANS 2028

Provides long term direction for **business** areas.

[Draft-EMRN Data Strategy_public_consultation November 2024]

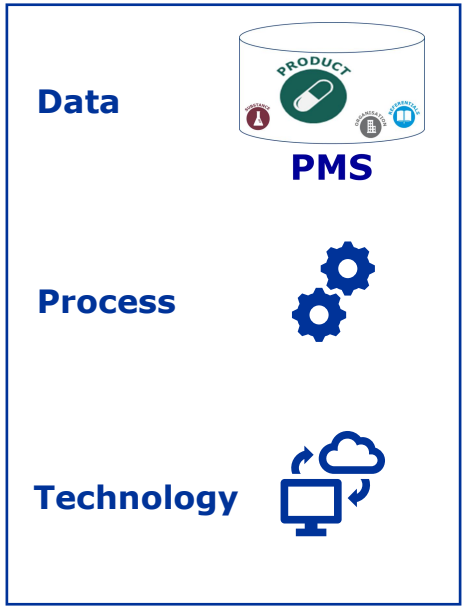
EMRN Data Strategy

Aligns uses of data with business priorities.

[Network Data Steering Group workplan 'Data and AI in medicines regulation to 2028']

NDSG Workplan

Ensures Data Management improvements align with expected business value.



Building blocks and processes

Ensures Data is managed in line with expected business needs.

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

Problems addressed by the Data Strategy

- **Data not findable, accessible nor reusable**
  What data do we have? Where is it? What standards apply? Who owns the data? Who can access? Who can I ask for data? Is this data the same as that data?
- **Data quality monitoring & fix not systematic/ standardised**
  How should data quality be monitored? Who should monitor? Who is responsible for fixing it? What is adequate data quality?
- **Roles, responsibilities & definitions in data management vary and are not formalised**
  Who works on what data? Who is responsible for what? What does a data owner do? What does "data asset" mean?
- **Difficulties to solve issues on data matters between systems**
  Who should be addressed? Who can decide - when, where and how? How can it be fixed?
- **Different working standards & structures, unclear processes**
  What working agreements apply? How can we understand the process?
- **Manual processing/ use of data is time-consuming, risk for errors, inconsistent outcomes**

Draft-EMRN Data Strategy_public_consultation November 2024

We can do better on Efficiency, transparency, collaboration, problem-solving, service and decision-making by **leveraging good local practices**

The EMRN is not fully realising public / animal health or business benefit from data – **better data governance is part of the solution**

SPOR PMS plays an important role in achieving the goals!

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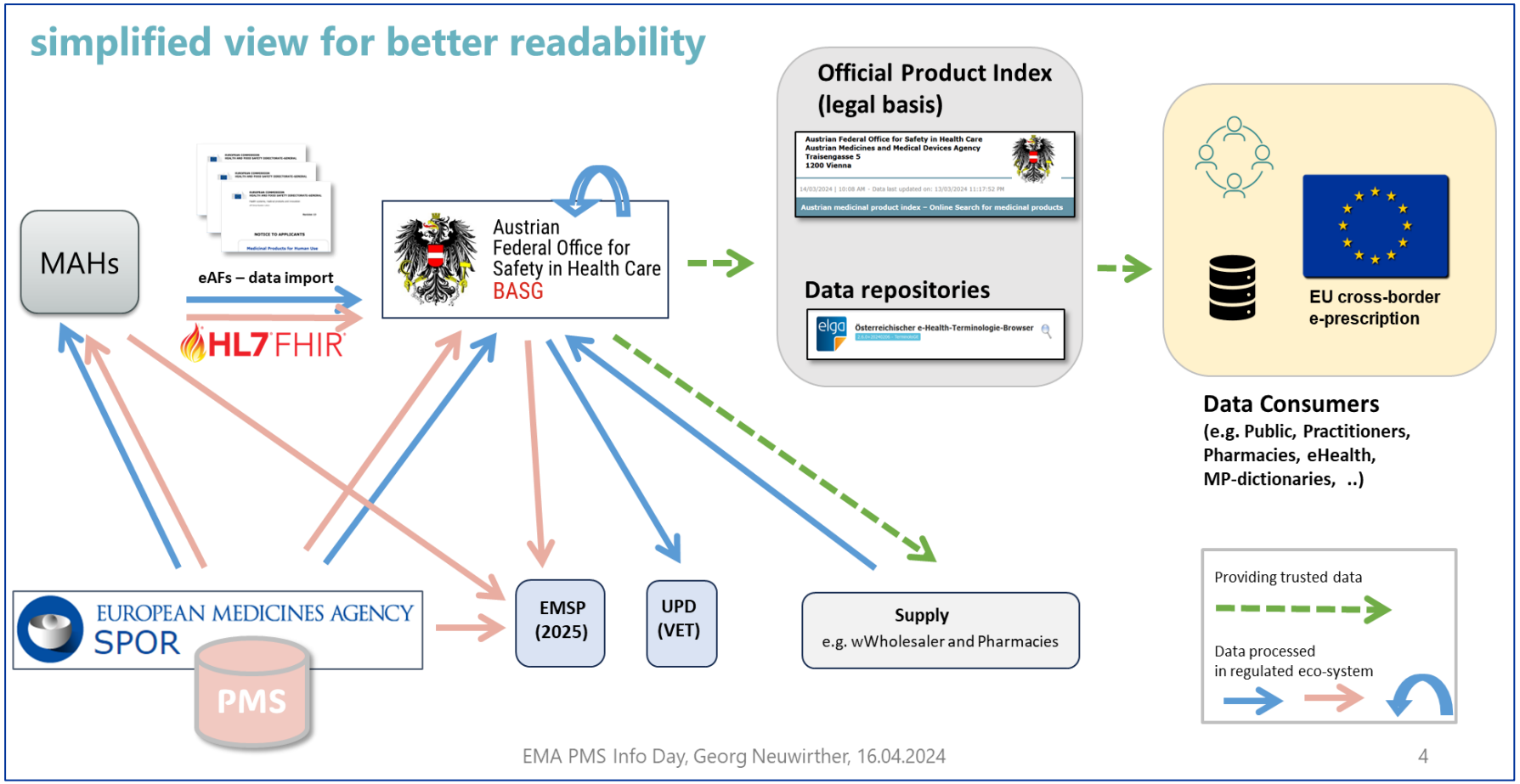
Need for alignment and interoperability



- The flow of data/information in the EU Network is **complex**
- Through SPOR/ PMS, we are **embedding common standards and master data into the daily work** of regulators across the network and facilitating efficient communication with industry.

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Product Master Data Management

Opportunities

A shared data repository for all Medicinal products

as a trusted data source for regulatory activities and data-driven processes in the EMRN (like ESMP)

PMS

Challenges

- How to achieve and maintain the expected data quality level?
  - *e.g. At moment data feeding via XEVMPD, therefore not supporting data consistency across the EMRN*
  - *e.g. "regulators systems, PMS and industry system's data might differ …"*
- How to implement efficient business and technical processes?

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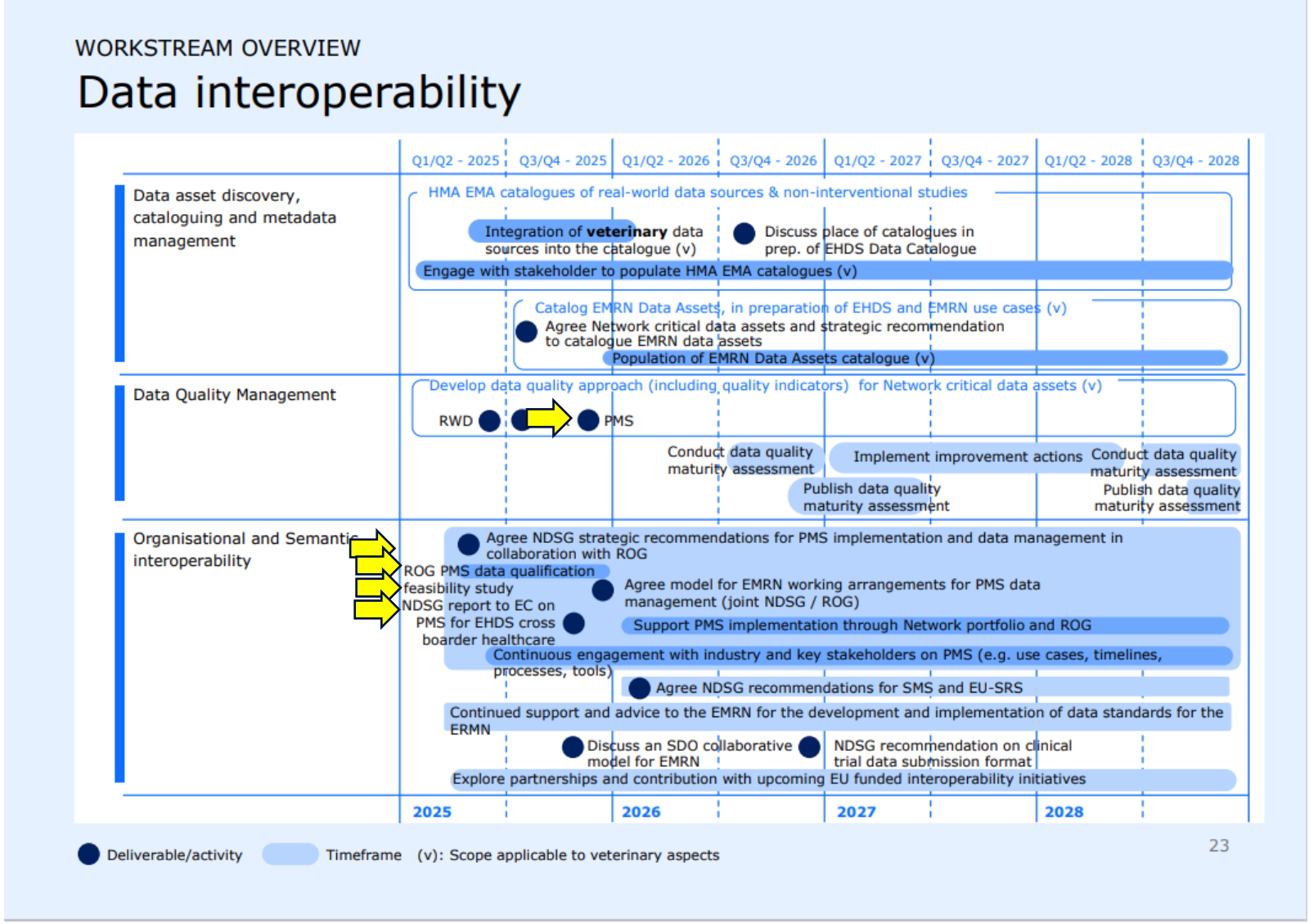
How managing master data is reflected in the NDSG workplan?



Key activities and milestones

- NDSG strategic recommendations for PMS implementation and data management in collaboration with ROG – Adopted by NDSG in April, presented to HMA and MB in May
- ROG PMS data qualification feasibility study – From June to December
- Agree model for EMRN working arrangements for PMS data management (joint NDSG/ROG) - December 2025
- PMS Data quality approach – December 2025

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Speakers:

Pelle Persson
Member of Network ICT Advisory Committee (NICTAC) and Network Data Steering Group (NDSG)

Topic:

PMS and interoperability, a joint effort on all levels

PMS: A strategic European asset

PMS: a shared trusted source of information

- Enables EMANS 2028 and Data Strategy objectives
- Foundation for interoperability, regulatory efficiency
- Trusted shared source for both regulators and external stakeholders

Network opportunities

- Harmonising national exchange formats
- Cross border – from bi-national to European wide through EHDS
- PMS as source for richer, higher-quality patient information - ePI

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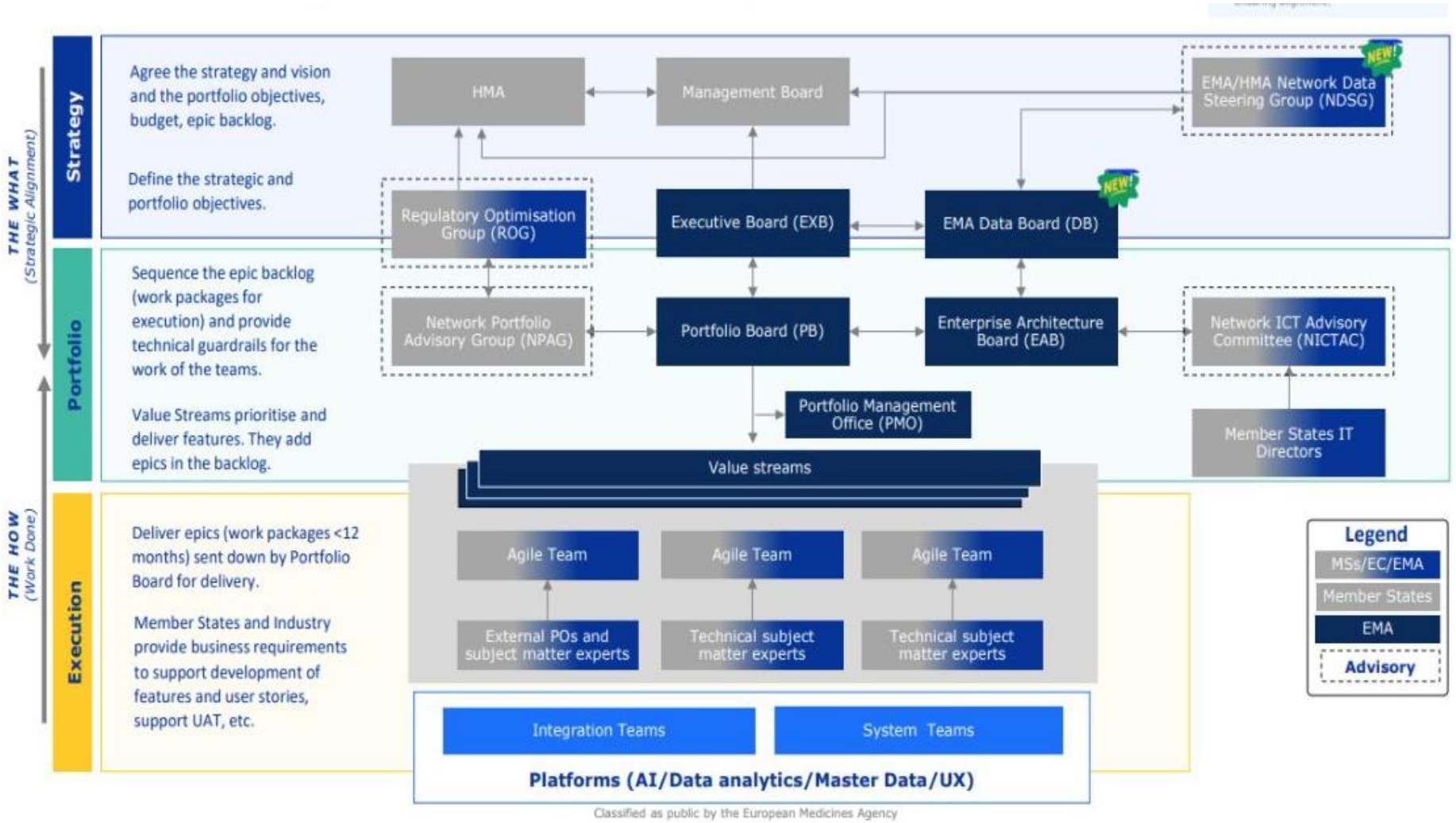
Network Portfolio Governance



- **Network portfolio is supported by multiple groups who contribute at different levels and from different perspectives**:
  - *NDSG > data flows, data management*
  - *ROG > operating models, business process*
  - *NICTAC > interoperability*
  - *Agile delivery > prioritisation, implementation*

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Make it happen – PMS and interoperability enablers

PMS and interoperability it delivers is a joint effort on all levels

- **PMS in the Network portfolio**
- **NDSG workplan**
- **NICTAC workplan**
- **HMA initiative – joint collaboration**
- **NCA activities**

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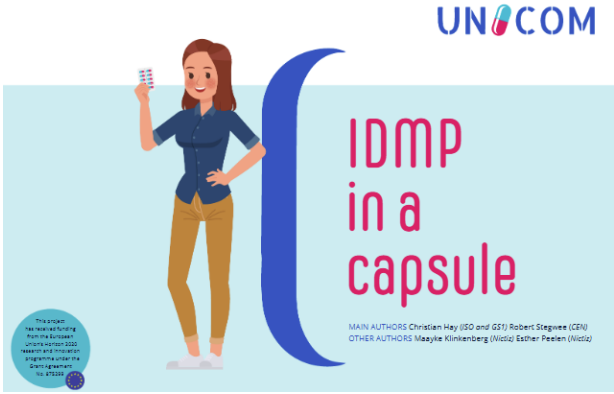
HMA IDMP Community of Experts (CoE)

- HMA established of an **IDMP Community of Experts (CoE**)
  - Include experts from EMA and all willing NCAs: to strengthen the ongoing IDMP implementation at regulator level
  - Lead: SE (Pelle Persson, Christer Backman) and AT (Georg Neuwirther)

- **Keep up momentum and teamwork**, build on the positive collaboration in UNICOM
- in close collaboration with EMA initiatives by
  - Supporting knowledge sharing
  - Providing overview of IMDP status at NCA level
  - Enhancing Data harmonisation
- Regular liaison with NDSG, HMA, ROG



Supporting network activities

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Speakers:

Jerome De Barros
European Commission representative (DG SANTE)

Topic:

European Health Data Space (EHDS)

European Health Data Space (EHDS) in a Nutshell – what is it about?

1 Primary use = use of data for the delivery of healthcare

- Improving patients' access to their health data;
- Ensuring seamless exchanges for continuity of healthcare.

2 Requirements for electronic health record (EHR) systems

- Creating a single market for electronic health records systems, supporting both primary and secondary use.

3 Secondary use = use of data for research and public interest purposes

- Making data available for research, policy-making etc. in a safe and secure way.

See https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32025R0327.

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What are we talking about?

Primary use

- Patient summary
- e-Prescription
- Dispensation
- Medical images
- Medical test results
- Discharge reports

EHR systems

- compliance & interoperability

Secondary use

- Exchange of data

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Value of a trusted EU wide product data source for EHDS

A trusted EU-wide product data source:

is essential for ePrescription and eDispensation because it:

- ✓Ensures **accurate identification of medicines** across countries.
- ✓Supports **cross-border interoperability**, enabling prescriptions from one country to be correctly interpreted and dispensed in another.
- ✓Improves **patient safety** by reducing medication errors.
- ✓Streamlines **workflows** for pharmacies and healthcare providers.

It enables safer, smoother, and more consistent digital prescribing and dispensing across the EU.

adds key value to secondary use of health data in the EHDS by:

- ✓ Ensuring **data consistency and quality** across countries.
- ✓ Enabling **accurate links between treatments and outcomes**.
- ✓ Supporting **cross-border research and public health comparisons**.
- ✓ Enhancing **public health surveillance** and early safety signal detection.
- ✓ Informing **evidence-based policy and regulation** at EU level.

It ensures that research and public interest uses of health data are reliable, comparable, and impactful across the EU.

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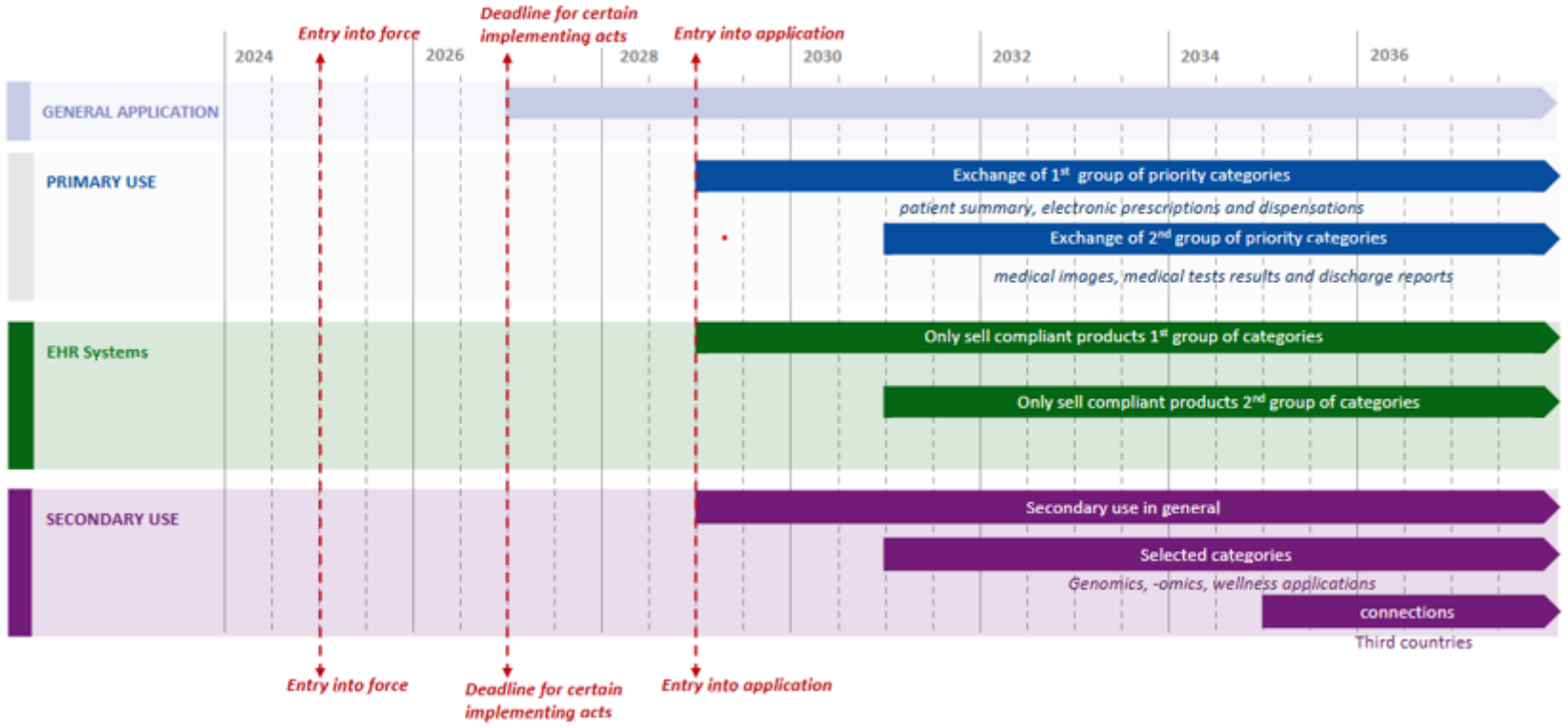
EHDS – Overall timeline for application



Key milestones

- 2025: EHDS entry into force
- **2027: Implementing acts published** (expected to based on existing eHealth ePrescription/eDispensation guideline)
- **2029: entry into application - all in place for Presc/eDisp** and most secondary use
- 2031: entry into application - advanced set of categories

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Panel Discussion

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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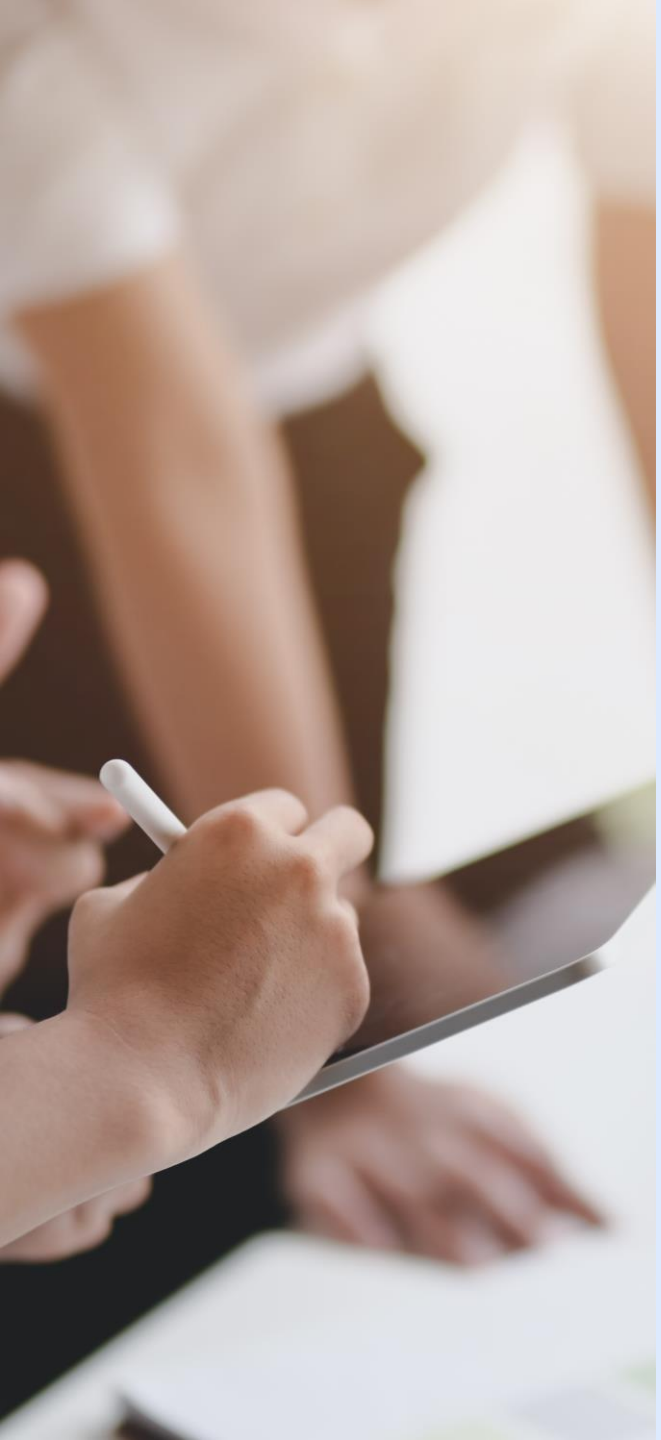

Your feedback matters

- 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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Session 2: From strategy to reality – PMS in the Network Portfolio

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Pelle Persson
Member of Network ICT Advisory Committee (NICTAC) and Network Data Steering Group (NDSG)

Speakers:

Steven Le Meur
R&D Value Stream Owner

Anne-Marie Van NederKassel
PLM Value Stream Owner

Pedro Pina Ferreira
MON Value Stream Owner

Isabel Chicharo
PMS Epic Owner and Head of Regulatory Data Management

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Speakers:

Steven Le Meur
R&D Value Stream Owner

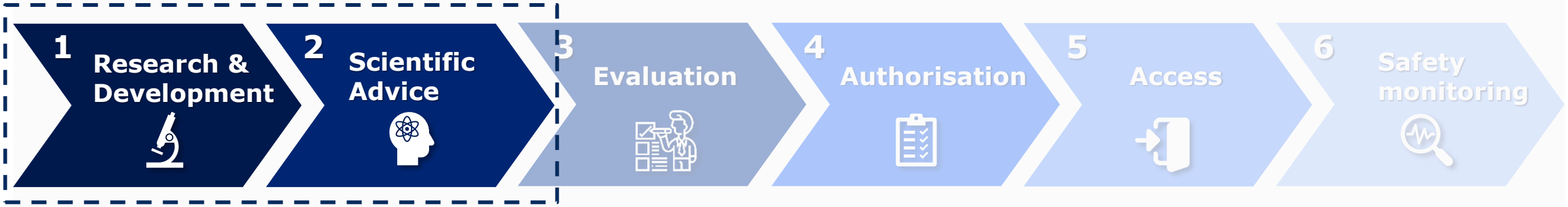
Topic:

PMS in the Research & Development value stream

Managing the medicinal product lifecycle

Integrating data and technology, the R&D value stream enables the development of medicines through efficient processes and generation of scientific evidence for the benefit of public and animal health in the EU.

Lifecycle of a medicinal product



Research & Development value stream

Product Lifecycle Management value stream (PLM value stream)

Monitoring value stream

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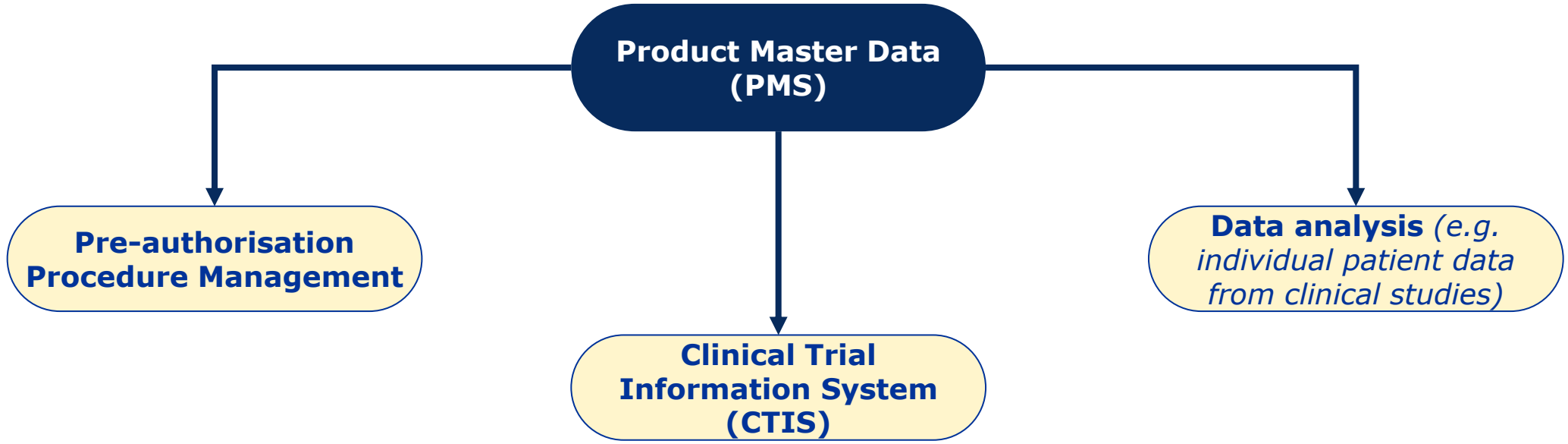
PMS in the R&D value stream

"Integrating data and technology, the R&D value stream enables the development of medicines through efficient processes and generation of scientific evidence for the benefit of public and animal health in the EU."



PMS-supported R&D value stream solution

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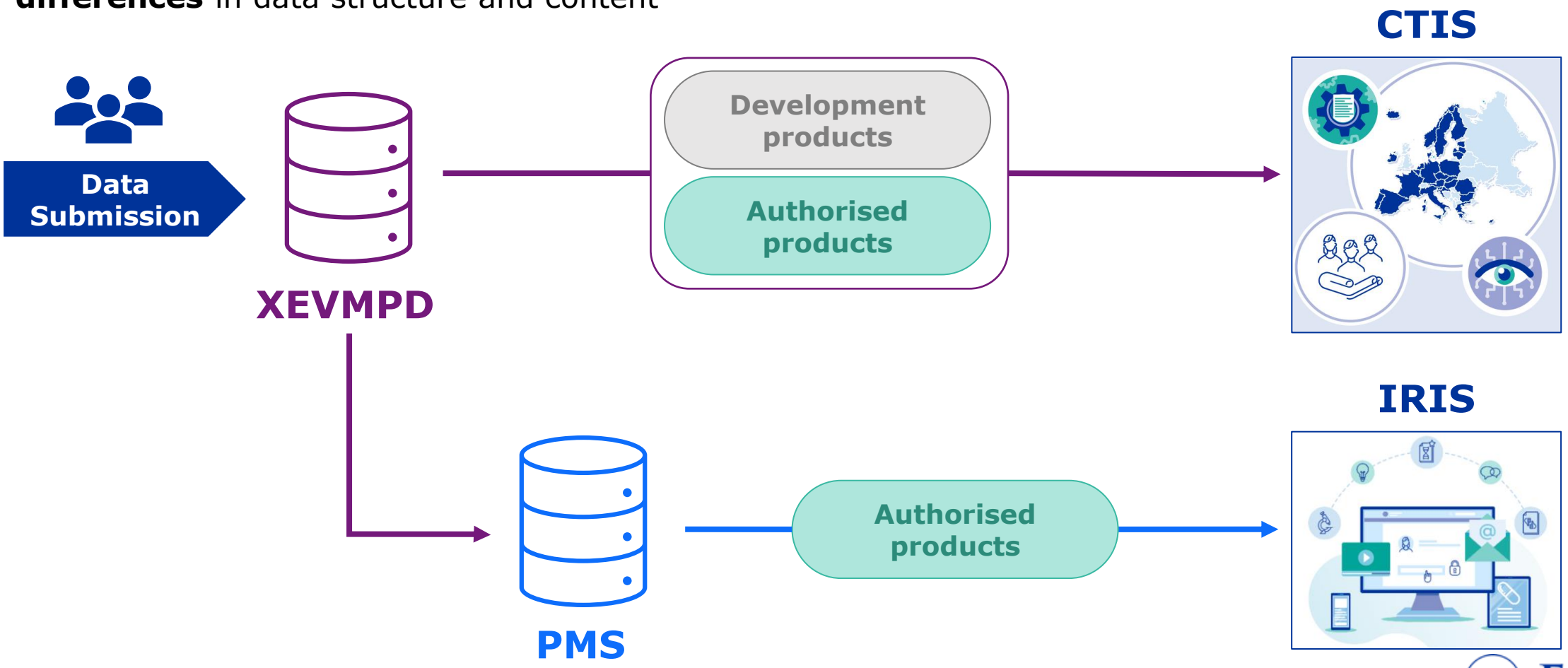
As-is situation and challenges

- **2 repositories** of medicinal product information
- **differences** in data structure and content



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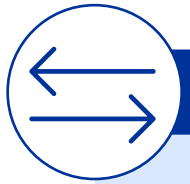
Key benefits of replacing XEVMPD with PMS

Improved Product Lifecycle Management

Management of the lifecycle of medicinal products, from development to commercialisation, in one system to facilitate regulatory, safety, and clinical trial management activities.



Enhanced interoperability

Benefits from the ISO IDMP (Identification of Medicinal Products) data standard, facilitating cross-border data exchange

Advanced reporting and analytics

Allows stakeholders (e.g. regulatory authorities, sponsors, MAHs, manufacturers) to track updates on a medicinal product more efficiently *(including regulatory status, safety monitoring and adverse event reporting, clinical trial results, …)*

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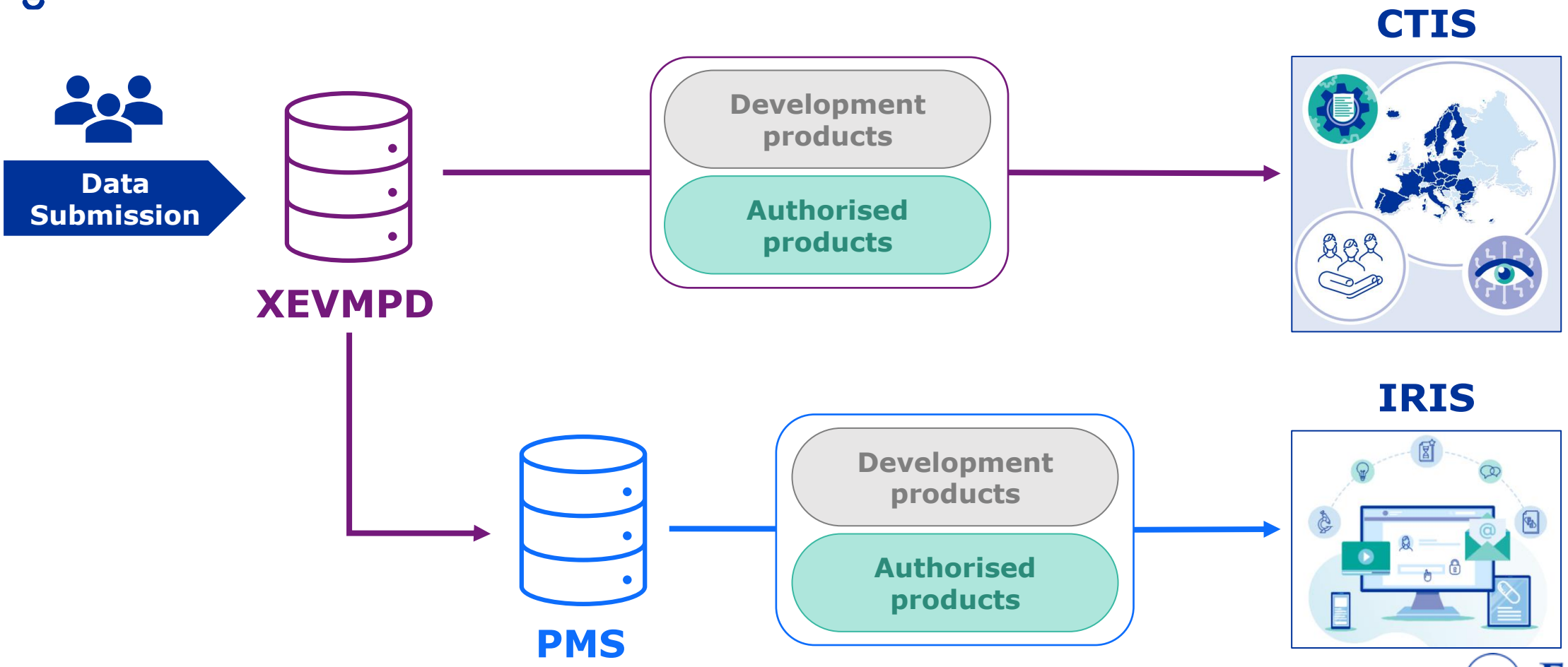
To-be situation and opportunities (1)

Key change → Migrate the **human development product information to PMS**, i.e. both development and authorised medicinal products now available in PMS



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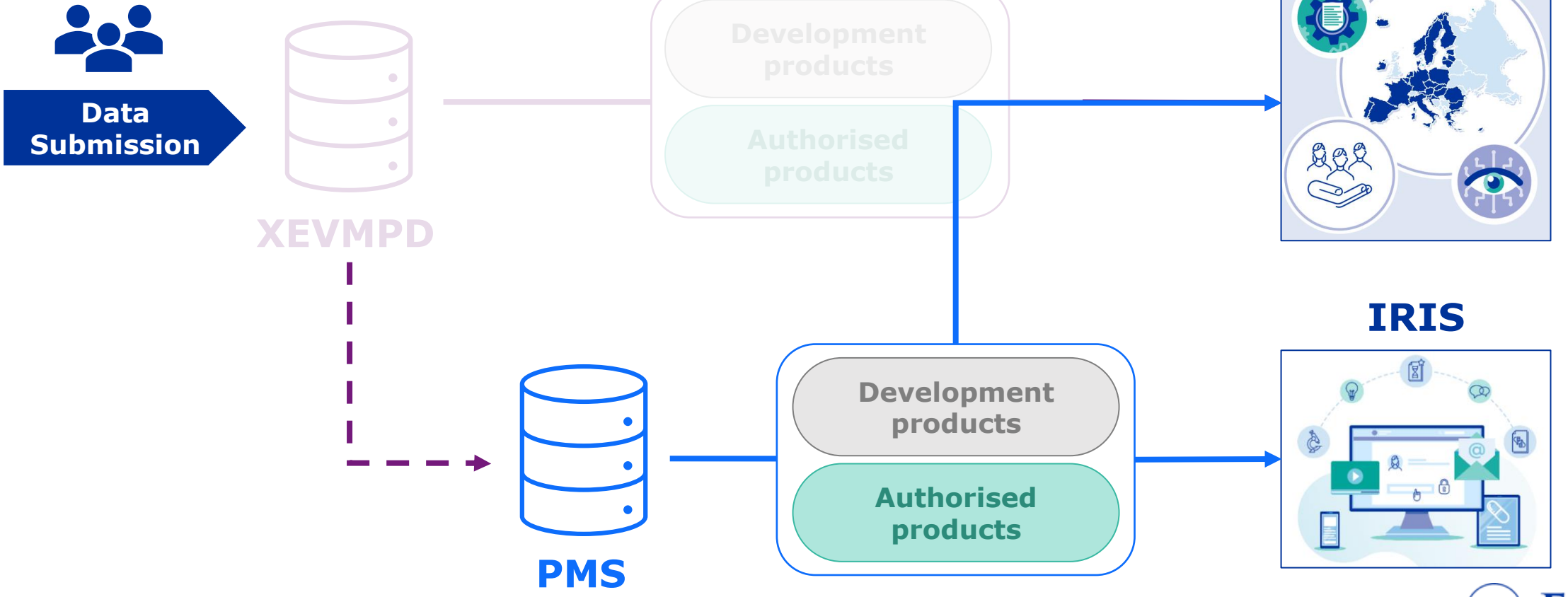
To-be situation and opportunities (2)

Key change →

- Remove dependency on XEVMPD
- Repoint consuming systems to PMS



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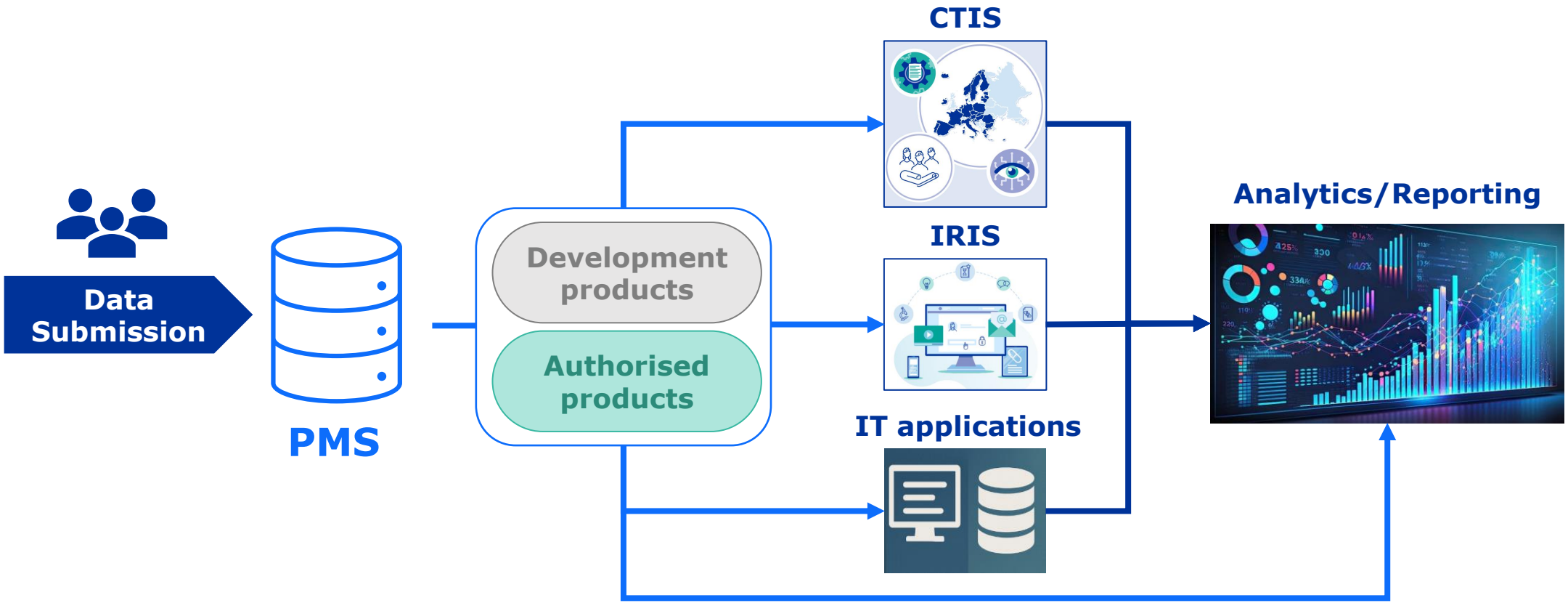
To-be situation → Benefits

- Submission of development and authorised medicinal product information in PMS only
- Consuming systems are all connected to PMS (master data)
- Develop and integrate analytics capabilities



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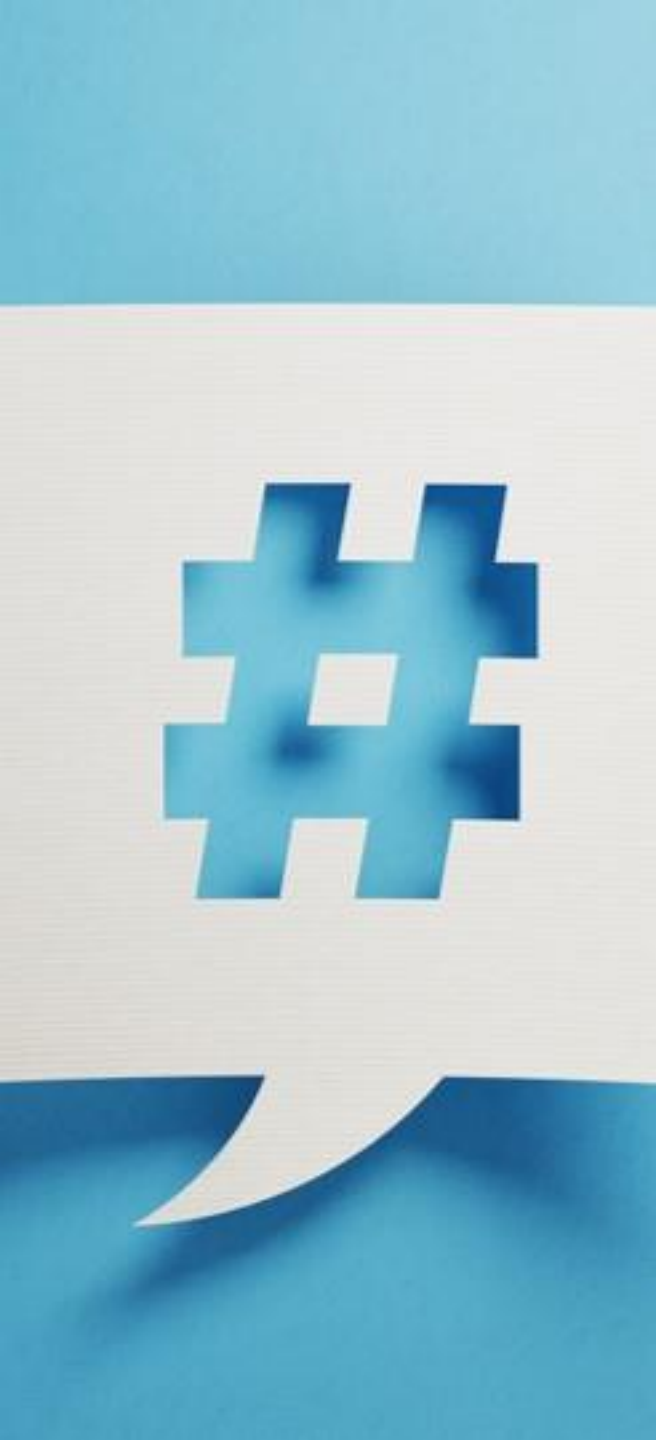

Key takeaways & conclusions

1. **Unique and shared repository** of trusted product master data for all human medicinal products in the EU throughout their life cycle (development and authorised)

2. Management of **human medicinal product information in only one system** – i.e. PMS - provides significant benefits: data submission, data quality and data management **based on the ISO IDMP standard**

3. Availability of both development and authorised medicinal product information in PMS will **streamline the regulatory and product lifecycle management**, benefiting all stakeholders

4. **Better data analytics / reporting capabilities** to generate insights across systems

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EMA

EMA
EUROPEAN MEDICINES AGENCY

Speakers:

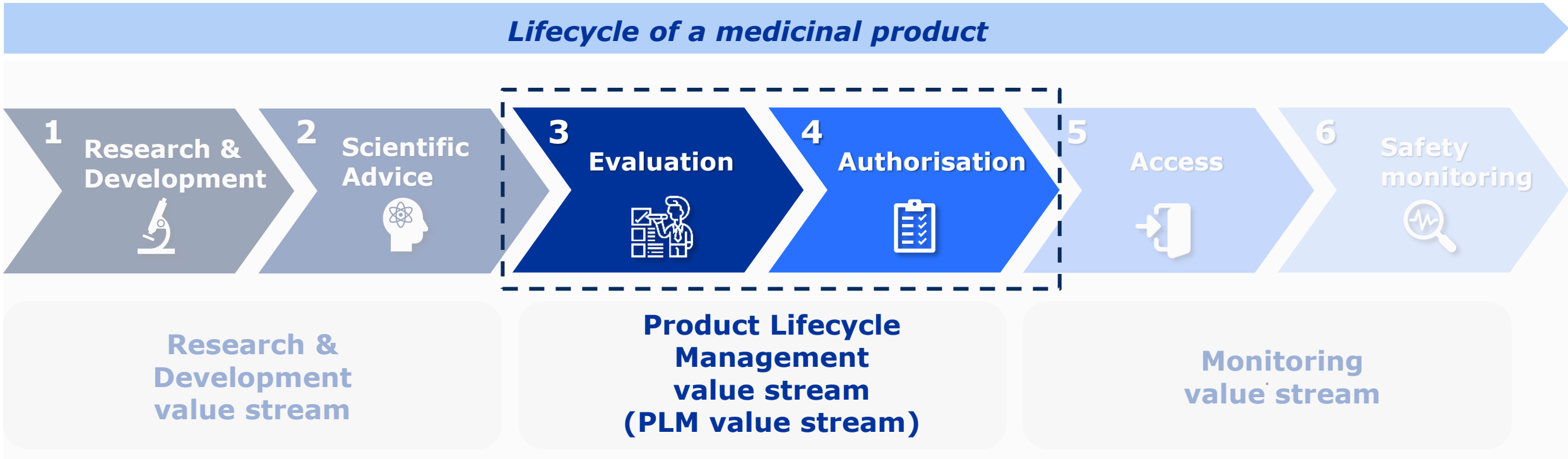
Anne-Marie van Nederkassel
PLM Value Stream Owner

Topic:

PMS in the Product Lifecycle Management value stream

Managing the medicinal product lifecycle

*Empower stakeholders with the **best possible digital tools and data** to enable efficient, data-driven management of the medicinal Product Lifecycle, and to exchange product data and product information for the benefit of public and animal health in the EU.*



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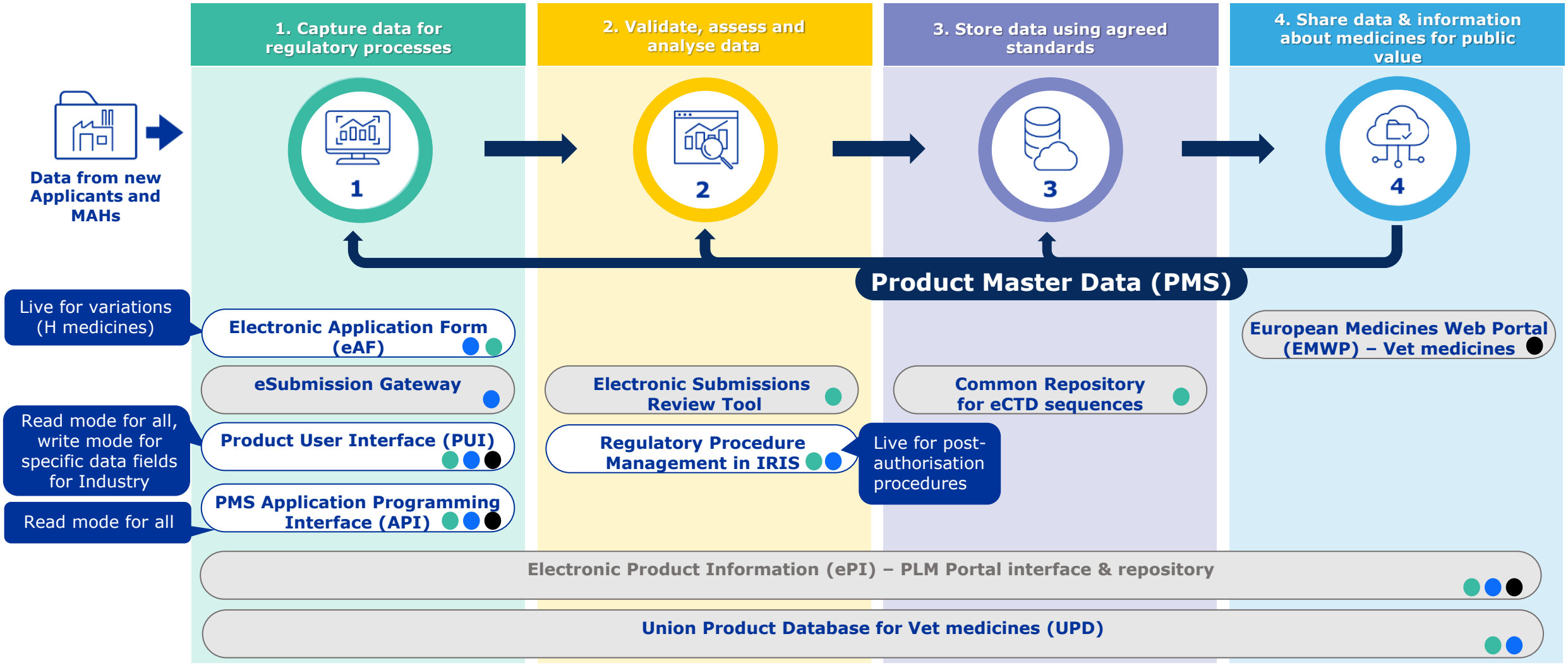
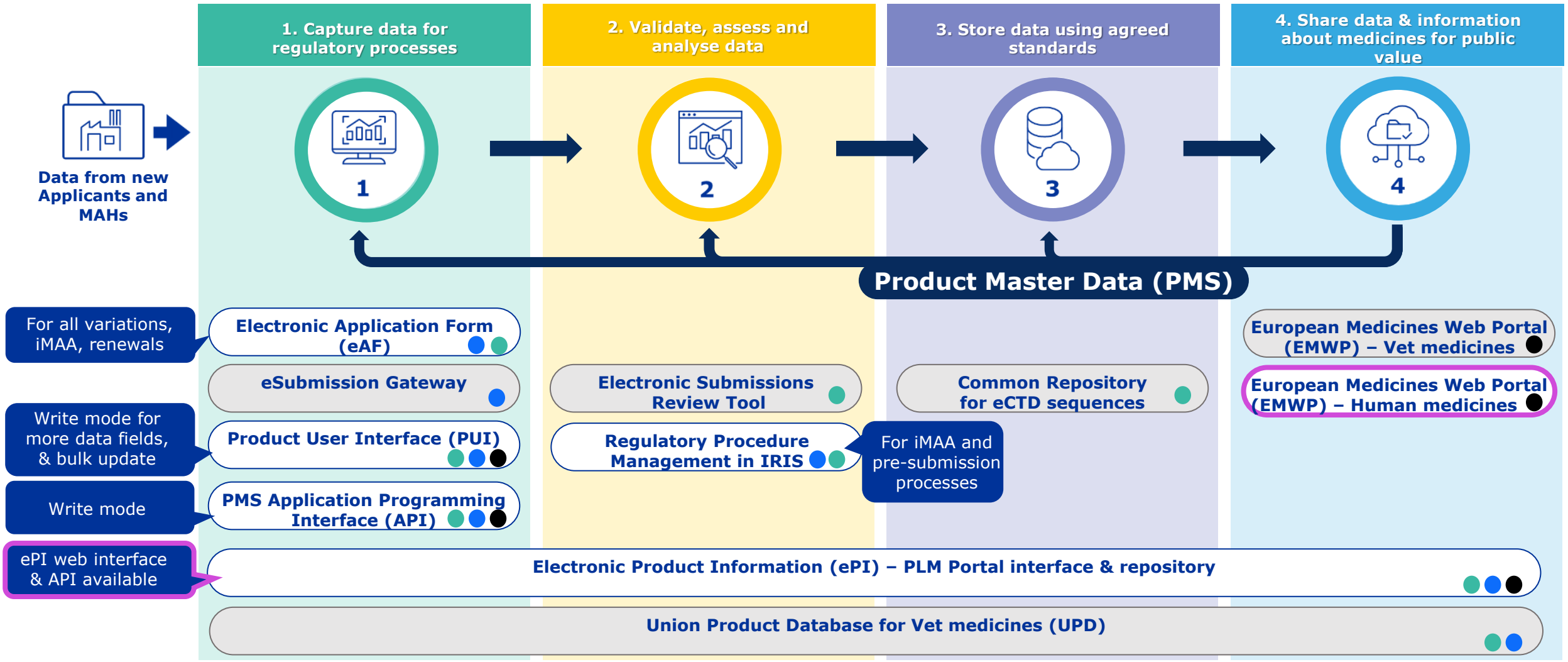
Delivering value through integrated data journey – 2025 status



Delivering value through integrated data journey – Future aspirations



Solution status

Live – Consuming PMS product master data

Live - Not consuming PMS product master data

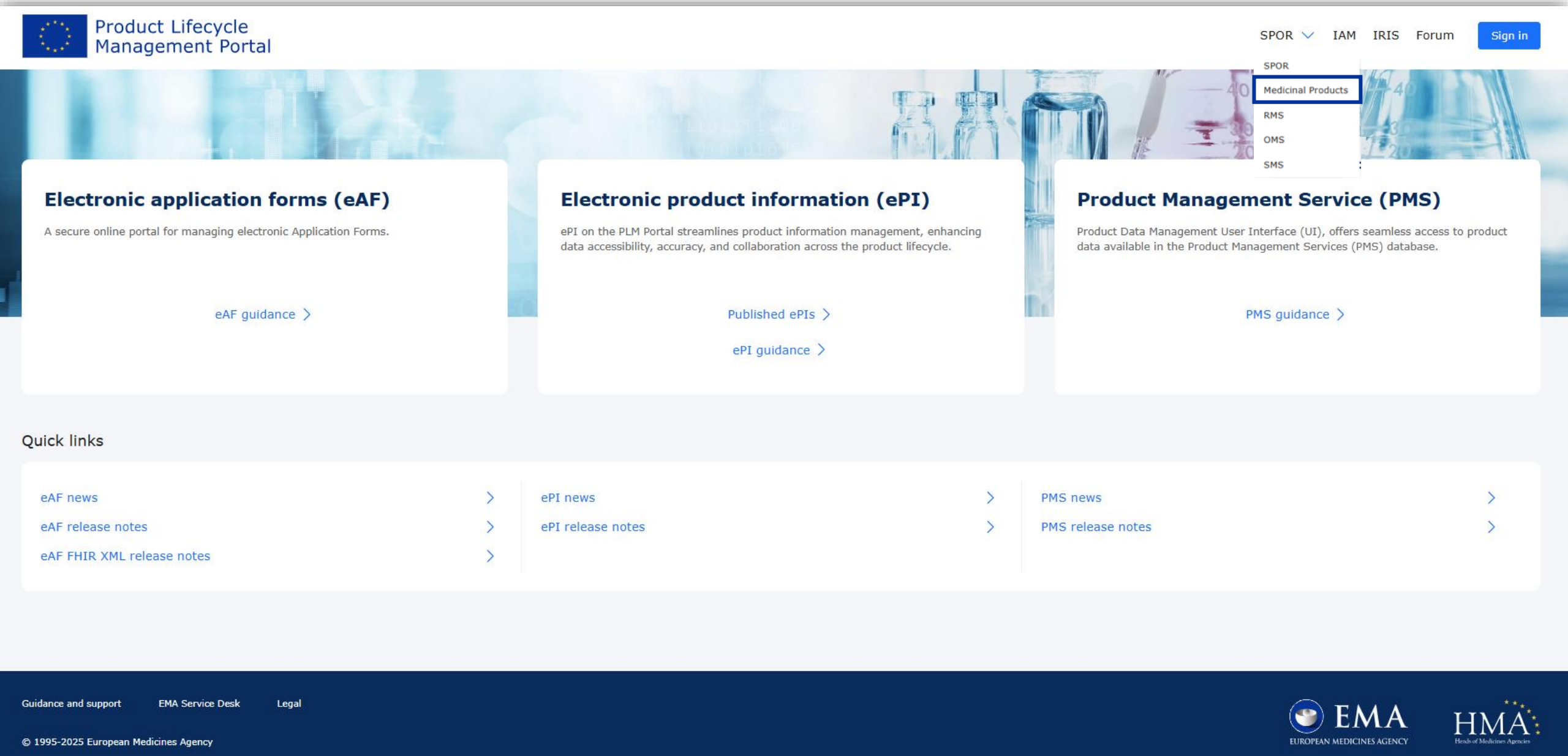
Target users

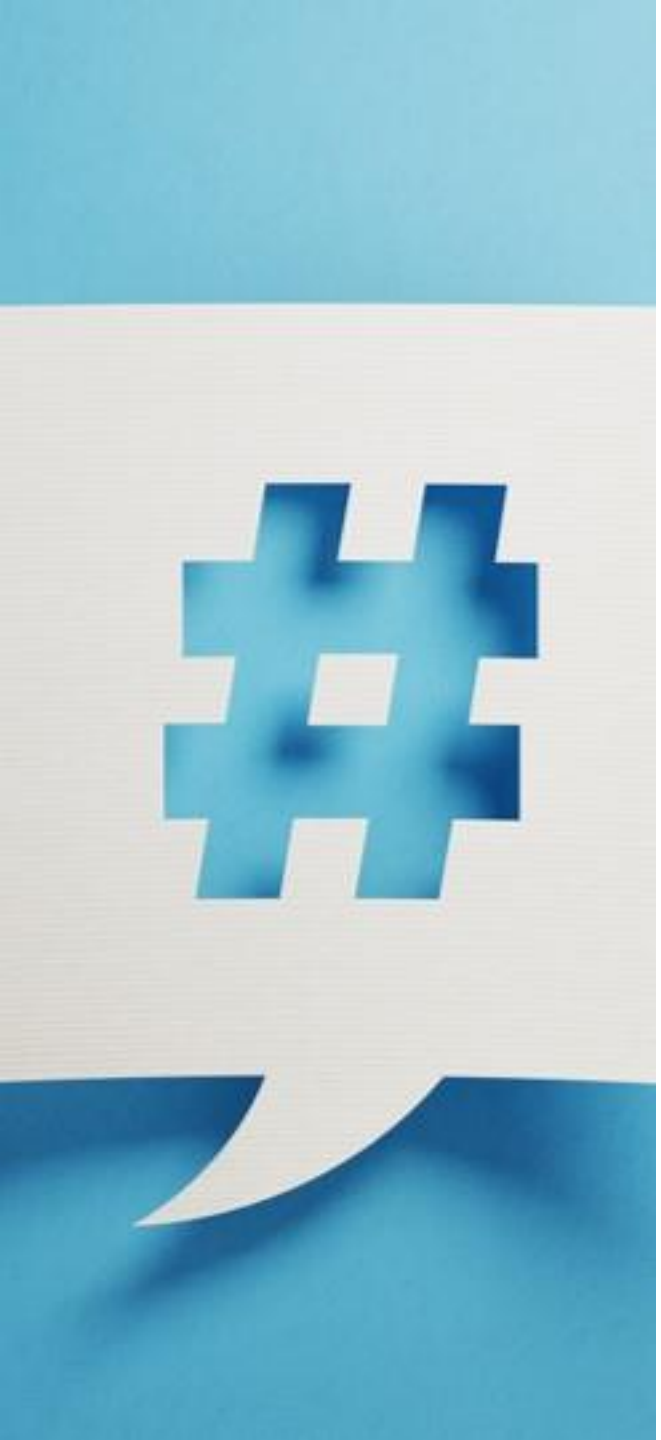
EMA and NCA

Industry

Public

PLM portal: web user interface to capture structured product data





Key takeaways & conclusions

1. PMS enables a **data-driven**, **efficient and digitally connected** way to manage the medicinal product lifecycle.

2. **Great achievements for PMS in 2024-2025**
   - PMS contains CAPs and non-CAPs structured product data for H medicines.
   - NCA and Industry have access to PMS through API and Product UI.

3. **Further PMS development** needed to realise more value:
   - Data quality
   - Enrichment of data fields
   - Processes to keep PMS up-to-date at all times with validated data.

4. **Millions of PMS beneficiaries**, directly or indirectly: regulators, industry and patients!

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EMA

EMA
EUROPEAN MEDICINES AGENCY

Speakers:

Pedro Pina Ferreira
MON Value Stream Owner

Topic:

PMS in the Monitoring value stream

Managing the medicinal product lifecycle

Empowering stakeholders with optimal data and tools to assess and monitor availability, safety and quality of medicines **to achieve higher standards of public and animal health protection in the EU**

Lifecycle of a medicinal product

1 Research & Development

2 Scientific Advice

3 Evaluation

4 Authorisation

5 Access

6 Safety monitoring

Research & Development value stream

Product Lifecycle Management value stream (PLM value stream)

Monitoring value stream

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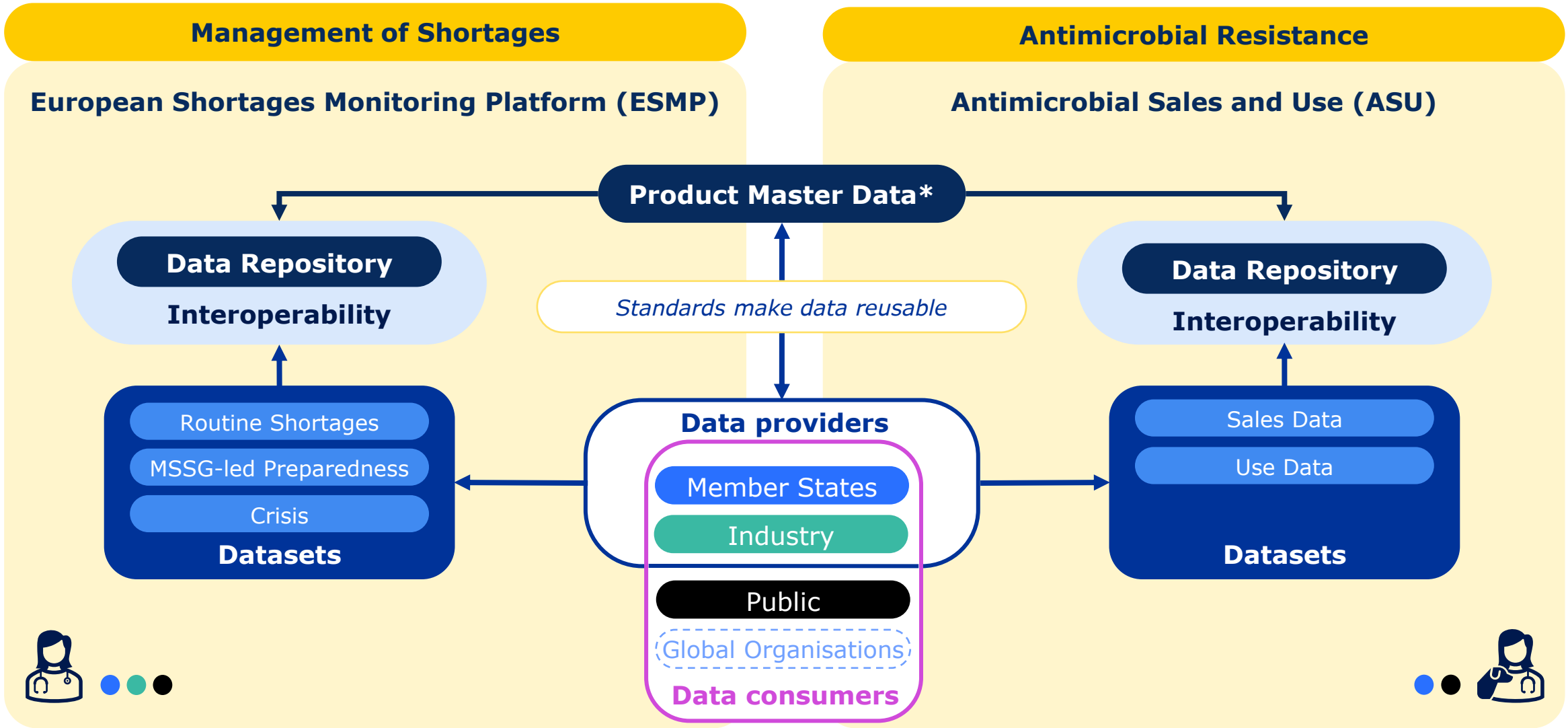
Master data is king on EU platforms



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**Product master Data is sourced from PMS and UPD*

Future

EMA

Numbers enabled by interoperable data

Sustainable business practices and transparency

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(1) Data reflects the status at the end of April 2025
(2) 2023 data collected during last year's data call

EMA

Data is a shared investment

Multiple stakeholders can provide value

The Power of Product Master Data Identifiers

Data Standardisation	Data Exchange	Data Globalisation
Product Dictionary	Information	Collaboration

ESMP

- EU coordination for faster actions
- Increase predictability during PHE/ME
- Mitigate the impact of shortages on patients
- Improve crisis preparedness

→ **Patients have their medicines** when they need them

ASU

- Promote appropriate antimicrobial use
- Implement targeted actions and measures
- Review AMR EU and national action plans

→ **Increased awareness** of animal antimicrobial consumption in the EU

Investment (*)

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(*) Data Enrichment, Data Mapping, Data Quality

Unlocking the value of data for patients

Aim for an impactful Return On Investment (ROI)

The Power of Product Master Data Identifiers

Data Standardisation	Data Exchange	Data Globalisation
Product Dictionary	Information	Collaboration

Benefits

- ESMP: **Patients have their medicines** when they need them
- ASU: **Increased awareness** of animal antimicrobial consumption in the EU

Investment =

ROI

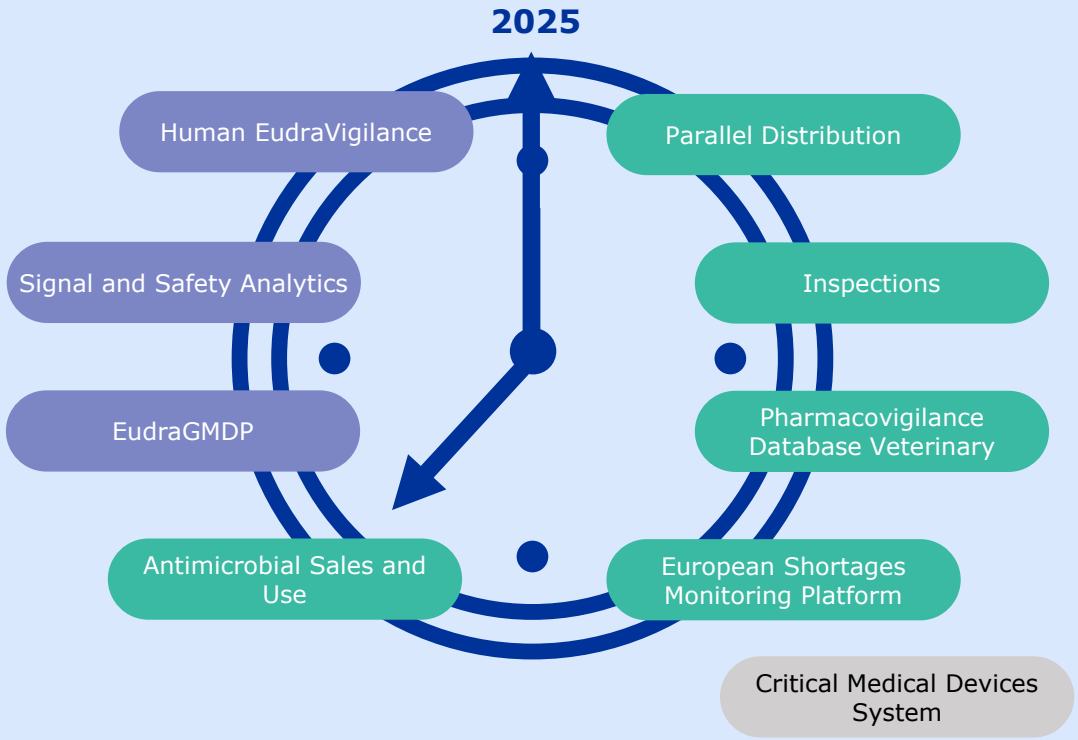
Human and Animal Health

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

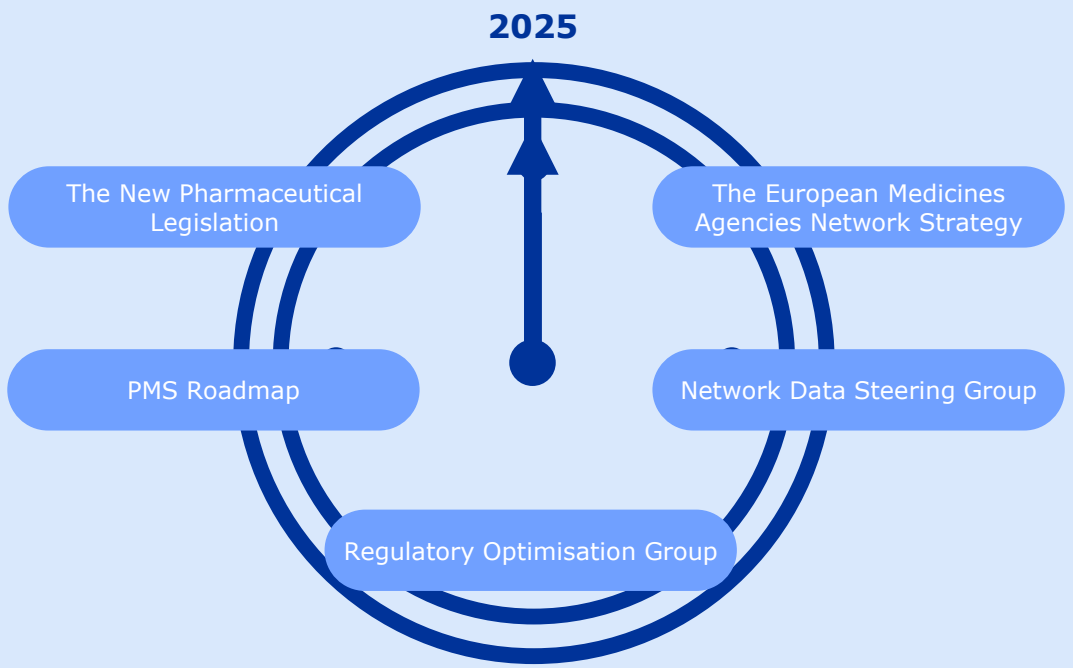
Coordinated alignment for shared success

The multi-clock dilemma

Monitoring value stream clock



Time-critical clocks



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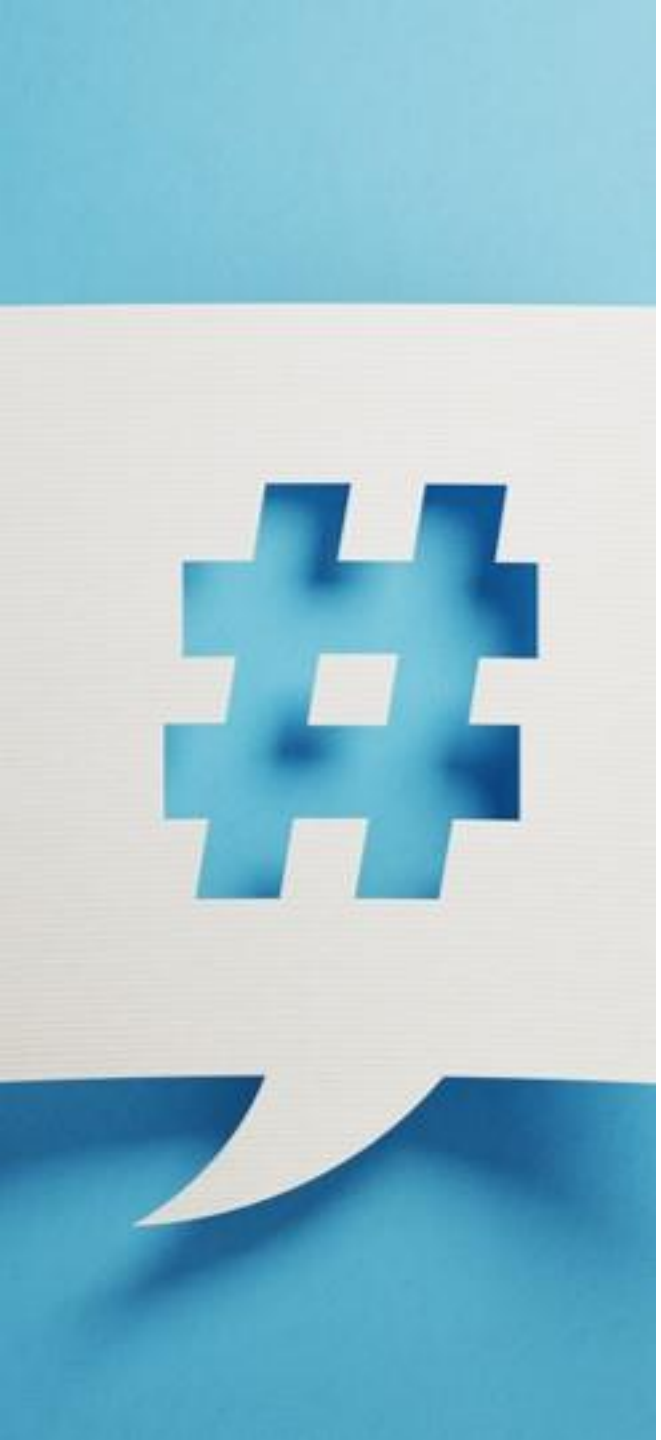
Product Master Data compliance Done/Progress

Product Master Data compliance To Be Planned

No need for Product Master Data compliance

EMA



Key takeaways & conclusions

1

Product master data is king

Standardised data creates a sustainable, reusable, and transparent common language for EU-wide communication.

2

Data is a long-term asset

Shared investment in product master data today builds a more efficient, AI-ready future for the benefit of human and animal health.

3

Coordinated alignment for shared success

Collaborating and sharing the same targets requires trade-offs and prioritisation to maximise value delivery.

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

EMA

EMA
EUROPEAN MEDICINES AGENCY

Speakers:

Isabel Chicharo
PMS Epic Owner and Head of Regulatory Data Management

Topic:

PMS, where is it heading

Opportunities brought by standardised, shared product data

Automations and interoperability across the Network

Faster, more efficient regulatory actions

- managing procedures
- reporting shortages reporting
- monitoring antimicrobial sales & use

Public access to product information

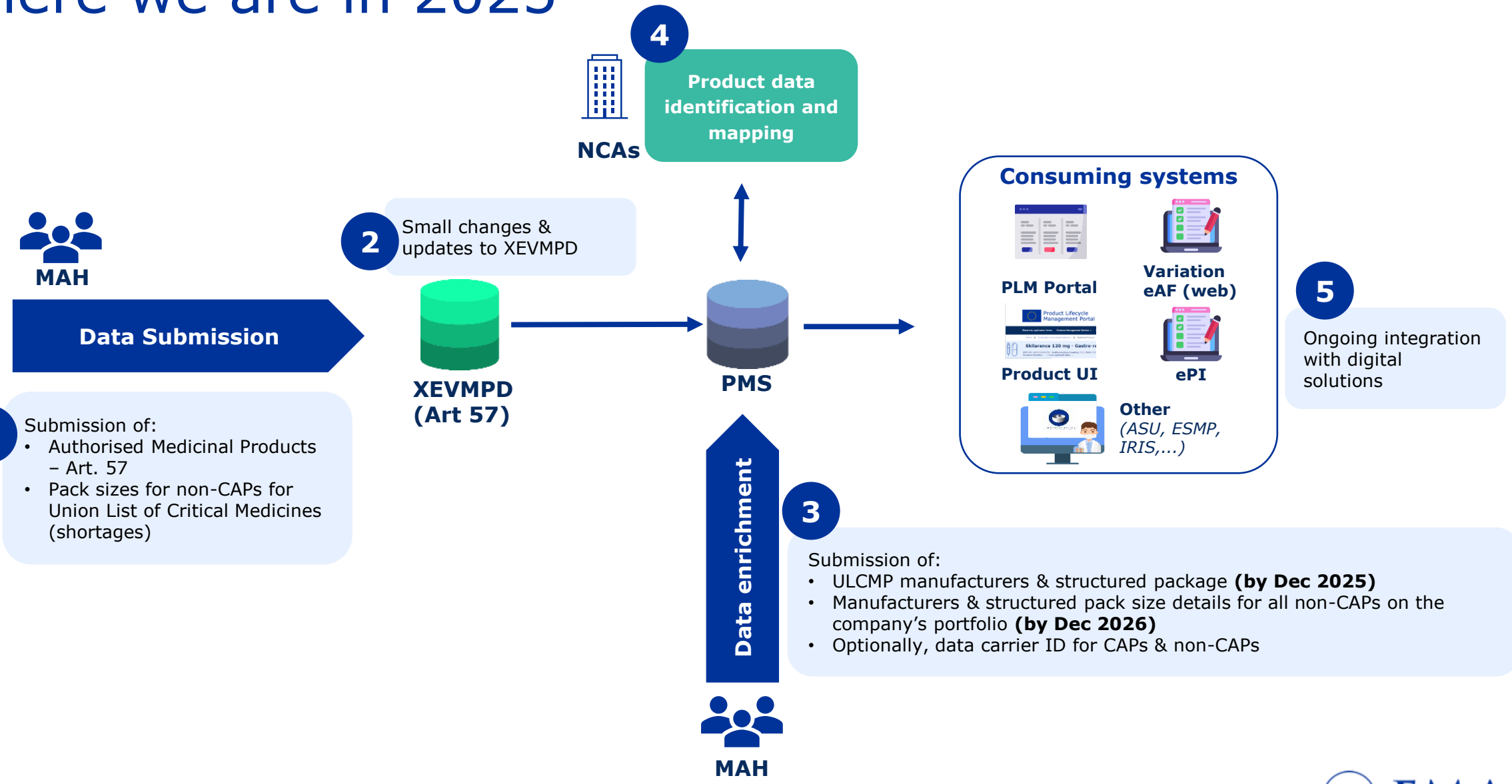
European Health Data Space support

e.g. cross-border e-prescription and e-dispensation

Enabling future regulatory compliance

EMA

Where we are in 2025



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Where we are heading in 2026

Legend

+ New activities

MAH

Data Submission

1 Submission of:
- Authorised Medicinal Products – Art. 57
- Pack sizes for non-CAPs for Union List of Critical Medicines (shortages)

+ Pack sizes for all non-CAPs on the company's portfolio

2 Small changes & updates to XEVMPD

+ UI upgrade

XEVMPD (Art 57)

NCAs

4 **Product data identification and mapping**

+ Aligning data
+ Address missing products

PMS

Consuming systems

PLM Portal

Variation eAF (web)

Product UI

ePI

Other *(ASU, ESMP, IRIS,...)*

5 Ongoing integration with digital solutions

Data enrichment

MAH

3 Submission of:
- ULCMP manufacturers & structured package **(by Dec 2025)**
- Manufacturers & structured pack size details for all non-CAPs on the company's portfolio **(by Dec 2026)**
- Optionally, data carrier ID for CAPs & non-CAPs - recommended in there is an ePI

+ Additional data enrichment

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

Moving forward with PMS

What it takes

- Enable data submission & management in PMS
- Address legacy data and systems
- Integrate with regulatory processes

Who needs to be involved

- Multiple teams across different value streams
- NCAs, MAHs and sponsors

When it will be done

- Many network and portfolio priorities
- NDSG & ROG recommendation
- No formal prioritisation has taken place yet

How it will be done

- With consideration of resource & system dependencies
- Close collaboration
- Open stakeholder communication

*PMS implementation (particularly XEVMPD replacement) is a **multi-year effort.***

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First step

Legend

✓ Benefits

NDSG & ROG recommendations

- *In a timely manner to support New Pharma Legislation*
- *Enabling submission of Investigational (IMP) and Authorised medicinal product (AMP) data via the PMS API or PUI*
- *Consuming existing/legacy systems repointed to PMS*
- *Discontinue XEVMPD at a given cut-off date*
- *Data quality is ensured via an agreed validation process - Various models of NCA and MAH involvement to be considered and to be informed by the EMA/HMA ROG feasibility study*
- *Regular updates to partners and stakeholders*

2 **Dedicated Data qualification of legacy data**
Various models to be proposed by ROG OG

NCAs

Product data qualification

MAHs & Sponsors

Data Submission

XEVMPD

PMS

1
MAHs & Sponsors submit all product data in the same way:
- investigational
- pending
- Authorised
- Any required enrichments

✓ Submission simplification

✓ Maintenance of a single repository
✓ Data flow simplification
✓ Data Quality improved

Consuming systems

PLM Portal

Variation eAF (web)

Product UI

ePI

Other *(ASU, ESMP, IRIS,...)*

Newly developed systems:
- Data Analytics Platform (DAP)
- …

Repointed existing /legacy systems:
- SAP
- CTIS
- EV
- PSUR
- EV DAS, SSA,
- …

3 Existing /legacy systems integrated, ongoing integration with new solutions

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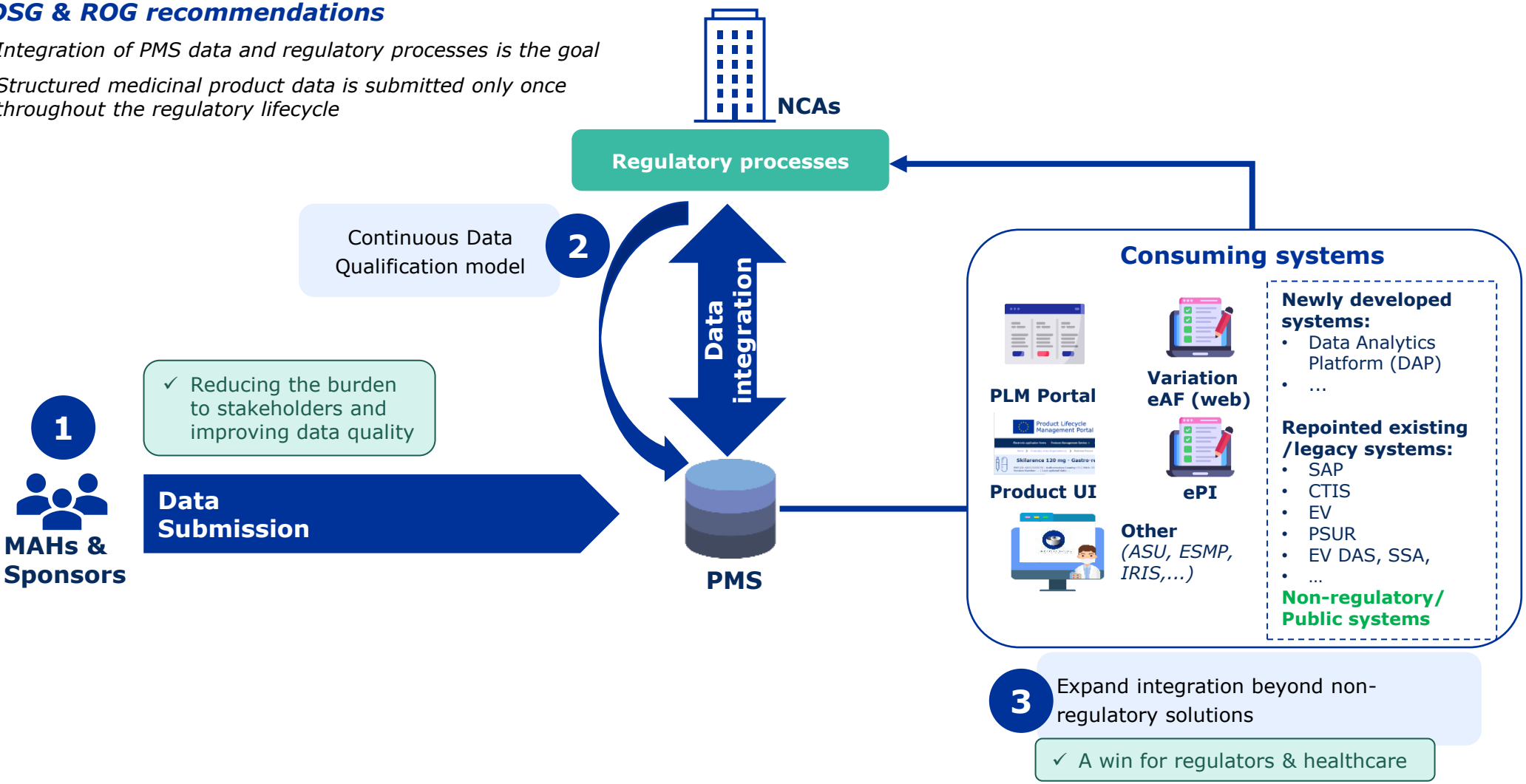
Goal for PMS

Legend

✓ Benefits

NDSG & ROG recommendations

- *Integration of PMS data and regulatory processes is the goal*
- *Structured medicinal product data is submitted only once throughout the regulatory lifecycle*



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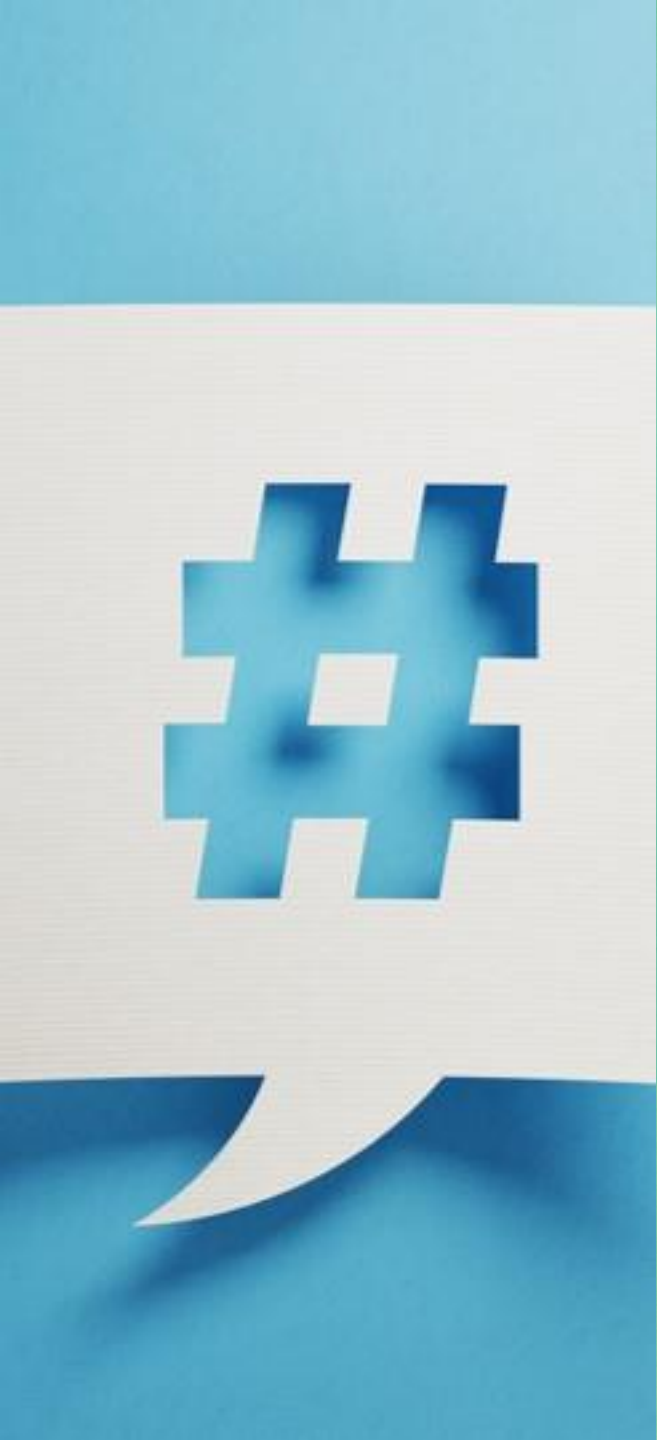

Key takeaways & conclusions

1

In the near future

- XEVMPD submissions support Art 57 obligations as well as needed enrichments
- Enrichments are expanded to all products in the portfolio
- NCAs mapping activities are progressing, initially aligning products and then ensuring that information in them is consistent across PMS and National systems

2

A first step is foreseen to simplify submissions and data flows

- In a timely manner to support New Pharma Legislation
- Enabling submission of both Investigational (IMP) and Authorised medicinal product (AMP) data via the PMS API or PUI
- Consuming existing/legacy systems repointed to PMS
- Discontinuation of XEVMPD at a given cut-off date

3

***To further reduce the burden to stakeholders and improve data quality*:**

- Integration of PMS data and regulatory processes is the goal
- Structured medicinal product data submitted throughout the regulatory lifecycle

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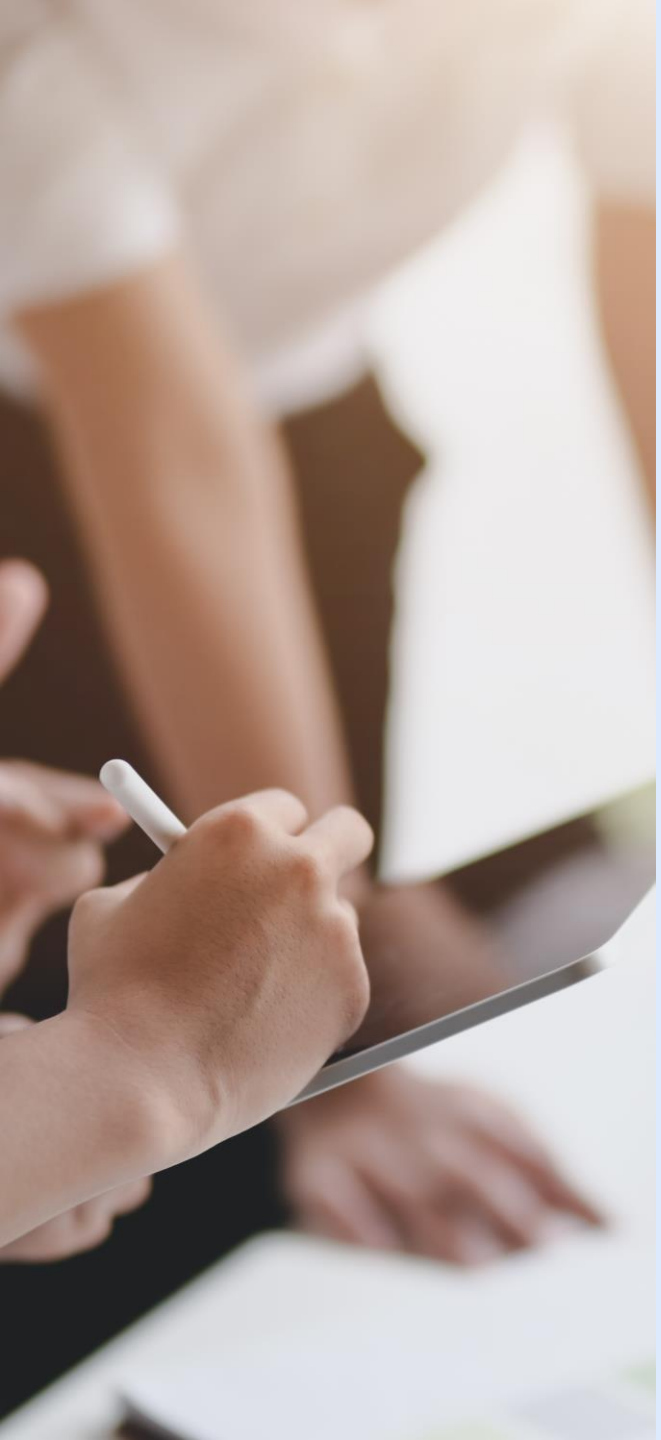
EMA



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*

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

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.*

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

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EMA
EUROPEAN MEDICINES AGENCY

Chairs:

Hilmar Hamann
Co-chair of Network ICT Advisory Committee (NICTAC) and Head of Information Division

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

Speakers:

Marcos Fernandez Gomez
PMS Product Owner

Elizabeth Scanlan
ePI Product Owner

Kristiina Puusaari
eAF Product Owner

Anna Fiodorova
Parallel Distribution and Inspections Product Owner

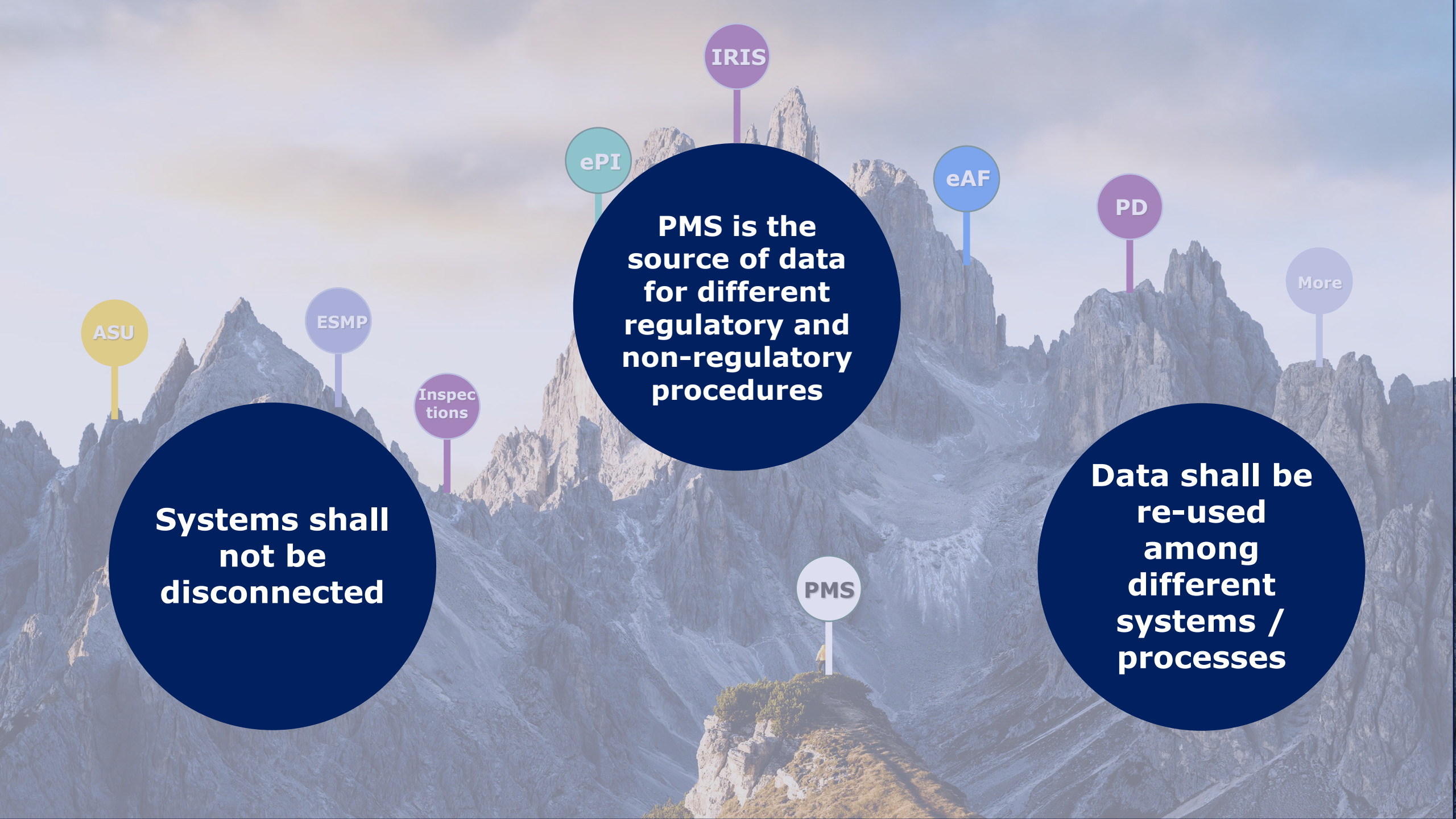
Madalina Duta-Mare
RPM Product Owner

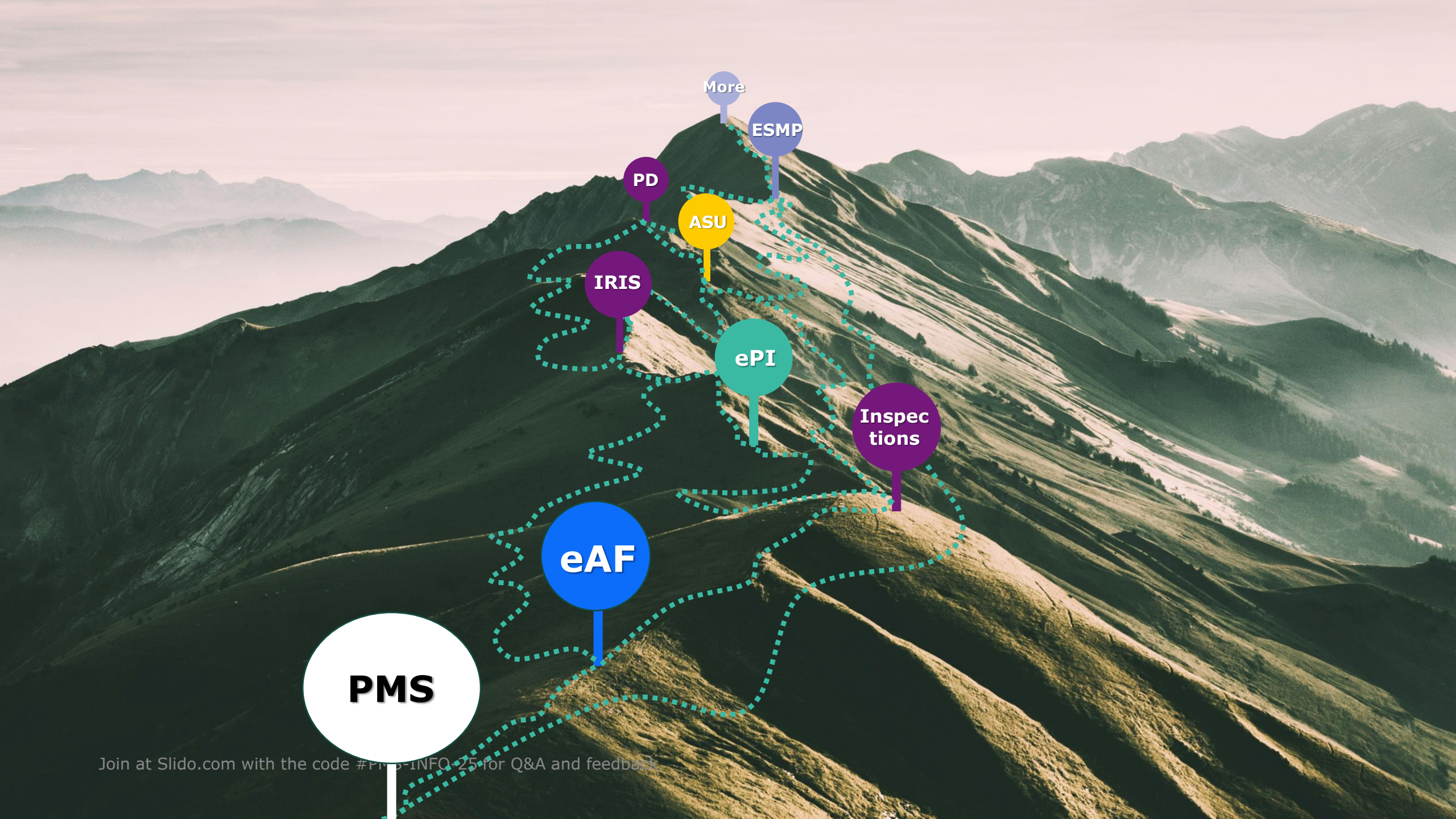
Pieter Jan Desiere
Supply and Availability of Medicines and Devices Specialist

Anastasia Pickford
ASU Product Owner


ASU
ESMP
ePI
eAF
Others
PMS


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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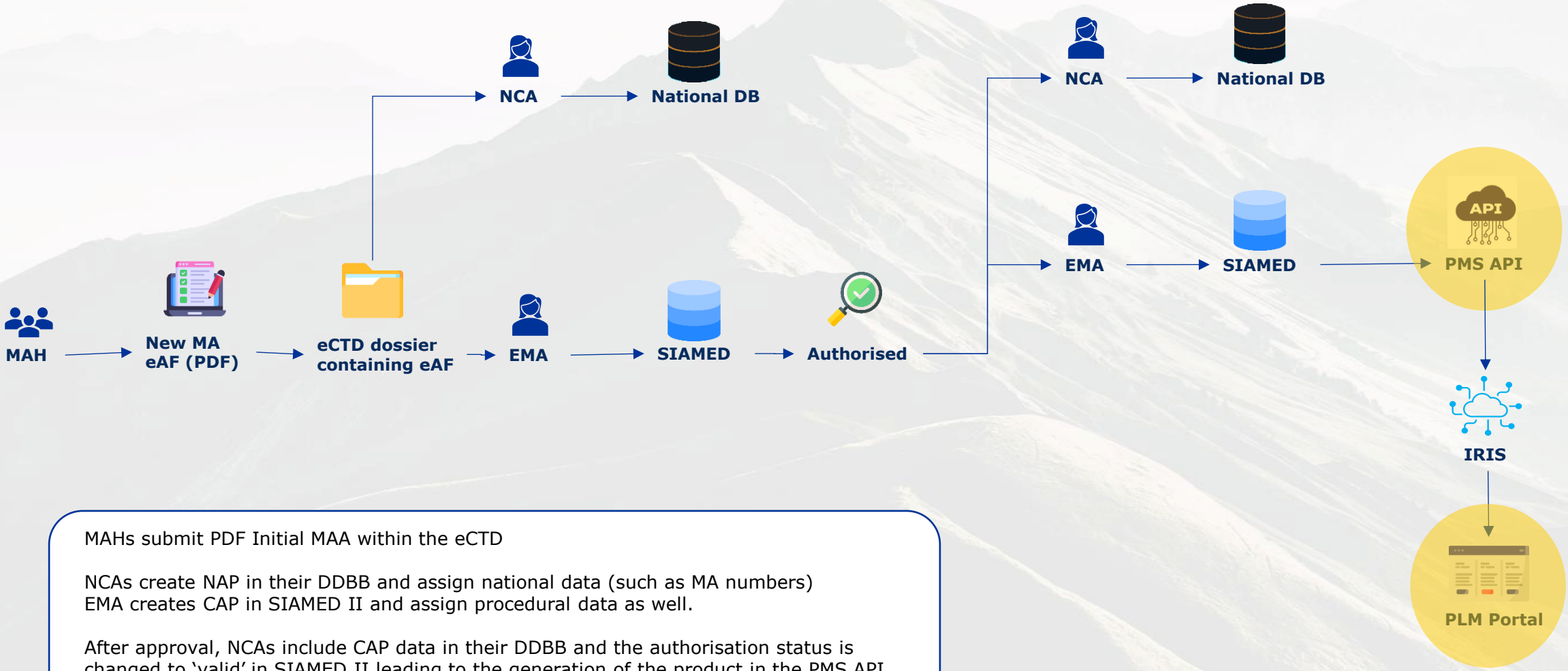
Submission and approval of initial MAA



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" />
```

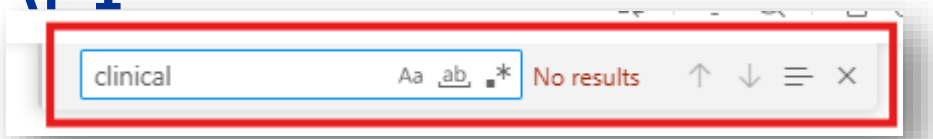
Version 1 of the medicinal product

```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

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

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

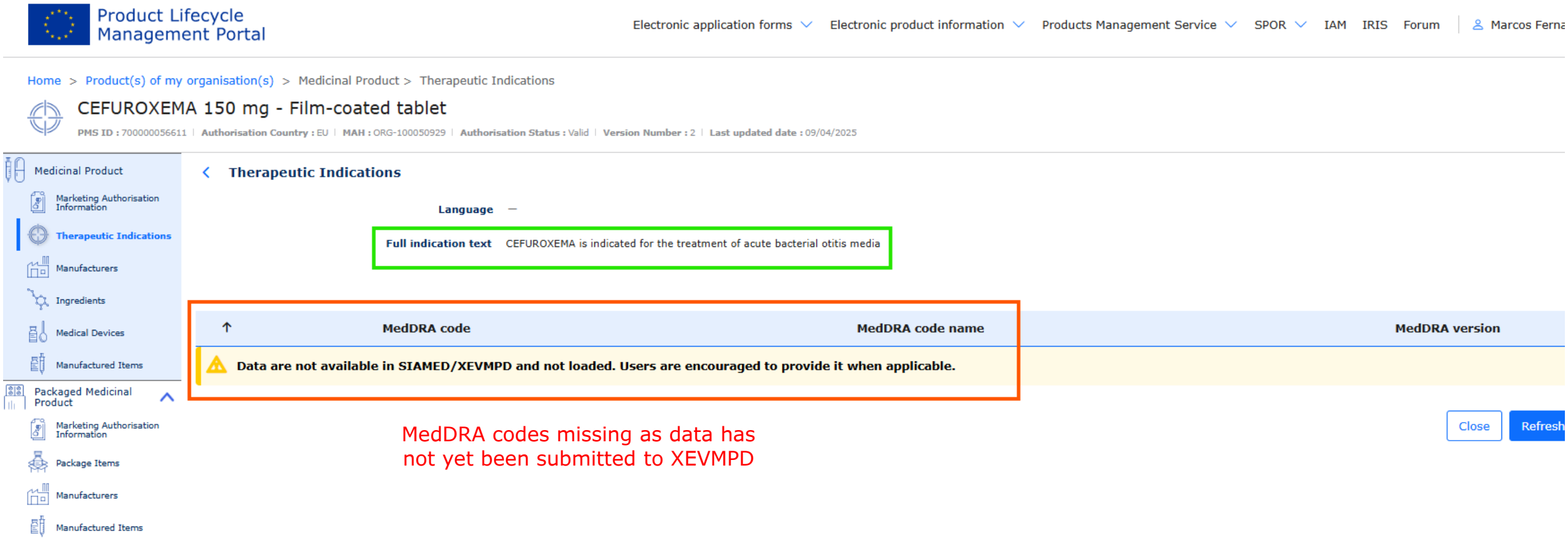
Full name	Country	Language
CEFUROXEMA 150 mg - Film-coated tablet	European Union	English

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

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

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

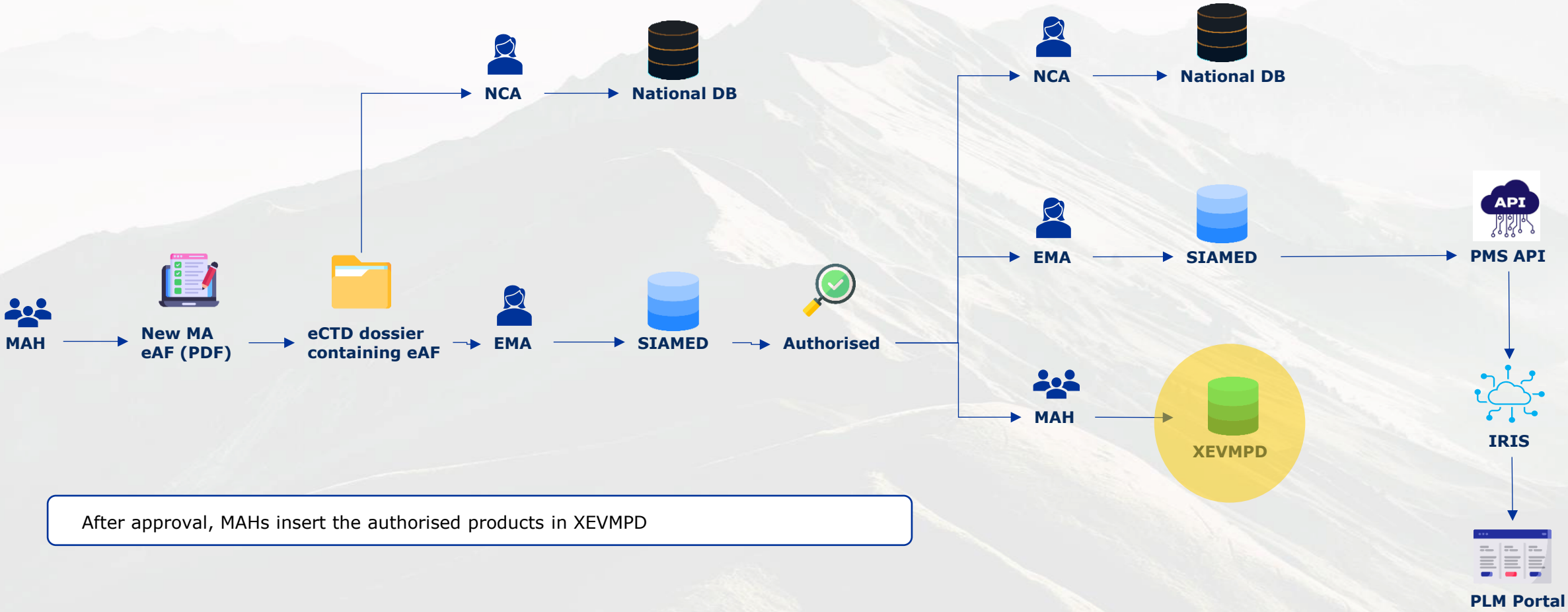
Showing **1** to **2** of **2** entries

Close | Refresh

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

EMA

Insert of products in XEVMPD

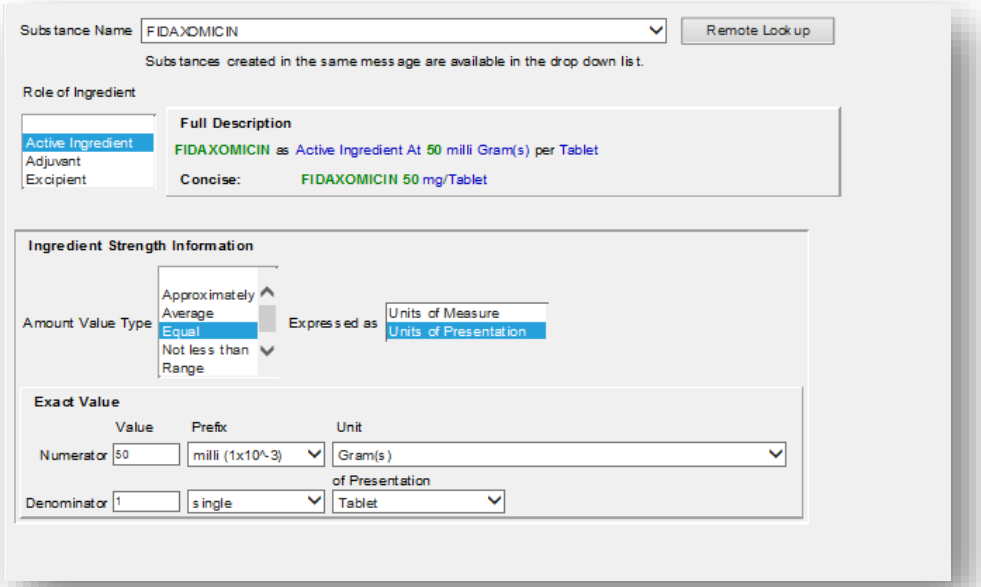


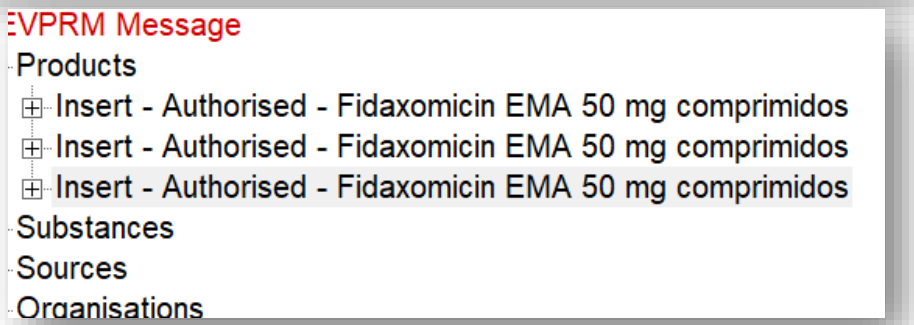
After approval, MAHs insert the authorised products in XEVMPD

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

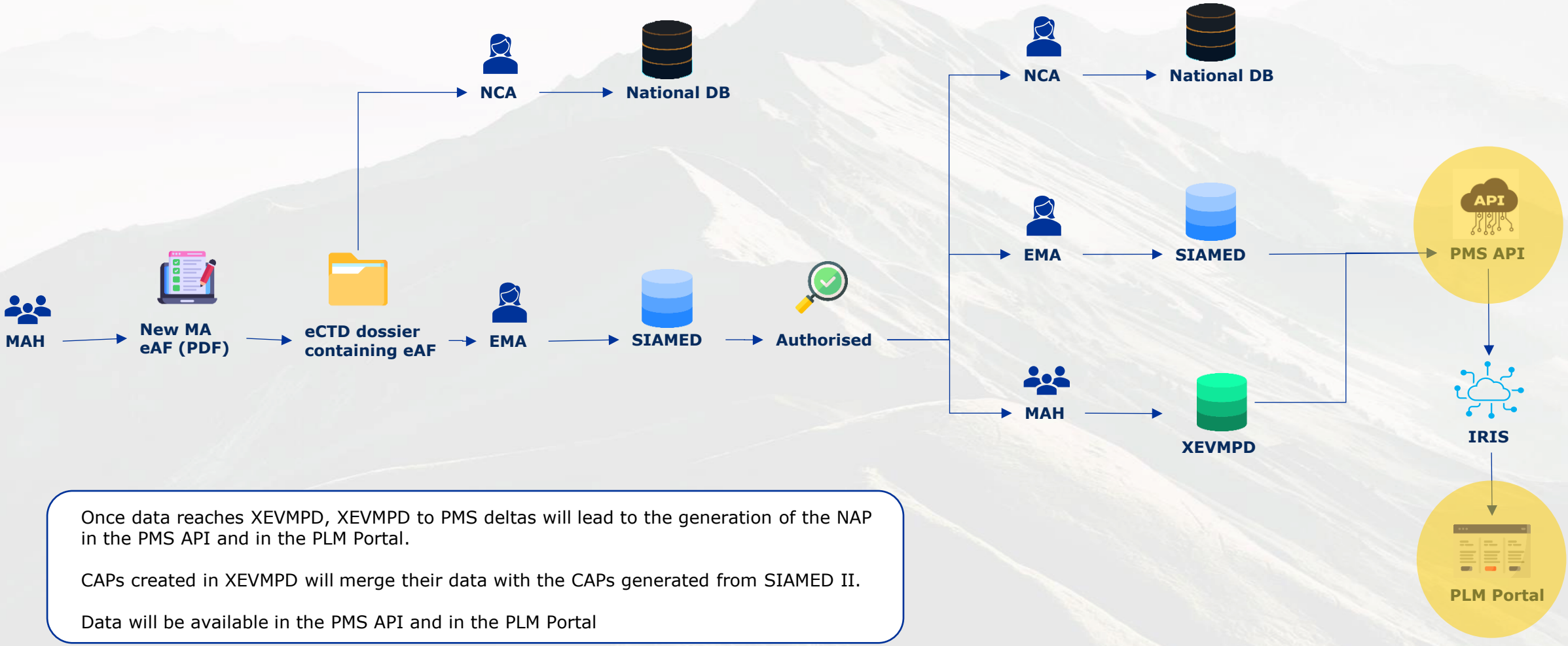




Products can be submitted using EVWEB or gateway submission. CAPs and NAPs should be submitted to XEVMPD following the business rules described in Chapter 3.II of XEVMPD

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

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

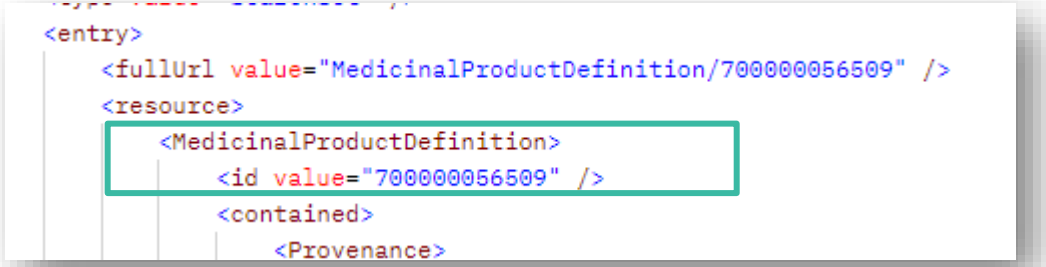
```xml
<name id="72203">
    <productName value="Cefuroxema EMA 150 mg film-coated tablets" />
```

Product name is updated with data from XEVMPD

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

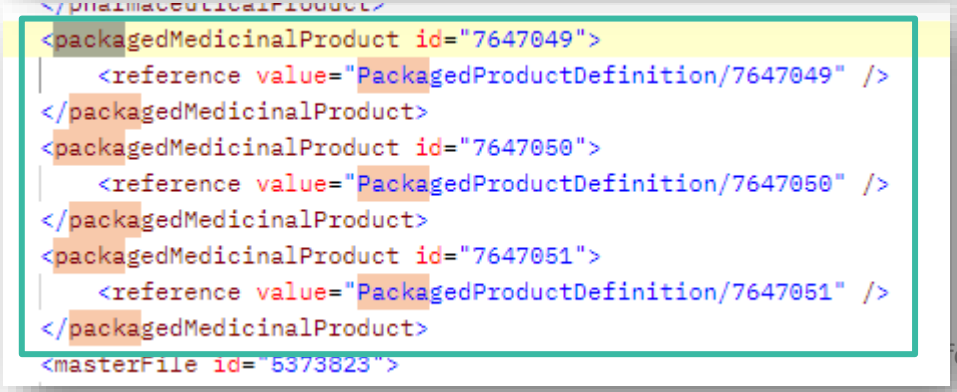
Paediatric use is updated with data from XEVMPD

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 —

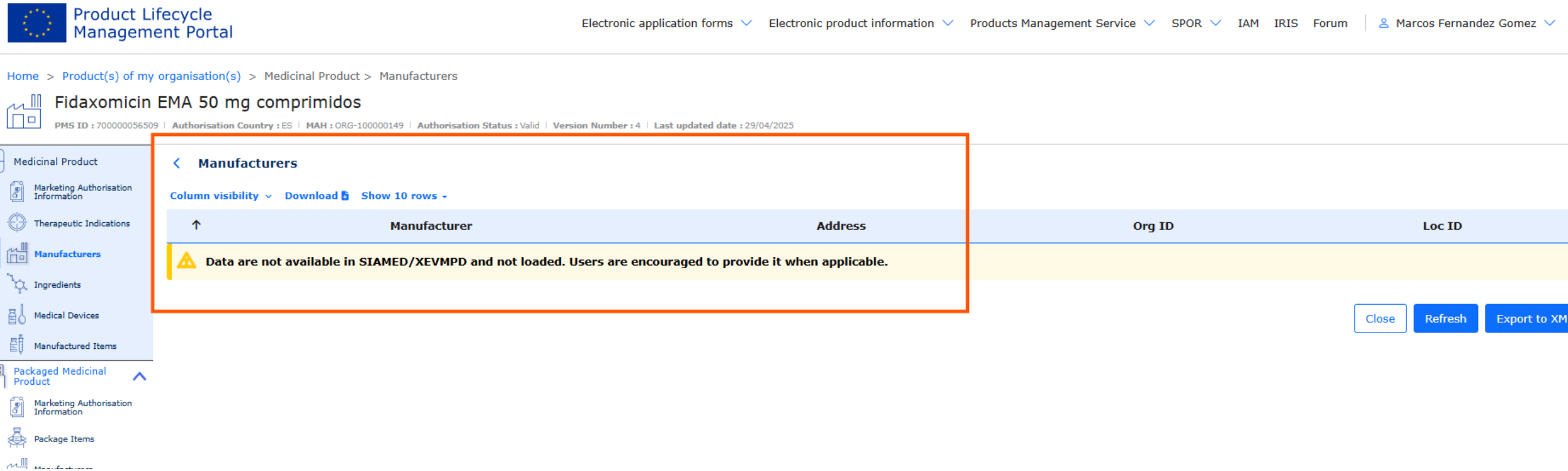
Product Classification

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



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

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) > 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

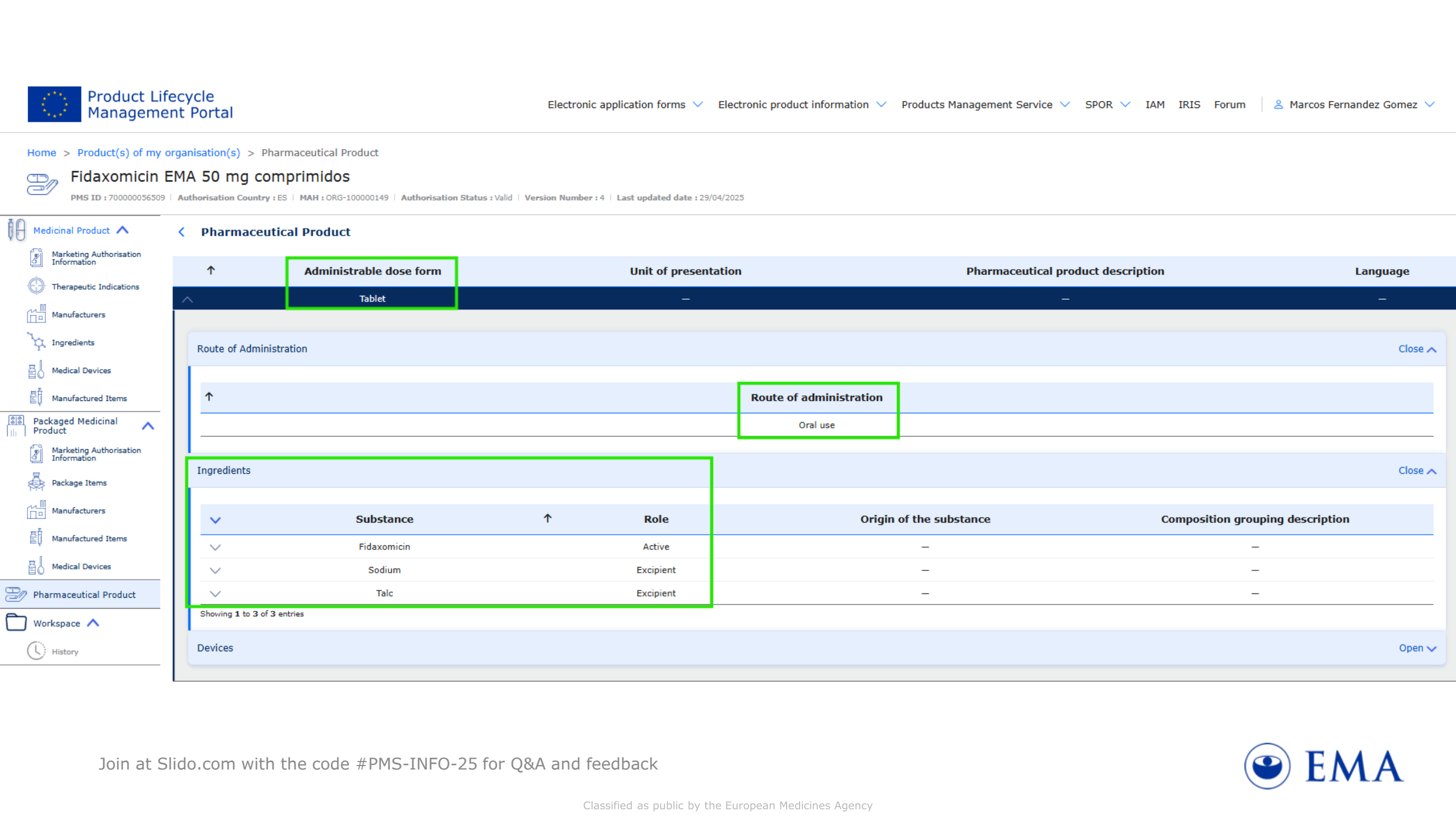
v	091990	–	–	PRD11169139	–	Valid
v	091990	–	–	PRD11169138	–	Valid

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

Close | Refresh | Export to XML

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

EMA



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

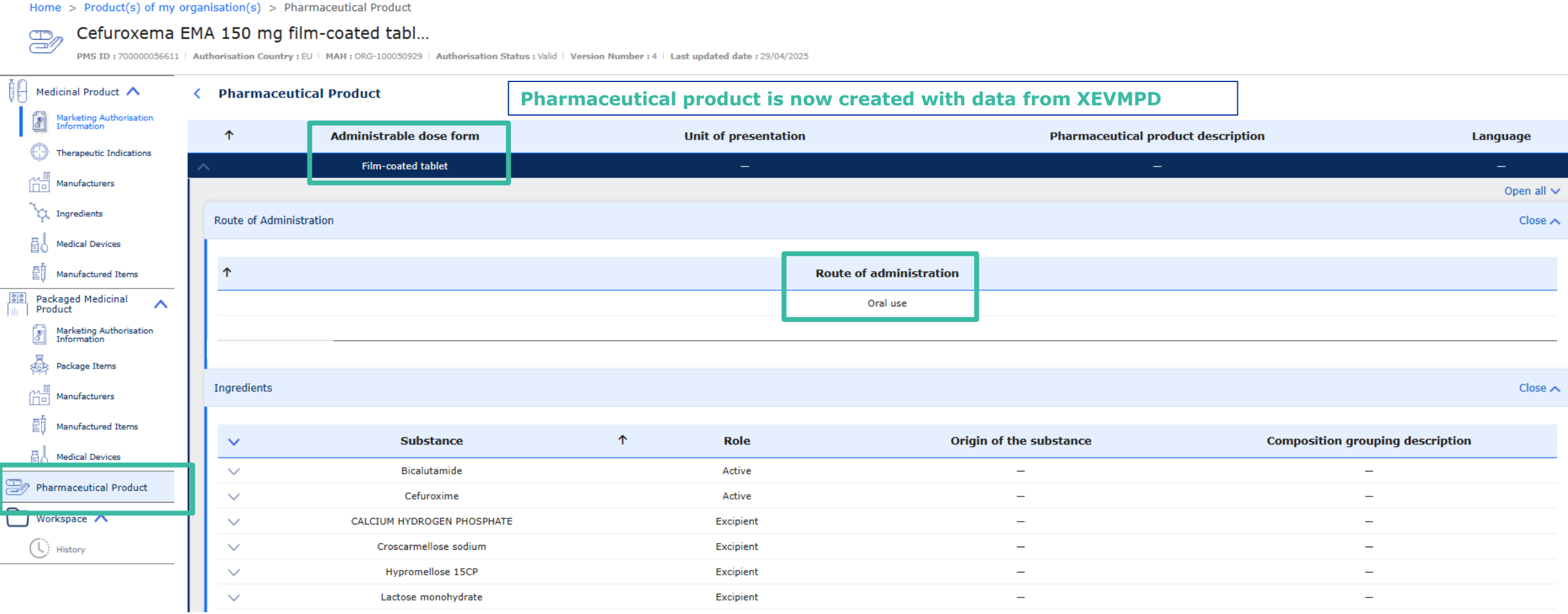
Legal status of supply	Medicinal product subject to restricted medical prescription		
(Authorised) Pharmaceutical form	Film-coated tablet		
Combined pharmaceutical dose form	—		
Paediatric use indicator	Yes	**Additional monitoring (Y/N)**	Yes
		EURD ID	—

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

Product Classification

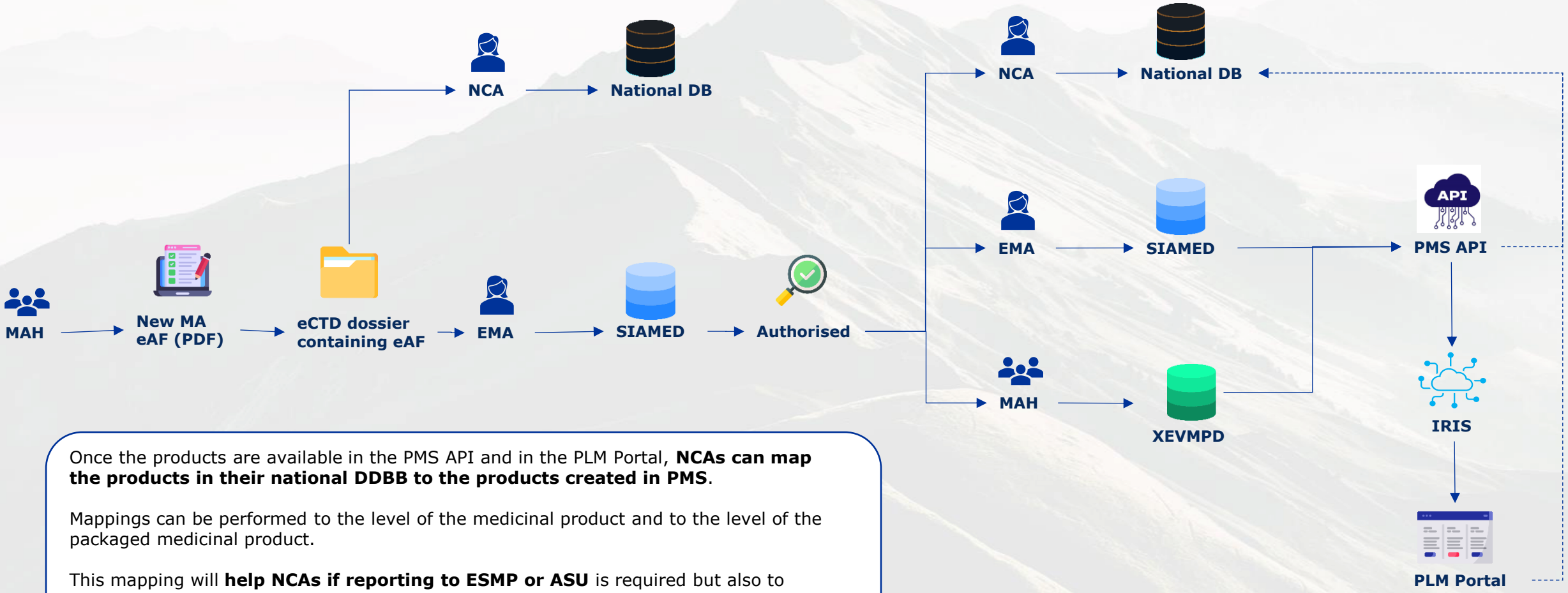
ATC code	ATC code name	ATC code – Flag
J01DC02	cefuroxime	Not applicable

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



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

NCAs data mapping and use of PMS data



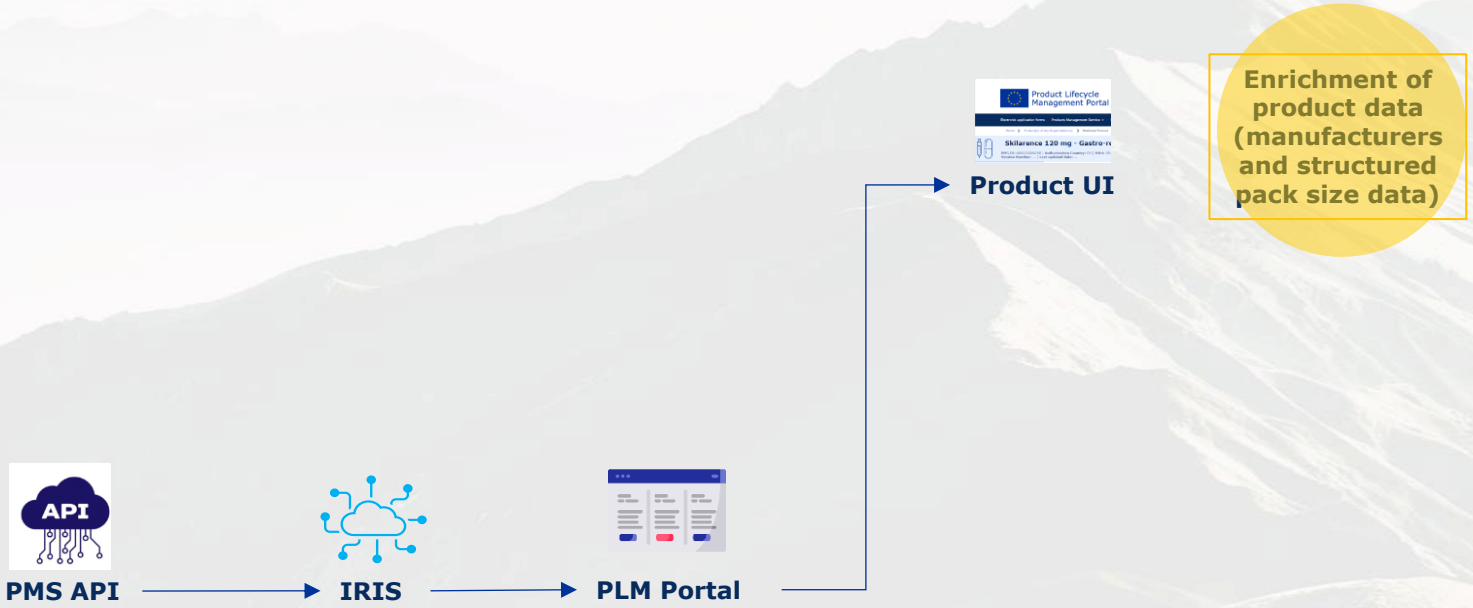
Once the products are available in the PMS API and in the PLM Portal, **NCAs can map the products in their national DDBB to the products created in PMS**.

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.

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

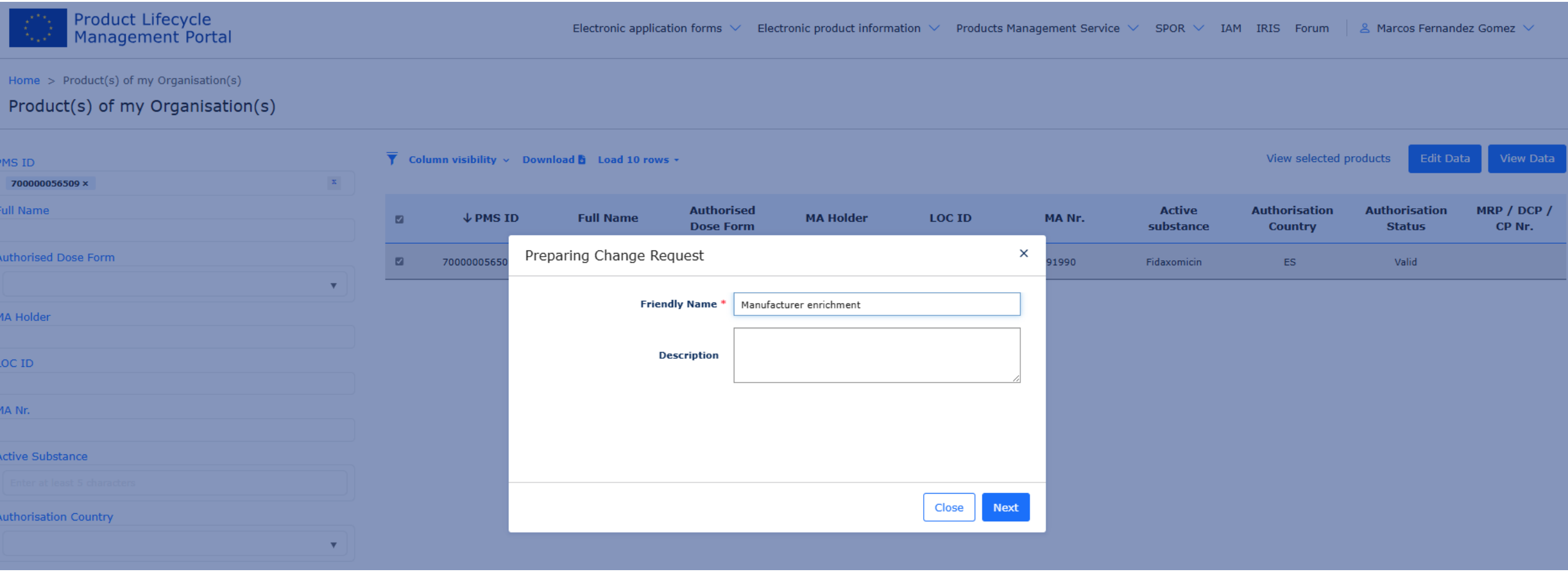
Enrichment of product data



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.

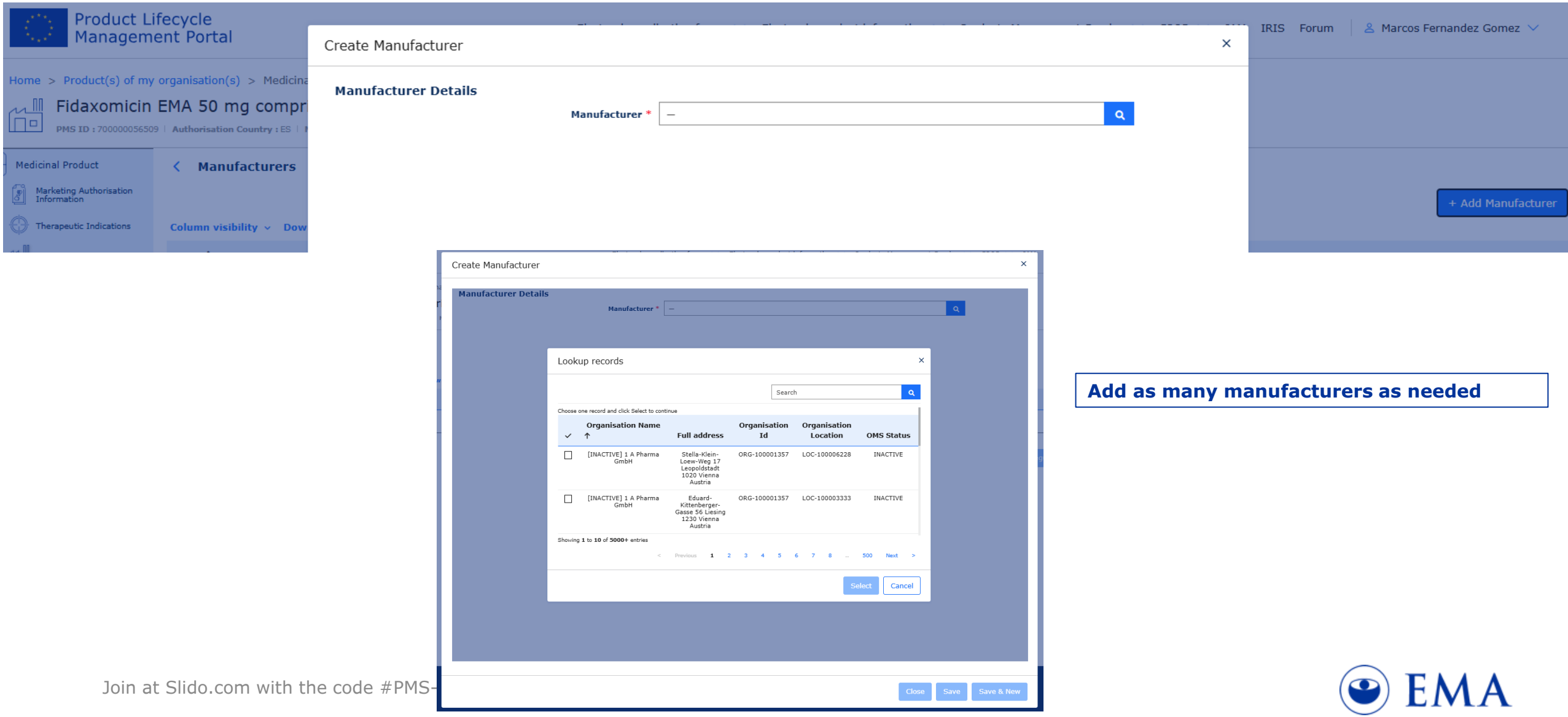
Enrichment of product data



Edit NAP product and create a change

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

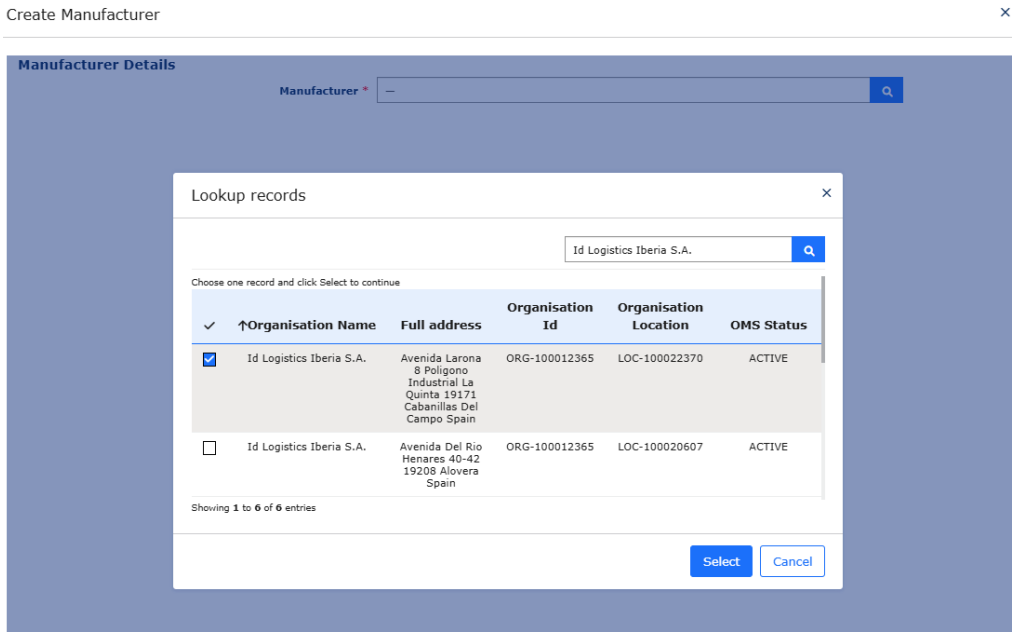
Enrichment of product data



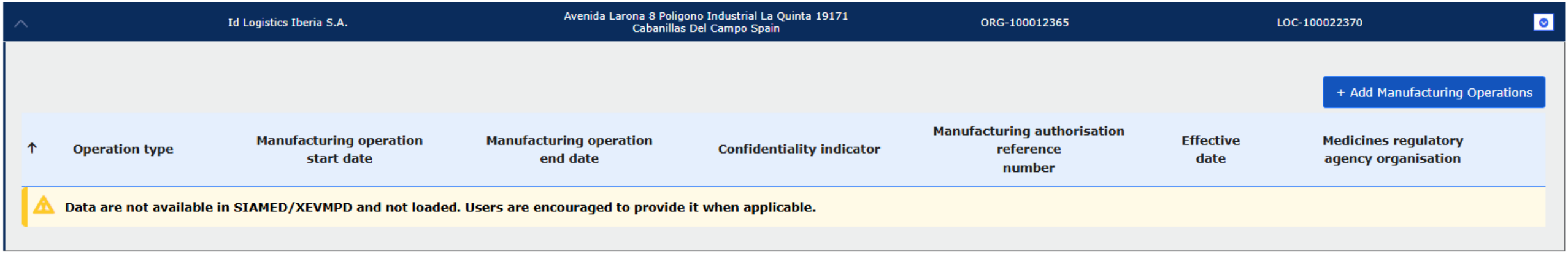
Add as many manufacturers as needed

Join at Slido.com with the code #PMS-

Enrichment of product data

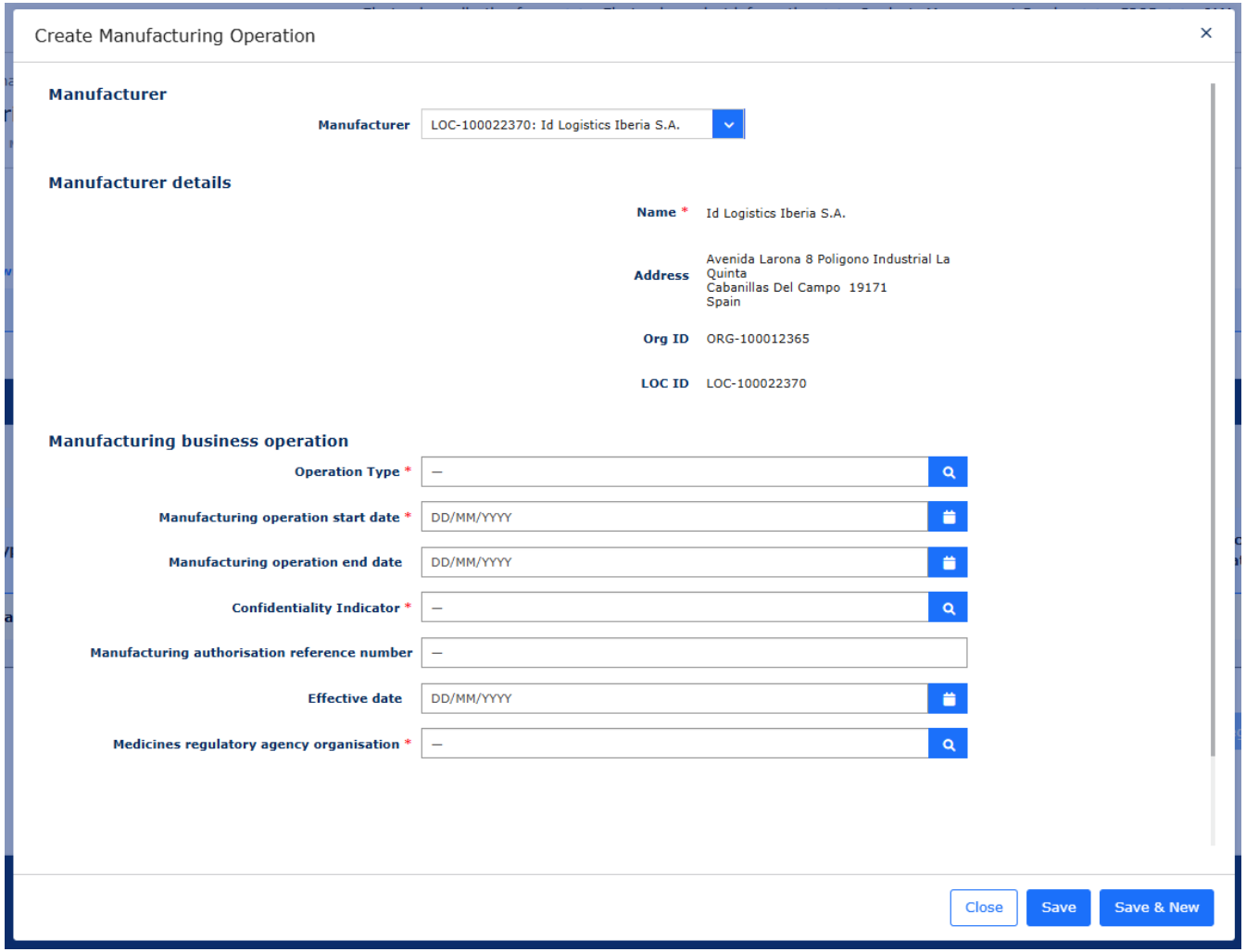


Add as many manufacturers as needed



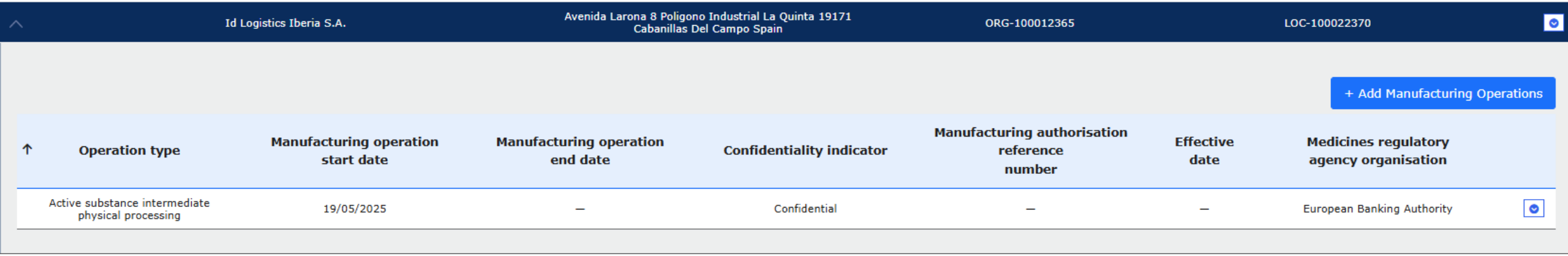
Join at Slido.com with the code #PMS-INFO-25 for Q&A and feedback

Enrichment of product data



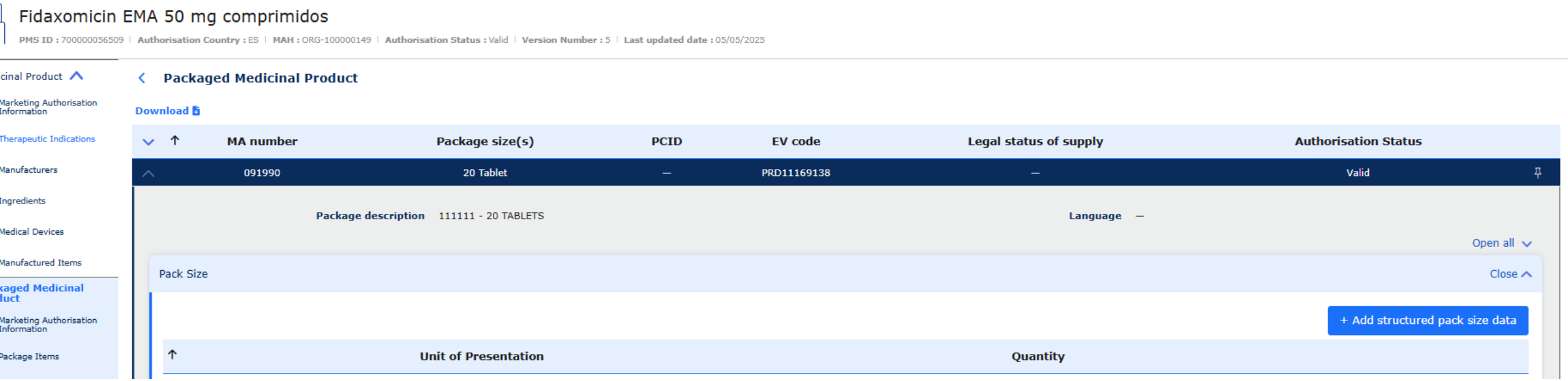
Include additional information such as manufacturing business operations and additional data required for each manufacturer.

Enrichment of product data

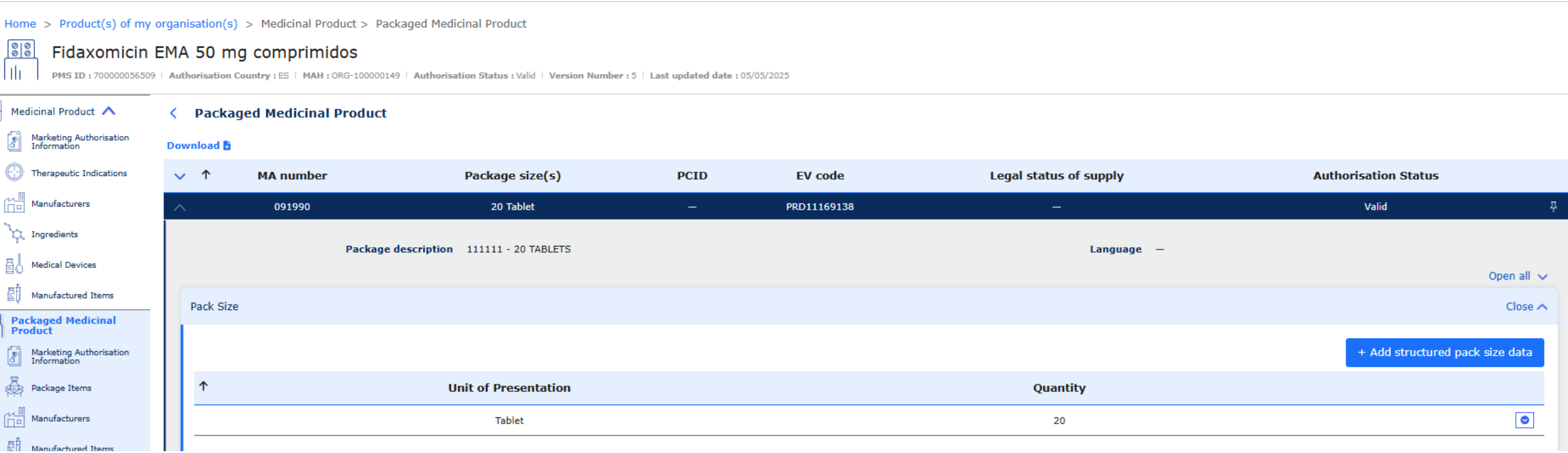


Changes can be validated before they are submitted.

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



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

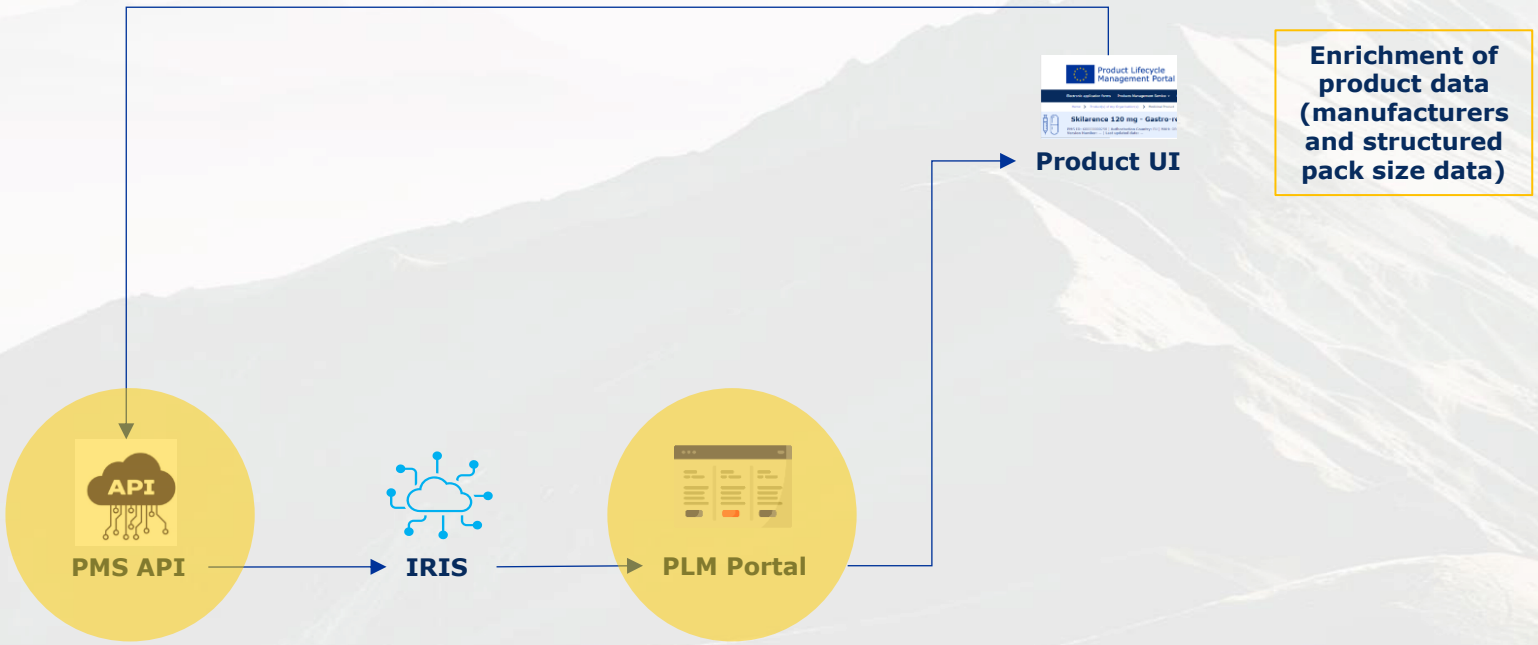
Change Request Activities — Open

Selected Products — Open

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

Change can be finalized and submitted.

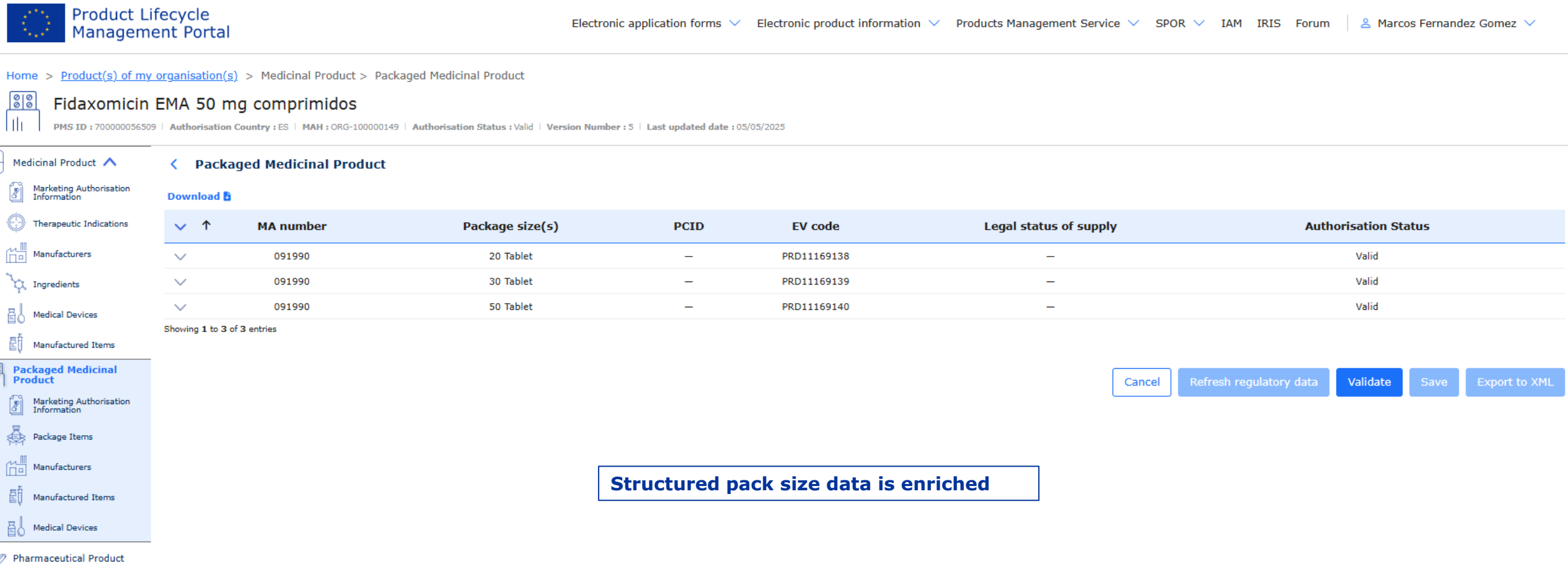
Enrichment of product data



Enriched data will be forwarded to the PMS API.

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

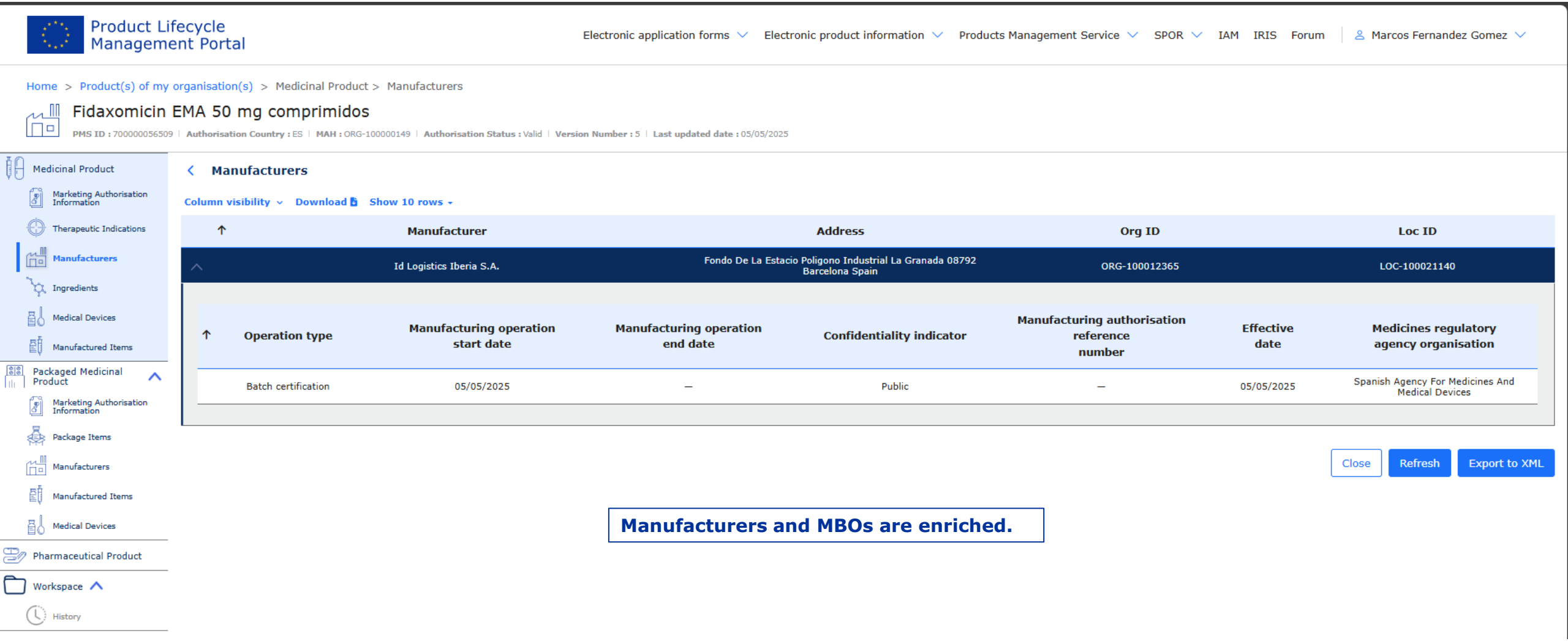
Enrichment of product data



Structured pack size data is enriched

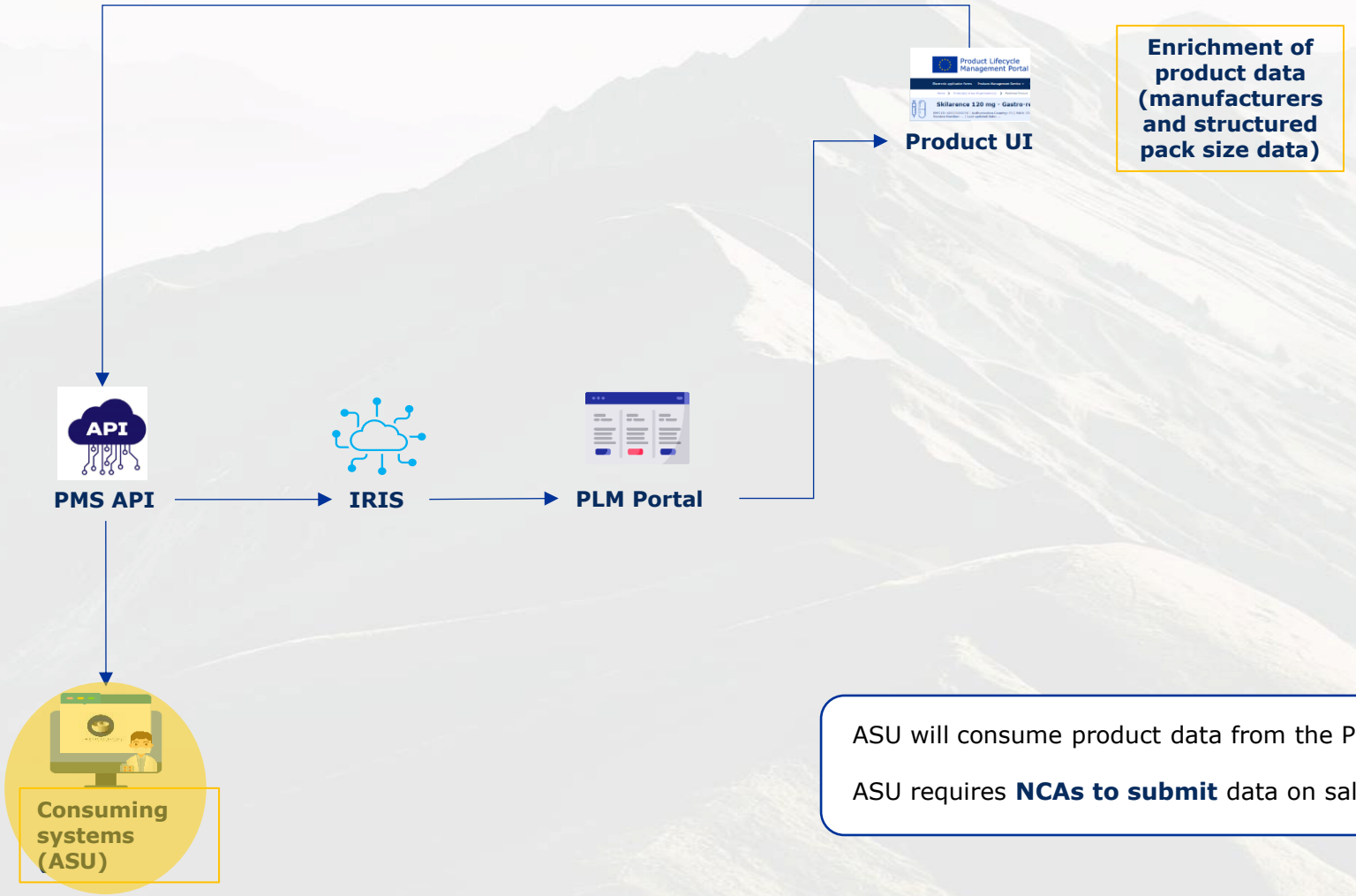
Join at Slido.com with the code #PMS-INFO-25 for Q&A and feedback

Enrichment of product data



Manufacturers and MBOs are enriched.

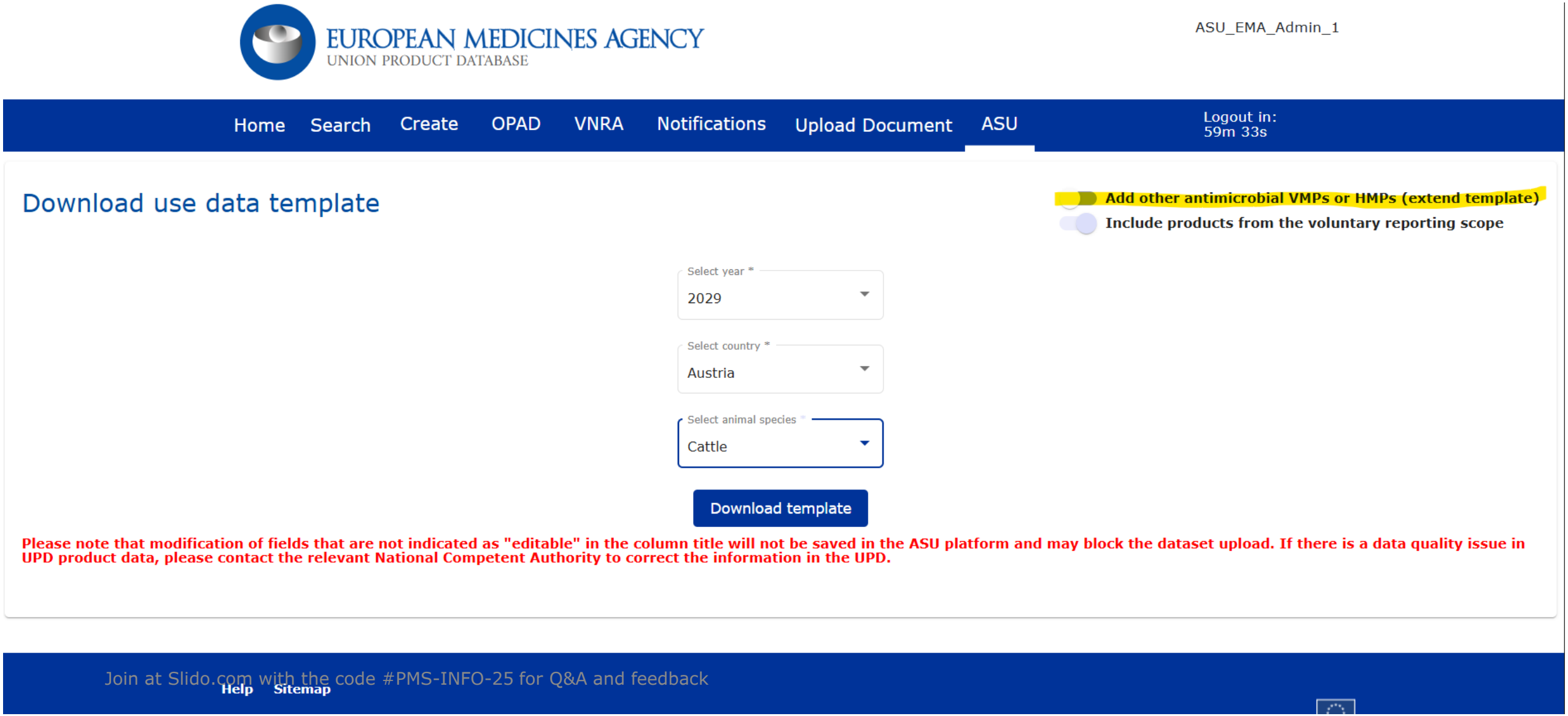
ASU use case - Monitoring of antimicrobials sales and use



ASU will consume product data from the PMS API.

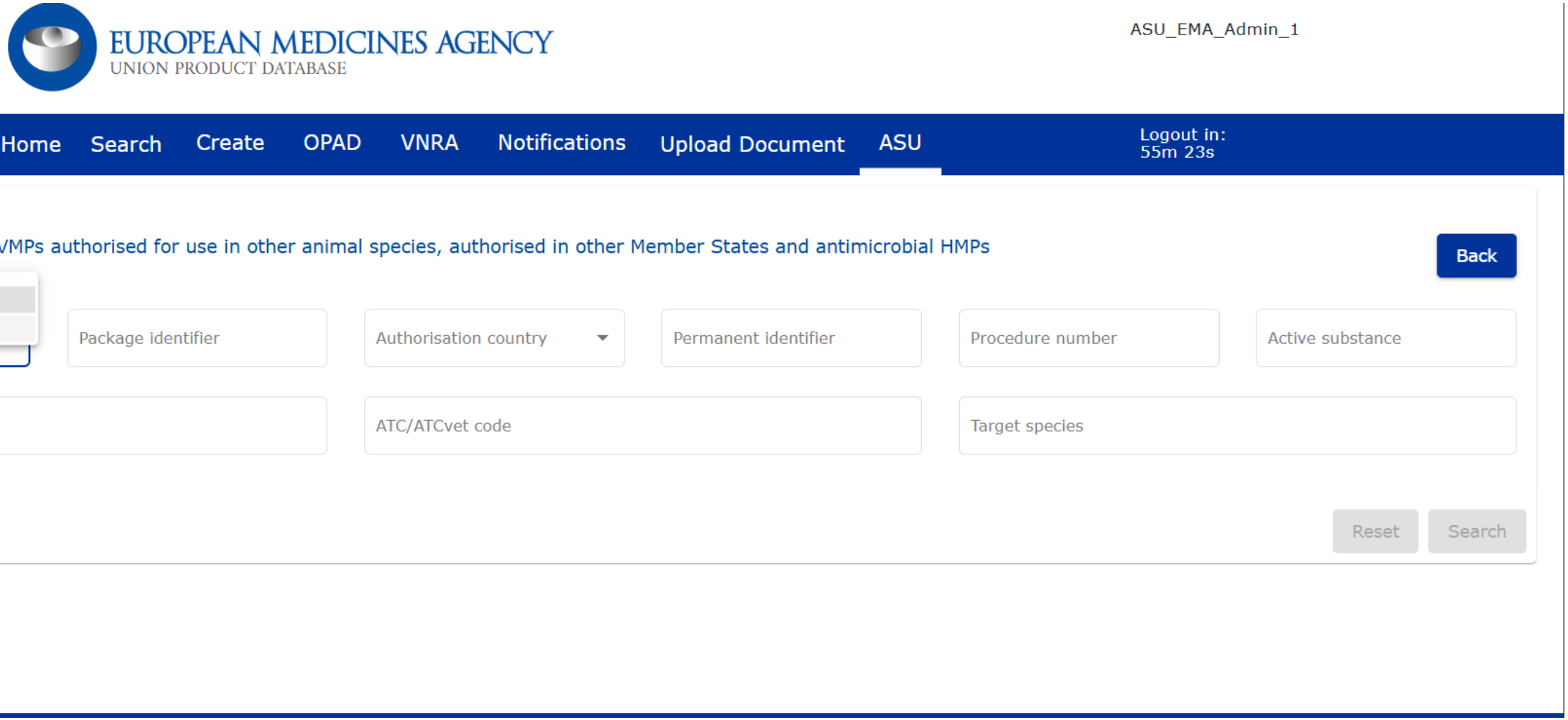
ASU requires **NCAs to submit** data on sales and use of antimicrobials in animals.

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



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

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

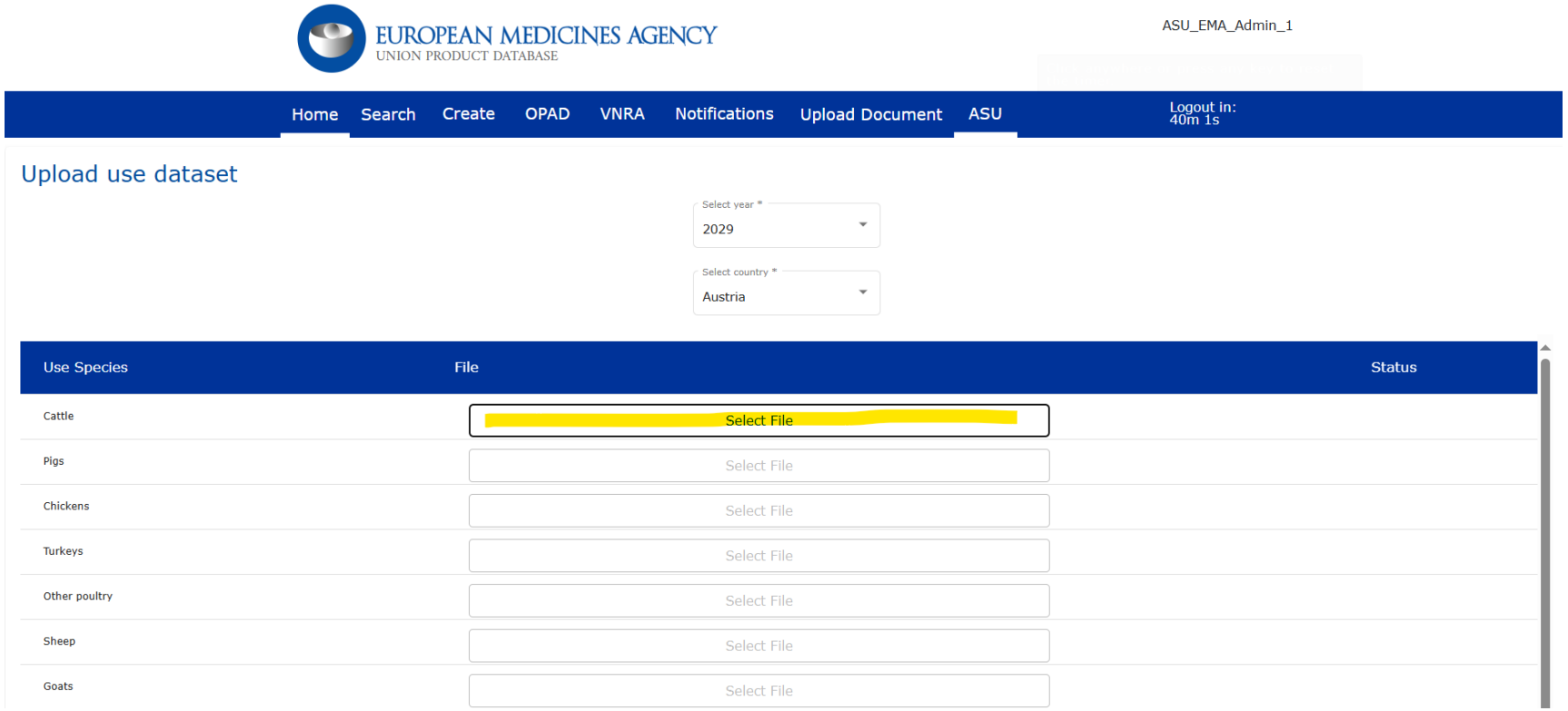
Authorisation country	Domain	Procedure number	Permanent identifier	Package identifier	Medicinal product name	Pharmaceutical composition	ASU product form	ATC/ATCvet code	Target species	Pack size description
AT	Human	EMEA/H/C/000264	600000002219	28688	Agenerase (SRD) 15 mg/ml - Oral solution	Amprenavir 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



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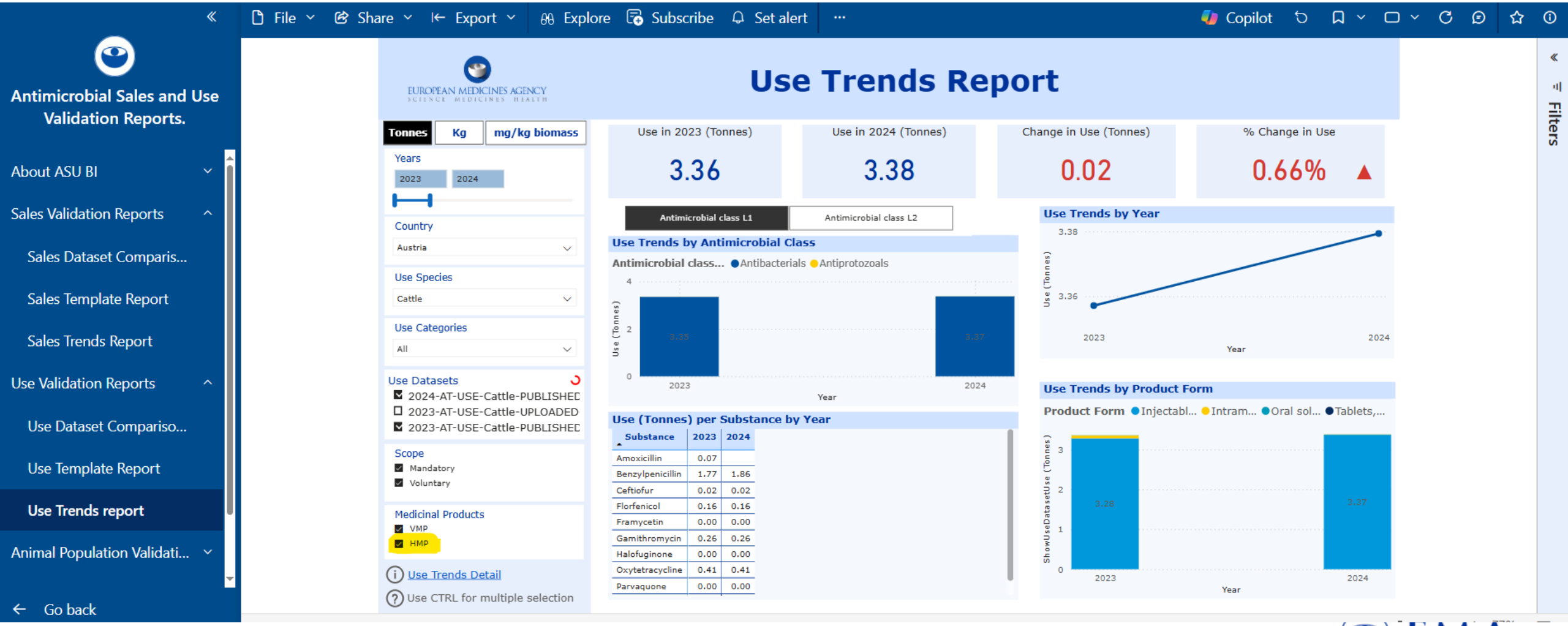
6. NCA user can visualise their data in the ASU Power BI application and see the impact of the use of HMPs on their antimicrobial consumption trends



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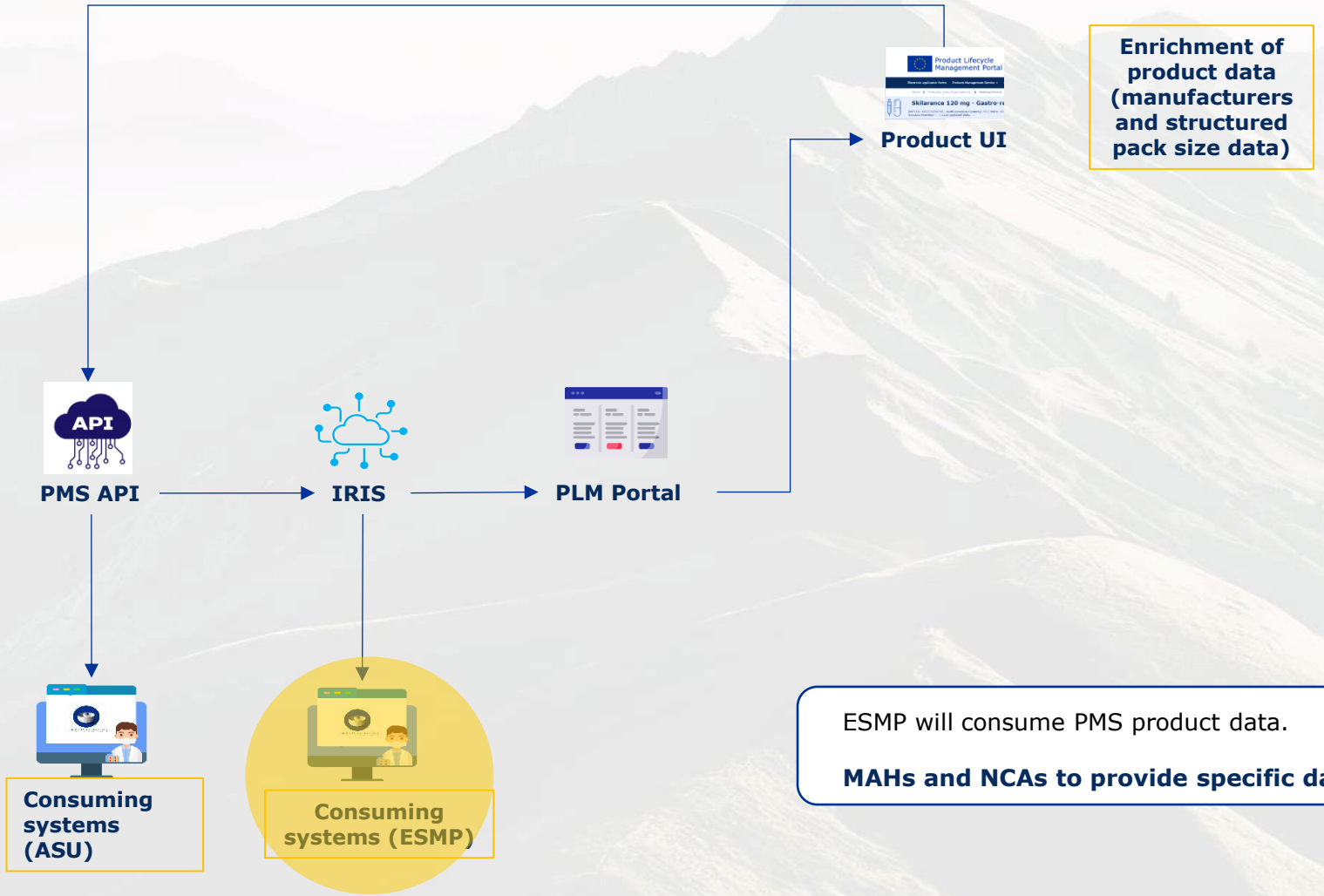
ESMP use case - Monitoring of shortages



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

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

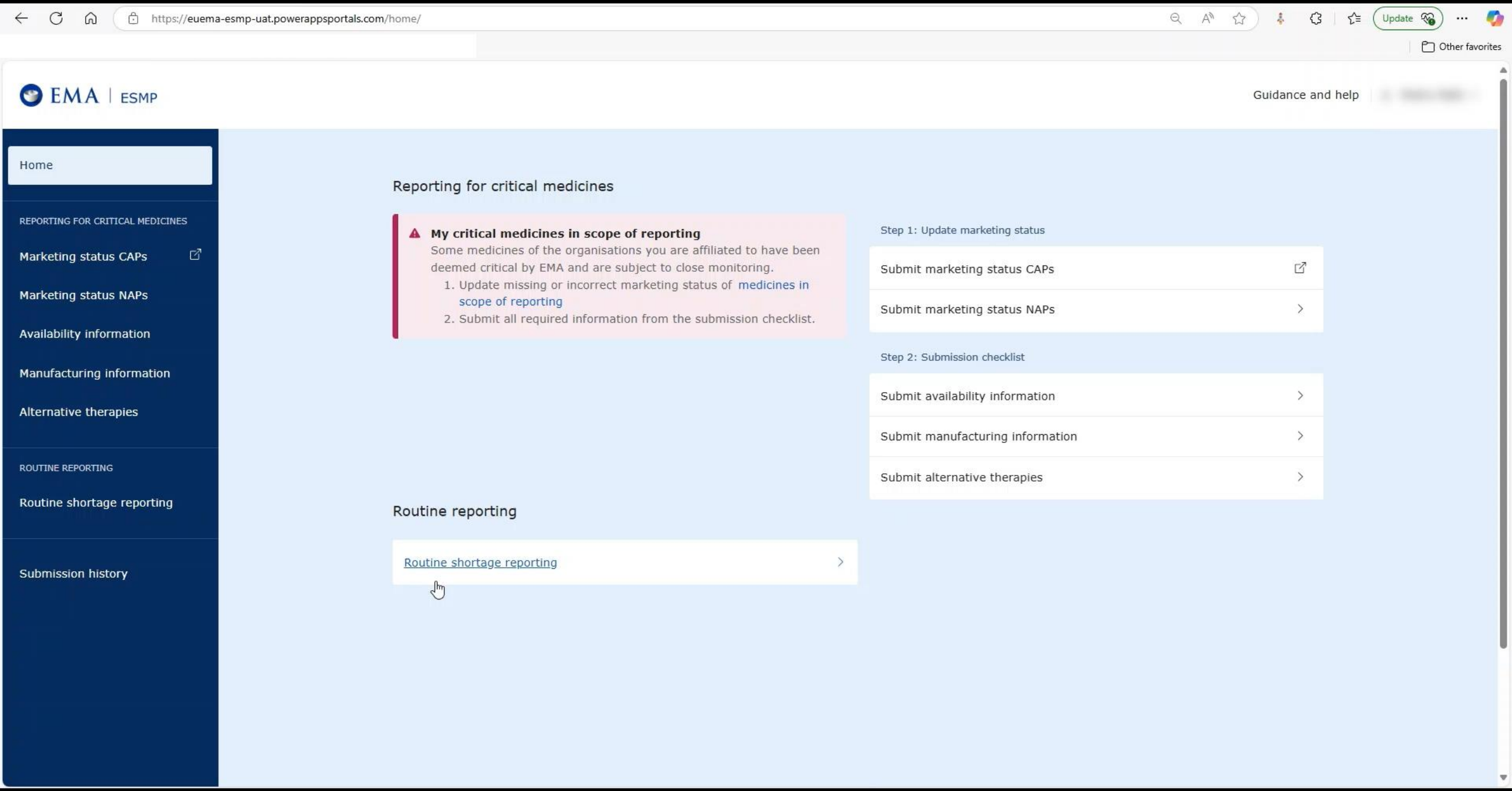
Shortage Status

- 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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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

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

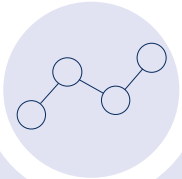
Submit manufacturing information

Submit alternative therapies

Routine reporting

Routine shortage reporting

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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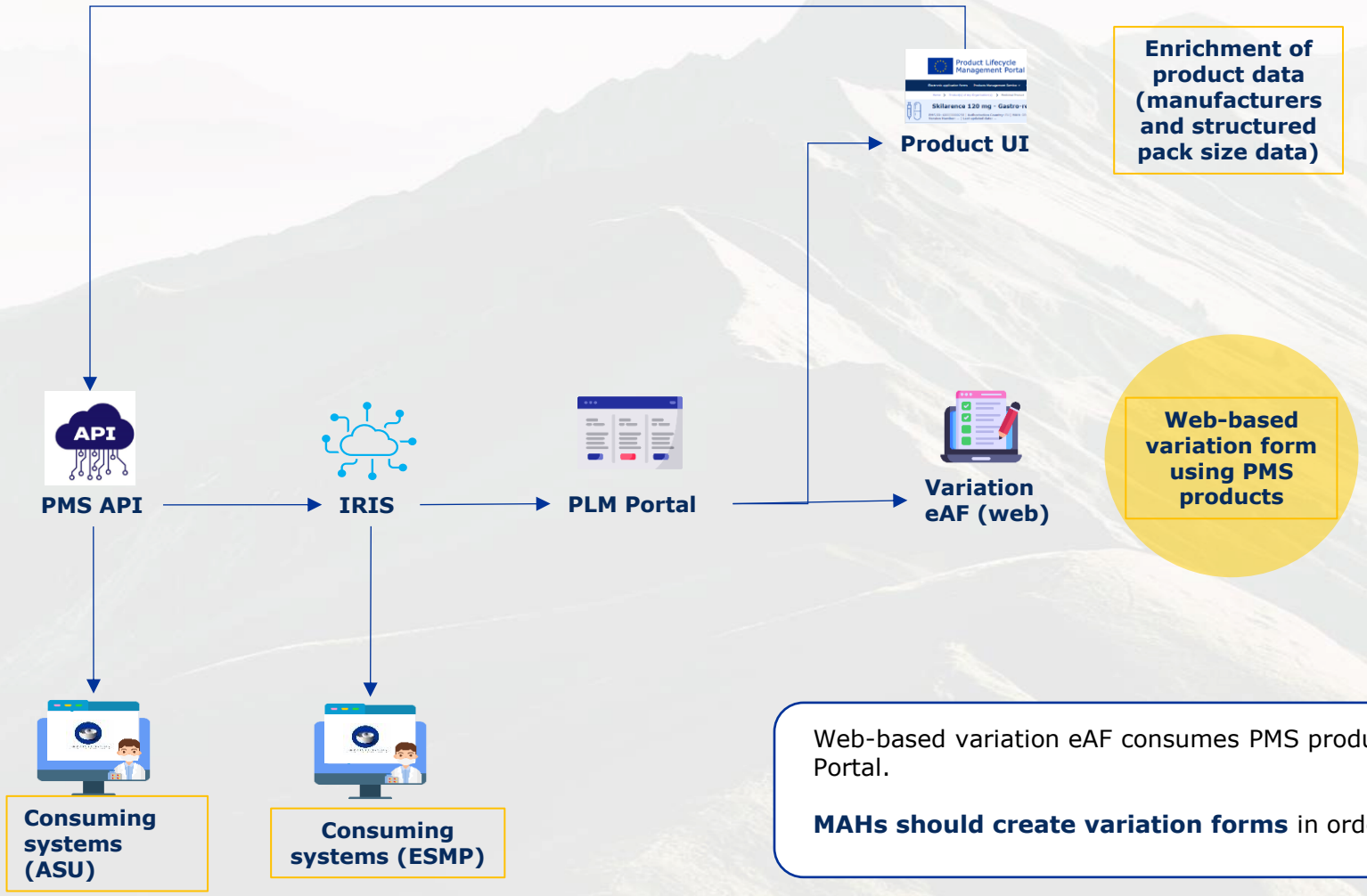
EMA

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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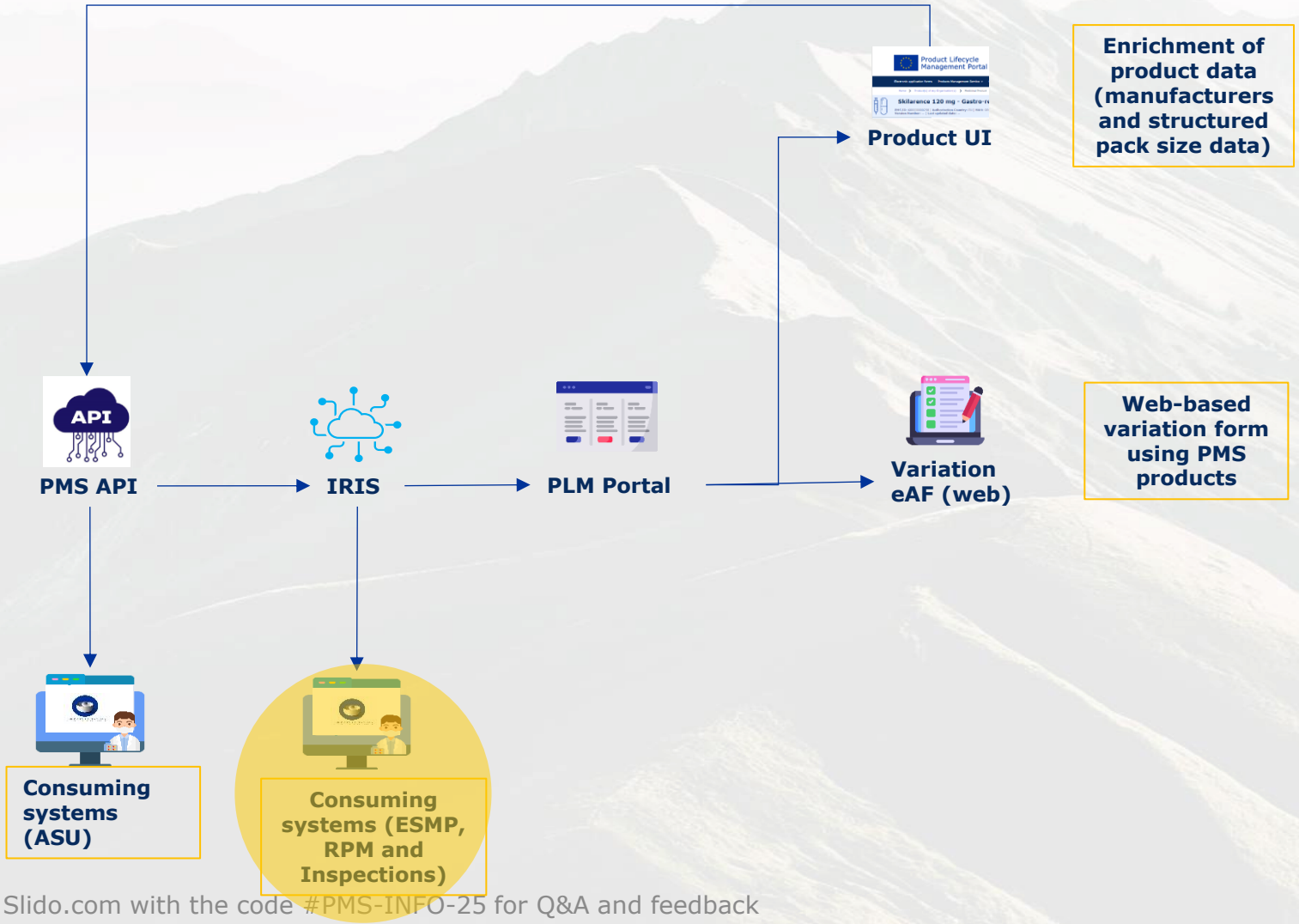
IRIS procedure management & Inspections use case

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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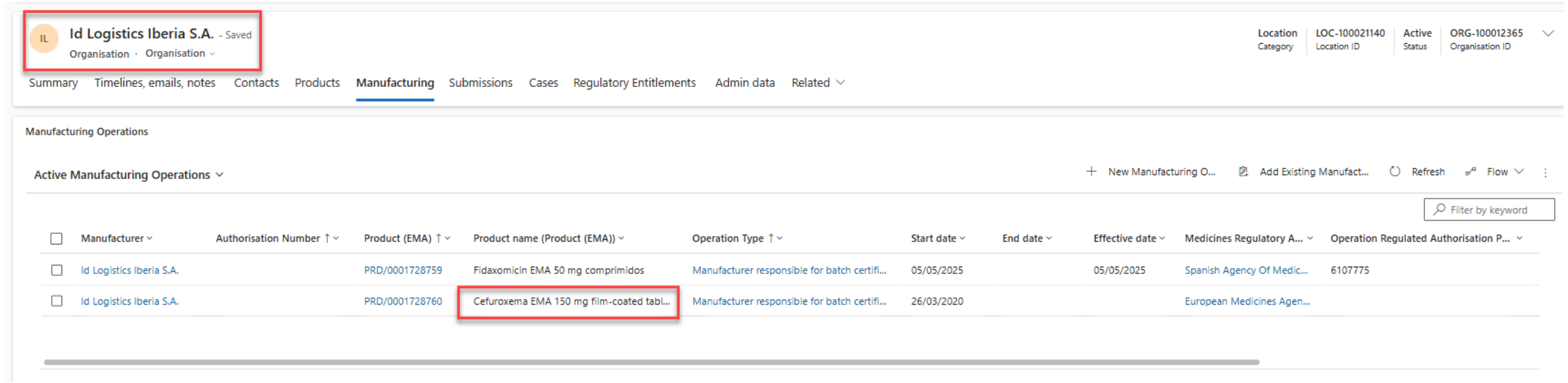
Inspections use case – creation of GMP inspection case



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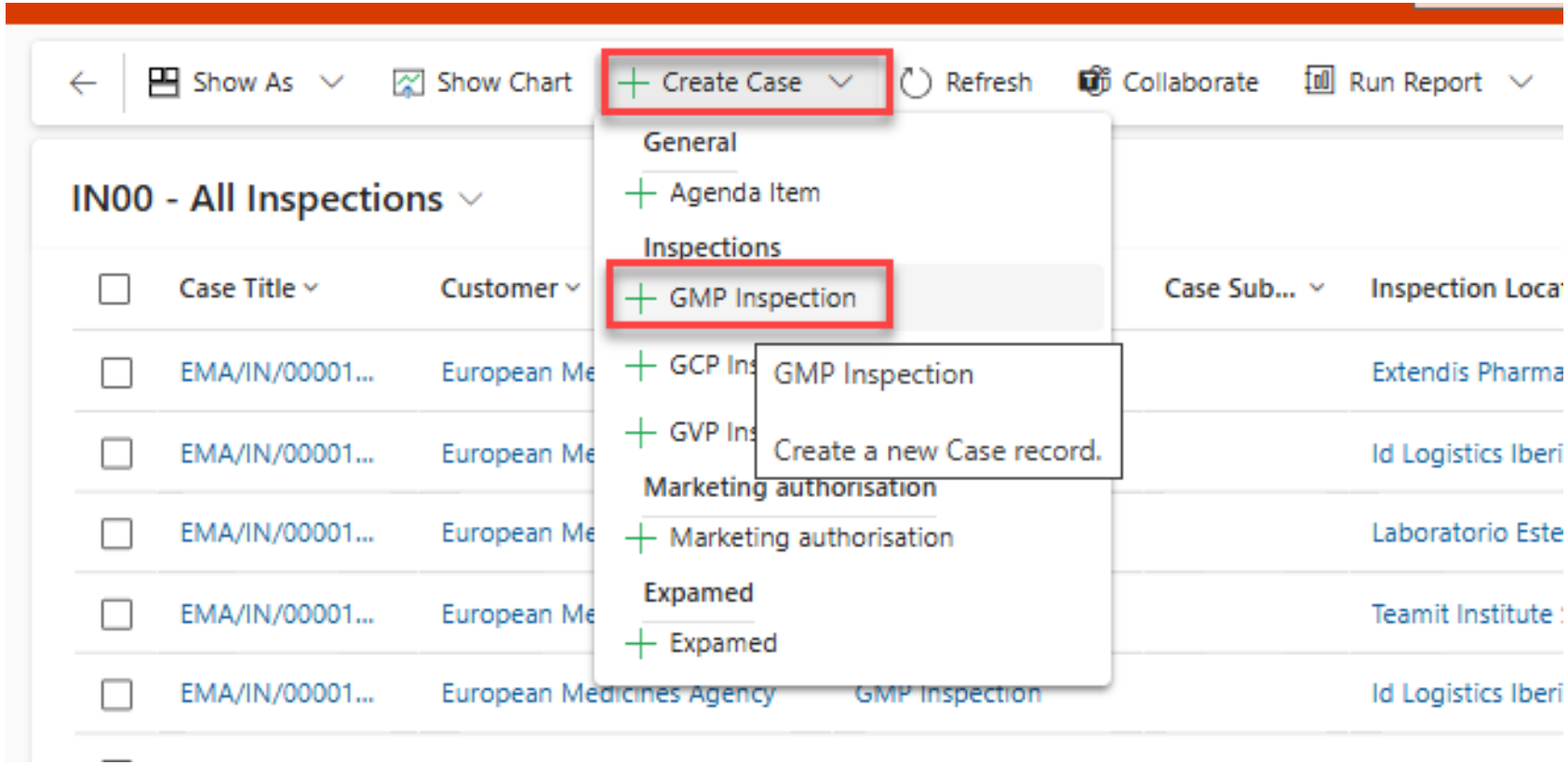
Inspections use case – creation of GMP inspection case



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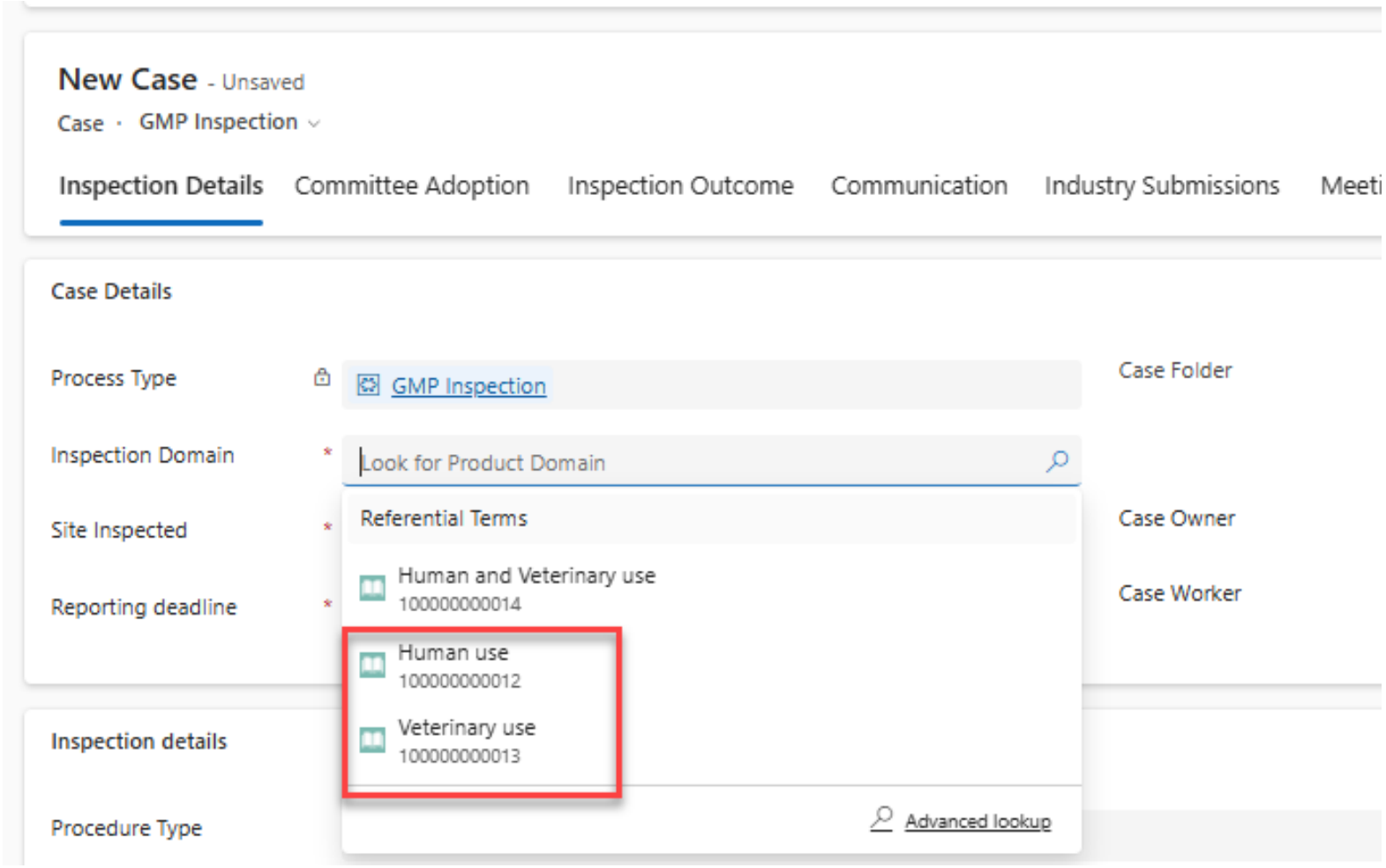
Inspections use case – creation of GMP inspection case



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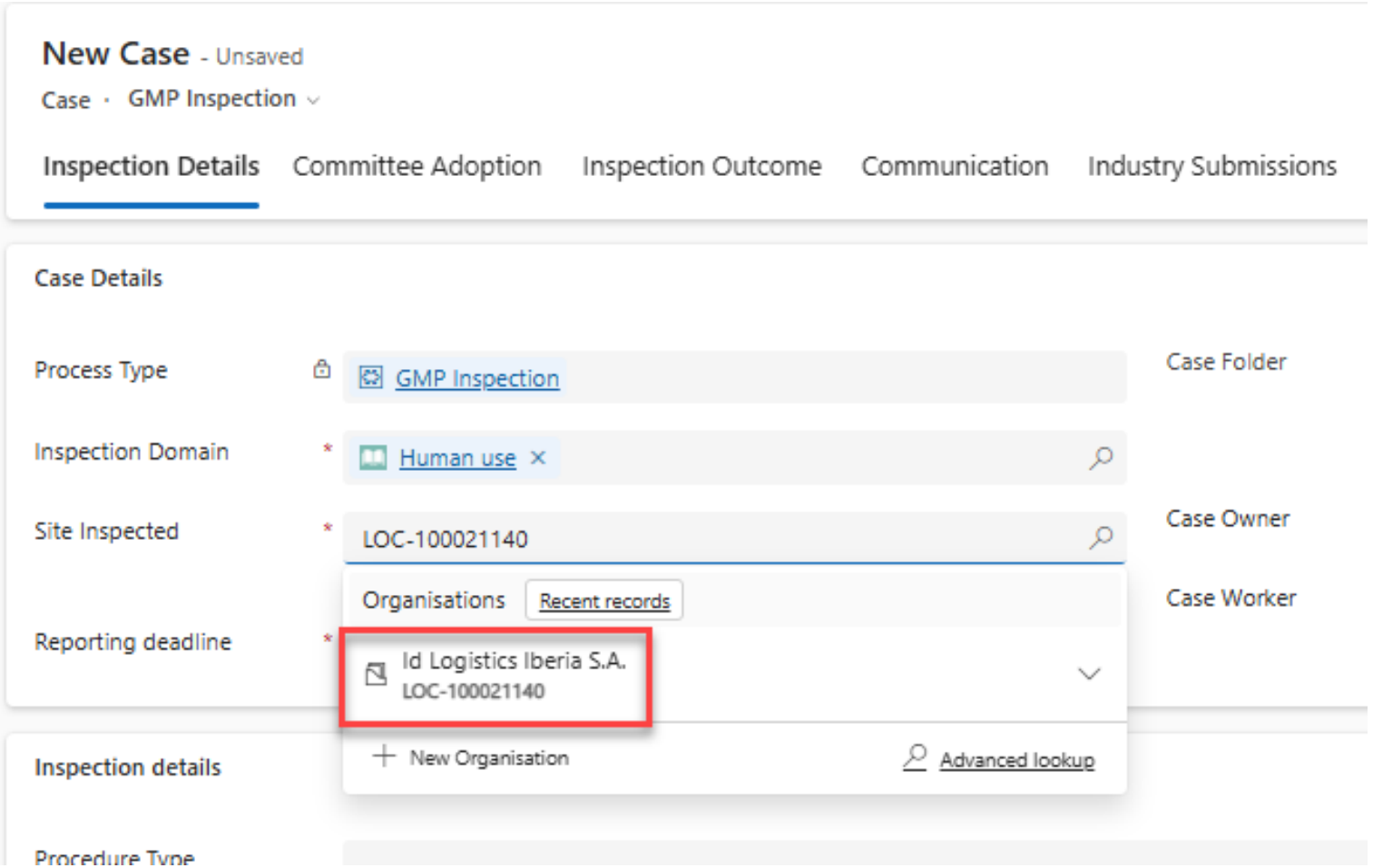
Inspections use case – creation of GMP inspection case



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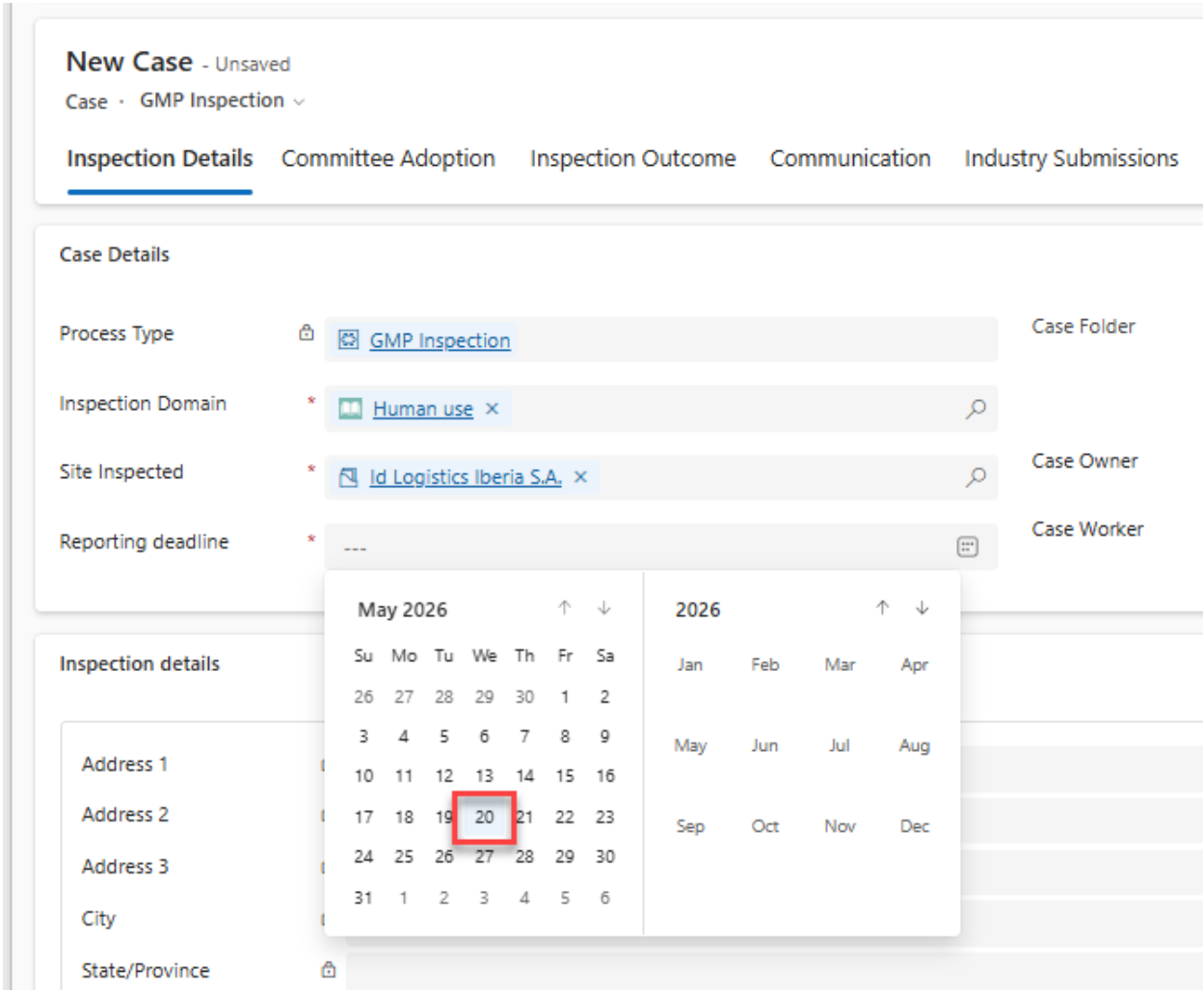
Inspections use case – creation of GMP inspection case



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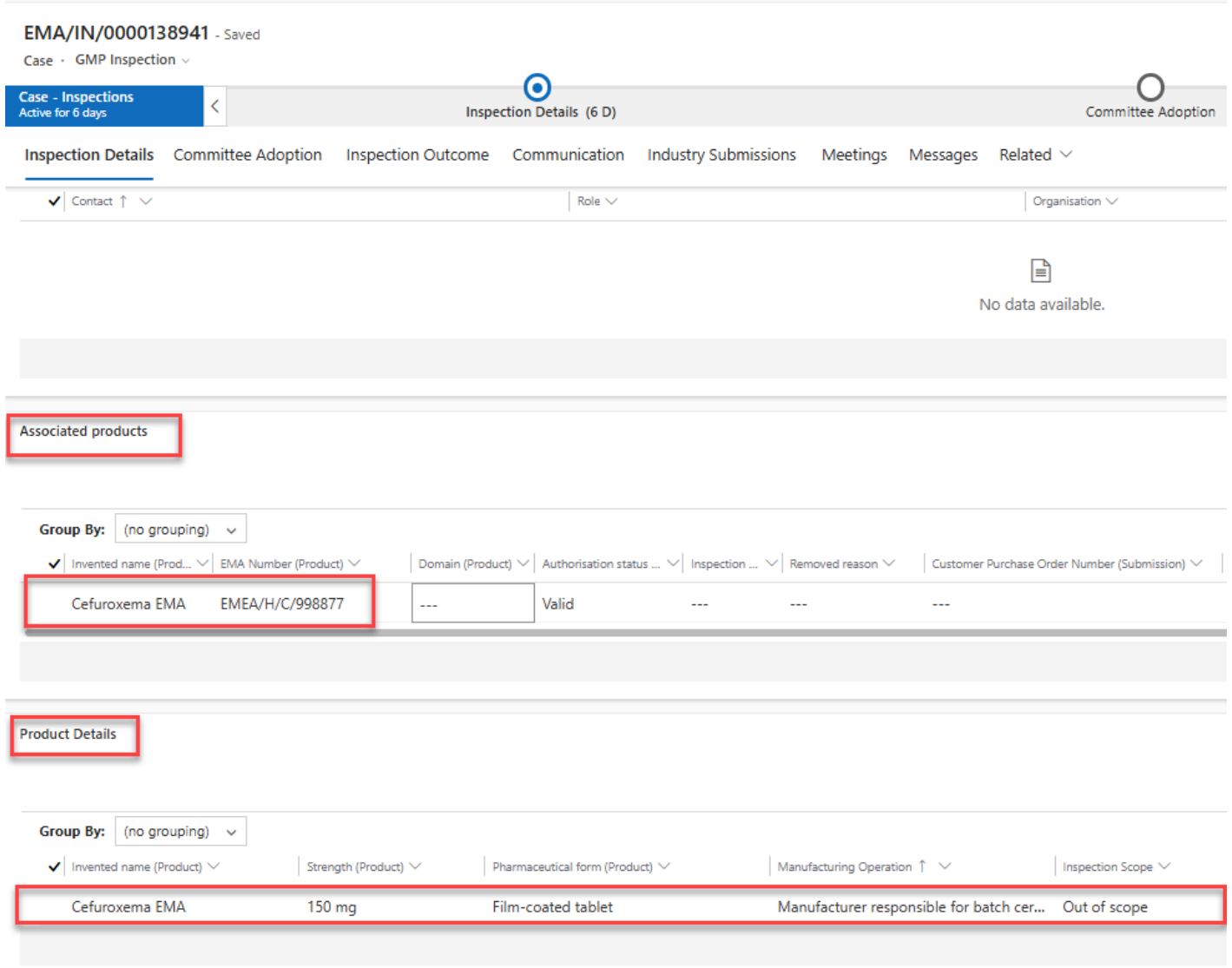
Inspections use case – creation of GMP inspection case



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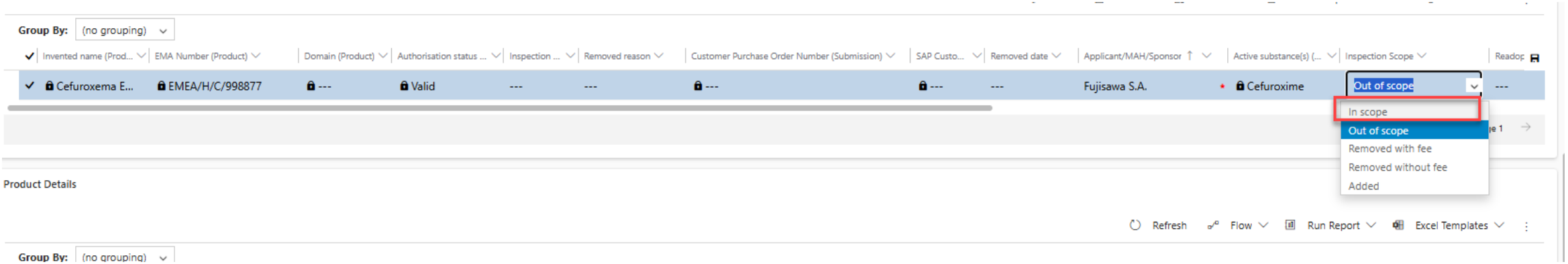
Inspections use case – creation of GMP inspection case



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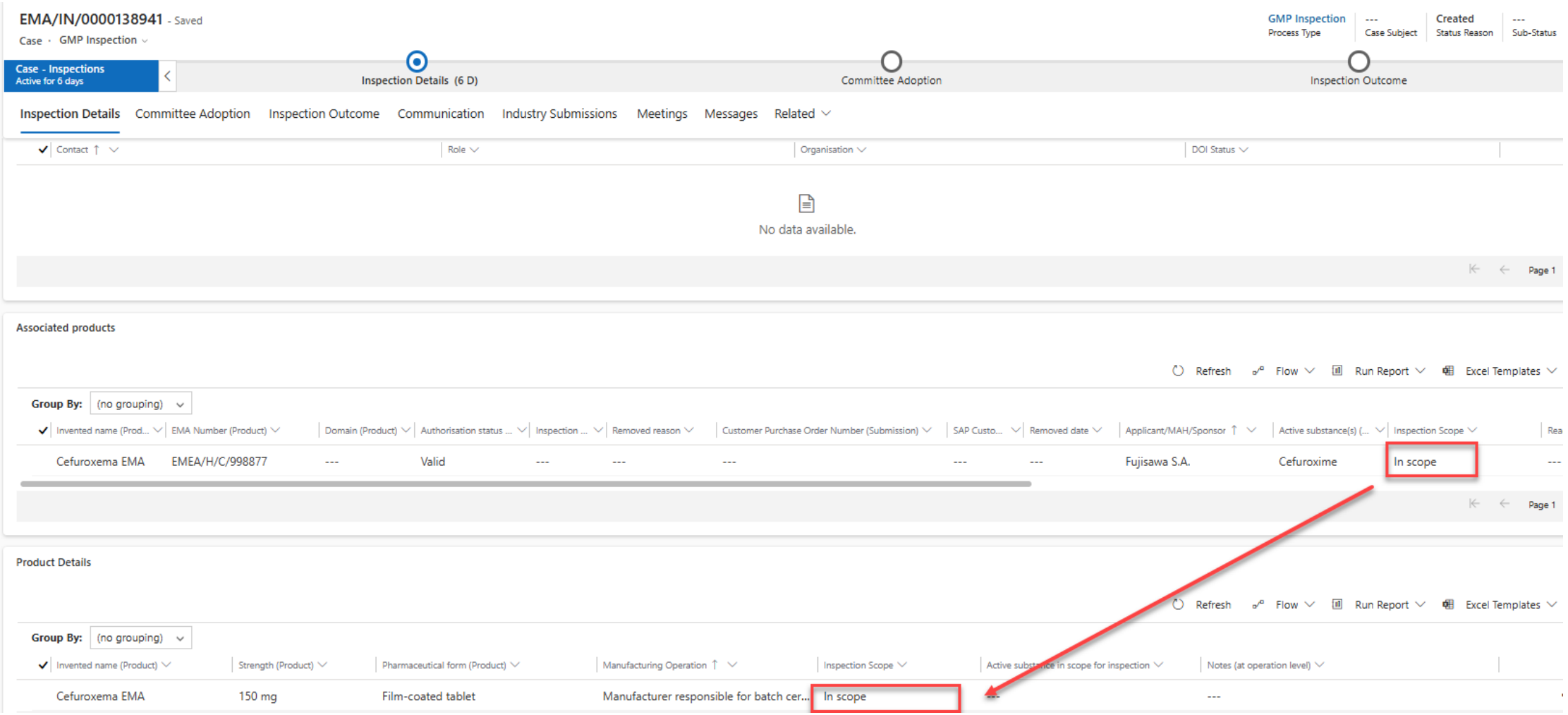
Inspections use case – creation of GMP inspection case



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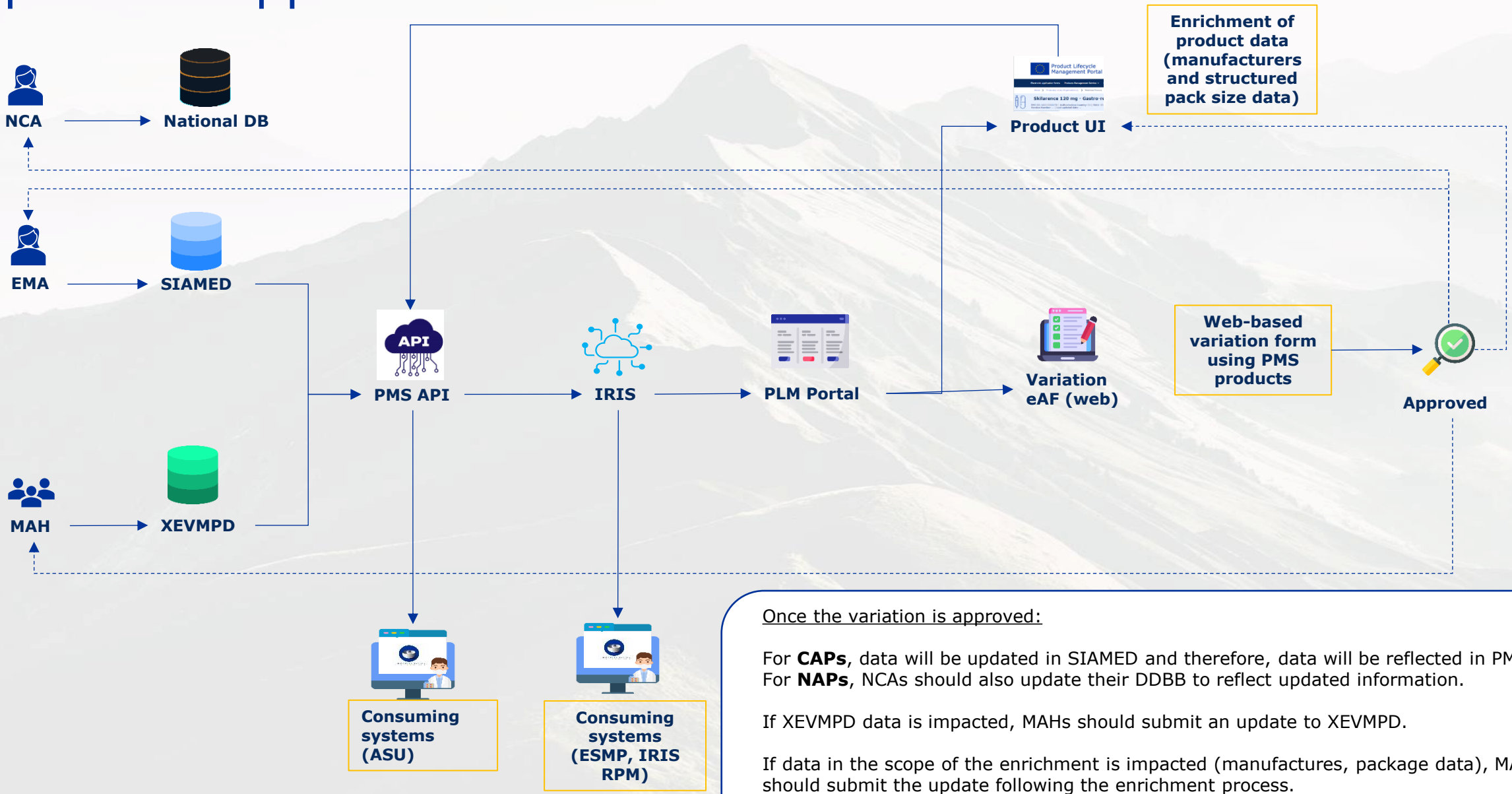
Update of approved data



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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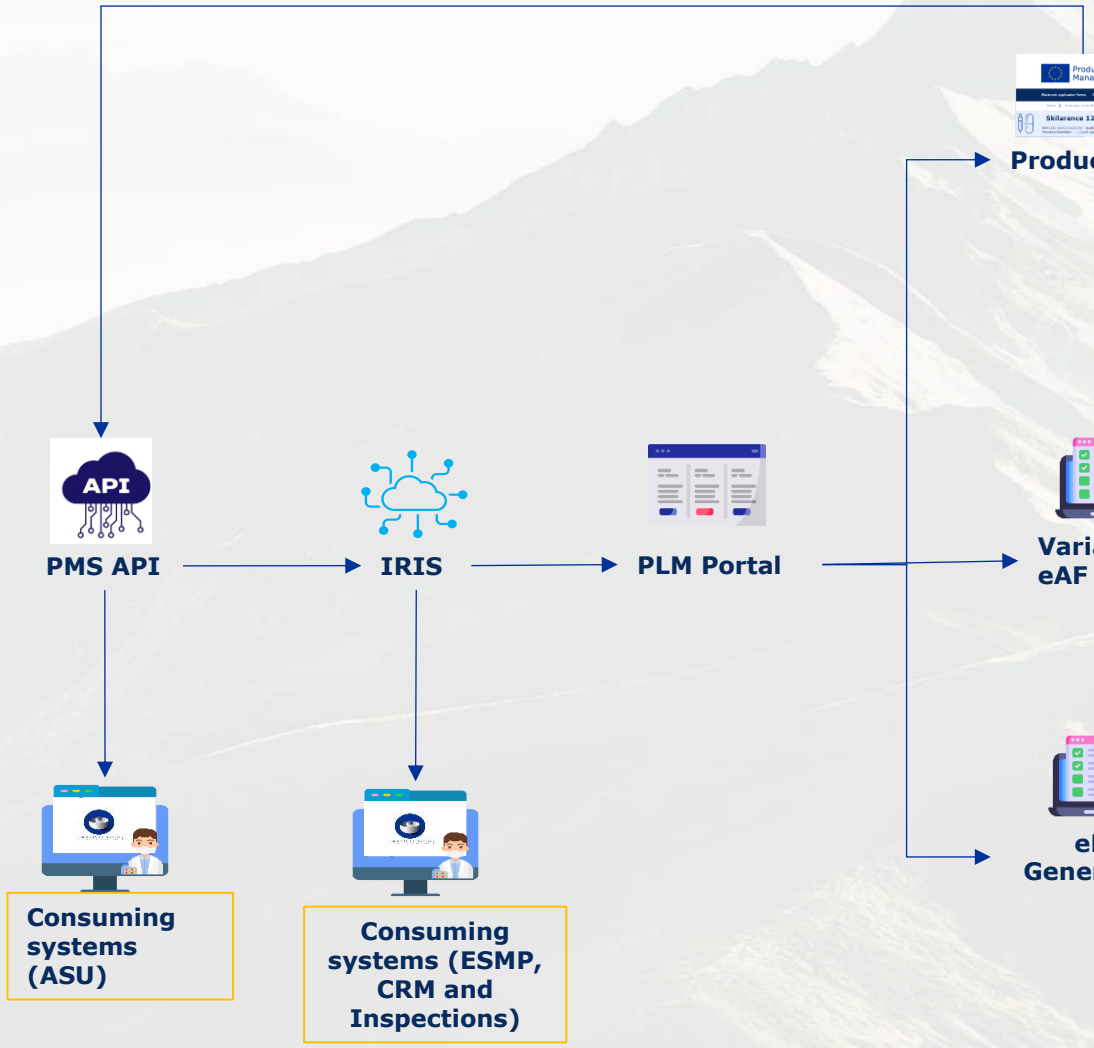
ePI use case – creation and publication of ePI



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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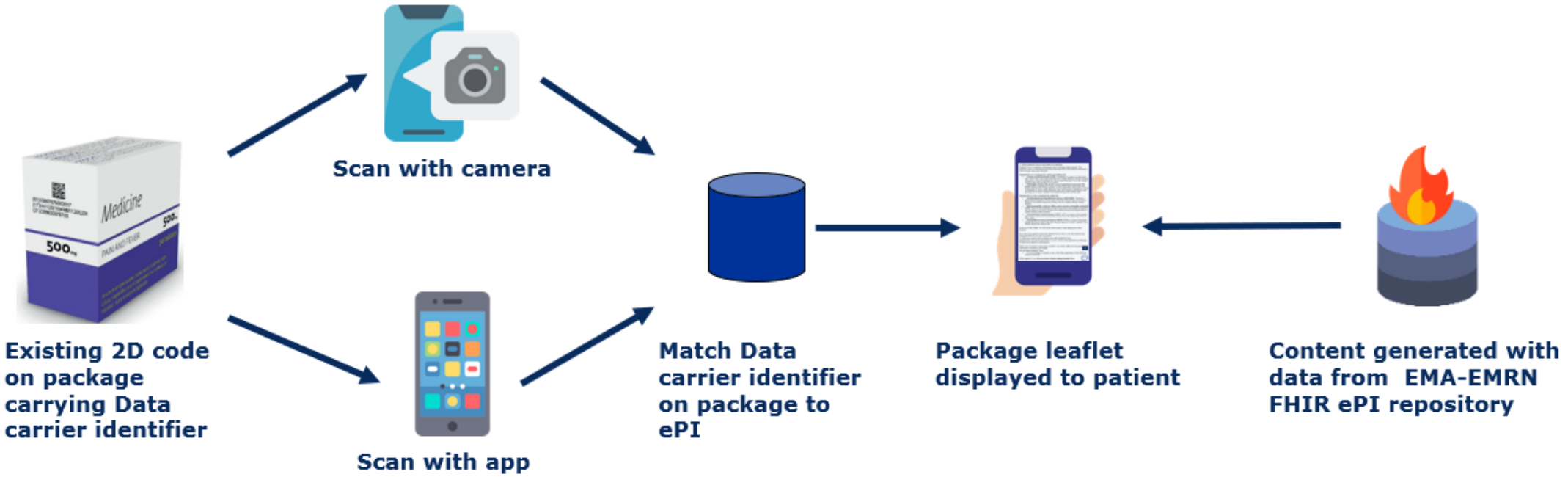
ePI use case

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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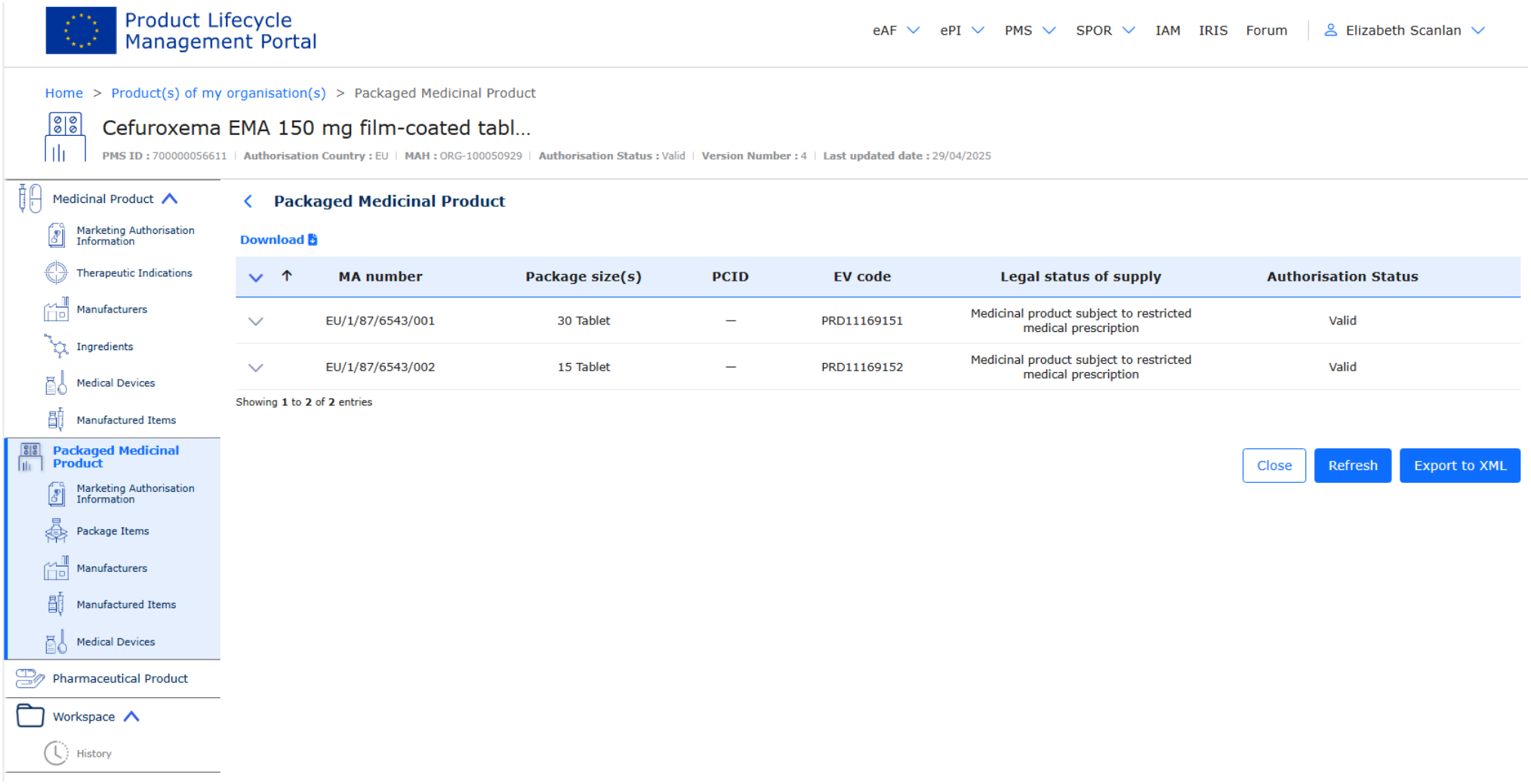
ePI use case – view from PLM: Product UI



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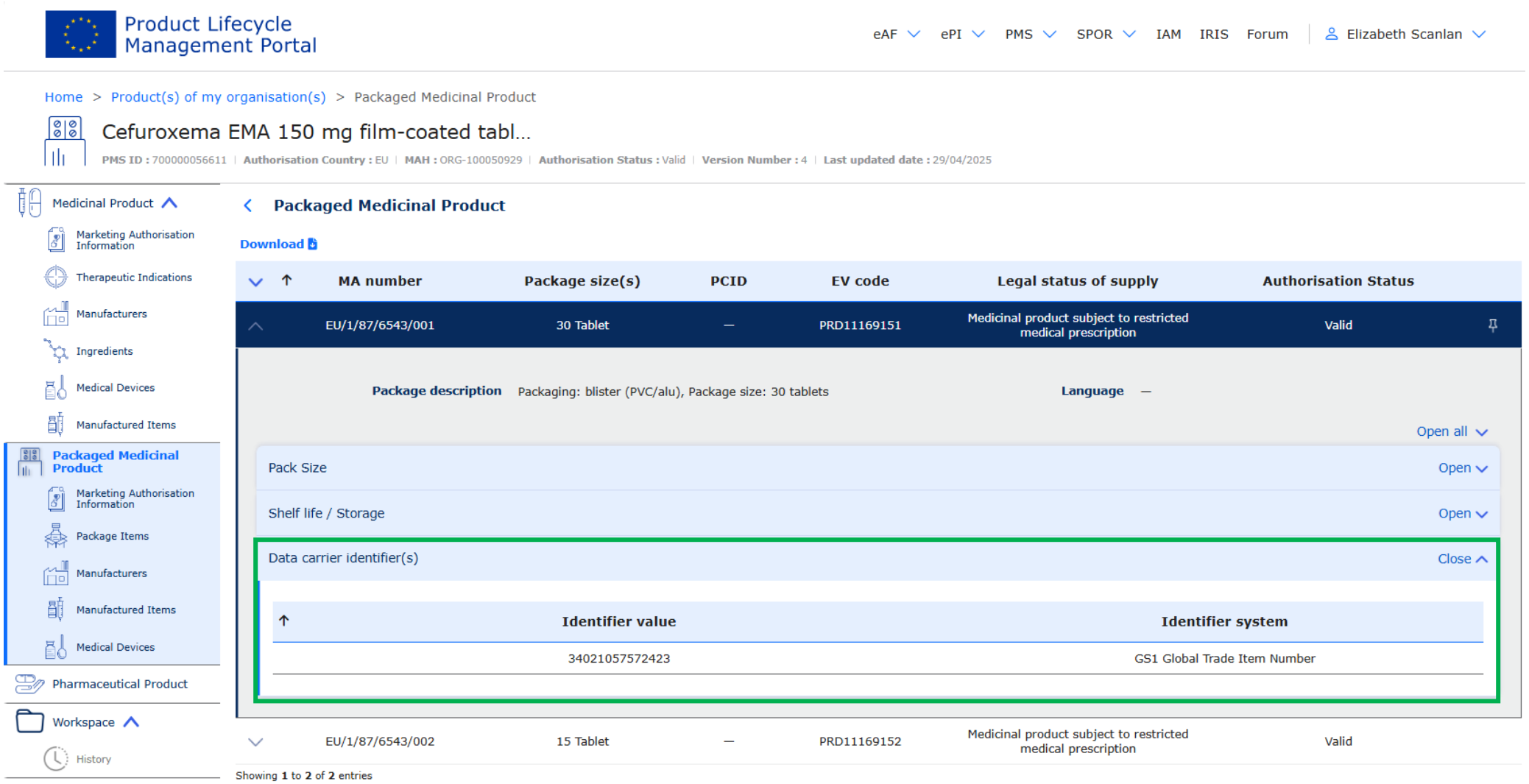
ePI use case – view from PLM: Product UI



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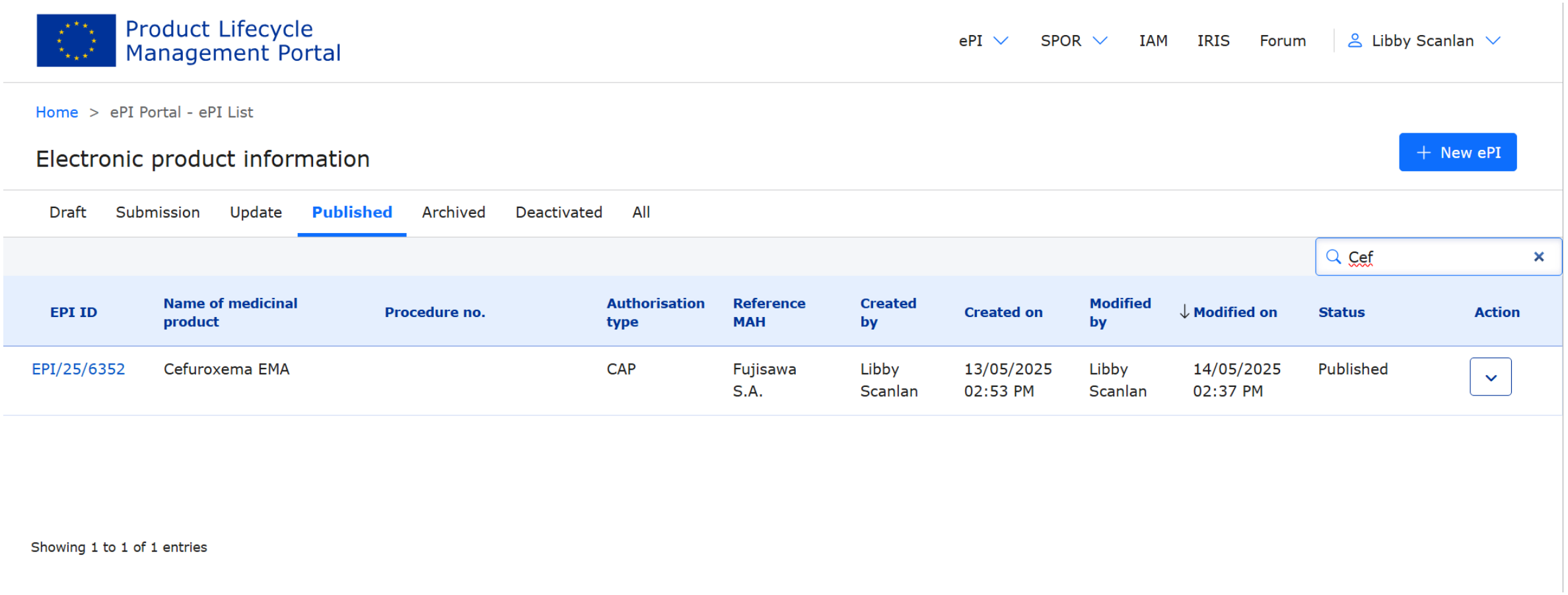
ePI use case – view from PLM: ePI



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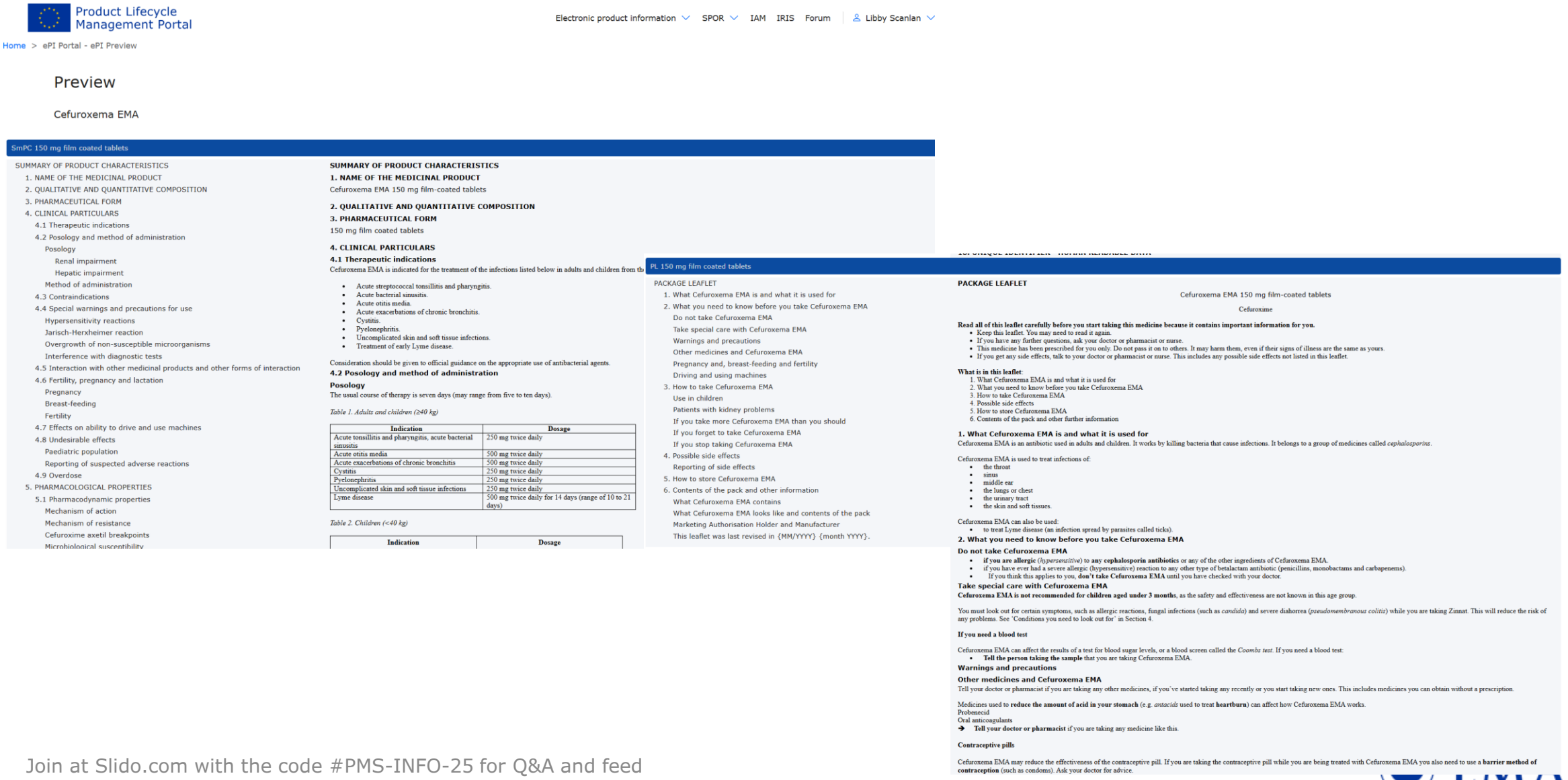
ePI use case – view from PLM: ePI



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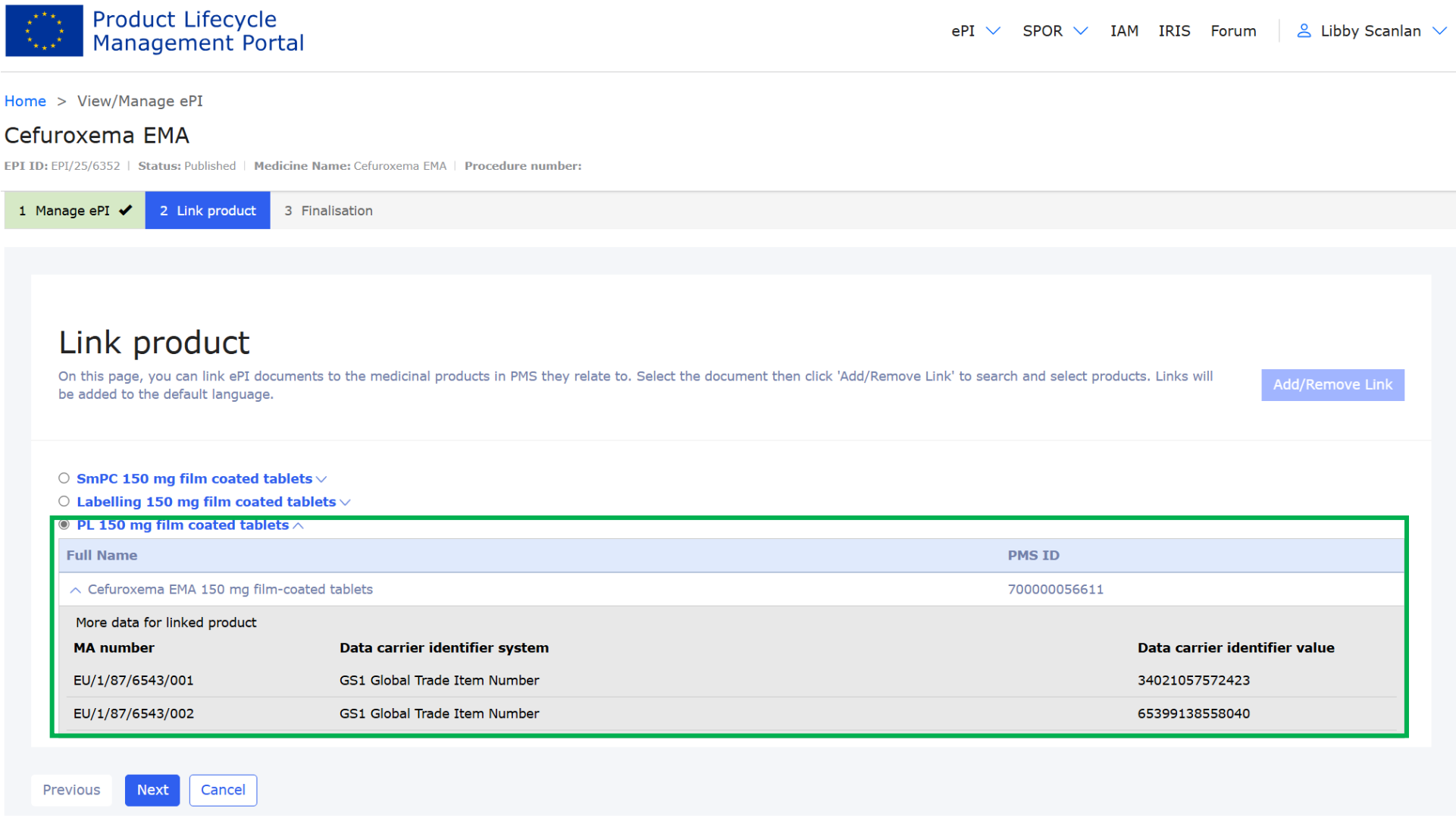
ePI use case – view from PLM: ePI



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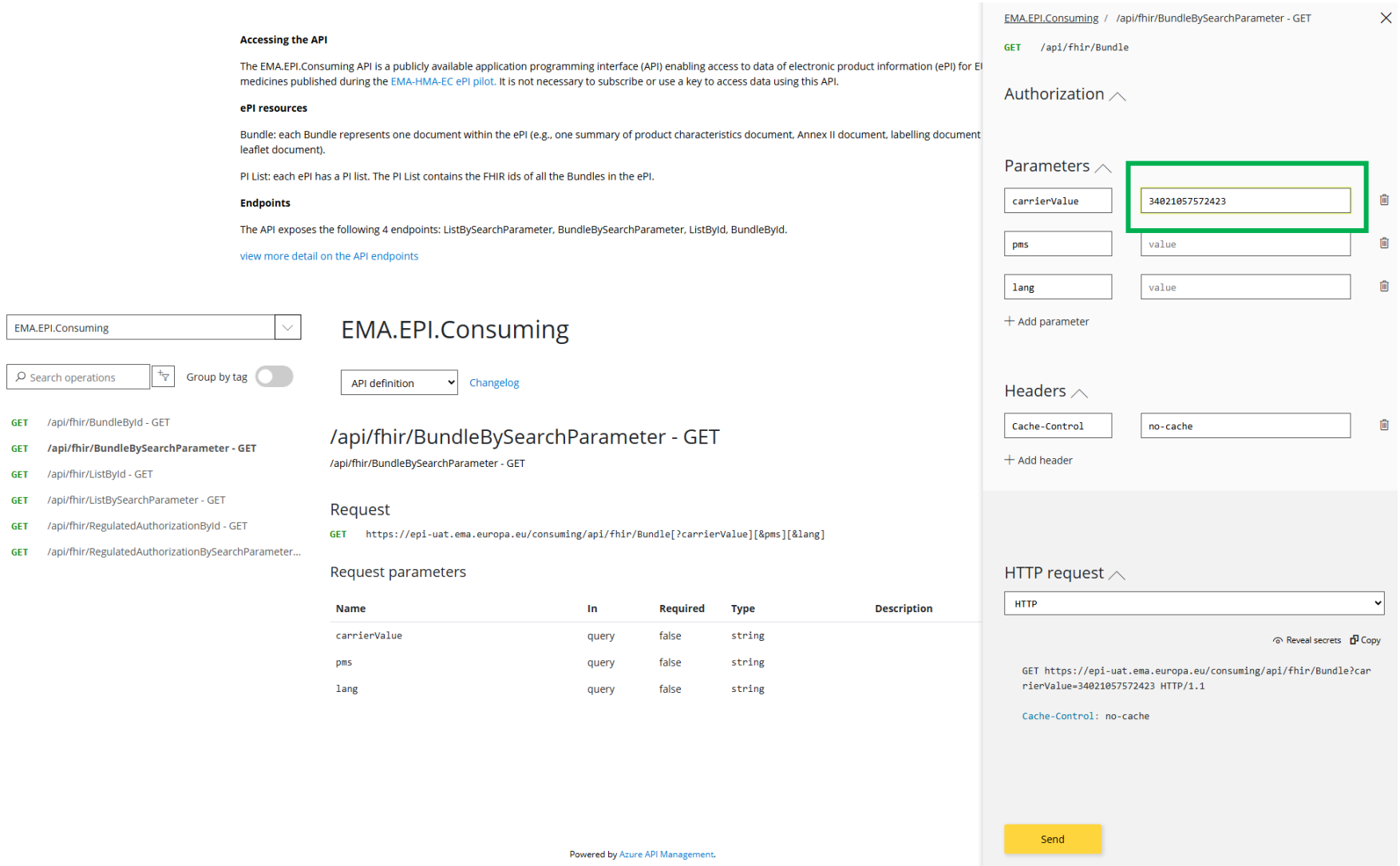
ePI use case – view from ePI API



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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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span></s></p>\n<p style=\"text-align: center; line-height: no
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oman', serif;\"> </p>\n<p style=\"line-height: normal; m
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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
style=\"margin: 0cm -0.1pt 0cm 0cm; line-height: normal; font
-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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f;\">What is in this leaflet:</p>\n<ol>\n<li
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imes New Roman', serif;\">What Cefuroxema EMA is and what it
is used for
\n<li style=\"line-height: normal; font-size:
11pt; font-family: 'Times New Roman', serif;\">What you need
to know before you take Cefuroxema EMA
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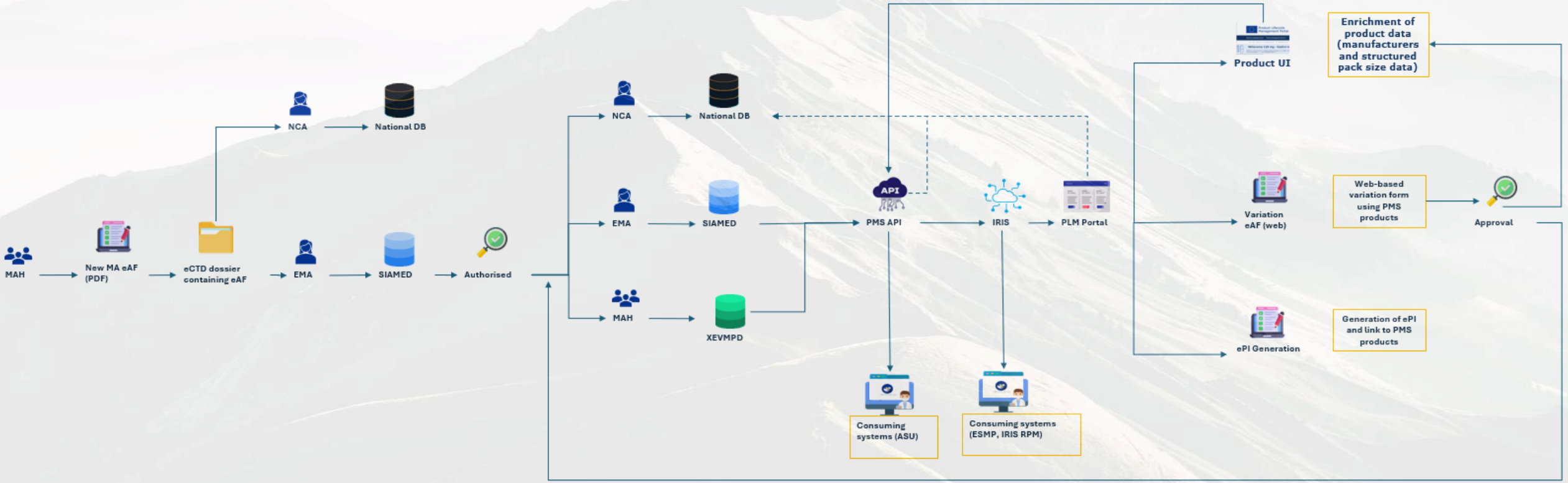
Overview of data workflow



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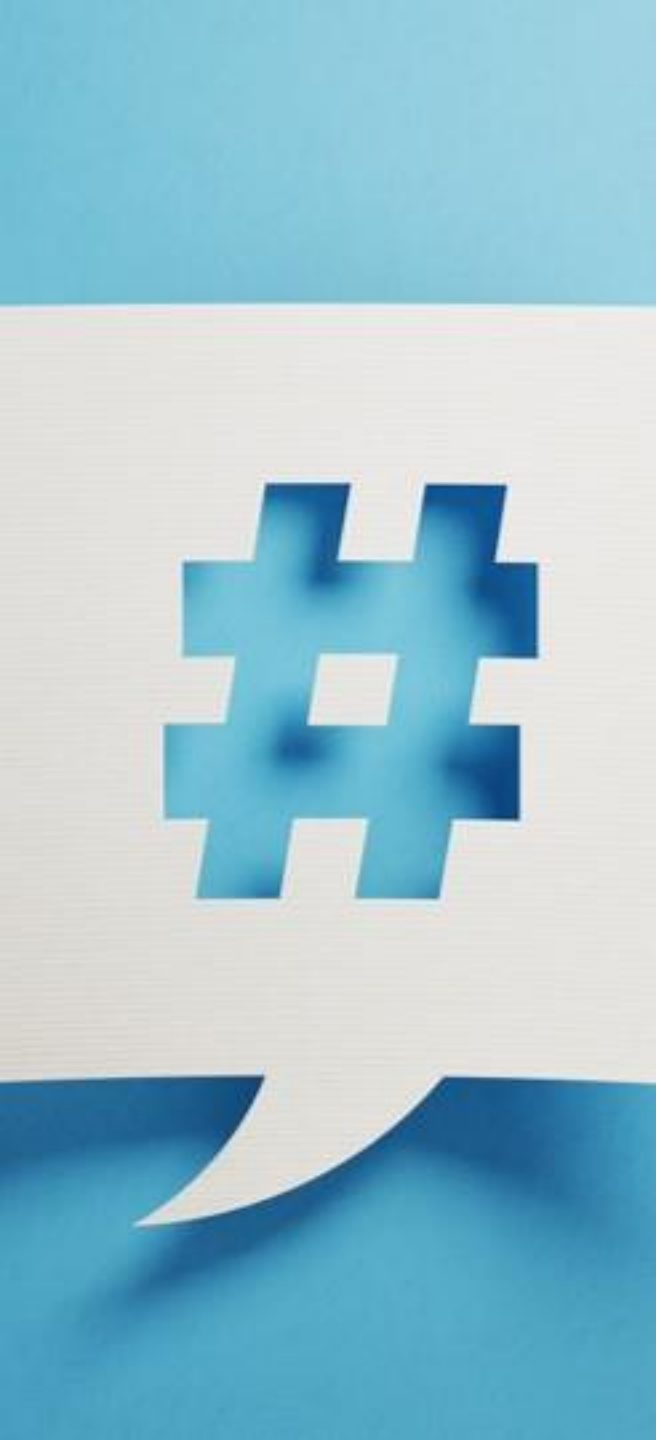


Key takeaways & conclusions

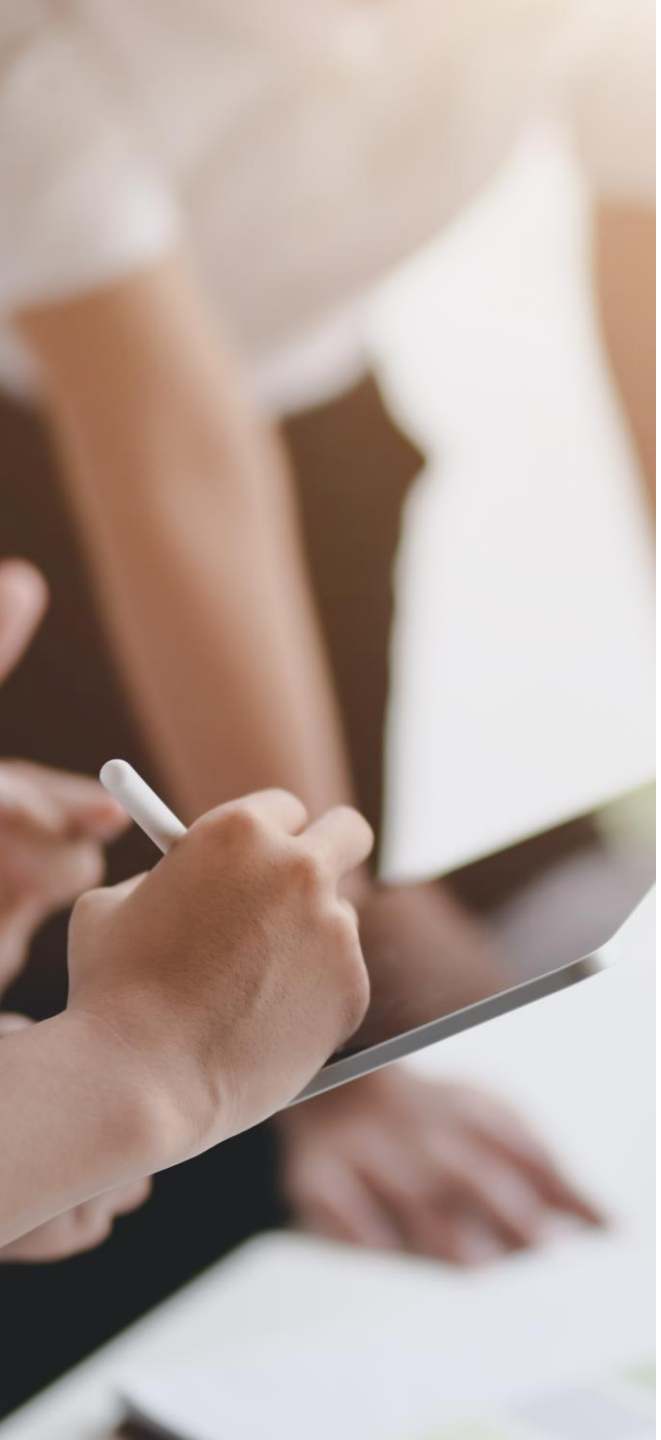
1. **Data submitted by MAHs is re-used** to feed PMS and its consuming systems (ePI, eAF, ASU, ESMP or the RPM in IRIS).

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*

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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Session 4:
PMS, our shared journey

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EMA
EUROPEAN MEDICINES AGENCY

Chairs:

Alexis Nolte
PMS Business Sponsor and Head of Human Medicines Division

Aimad Torqui
Member of Network Portfolio Advisory Group (NPAG), Network Data Steering Group (NDSG) and Regulatory Optimization Group (ROG)

Speakers:

Veronica Lipucci Di Paola
EMA PMS Product Owner

Dino Soumpasis
Network PMS Product Owner, BfArM

Elisabeth Godet
PMS Subject Matter Expert (SME), Vaccines Europe

Javier Monvoisin
PMS Subject Matter Expert (SME), Medicines for Europe

Fakredin Sayed Tabatabei
PMS Subject Matter Expert (SME), Medicines Evaluation Board

EMA
EUROPEAN MEDICINES AGENCY

Speakers:

Veronica Lipucci Di Paola
EMA PMS Product Owner

Dino Soumpasis
Network PMS Product Owner, BfArM

Topic:

PMS Status Update

Product Management Service achievements

Date	Product UI Milestone	PMS API Milestone
May 2024	**Read-only** for MAHs & NCAs (CAPs)	–
July 2024	–	**Read-only** for MAHs (CAPs & non-CAPs)
Sep 2024	**Read-only** for MAHs & H&V NCAs (CAPs & non-CAPs)	**Read-only** for H&V NCAs (CAPs & non-CAPs)
Dec 2024	-	**Read-only** for H-only NCAs (CAPs & non-CAPs)
Jan 2025	**Write access** for MAHs (non-CAPs)	-

In **2024:** all authorised CAPs and non-CAPs data have been migrated to PMS from XEVMPD/SIAMED, enabling read access for all stakeholders to PUI and API

In **2025:** Enrichment of data in PMS is launched

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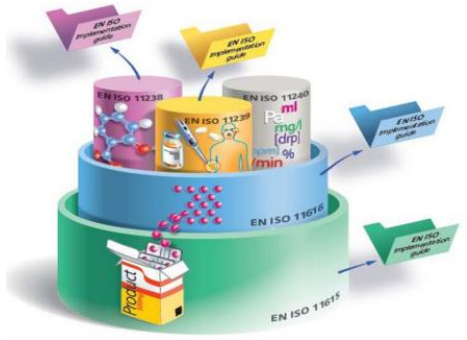
PMS Data Model

Colour legend

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

ISO IDMP	Description
ISO 11238	Data elements and structures for unique identification and exchange of regulated information on Substances
ISO 11239	Data elements and structures for unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging
ISO 11240	Data elements and structures for unique identification and exchange of units of measurement
ISO 11616	Data elements and structures for unique identification and exchange of regulated pharmaceutical Product information
ISO 11615	Data elements and structures for unique identification and exchange of regulated medicinal Product information



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PMS

ePI

eAF

ASU

ESMP

IRIS Portal

PMS

ePI

eAF

ASU

ESMP

IRIS Portal

PMS data needed for ePI

"The linkage of an ePI and its product in PMS is done through the PMS ID and the Data Carrier Identifier (CDI) ensuring full traceability from regulatory, public and marketed information."

PMS Data Element	ePI Field	Purpose/Impact
Product Management Service Identifier (PMS ID)	PMS ID	• Auto-filled for consistency • Standard terminology used • Ensures controlled vocab • Enables structured tracking • Enables data exchange
Data Carrier Identifier	Data Carrier Identifier Value	

PMS → IRIS Dataverse → ePI → Regulatory/Public Use

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PMS

ePI

eAF

ASU

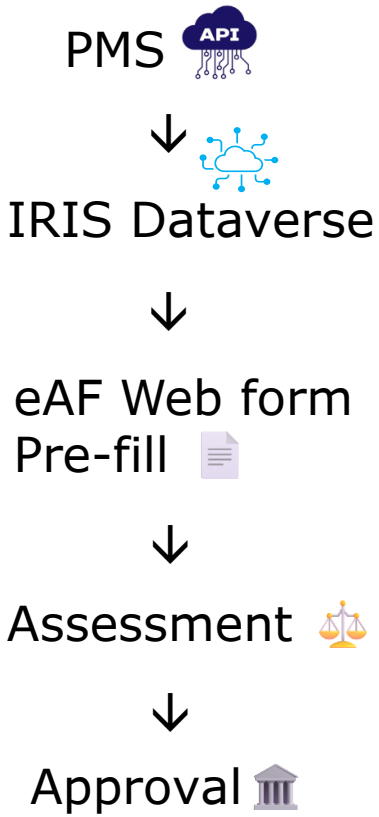
ESMP

IRIS Portal

PMS data needed for eAF

"PMS delivers structured product data that pre-populates and supports key fields in the electronic Application Form (eAF) for variations."

PMS Data Element	eAF Section	Purpose/Impact
Product Management Service Identifier (PMS ID)	Product Selection	• Auto-filled for consistency • Standard terminology used • Avoids free text errors • Ensures controlled vocab • Enables structured tracking • Enables data exchange
Medicinal Product Identifier (MPID)		
Domain		
Type		
(Authorised) pharmaceutical form		
Medicinal Product Full Name		
Marketing authorisation number (MP/PMP)		
Marketing authorisation Country		
Marketing authorisation holder (organisation)		
Marketing authorisation procedure (Id, type)		
Marketing authorisation status (MP/PMP)		
Packaged Medicinal Product Identifier (PCID)		
Package description; Pack size		
Ingredient (Active substance)		
ATC code(s) & ATC Flag; GMO; PSMF; Medical Device;	Proposed Changes/Structured Changes	



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PMS

ePI

eAF

ASU

ESMP

IRIS Portal

PMS data needed for ASU

"PMS enables the collection and analysis of ASU data by prepopulating the templates with standardised and complete product data."

PMS Data Element	ASU Field	Purpose/Impact
Product Management Service Identifier (PMS ID)	PMS ID	• **Product identification** • **Calculation of total amount of antimicrobial active substance per product presentation** • **Antimicrobial use data analysis**
Packaged Medicinal Product Identifier	Package ID	
Marketing authorisation number	Marketing authorisation number	
Procedure type – Medicines approval system	Procedure type	
Medicinal product name	Medicinal product name	
(Authorised) pharmaceutical form	ASU product form	
Pack size	ASU pack size	
Manufactured item quantity	ASU pack size	
ATC code(s)	ATC code	
Reference substance or Substance	ASU substance	
Reference strength or Strength (concentration and presentation)	ASU strength	

API PMS → 📄 ASU Template Pre-fill → 📈 Analysis

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PMS

ePI

eAF

ASU

ESMP

IRIS Portal

PMS data needed for ESMP

"PMS provides structured product data that supports the fulfillment of ESMP requirements for critical medicines."

PMS Data Element	ESMP Section	Purpose/Impact
Product Management Service Identifier (PMS ID)	Product Information	• Auto-filled for consistency • Standard terminology used • Avoids free text errors • Ensures controlled vocab • Enables structured tracking • Enables data exchange
Packaged Product Management Service Identifier (PMS ID)		
Full Product Name		
Short Product Name		
Active Substance		
Strength		
Pharmaceutical Dose Form		
Pack Size		
Packaging		
PCID		
Country of Authorisation		
Organisation ID/Name	Manufacturer's Organisation Information	
Organisation Location ID/City/Country		
Operation ID/Type		

API PMS → IRIS Dataverse → ESMP Template Pre-fill → Analysis/Crisis Preparedness

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EMA

PMS

ePI

eAF

ASU

ESMP

IRIS Portal

PMS data needed for IRIS Portal procedures

"Procedures taking place on the IRIS Portal leverage PMS data to support various regulatory activities, including:

- *Inspections, using medicinal products, manufacturer data and operations migrated from SIAMED to PMS*
- *Parallel Distribution, relying on PMS data for centrally authorised products (CAPs) to track distribution case forms*
- *CAPs marketing status*
- *PSURs, PASS, referrals: CAPs and non-CAPs*
- *Variations for CAPs and non-CAPs WS*
- *Other procedures of the product lifecycle for CAPs (e.g. renewals, post authorisation measures, etc)*

IRIS Portal uses PMS Data Derived From:	**Purpose/Impact**
• Product data uploads from **XEVMPD** and **SIAMED** • Enrichment data submissions by non-CAP MAHs (i.e. structured manufacturer operations and pack size data)	• Auto-filled for consistency • Standard terminology used • Avoids free text errors • Ensures controlled vocab • Enables structured tracking • Enables data exchange

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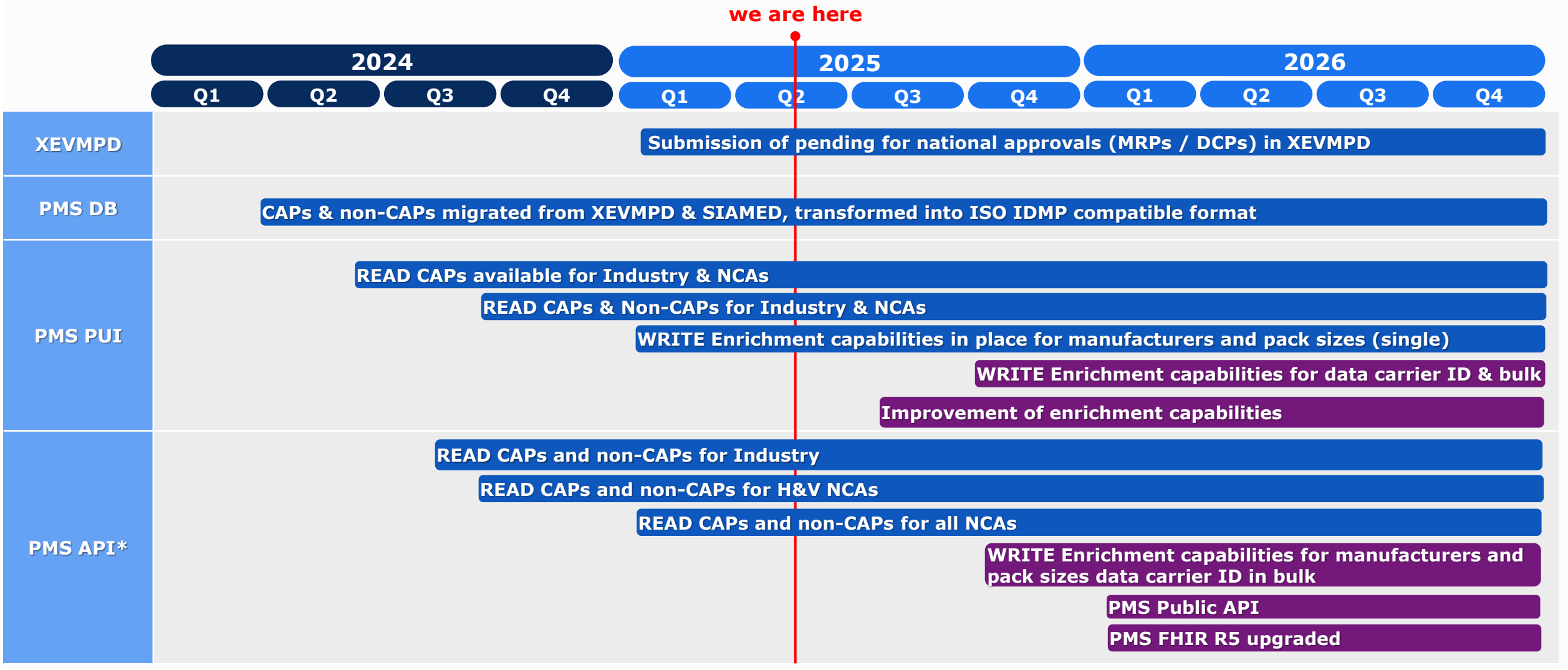
What capabilities are and will be available to users



Legend | **Delivered capability** | **Planned delivery**

*Write PMS API IG updated in May

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Key Activities for NCAs

- **Request PMS access** to the **Product User Interface** or **Application Programming Interface** and **optional review structured products data** including the manufacturers and pack sizes information submitted by MAHs for non-CAPs.
- **Continue adoption of ISO IDMP standards** and **align NCA databases with the PMS data model**, where applicable, to enable ISO IDMP compatibility, seamless machine-to-machine communication, and interoperability.
- **NCA vs PMS Data Mapping:** Ensure medicinal product data in the NCA database is accurately **mapped to PMS** master data. **Seek EMA support** to map legacy product data to PMS and establish a process to keep new PMS product data updated in your system.
- **Collaborate with software developer/vendors** to ensure seamless **machine-to-machine integration** between NCA databases and the PMS API for accurate data exchange from PMS to NCA systems.

What EMA is doing to support NCAs

1) Monthly PMS data mapping meetings *until December 2025 for NCA staff representatives to:*

- Report on **data mapping progress** (number of NCAs that submitted data, records mapped, and identified issues)
- Facilitate the **exchange of lessons learned** among NCAs
- Host **Q&A sessions** to address NCA data mapping queries

2) Public monthly PMS Q&A Clinics*:* 17 June, 22 July, 28 August, 18 September, 14 October, 18 November, 18 December

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Key Activities for MAHs pt.1

- **Request PMS access** to the PUI or/and API and ensure RIM systems are ready for MAHs to access product data through PMS API.
- **Align product data to ISO IDMP**. Ensure data is accurate, up-to-date, and ready for submission.
- **Submit & maintain products following data under Art.57 requirement:**
  - Packaged products in XEVMPD & initial dataset of structured data [i.e. ***manufacturer,*** *(including CRO data*),* and ***pack size*** data] in PMS according to the timelines:
    - Products **under ULCM** list: Deadline for data submission is **December 2025**.
    - All **other products**: Deadline for data submission is **December 2026**.
- **Work closely with software developers/vendors** to ensure a seamless machine-to-machine connection between the MAH's RIM system and the PMS API for accurate future data submission.

What EMA is doing to support MAHs

1) **Public training webinars** to demo new releases and explain key actions for MAHs
2) **Public PMS Q&A clinics**
3) **Publish PMS-related guidance documents** (i.e. PMS Q&A, EU IG, PUI Navigation guide etc.)

*: Contract Research Organisations (CRO) data apply to non-CAPs with BE studies and support ESMP and referral procedures.

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Key Activities for MAHs pt.2

XEVMPD/PMS Data submission timelines

Regulatory activity	XEVMPD	PMS *(Recommended)*
Initial MA	Within 15 calendar days from the date of MA notification	Within 15 calendar days from the date of MA notification
Post-approval ie. variation	Within 30 calendar days from the date of the authorised changes	Within 30 calendar days from the date of the authorized changes

For the moment, EMA accepts that PMS manufacturers and pack size data are submitted monthly.

Reference documents

1) Electronic submission of medicinal product information by marketing-authorisation holders
2) PMS EU IG Chapter 2 (updated in May)
3) PMS EU IG Chapter 3 (updated in May)

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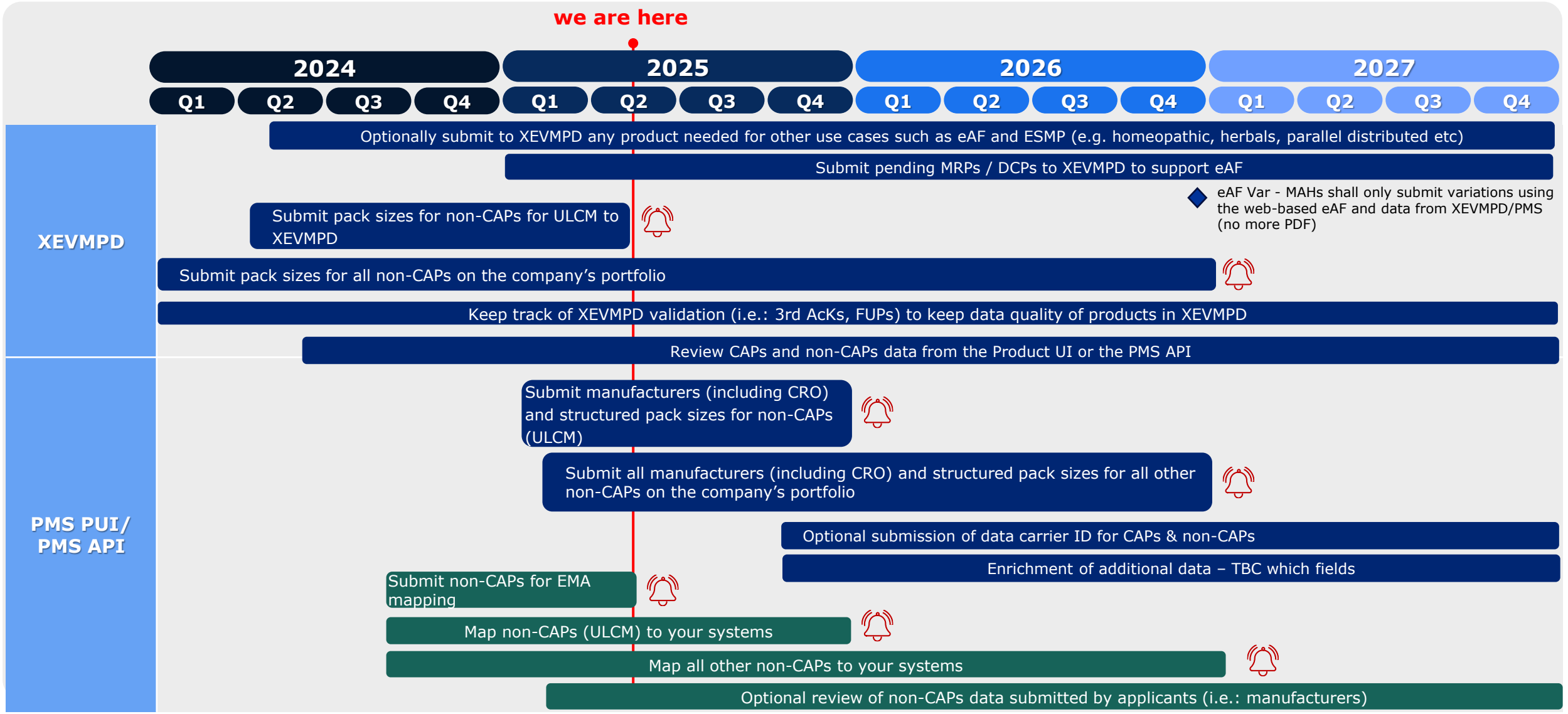
Key PMS activities for Industry and NCAs to support other use cases



Legend Industry action | NCA action | Deadline

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

Upcoming events

Q&A clinics on Product UI and API

- **17 June 2025** (11:00 – 12:00 CEST): Event page
- **22 July 2025** (11:00 – 12:00 CEST): Event page
- **28 August 2025** (10:00 -11:00 CEST): Event page
- **18 September 2025** (10:00 – 11:00 CEST): Event page
- **14 October 2025** (11:00 – 12:00 CEST): Event page
- **18 November 2025** (11:00 – 12:00 CEST): Event page
- **18 December 2025** (11:00 – 12:00 CEST): Event page

Quarterly system demo

Live broadcast on event page

26 June 2025 (9:00 – 11:30 CEST)

Event page

SPOR & XEVMPD status update webinars

Live broadcast on event page

- **9 July 2025** (10:00 – 12:30 CEST): Event page
- **8 October 2025** (10:00 – 12:30 CEST): Event page

PMS Progresses: How to stay informed

PMS News page

Check:

- News
- Events announcements
- Downtime comms

Check regularly

PLM Newsletter

- See planned PMS engagement activities for upcoming quarter
- **Subscribe** here

Receive via email quarterly after subscription

PMS webinars

- **Q&A Clinics** to answer users' questions
- **Targeted training sessions** on PMS systems' use

Check EMA's Website Events Pages (when also targeting Industry), EU-NTC (for Network only)

PMS FAQ Document + PLM Portal Forum

- Check FAQs on PMS (Document)
- Ask questions (Forum)

Check regularly

Quarterly System Demos

- See the latest developments
- Give your feedback on features and priorities
- **Next system demo:** 26 Jun 2025

Announced via EMA's Website Events Pages - broadcast live

PMS Web Page

Find:

- PMS overview
- EU Implementation Guide

Check for general info on PMS

EMA
EUROPEAN MEDICINES AGENCY

Speakers:

Elisabeth Godet
PMS Subject Matter Expert (SME), Vaccines Europe

Topic:

Industry Overview: How is Industry prepared to implement PMS IDMP?

Substance, product, organisation and referential (SPOR) data are **a core asset** for evidence-based decisions
Sponsors and applicants play a crucial role in generating pivotal scientific data from substances and medicinal products

Preclinical Development | Clinical phases | Post-approval Lifecycle management

Data supporting public health

Regulatory Submissions Data

Real World Data
Clinical Trials

Real World Data
Pharmacovigilance

Data used to generate insights and evidence that support decisions on the safety, efficacy, and quality of medicines

Visit: Data in Regulation

European medicines agencies network strategy 2028

- **Path to accessibility**
- **Leveraging data, digitalisation and artificial intelligence**
- **Regulatory science, innovation and competitiveness** (Clinical Trials & Manufacturing)
- **Antimicrobial resistance and other health threats**
- **Availability and supply of medicines**
- **Sustainability of the network**

SPOR data are essential for the monitoring of medicines' safety and shortages

Visit: European Medicines Agencies Network Strategy to 2028

Sponsors, Applicants and MAHs are essential contributors, submitting structured product data throughout the lifecycle - crucial to leverage the power of data for public health

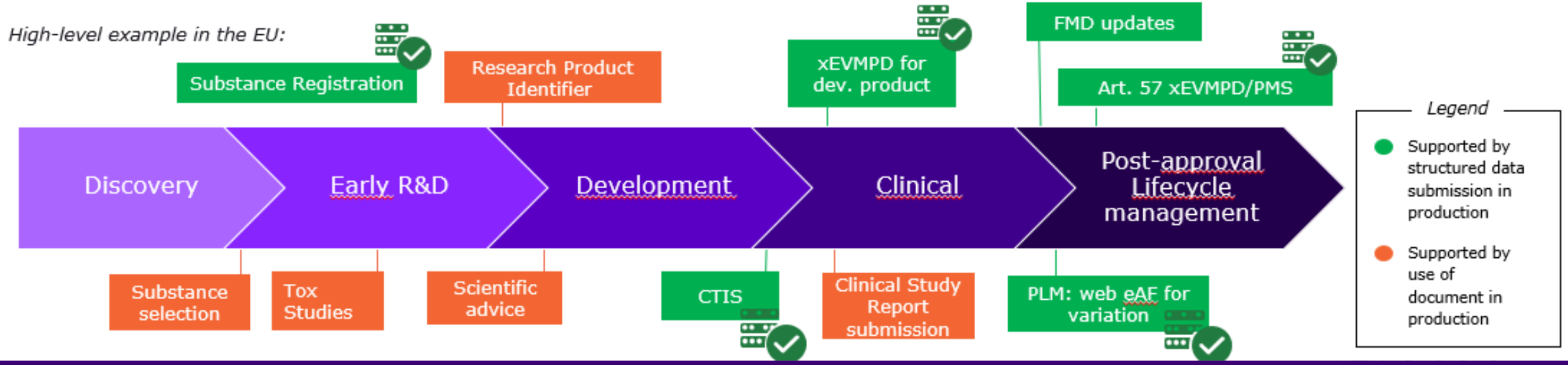
The implementation of IDMP standards marks a paradigm shift for the pharma industry

Towards Data-Driven - moving from documents to real-time data exchanges opens new possibilities for efficiency and innovation

Evidence-based decisions

- **Shift to data-driven processes**: Transition from **documents** to **data** as the primary source and for in-process exchanges.

- **Key implications**:
  - **Data** can be prioritized over documents in the **decision-making process**
  - **Data Lifecycle**: Managing both submitted and pending for approval/approved data for the same datapoint.
  - **Scientific vs. Regulatory truth**: Balancing scientifically approved information with regulatory data accuracy.
- **System requirements**: Need to manage data, not just documents.
- **Master data connectivity**: Complete knowledge integration through IDMP-compatible SPOR master data.



Substance and product structured data can strengthen evidence-based decisions, leveraging connected systems across the EU regulatory network

Industry drivers for implementing IDMP

Business drivers

- **Stronger Compliance & Access** – Meets PV regulations and improves patient access to approved, relevant information.
- **Accelerated Time to Market** – Enables faster submissions, reviews, and patient access to treatments.
- **Better Shortage Management** – Enhances reporting and reduces stockouts and overstocking.
- **Lower Admin Burden** – Minimizes post-approval work with easier data-driven updates.

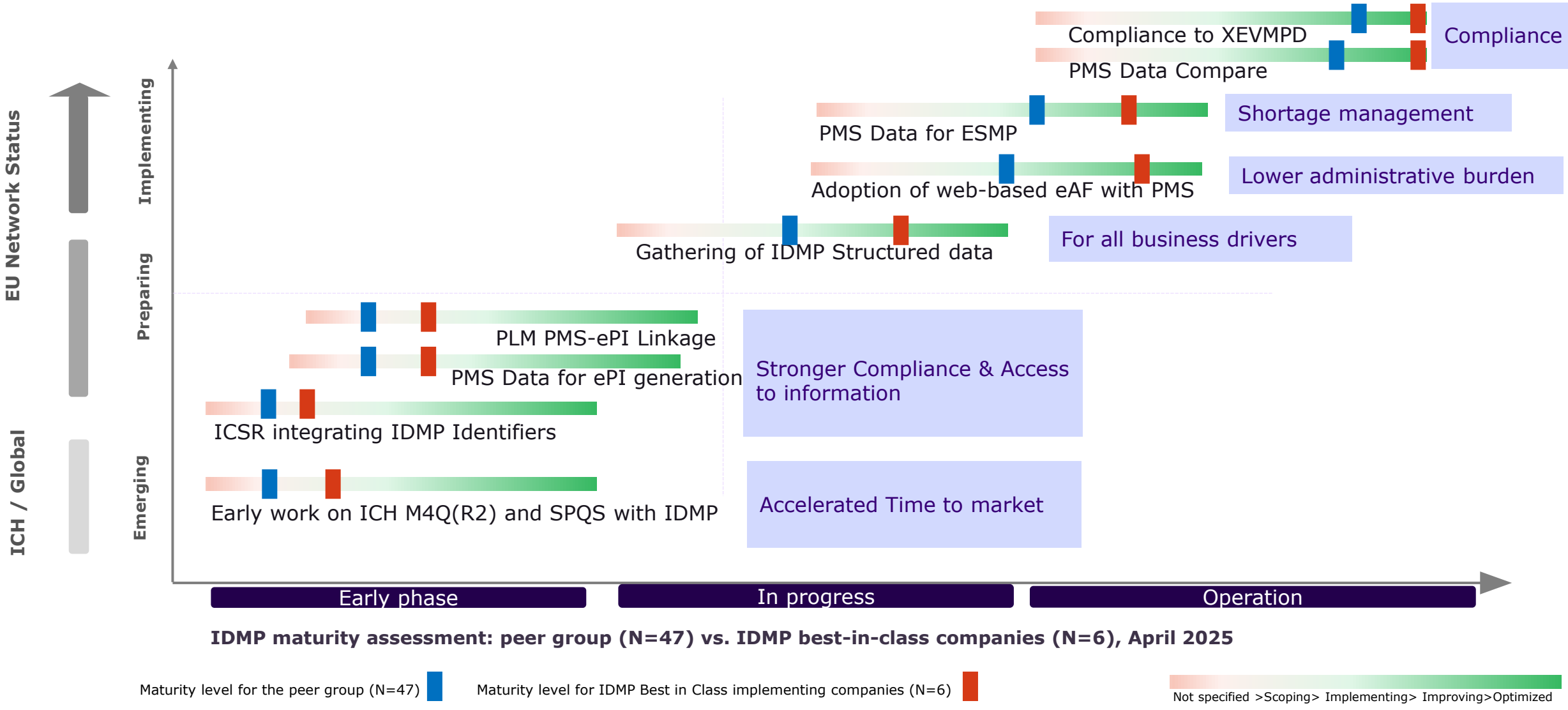
IDMP Program Objectives

- **Enhanced Data Quality** – Ensures accuracy, consistency, and reliable operations.
- **Improved Connectivity & Interoperability** – Value through data re-use. Enables seamless data flow and reduces manual work.
- **Boosted Efficiency**– Streamlines processes using AI and automation.
- **Simplified Reporting & Compliance** – Eases reporting and improves cross-functional data exchange.

The mutual benefits of SPOR leveraging consistent, high-quality data across the EU regulatory network can only be realized when the entire European Medicines Regulatory Network is fully committed to achieve interoperability through SPOR

Beyond PMS, ICH Structured Product Quality Submissions (SPQS) topic is IDMP North Star

Assessment of maturity level of product data activities, from a survey with 47 companies in April 2025: average and IDMP best-in-class companies - those reporting advanced capabilities and early, strong alignment with IDMP objectives.



IDMP maturity assessment: peer group (N=47) vs. IDMP best-in-class companies (N=6), April 2025

Maturity level for the peer group (N=47)

Maturity level for IDMP Best in Class implementing companies (N=6)

Not specified >Scoping> Implementing> Improving>Optimized

The execution of the EU network data strategy and the progress of ICH M4Q(R2), SPQS are key to achieving the full delivery of the industry IDMP implementation

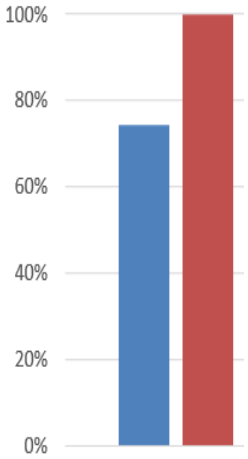
Survey indicates progress on Product Data Readiness for the PMS Compliance dates

Industry Key Steps to IDMP Readiness

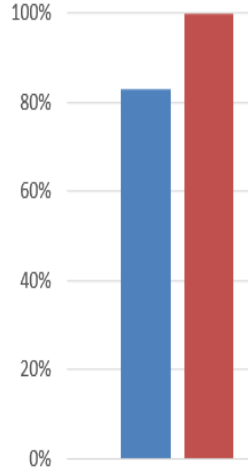
Strengthen expertise → Set up Governance → Build Process → Assess Data

On going PMS Data preparedness activities

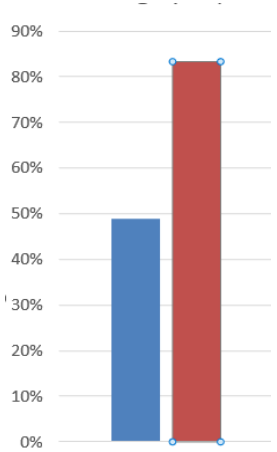
XEVMPD Data Quality → PMS map and compare → PMS Enrichment plan → PMS Enrichment execution



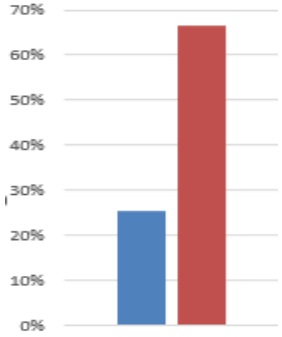
Process 3ACK and proceed with XEVMPD data correction or submit a ticket in EMA Service Now, as appropriate



Map and **compare** product data between **RIMs and PMS**



Have project structured to enrich PMS for ESMP by due dates



Have started using **PUI** to enrich PMS for ESMP use case

3ACK: xEVMPD message carrying the outcomes of the EMA data quality activities

Percentage of peers currently active (N=47)

Percentage of IDMP Best in Class implementing companies currently active (N=6)

Each step builds the foundation for sustainable IDMP compliance. Progress depends on PMS roadmap/features release, early alignment with SPOR expectations, portfolio (count of non-CAPs ULCM), processes, systems.

Industry recommendations to EU Network

1

Key Objectives guiding PMS delivery

- **Accelerate the release of the PUI Bulk edit** and **Write PMS APIs** to enable efficient data submission and maintenance
- **Progress on XEVMPD decommissioning of electronic submission of product data**
- **Consider minimising additional data enrichment** until a robust data validation and maintenance process is established

2

Data Validation & Conflict Resolution

- Consider implementation of **data validation process** applicable to the medium-long future for data submitted by MAHs in PMS
- Consider a **collaborative and structured process** for managing and reviewing enriched data and a way to **handle conflicts and data discrepancies**

3

Operational & Engagement

- Continue delivering **webinars** and **training materials** to provide regular updates as PMS rules evolve
- Maintain up-to-date **PMS Q&A** and **PMS Known Issues** reporting identified data quality issues and bug-fix timelines
- Enhance **EMA ServiceNow** process for **ticket resolution**
- **Timely address data sync issues** with quality controls
- Share insights with **PMS SME Group**

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

Conclusions

Industry and the EU Network **share a vision** of unlocking the full value of regulatory and health data. **Progressing** on the implementation of IDMP is foundational to **enabling data-driven decisions** and the responsible AI adoption – ultimately improving public health outcomes.

PMS is a **strategic asset**, and the industry remains **committed to progressing IDMP** implementation as a long-term enabler of regulatory agility, **interoperability**, and innovation. **High-quality master data** is central to unlocking this value across the product lifecycle.

Now is the **time to act**. To fully harness the power of data and AI, organizations must accelerate their efforts: fully implement the product and substance data standards, invest in governance and assess data quality maturity—driving faster, safer access to better medicines across the EU.

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Speakers:

Javier Monvoisin
PMS Subject Matter Expert (SME), Medicines for Europe

Topic:

Preparing for PMS Implementation: An Industry Perspective

Use Cases for Industry Implementation

Data Integrity and Quality

Data Integrity and Quality

- Enhance the accuracy and consistency of product data
- Internal integration of product data

Use Cases and Values

- Simplify execution of complex reporting and compliance
- Simplified shortages management.
- Create significant internal value via implementation of improved levels of interoperability across a company's infrastructure reducing administrative burden

Patient Access and Compliance

Use Cases for Industry Implementation

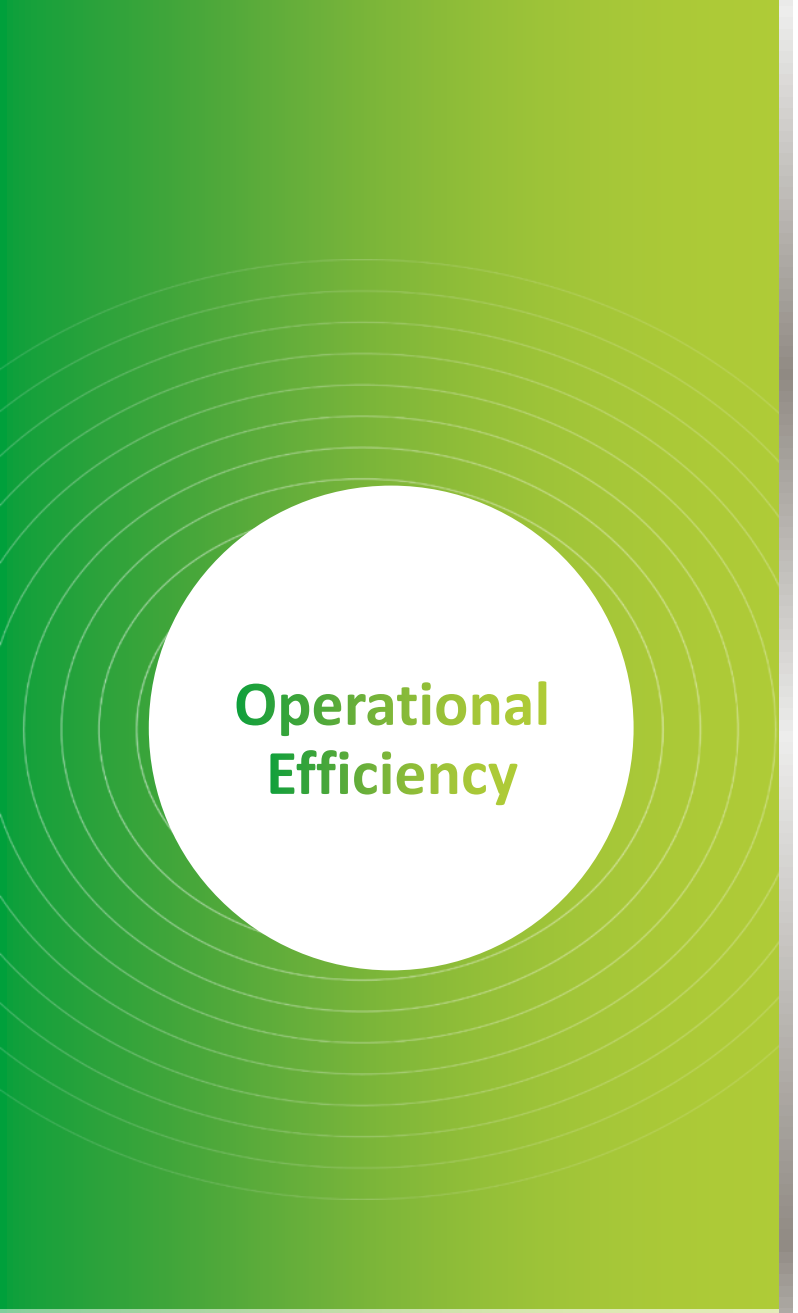
Patient Compliance and Access to Medicine Information

- Ensure adherence to legislative and operational requirements
- Improved access to medicines information for patients

Use Cases and Values

- Driver for ePI enabling better patient access to medicine information
- Industry value through realization in reduction in administration and a potential return on investment due to reduction in labour costs

Use Cases for Industry Implementation



Operational Efficiency

- Streamlining of processes
- Reduction in duplication
- Allow for easier utilization of AI and Automation

Use Cases and Values

- Increase opportunities to leverage AI and Automation
- Faster and more efficient submission and approval process resulting in benefits to Industry, Regulators, Patients and HCP’s
- Reduction in post approval workloads

Use Cases for Industry Implementation

Enhanced Safety

Improved Pharmacovigilance and Monitoring

- Proactive safety monitoring and improved risk management

Use Cases and Values

- Facilitate early detection and response to adverse events
- Enhance the ability to identify, assess and mitigate risks associated with medicinal products across the portfolio
- Increase transparency on where and how data is being leveraged.

Implementation Strategy

Companies with large portfolios

- Machine to machine exchange via API is a must
- Vendor lead times dictate implementation timelines
- Cost impact based on infrastructure needs
- Manual data transformation not practical

Companies with smaller portfolios

- Predominantly manually driven work
- More reliance on user interface
- More time spent on per record basis
- Cost impact based on FTE required to support process

This has a significant impact on the steps that Industry have already taken and are planning on taking in the future

Programme for PMS Implementation

- Establish a dedicated cross functional PMS implementation team
- Regular steering team meetings to oversee progress and discuss solutions to challenges
- Keep up to date with EMA developments surrounding PMS requirements and data standards (Regulatory Intelligence)

- Integration of PMS requirements into existing workflows across all relevant functions e.g PV, RA, Commercial
- Update internal SOPs to include PMS data validation steps

- Upgrade regulatory systems to include PMS data support
- Implementation of cross functional system data connectivity reducing duplication of data and divergence
- Upgrade and implement corporate master data management systems to incorporate PMS data fields as source data

- Article 57 data restructuring and submission to align with PMS (packset splits)
- Data cleansing and alignment with SPOR across multiple systems (not just regulatory owned systems)
- Implement corporate wide data standards for product data using PMS terminology. Requires extensive change management especially at internal manufacturing sites.

Legend

Low effort | Medium effort | High effort

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Conclusion

- PMS is a cornerstone in the regulatory framework, ensuring that the EMA, NCA's and industry can effectively manage and exchange medicinal product information, ultimately safeguarding public health and ensuring access to Medicines across the EU

- All Stakeholders across Industry and Regulators (NCA's and EMA) should collaborate closely, sharing expertise and resources, to ensure the successful implementation and maintenance of the PMS database to support internal and external use cases across the network

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Speakers:

Fakhredin Sayed Tabatabei
PMS Subject Matter Expert (SME), Medicines Evaluation Board

Topic:

Our Shared Journey
NCAs' Perspective

Data quality of legacy data in PMS

As Is

- Data is taken from XEVMPD (MAH), SIAMED (EMA) and enriched in PMS (MAH)
- Data format in PMS follows international standards (IDMP and FHIR)

To Be

- Enhanced standardization and interoperability for NCAs, EMA, MAHs and end users
- Trustworthy legacy data as a foundation for medicinal product lifecycle management
- Legacy data will fulfill data qualification agreements and will support use cases (e.g. Regulatory Activities via the eAF, ESMP, CTIS, IRIS)
- Legacy data will be consistent between PMS and EMA/NCA databases

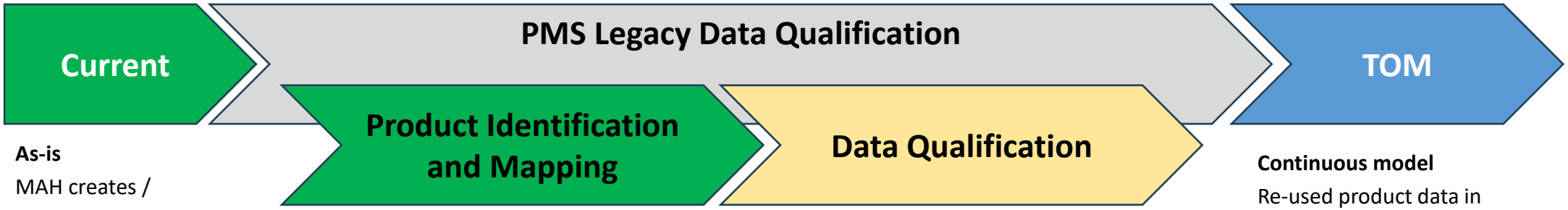
- ✓ **The goal is to reach quality of data desirable for identified use cases, while minimizing the workload of the Network by facilitating shared responsibilities**

Product Mapping and Data Qualification

Stepwise implementation towards a future Target Operation Model

Definition

- ✓ The process of ensuring that the data submitted by MAHs, stored and published in PMS, is the same as the data approved by the NCA, stored and published at national level
- ✓ When identifying missing product or data discrepancies, it may involve updating data



As-is
MAH creates / updates in PMS

Dedicated effort
Same product/ packages in PMS and EMA/ NCA databases

- EMA provides mapping support to NCAs

Dedicated effort
Identical data-elements in PMS and NCA databases

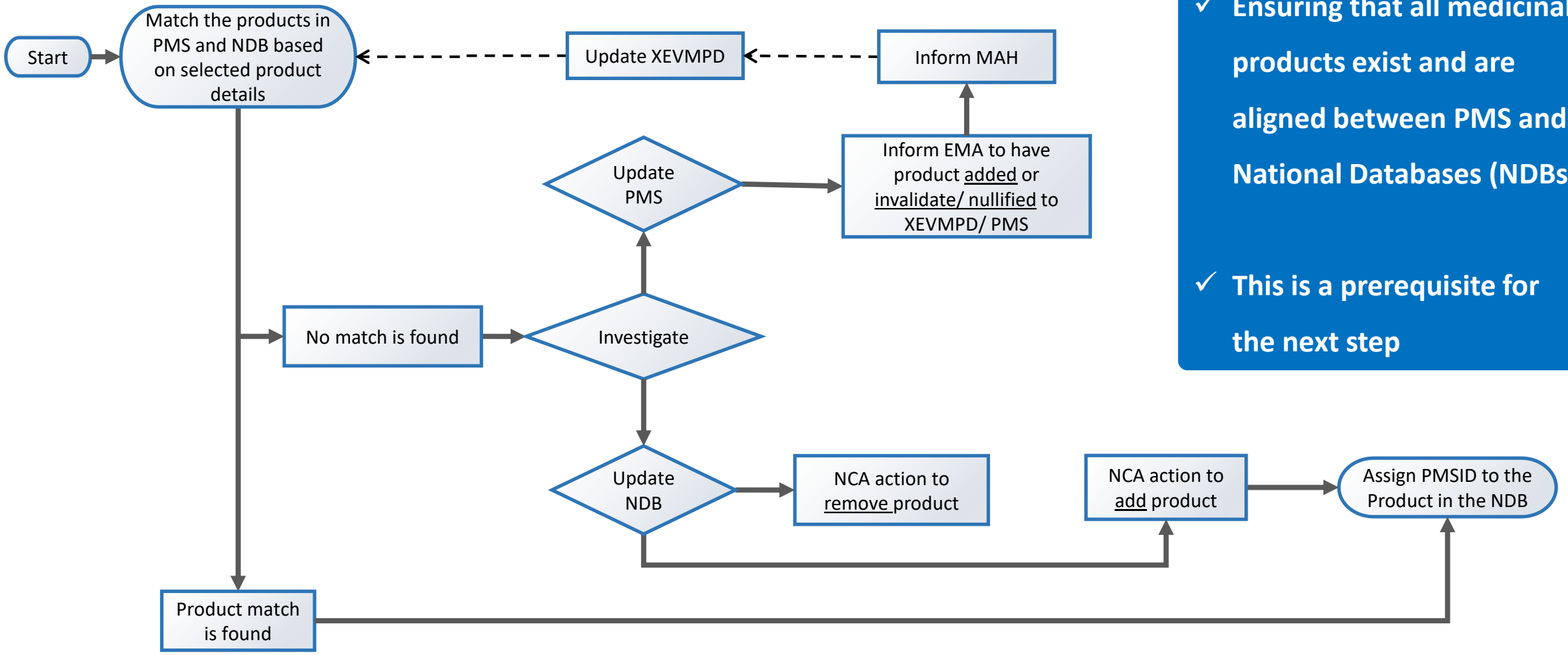
- Data-elements stored in PMS is aligned with the data approved by the NCA

Continuous model
Re-used product data in regulatory processes and applications using the eAF

Ongoing
Under planning
To be

Product Identification and Mapping

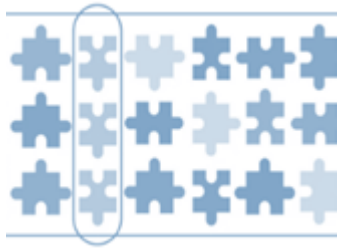
Simplified Flowchart



- ✓ Ensuring that all medicinal products exist and are aligned between PMS and National Databases (NDBs)
- ✓ This is a prerequisite for the next step

Data Qualification

Feasibility Study

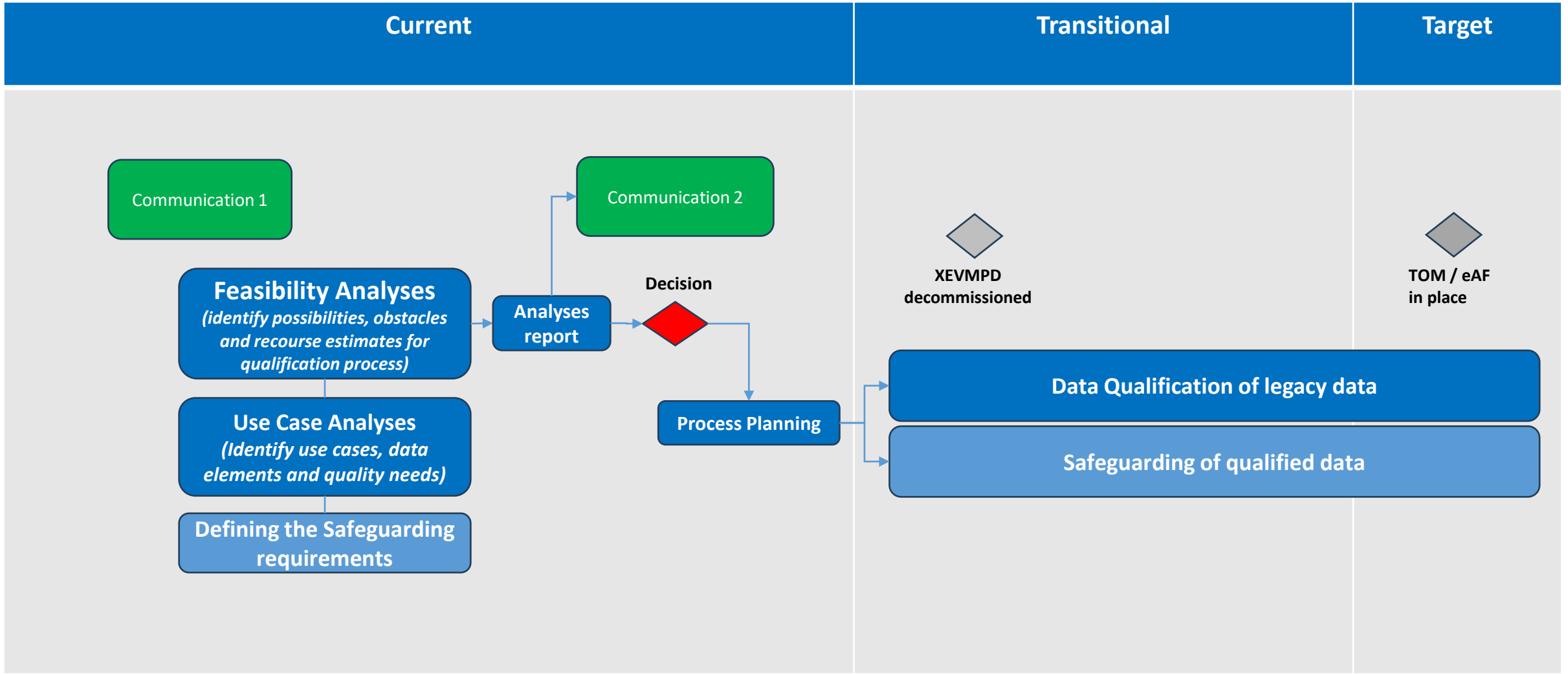


Evaluate the consistency of selected data elements between PMS and EMA/NCA databases

Draft a feasible process that is to ensure legacy data qualification and inform the network

- ✓ **Objectives are to identify possibilities, obstacles and resource estimates for qualification process, as well as use cases, data elements and quality needs**
- ✓ **Some systems initially benefiting from data qualification are ESMP, PLM portal, eAFs, ePI**

PMS Legacy Data Qualification Roadmap



Moving forward toward Product Master Data

Preparation

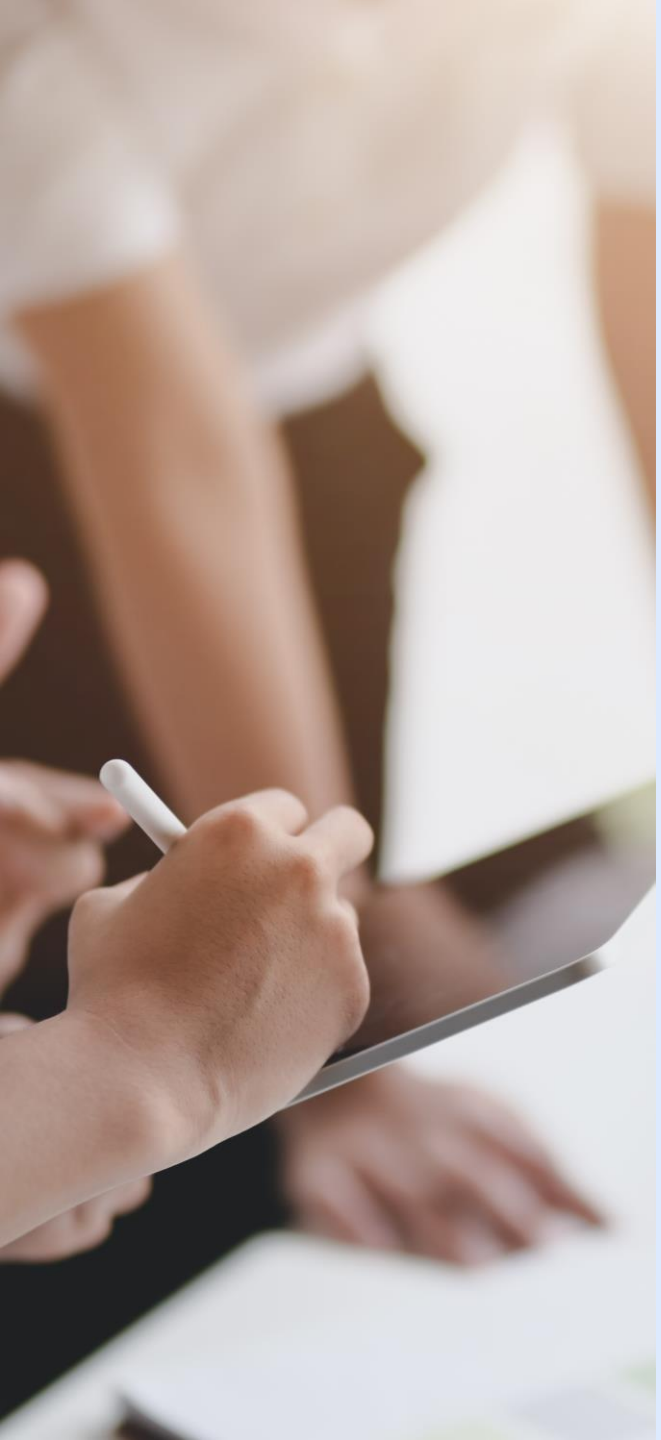
Collaboration

Outcome

CBG MEB

MEDICINES EVALUATION BOARD

GOOD MEDICINES USED BETTER



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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

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- Ask your questions and vote the ones you would most like to be answered

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Conclusions and closing remarks

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Conclusions and closing remarks

Chairs / speakers:

Peter Arlett
Co-chair of the Network Data Steering Group (NDSG) and Head of Data Analytics and Methods Task Force

Hilmar Hamann
Co-chair of Network ICT Advisory Committee (NICTAC) and Head of Information Division

What did we cover today?

1 Strategic engagement

- PMS is a strategic asset for EU regulatory use cases and beyond
- Multiple groups and stakeholders engaged

2 Portfolio delivery

- PMS should support full product lifecycle
- NDSG Step wise recommendation

3 Business process

- Re-use of PMS data in multiple regulatory process is a reality

4 Network Mobilisation

- EMA, NCAs and Industry are mobilizing towards shared goals

EMA, NCAs and Industry share common vision and common goals for PMS!

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Main conclusions

Chairs Impressions

What was covered today

Open points

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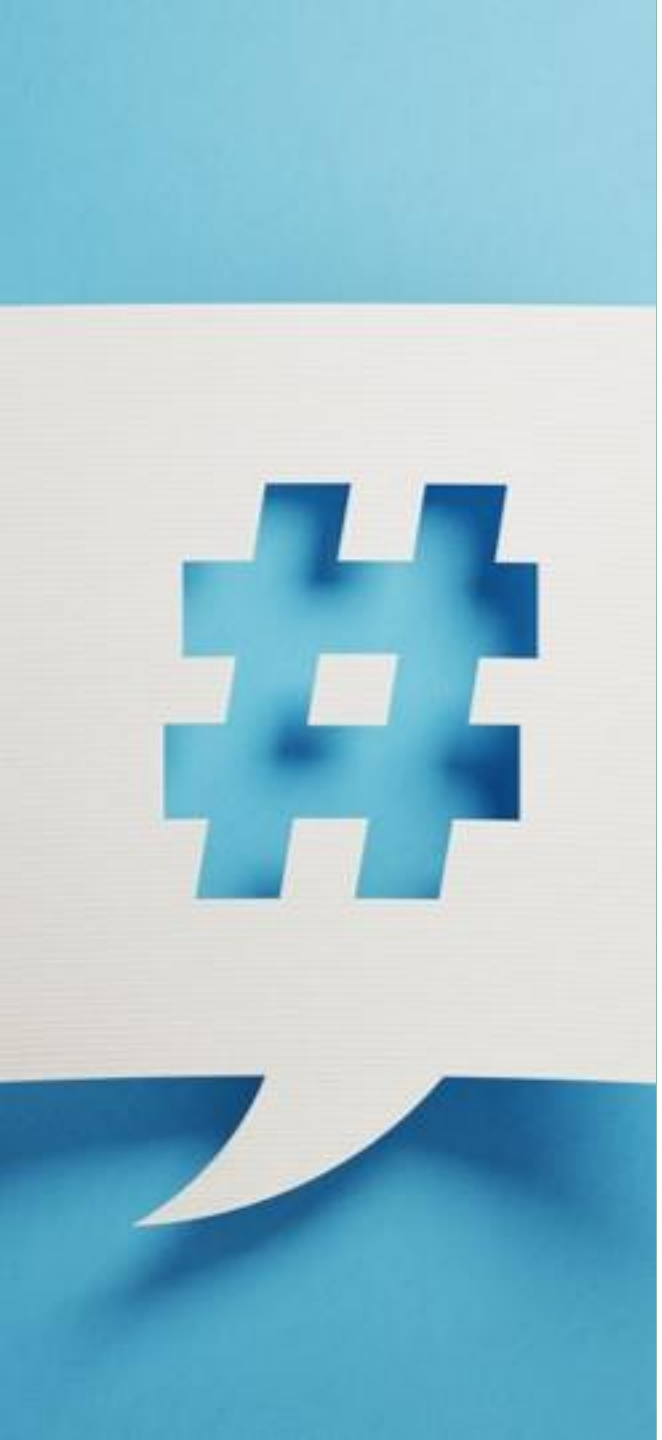

Key takeaways & conclusions

1

In the near future

- XEVMPD submissions support Art 57 obligations as well as needed enrichments
- Enrichments are expanded to all products in the portfolio
- NCAs mapping activities are progressing, initially aligning products and then ensuring that information in them is consistent across PMS and National systems

2

A first step is foreseen to simplify submissions and data flows

- In a timely manner to support New Pharma Legislation
- Enabling submission of both Investigational (IMP) and Authorised medicinal product (AMP) data via the PMS API or PUI
- Consuming existing/legacy systems repointed to PMS
- Discontinuation of XEVMPD at a given cut-off date

3

***To further reduce the burden to stakeholders and improve data quality*:**

- Integration of PMS data and regulatory processes is the goal
- Structured medicinal product data submitted throughout the regulatory lifecycle

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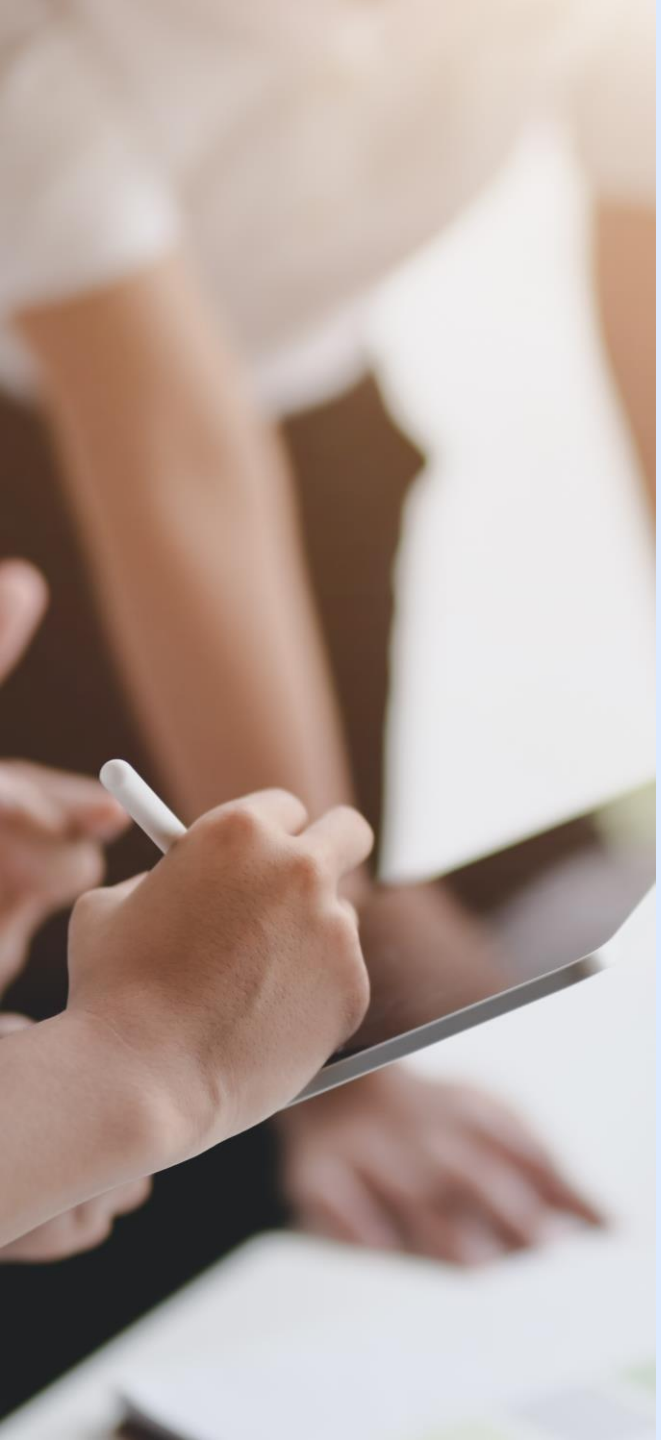

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Thank you

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