

How does eAF, PMS, ePI, Shortage Monitoring fit together?

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Agenda

45min

- **Introduction**
- **PMS, eAF, ePI, ESMP**
- **UNICOM – a best practice of bringing topics together**
- **Take Home Message**



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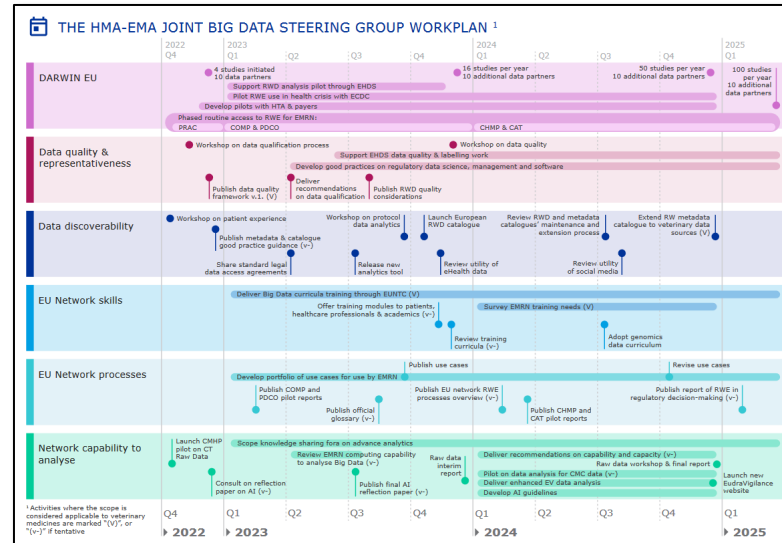
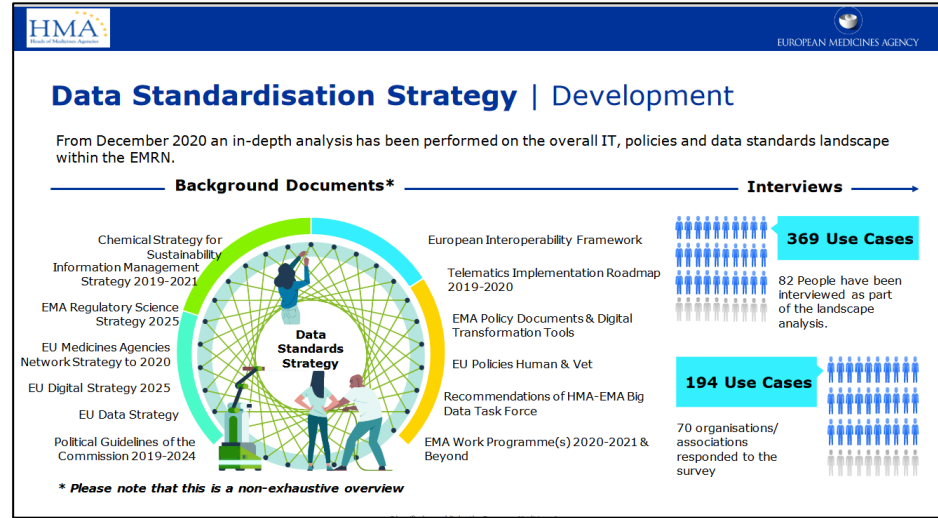


Spoiler

" It's about data and new opportunities through (extended) digitalisation of our business processes ... "

Data in all minds

Many initiatives



-  **Substance Management Services (SMS)**
-  **Product Management Services (PMS)**
-  **Organisation Management Services (OMS)**
-  **Referentials Management Services (RMS)**

Expectations (internally and externally)

Faster decisions

Faster processes

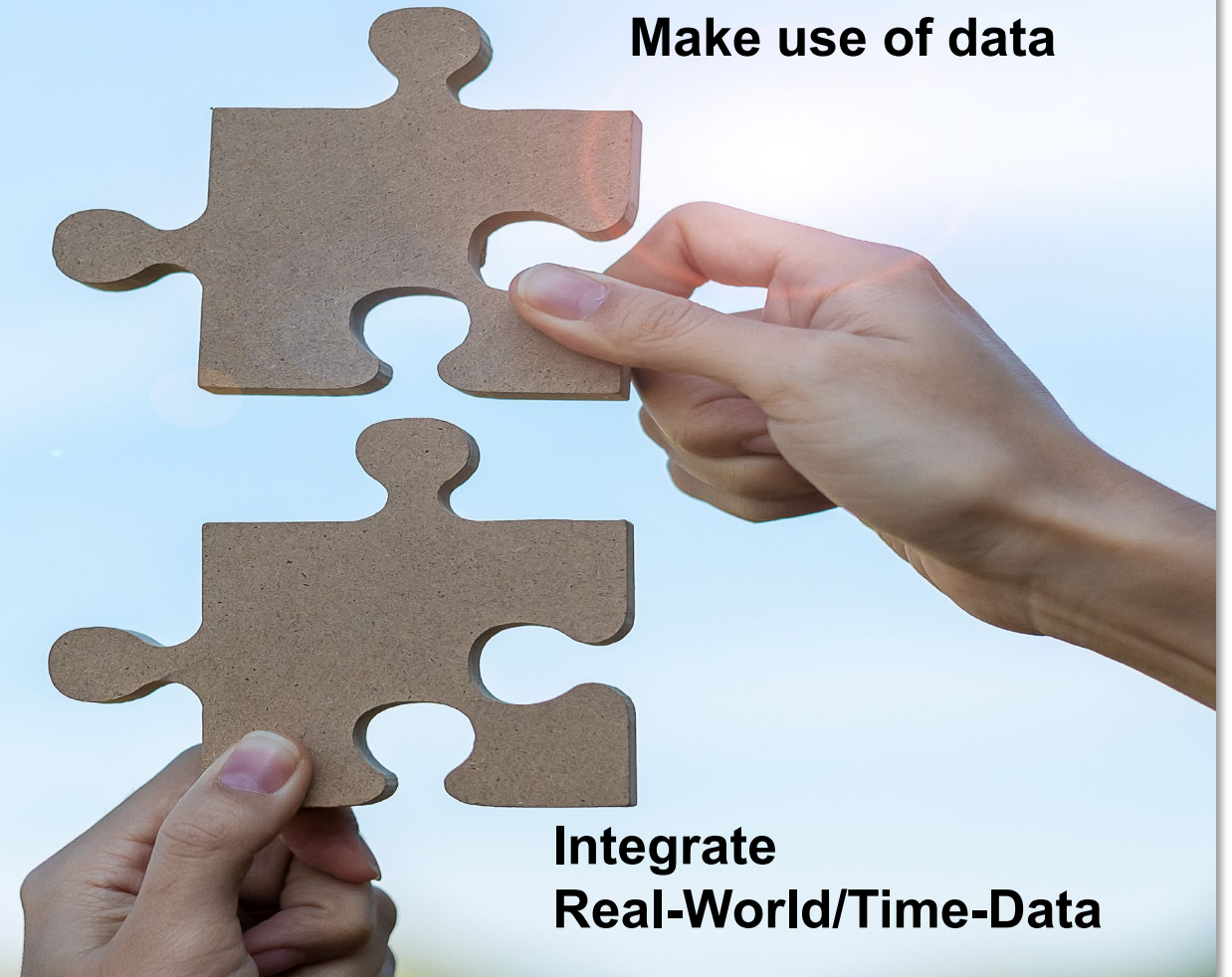
**Machine-to-machine
communication**

Data and AI

**Document submissions
vs. data feeds**

High quality data – Trusted data

Make use of data



**Integrate
Real-World/Time-Data**

Motivation for today ...

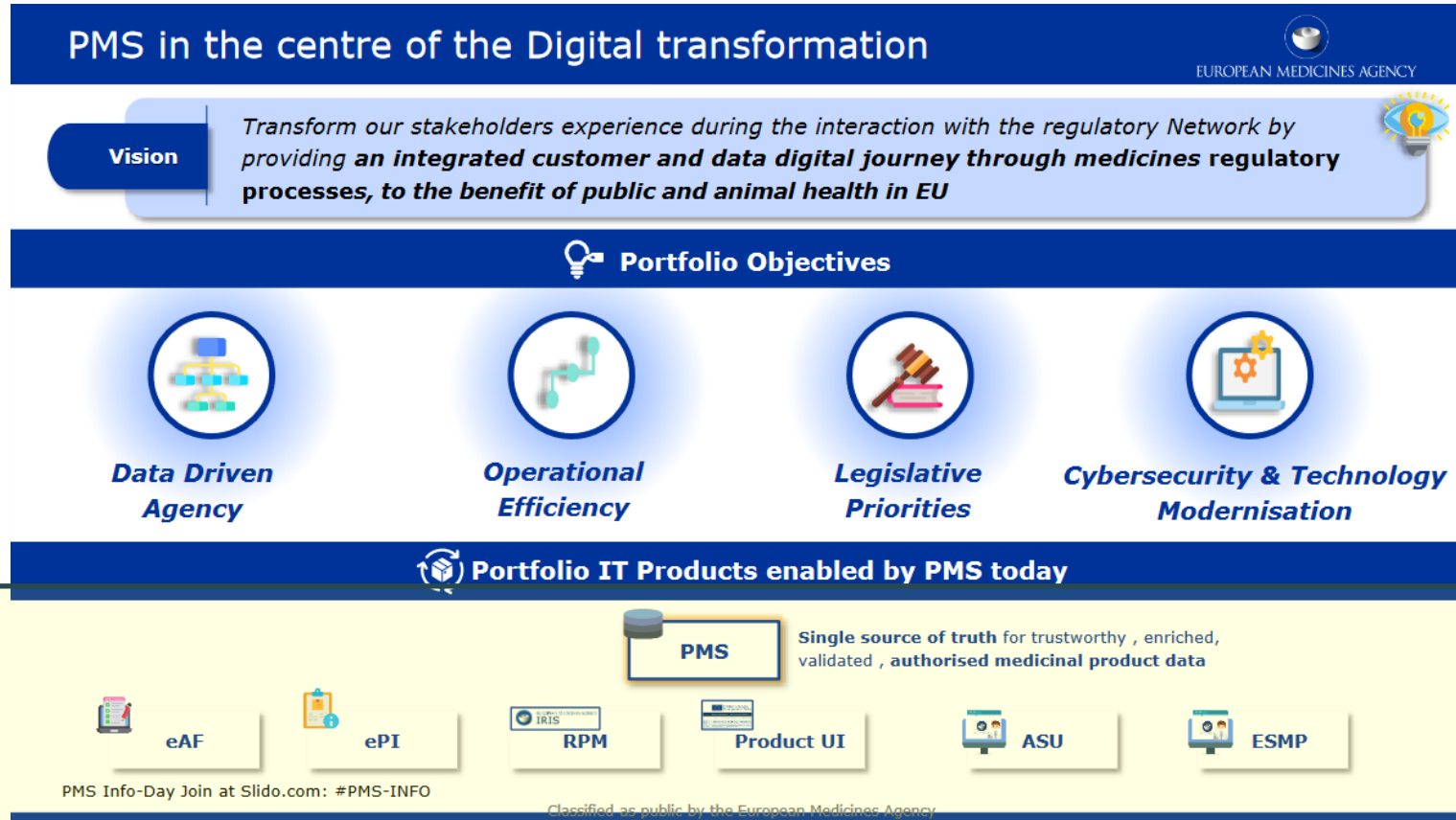
.... let's go on an early summer journey through interesting subject areas and identify potential benefits - plus how to prepare for the journey ...

SPOR PMS

... a new player goes online ...



PMS Vision

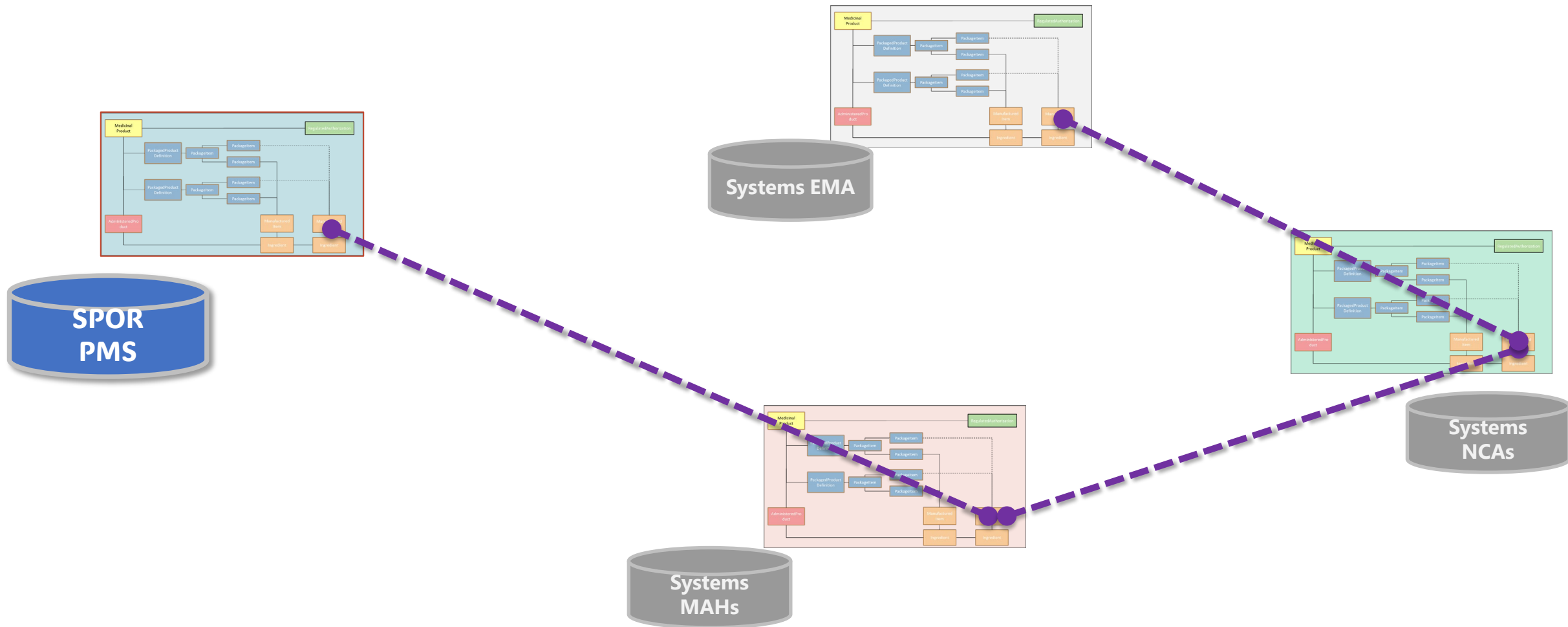


Source: EMA PMS Info-Day, April 2024

„... PMS' objective is to become a **SHARED** data source for several pan-European use cases ..“

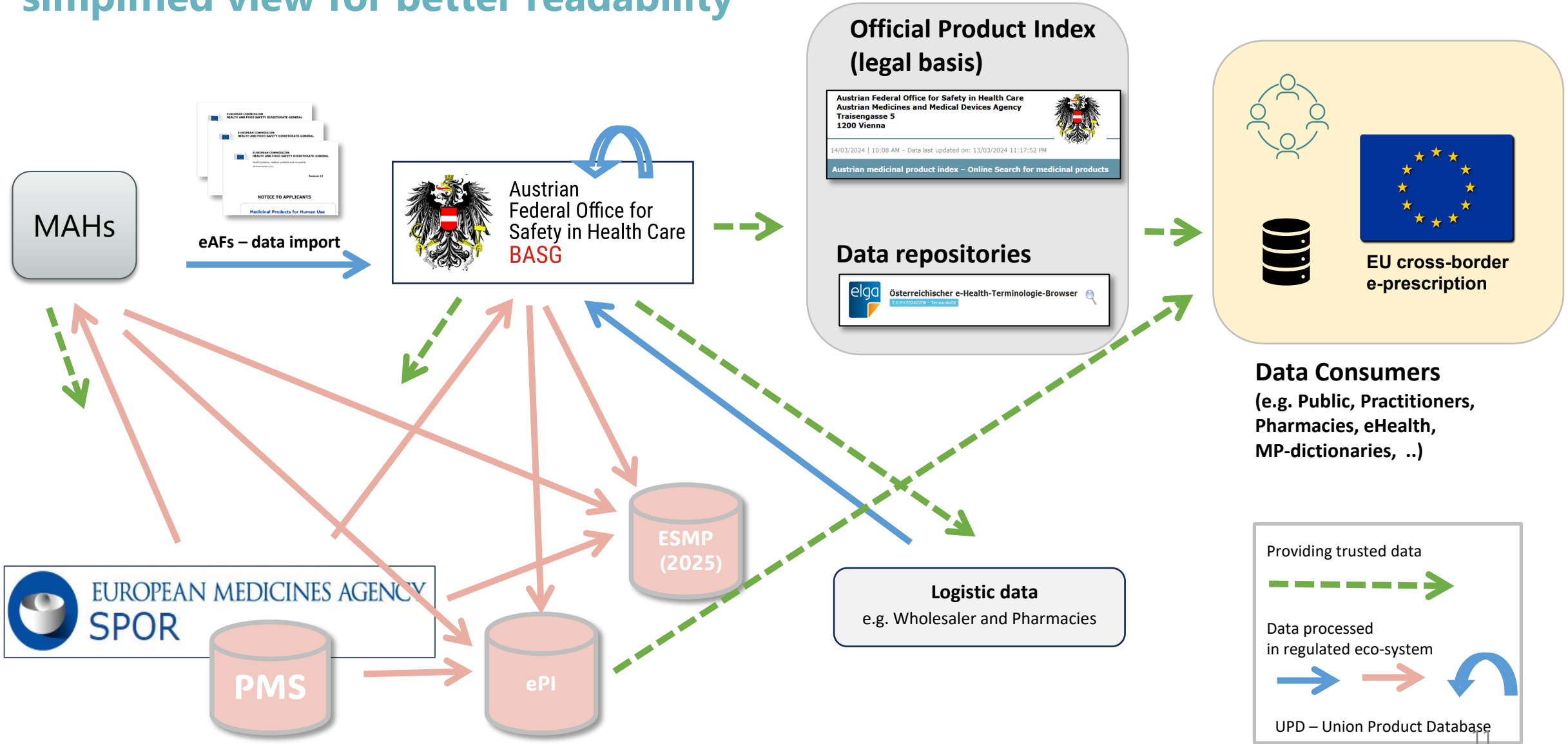
If so, then we need to ensure compatibility


“Virtual connections”





Medicinal Products – Data Flow

simplified view for better readability



Providing trusted data


Data processed in regulated eco-system


UPD – Union Product Database


1st conclusion



Austrian
Federal Office for
Safety in Health Care
BASG

In our data value chain we* are simultaneously creators, contributors and consumers of high-quality trustworthy data.

Interoperability of data, processes and IT systems are key success factors.

* Regulators, Applicants, Industry stakeholders, eHealth stakeholders, MP-Dictionaries, ..

Interoperability considering SPOR PMS 1/2

Shared data repository



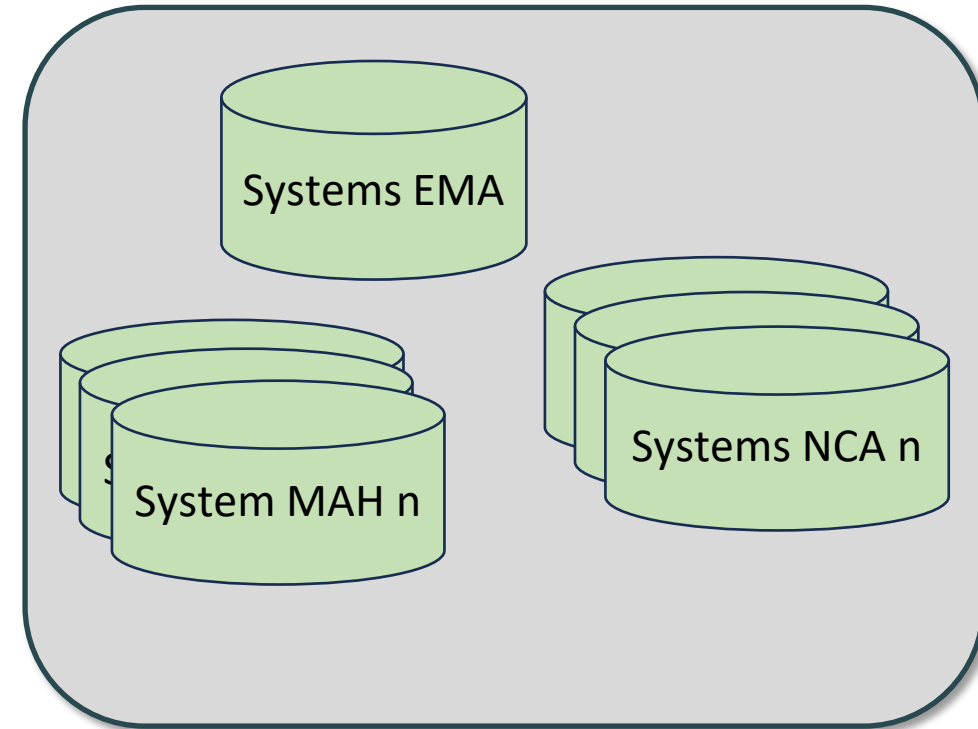
Interoperability measures, e.g.

- ISO-IDMP standards and annexes
- **European IDMP Implementation guide**
- FHIR definitions
- FHIR implementation guides and profiles
- Shared common dictionaries
- SPOR interface (API)

ISO IDMP

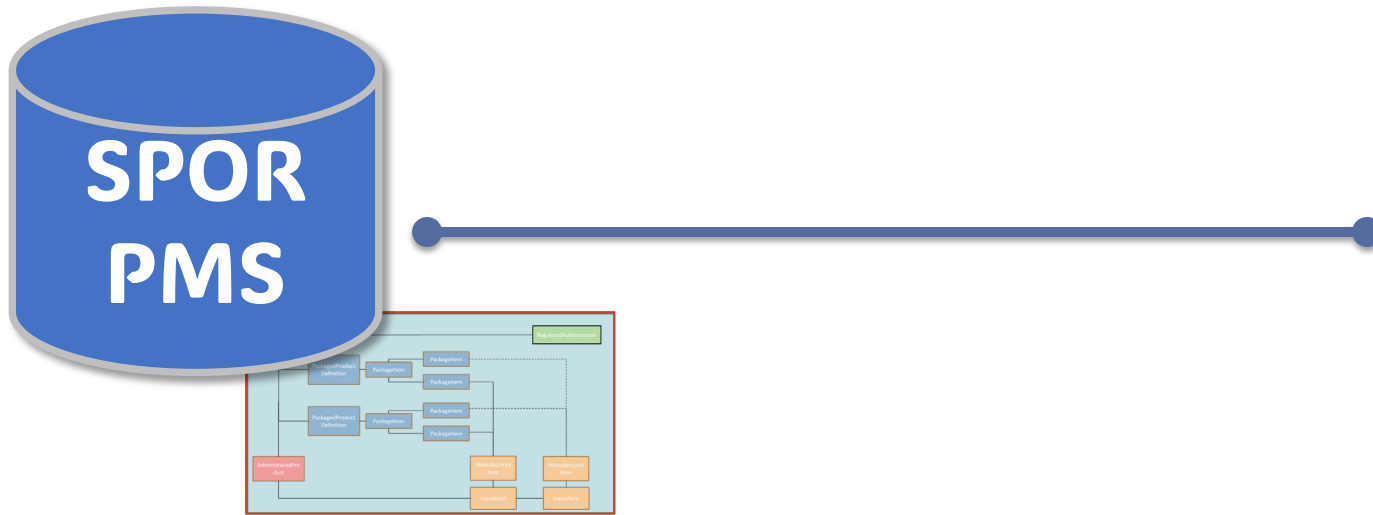


S(P)OR



IT-systems in the EMRN

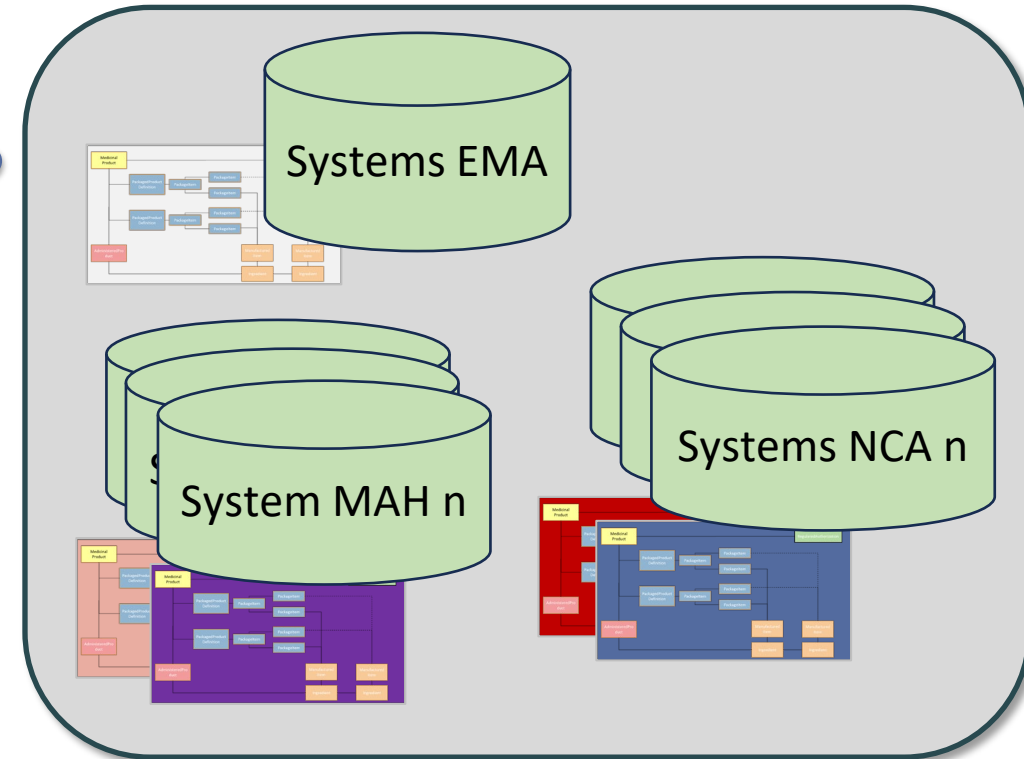
Interoperability considering SPOR PMS /2



Interoperability measures will result in:

- Compatible data models
- IT-enabled business rule execution and validation
- Shared unique identifiers across systems
- Efficient exchange and synchronisation processes

→ Trust in data (flows)

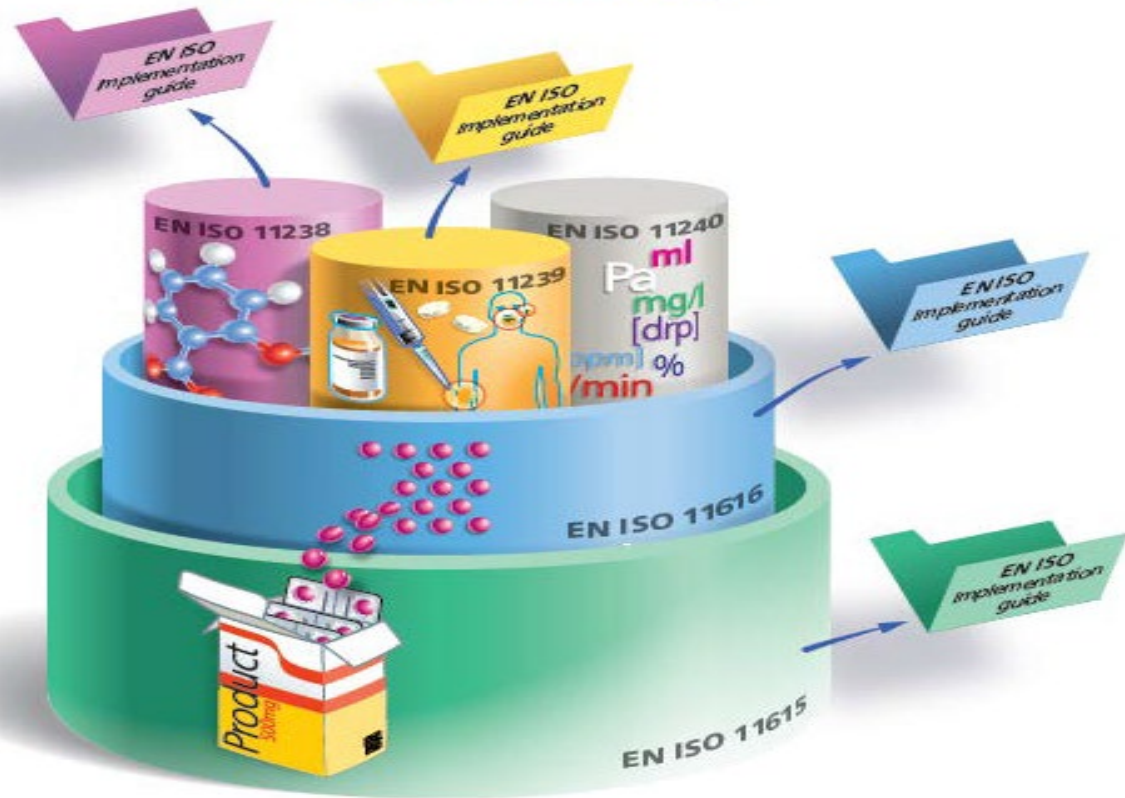


IT-systems in the EMRN

Re-Cap – PMS implements ISO-IDMP

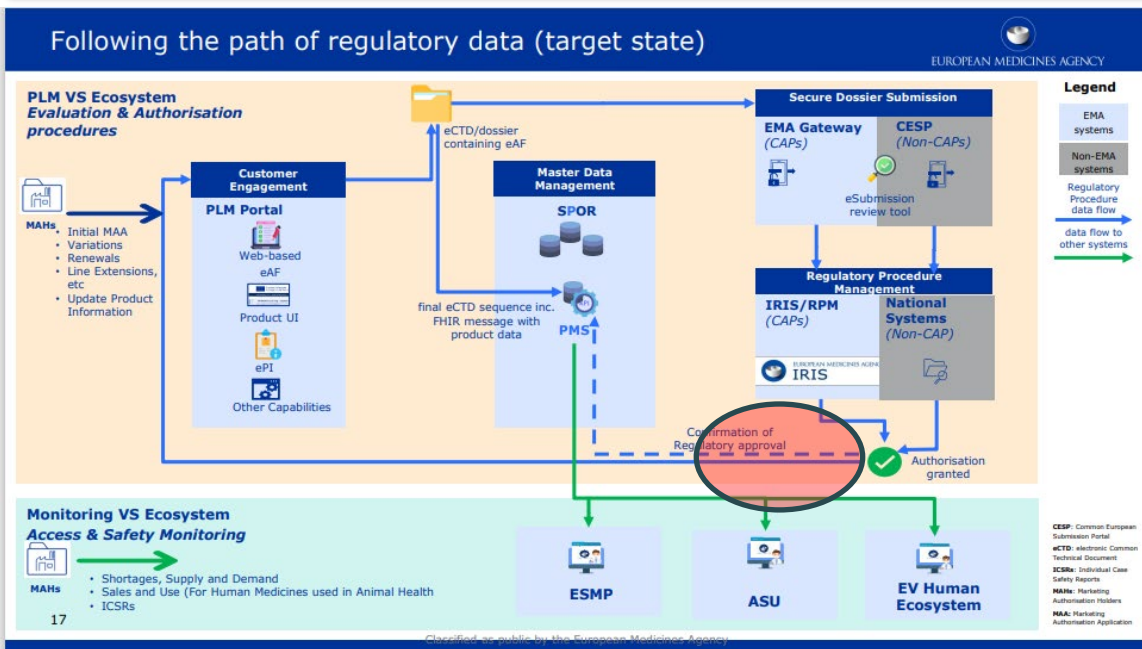
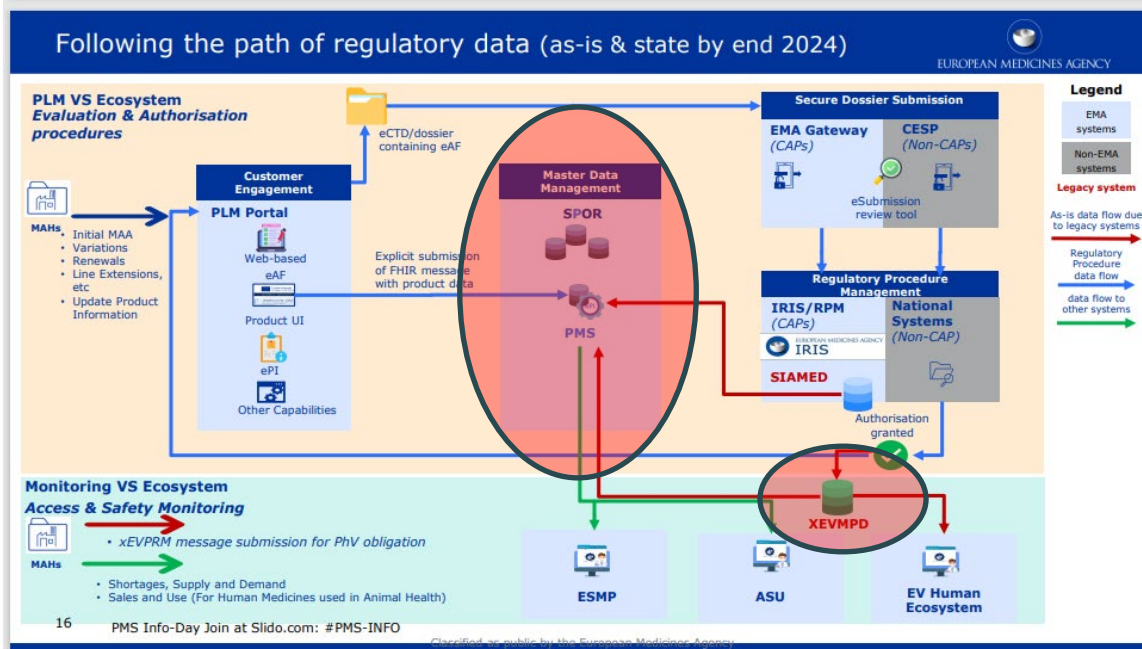
IDMP

Identification of Medicinal Products
Data elements and structures
for the unique identification and exchange



- The **ISO IDMP standards** establish definitions and concepts and describe data elements and their structural relationships that are required for the unique identification of:
 - **Medicinal product information (MPID/PCID)**
- ISO 11615
 - **Pharmaceutical product information (PHPID)**
- ISO 11616
 - **Substances (Substance ID)**
- ISO 11238
 - **Pharmaceutical dose forms, units of presentation, routes of administration and packaging**
- ISO 11239
 - **Units of measurement (UCUM)** - ISO 11240
- ISO IDMP standards apply to both authorised and developmental medicinal products for Human and Veterinary use
- **PLUS EU implementation guidance!**





Key Findings

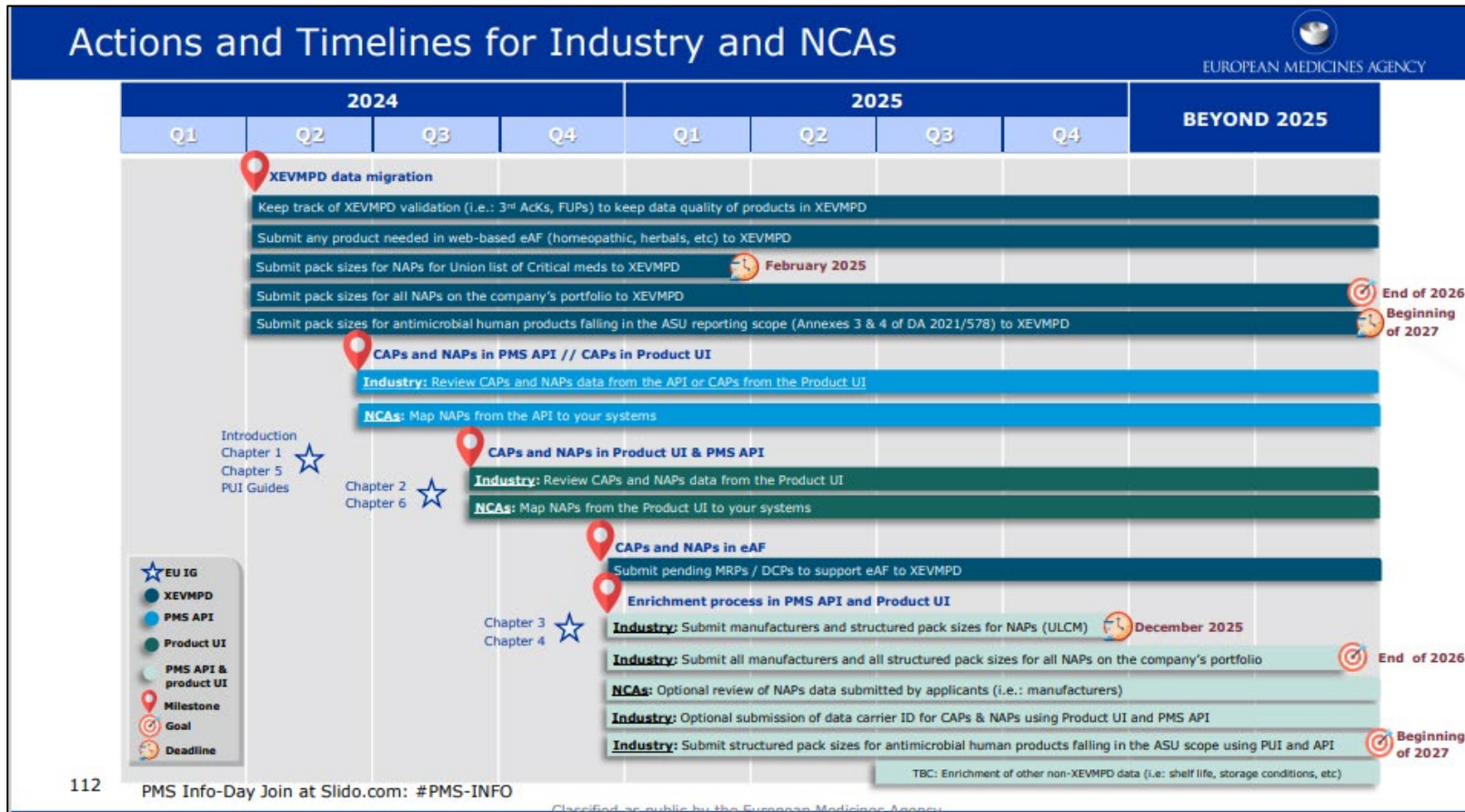
- PMS will become a **shared** source for several **EMA organised pan-European use cases**
 - like ESMP, ASU, eAFs, ePI, ..
- **XEVMPD (ART57)** data - originally collected for **PHV purposes** - is now also used **for regulatory activities**
- PMS will also support **the EV Human Ecosystem**
 - **no separate messages for XEVMPD and PMS** are foreseen in future
- PMS data will be updated **via eAF FHIR datasets provided in dossier submissions**
 - **!Currently several options of the data feeding process are under discussion - "TOMs"**
- Regulator systems can connect to SPOR PMS for **approval purposes**
 - **No details available (see also "TOM" discussions)**

Source @ EMA: [here](#)

- Start reading with examples (**Chapter 8 – Practical examples**)
This gives a good overview.
- Make sure that XEVMP data is of good quality – due to usage in regulatory activities
- *Plan resources (personal, perhaps IT) for the following tasks ...*

Status PMS

Timelines

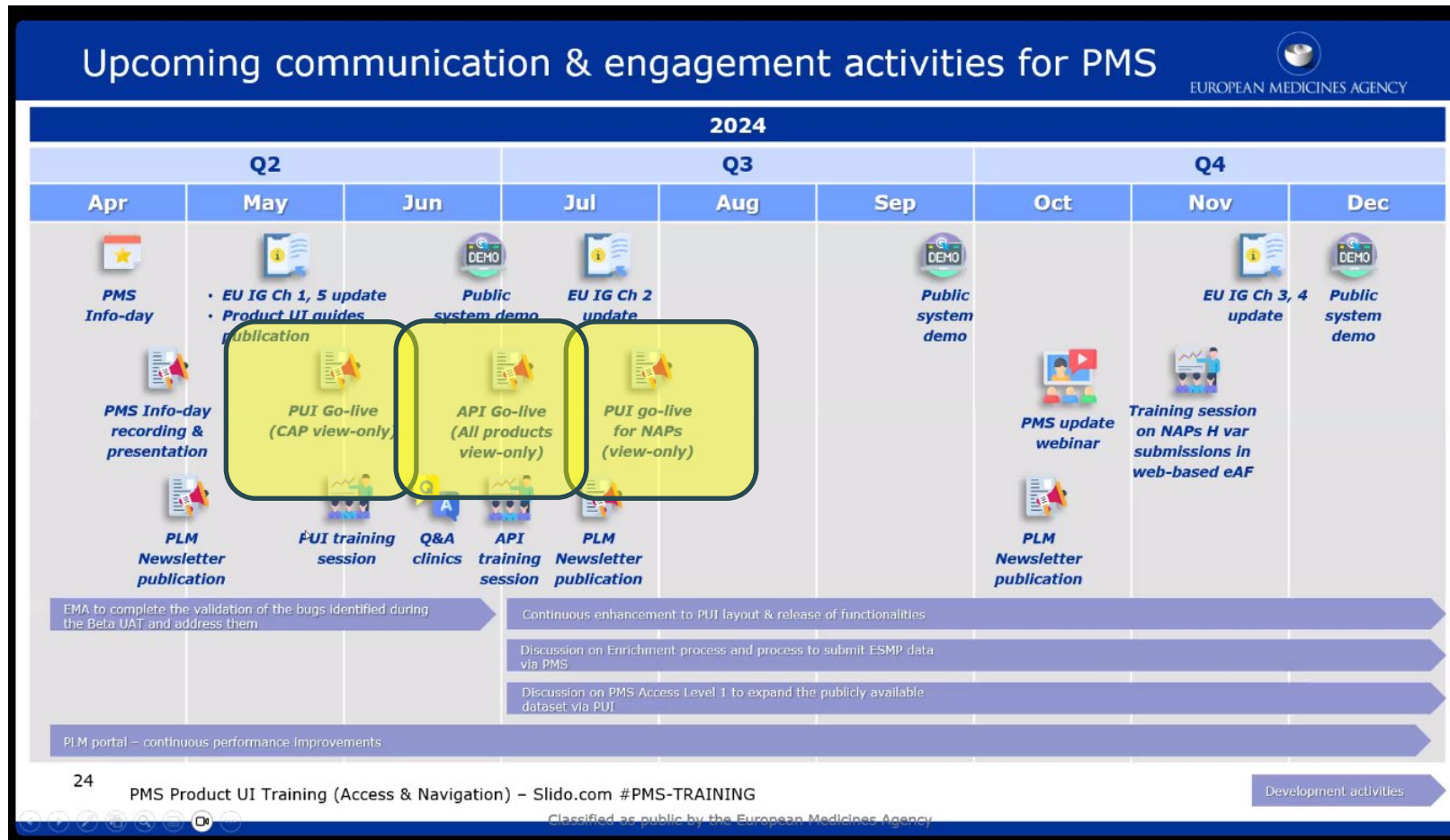


Todos:

- Do „Stichproben“ of your products in XEVMPD and PMS
- Add missing products needed for eAFs (e.g. herbals)
- Activities for ESMP and ASU (see next pages)

Source: EMA PMS Info-Day, April 2024

PMS: Access to medicinal product data



Read Access for PMS data

- PUI* CAPs: End of May 2024
- PUI* NAPs: End of July 2024
- API* all: End of June 2024

***PUI**: User-Interface for PMS

***API**: machine-to-machine interface for PMS data

Source: EMA PMS Info-Day, April 2024

The new eAF creation tool

Georg Neuwirther

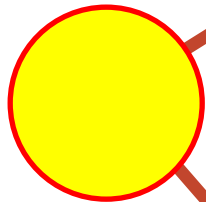
New technology for the Electronic Application Form eAF

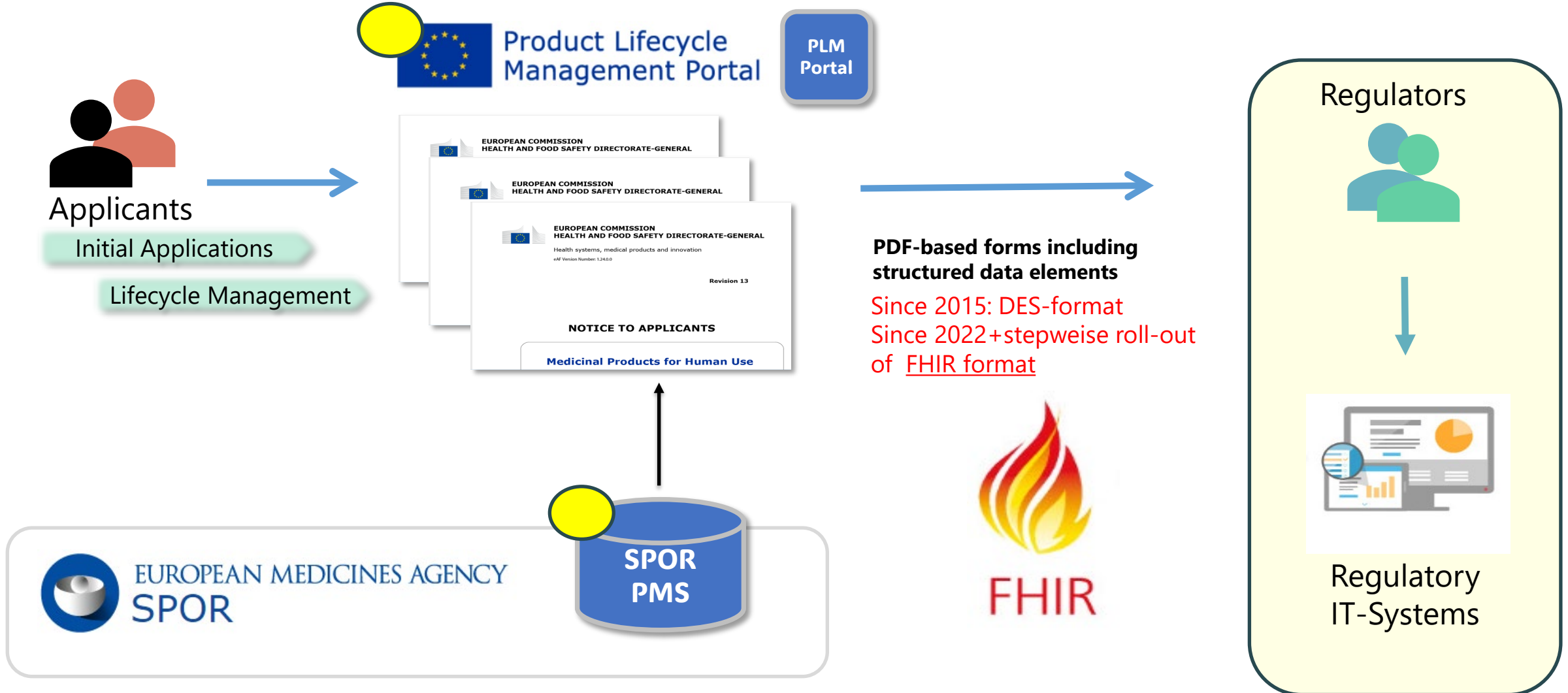
Business Value



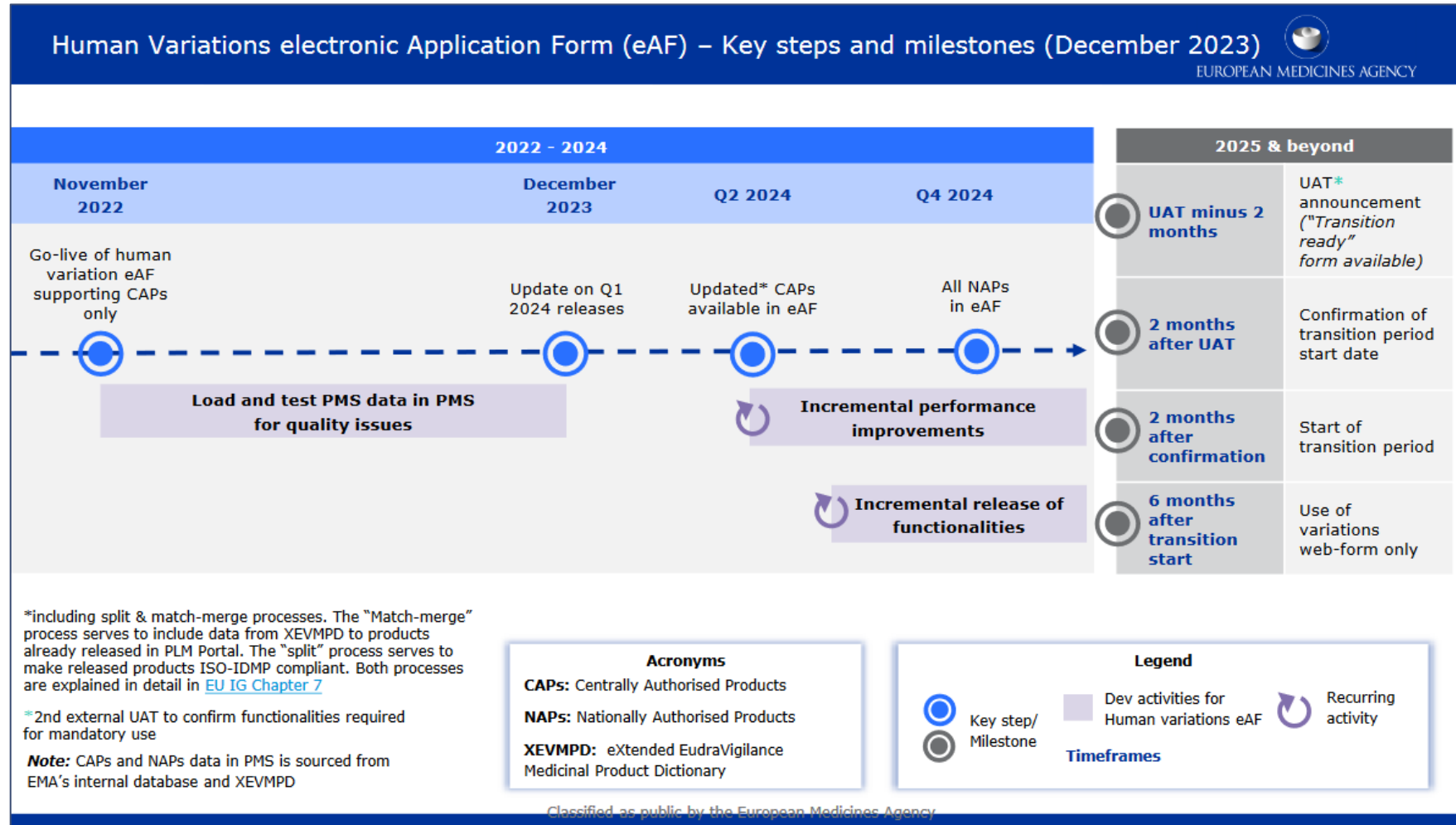
Provision of digital, user friendly, adaptable application forms

- Consistent **high-quality ISO IDMP** compliant data – right from the start of regulatory activities
- **Standardised data entry**, thus making forms easier to access, process, validate, transmit and re-use
- **Reuse of data** in end-to-end processes
- **Integration with product lifecycle management processes** to optimise regulatory procedure management
- **Easier and more automated** applications' validation and processing by National Competent Authorities (NCAs), reducing errors and discrepancies
- **Standardised data-backbone** supporting machine-to-machine communication





eAF - Roadmap



Source: https://esubmission.ema.europa.eu/cessp/202312_eAF%20implementation%20timeline.pdf

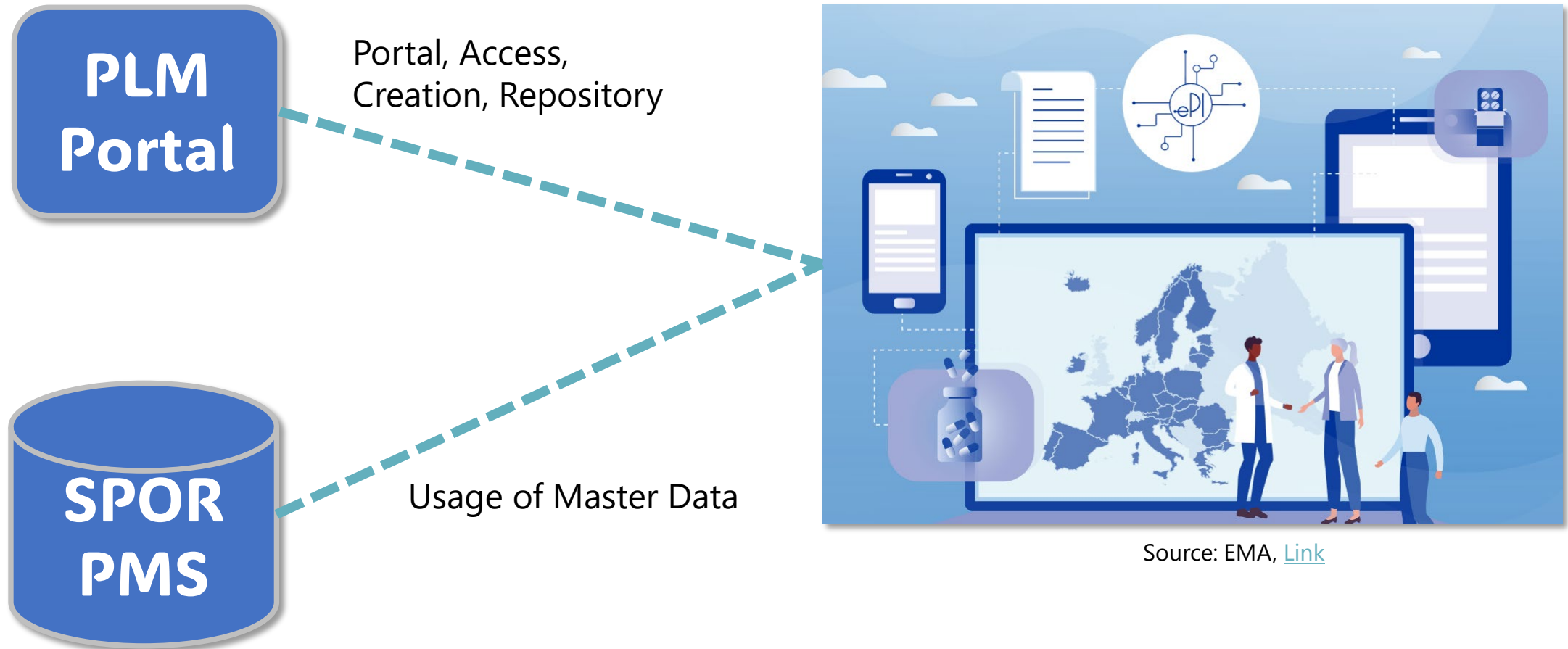
ePI

EMA-HMA-EC ePI pilot & beyond

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Landscape – PLM Portal – SPOR PMS - ePI

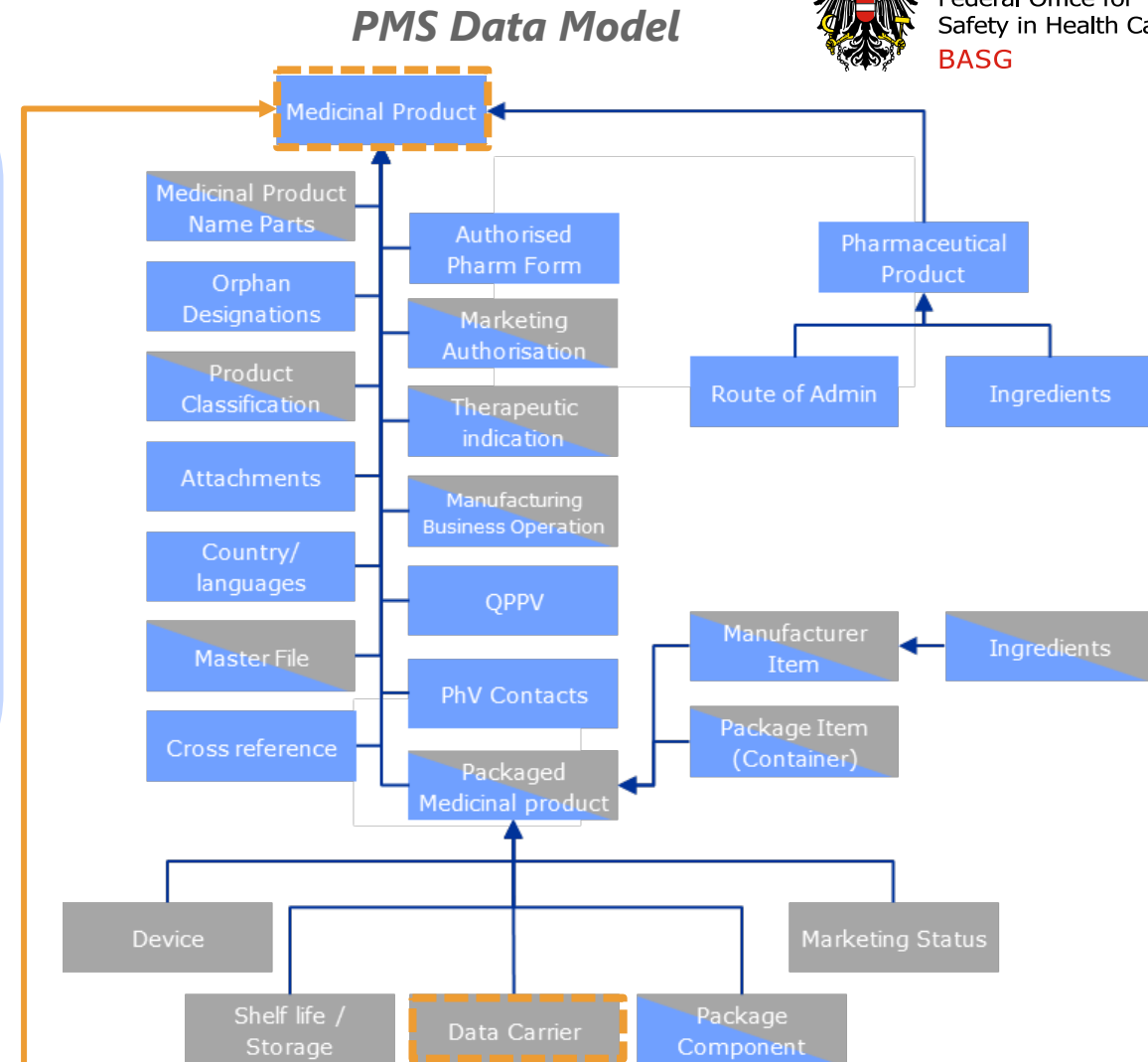
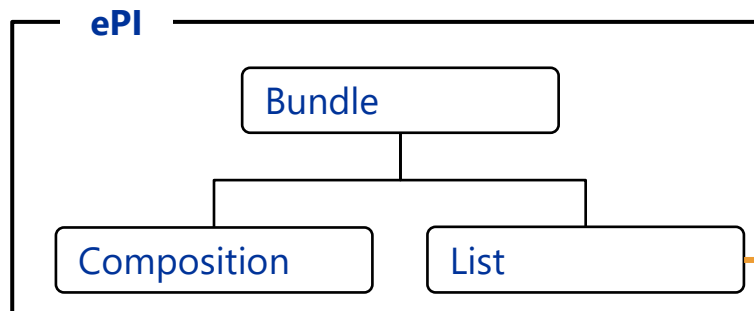


PMS Data used in ePI



- ePI will be **linked to the relevant medicinal product(s)** enabling consuming systems to leverage both ePI data and product data from PMS

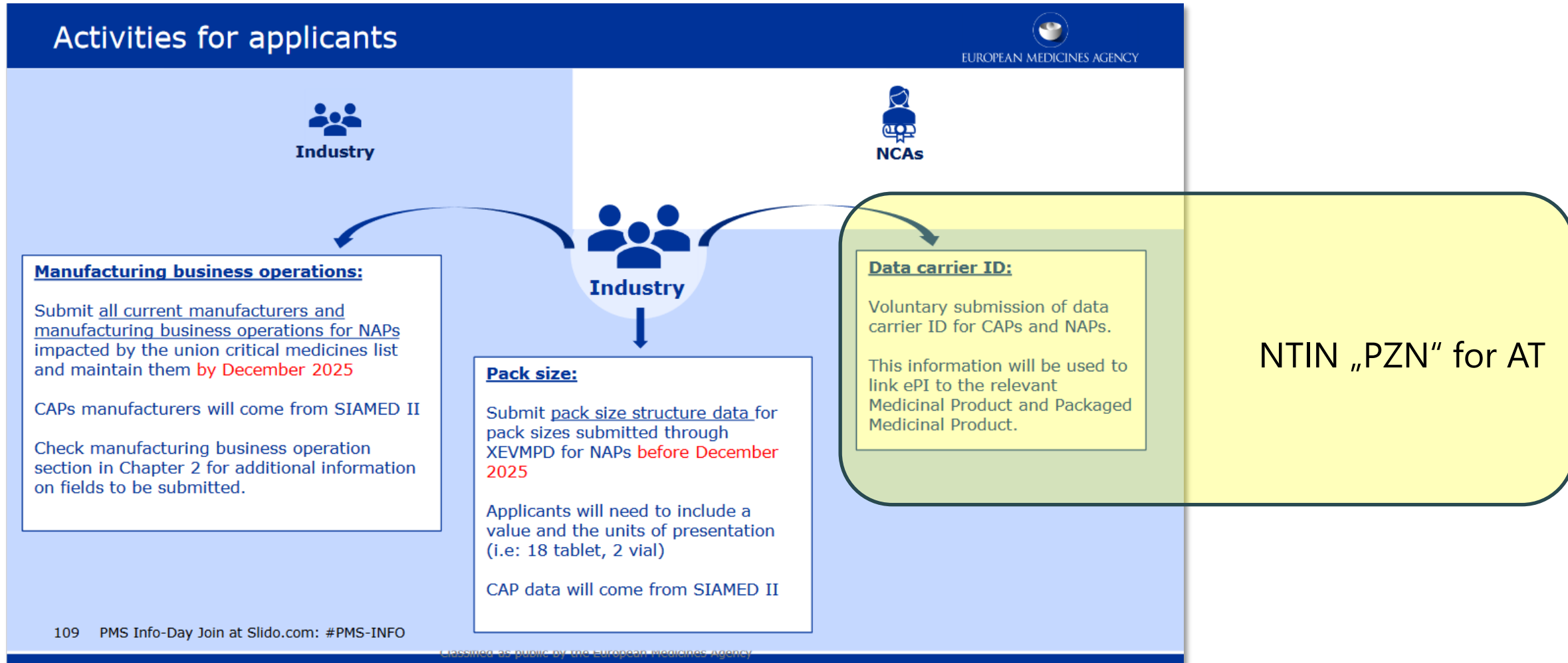
- ePI documents (e.g., PL, SmPC) will be associated with the relevant **GTINs** using the **Data Carrier field** enabling use of ePI data in applications linking to ePI by scanning the data matrix code on the medicine package



PMS Data fields used by ePI

Source: EMA, 2024

ePI – Data Enrichment



Source: EMA PMS Info-Day, April 2024

Notice

- *„ **for AT:** ... ePI does not mean that packs are now automatically distributed without printed information. These are separate topics with different timelines and legal bases ... “*

Re-Cap

- “.. **ePI** is authorised, statutory product information for human medicines (i.e. **summary of product characteristics, package leaflet and labelling**) in a semi-structured format created using the **EU ePI Common Standard**. ePI is adapted for electronic handling and allows dissemination via the web, e-platforms and print. ..”

Key principles outline ePI benefits: published January **2020**



Link @ EMA

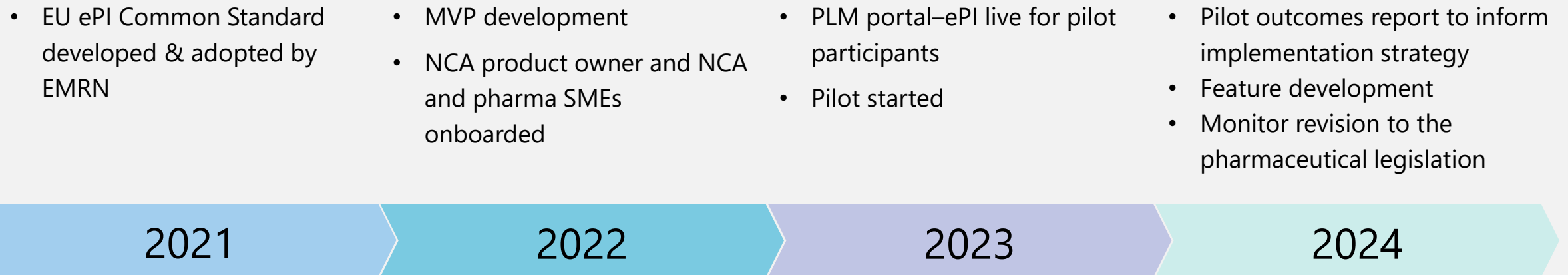
<https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/product-information-requirements/electronic-product-information-epi>

EU ePI common standard based on FHIR to support a harmonised ePI across the EU network

<https://github.com/EuropeanMedicinesAgency/EU-ePI-common-standard>



ePI - Roadmap and outlook



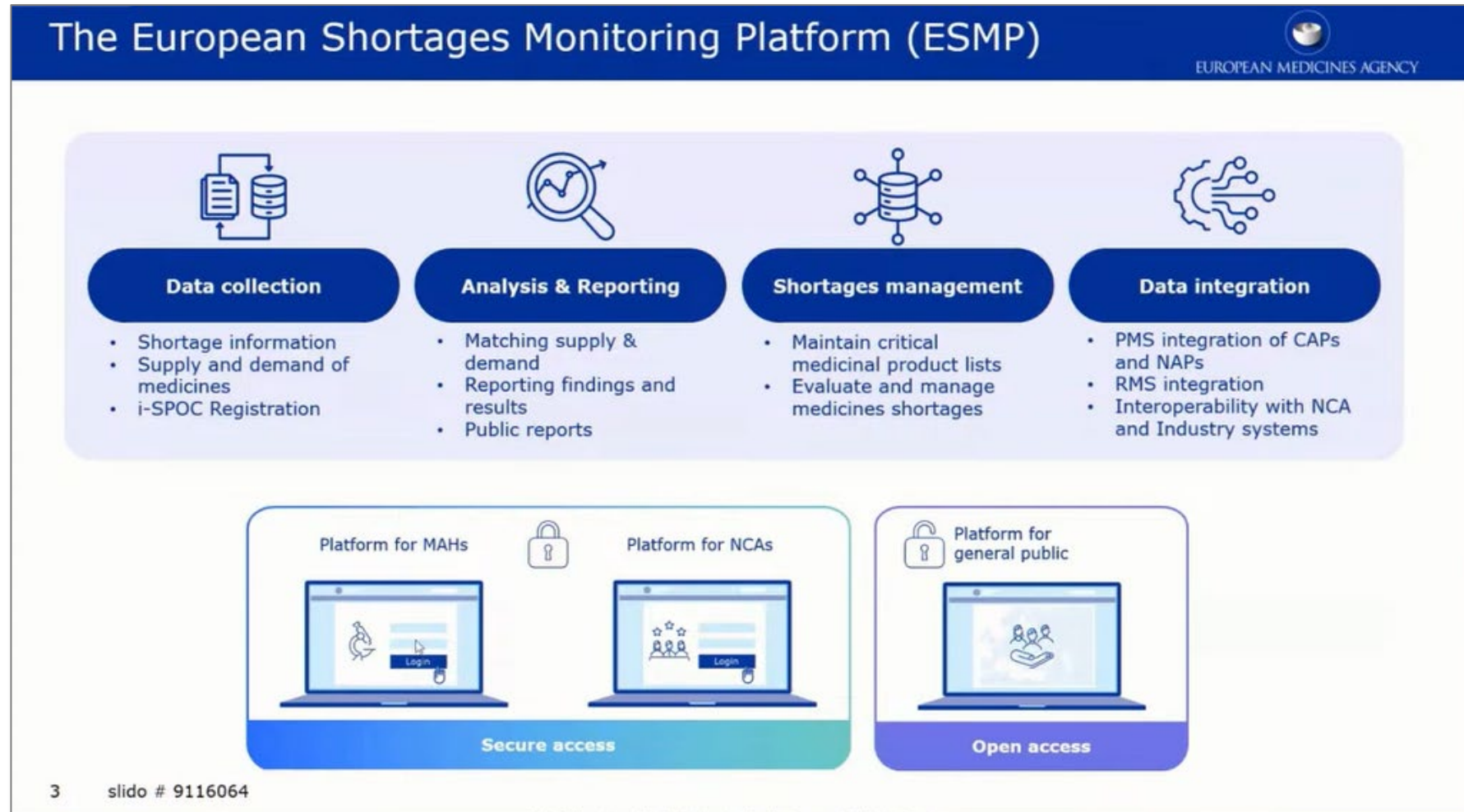
Next **system demo** live on YouTube and EMA website on 26th June

European Shortages Monitoring Plattform ESMP



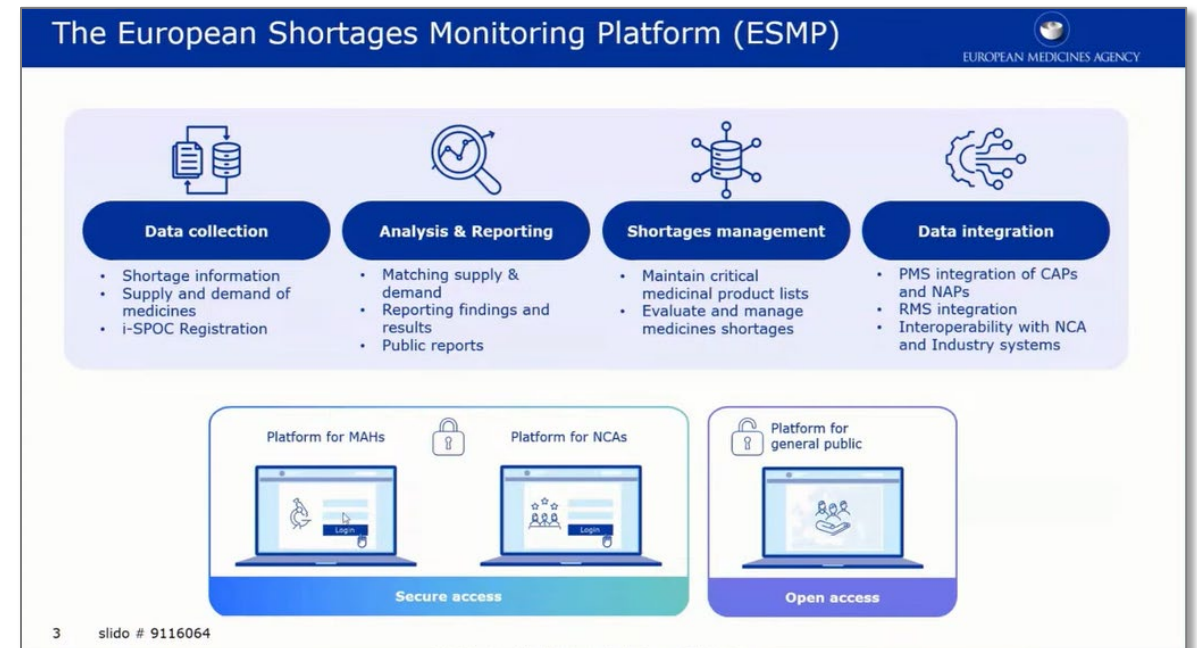
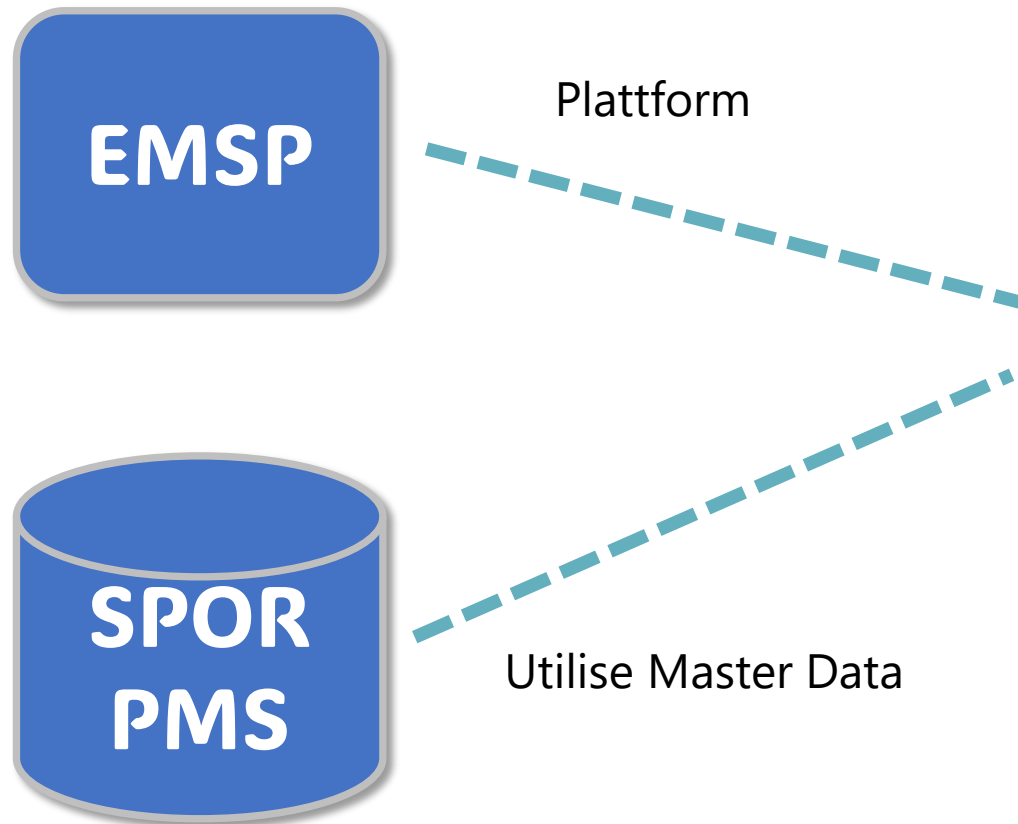
Overview

EU Regulation 123/2022



Source: EMA System Demo, 26.03.2024

Landscape – PLM Portal – SPOR PMS - ePI



The European Shortages Monitoring Platform (ESMP)
EUROPEAN MEDICINES AGENCY

Data collection

- Shortage information
- Supply and demand of medicines
- i-SPOC Registration

Analysis & Reporting

- Matching supply & demand
- Reporting findings and results
- Public reports

Shortages management

- Maintain critical medicinal product lists
- Evaluate and manage medicines shortages

Data integration

- PMS integration of CAPs and NAPs
- RMS integration
- Interoperability with NCA and Industry systems

Secure access

- Platform for MAHs
- Platform for NCAs

Open access

- Platform for general public

3 slido # 9116064

Source: EMA, [Link](#)

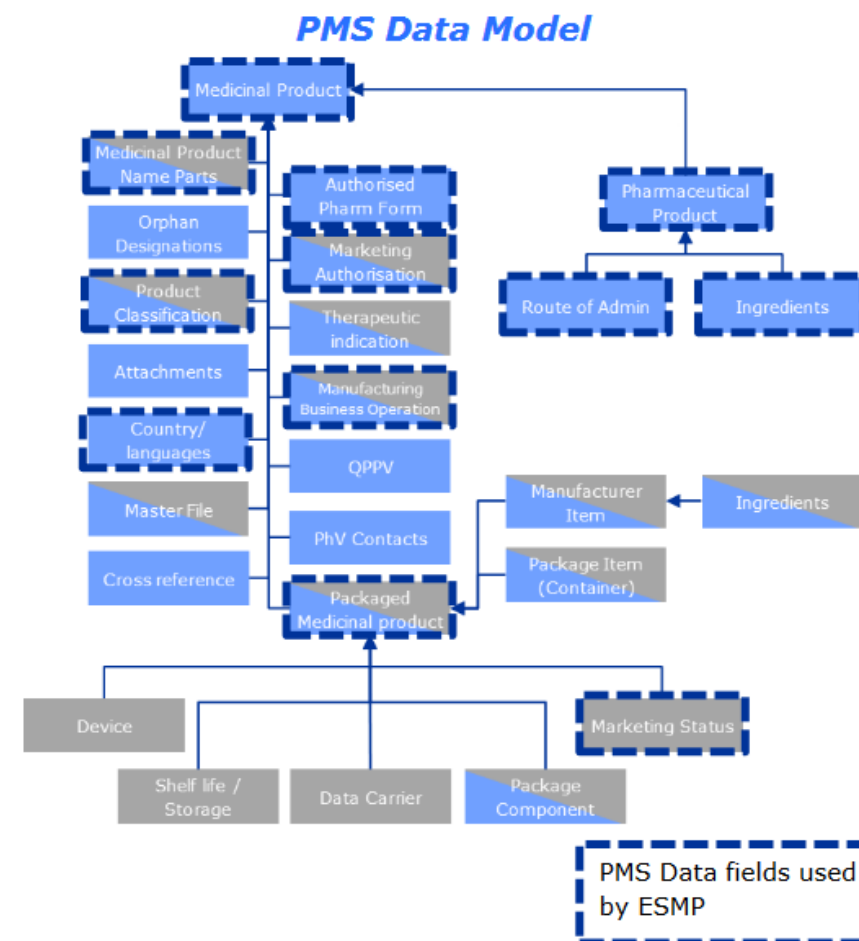
How ESMP uses PMS data (1/2)

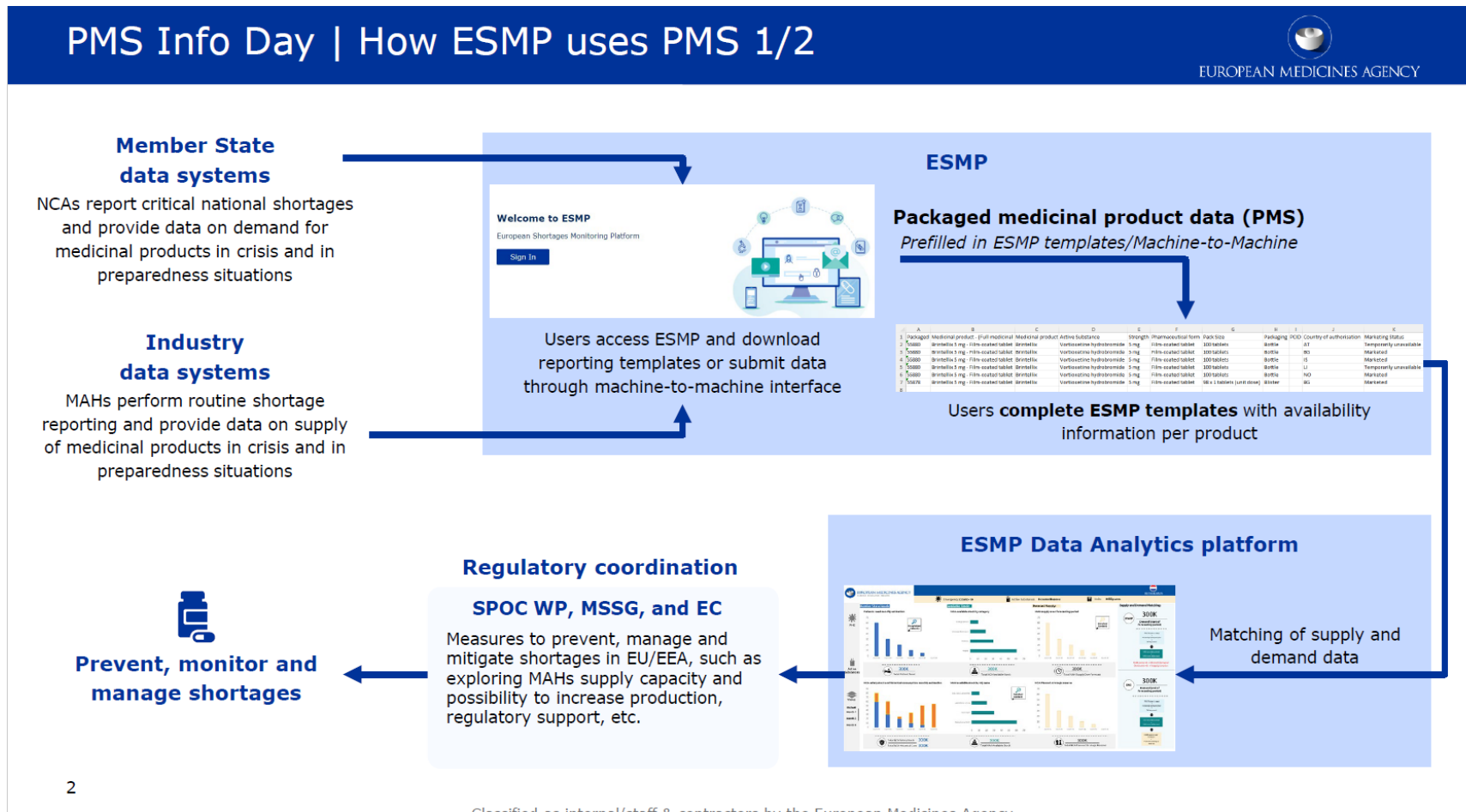


PMS will be used to retrieve data on **medicinal products** to pre-populate reporting templates in the ESMP, to **facilitate data collection, insertion, analysis, and management**

Examples of data uses:

- **pack sizes** for precise data submission, linkage to Industry and NCA databases and quantitative data analysis in matching of supply and demand
- **ATC codes** to identify and classify products
- **manufacturing site** information to assess supply chain vulnerabilities
- **marketing status** information for medicine availability





Reporting templates will be prefilled with PMS data

From 2025/26 further features for "machine-to-machine communication" are planned

-- Interoperability



Activities for applicants



Support ESMP and future regulatory processes

- Applicants should prepare to submit and maintain manufacturers data and structured data on pack sizes
- In particular:
 1. Focus on union list of critical medicines first
 2. Map manufacturing operations to the terms in the RMS list (manufacturing business operations)
 3. Map your manufacturers to OMS
- Start submitting individual valid pack sizes for products impacted by the union list of critical medicines list to XEVMPD.

Crisis-specific list and MSSG-led exercise for crisis preparedness

In case a crisis is declared or there is a MSSG-led exercise for crisis preparedness, MAHs will be required to submit pack sizes for impacted NAPs to XEVMPD **within 2 weeks**.

Submission of individual pack sizes to XEVMPD

- Check ATC codes in the union list
- Check products in XEVMPD with these ATC codes
- Review data quality of these products (RoA, dose form, ATC)
- For countries where MA number is assigned at pack level → all pack sizes should already be in XEVMPD
- For countries where MA number is assigned at product level → start submitting all authorised and valid pack sizes (use package description field to differentiate them)
- Follow Chapter 3.II of XEVMPD instructions

Timelines see next slide

ESMP and ASU

European Shortages Monitoring Plattform / Antimicrobial Sales and Use

Source: EMA PMS Info-Day, April 2024



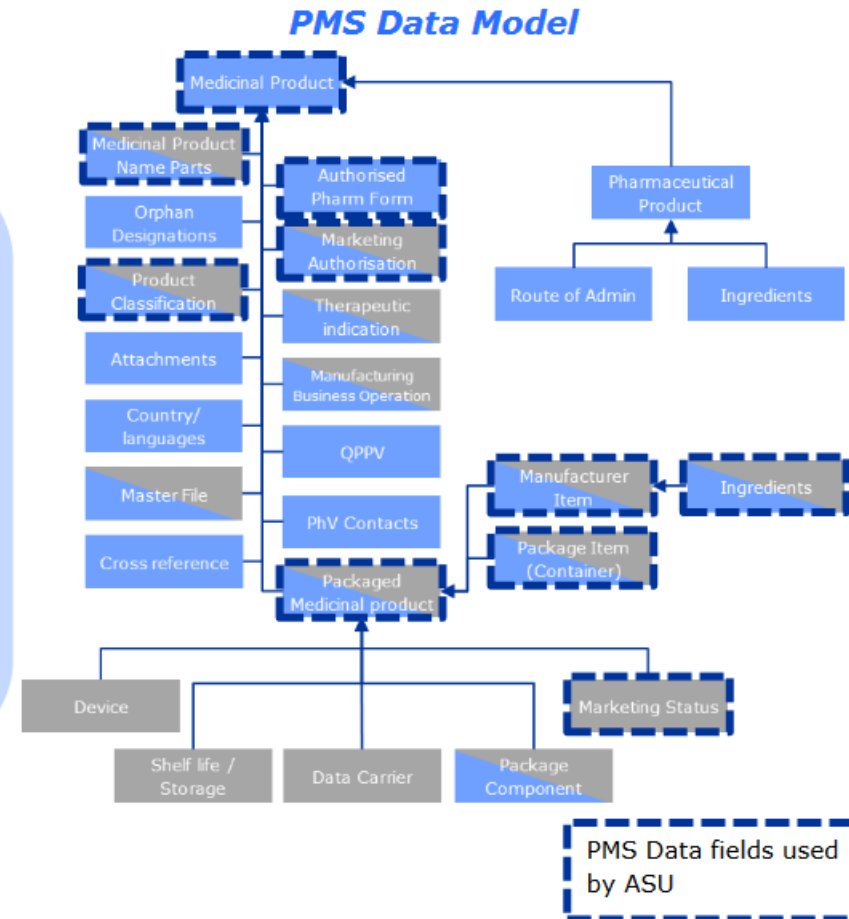
- Link to Union list of Critical medicines: <https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/medicine-shortages-and-availability-issues/availability-critical-medicines>
- For NCAs: Mapping NAPs and optional review

Another use case - ASU

How ASU use PMS data



- As per Art. 57 of Reg. (EU) 2019/6, Member States **shall report to the Agency data on the use of antimicrobial in animals** and this includes use of any human antimicrobial medicinal product that may have been prescribed to animals as per Articles 112, 113 and 114 of the same regulation.
- ASU will enable all users **to search across all human medicinal products that fall in the ASU reporting scope** to pick the ones they want to report on.



UNICOM

a best practice where “fitting together” happened



UNICOM – facts

H2020 Funded Project

11.2020 – 05.2024 (54 months)

21M € Total Budget

90 Deliverables (135 incl. versions)

41 partners, 19 countries

- 9 Standard Development Organisations
- 11 National Competent Authorities for Medicinal Products
- 10 National eHealth Competence Centers / National eHealth Contact Points
- 4 Industry partners (Health IT)
- 2 Research Organisations
- 2 Medicinal Database Providers
- 3 Non-profit organisations



[UNICOM \(unicom-project.eu\)](http://unicom-project.eu)

Key achievements in 8 minutes

Impact on Processes

- Gap Analysis of Existing and Need for New Standards and Profiles
- EU-SRS Implementation and going live
- DADI – Electronic application forms
- IDMP implementation on National level
- Contributions in eHDSI Waves 6 and 7 (2022-2024)
- IDMP Coding Principles and Guidance for ICSRs
- Implementation guidelines for use of IDMP within MPD

Resources and Assets

- IDMP in a capsule
- Minimum Attribute List and Pilot Product List (PPL)
- UNICOM FHIR IDMP server, UNICOM FHIR IG, and IDMP product browser for test and reuse
- Smart Substitution Component and Patient Facing App

Knowledge exchange

- Community of Expertise
- Trans-Atlantic exchange and workshops
- NCA Best Practice exchanges
- Contribution to Research papers

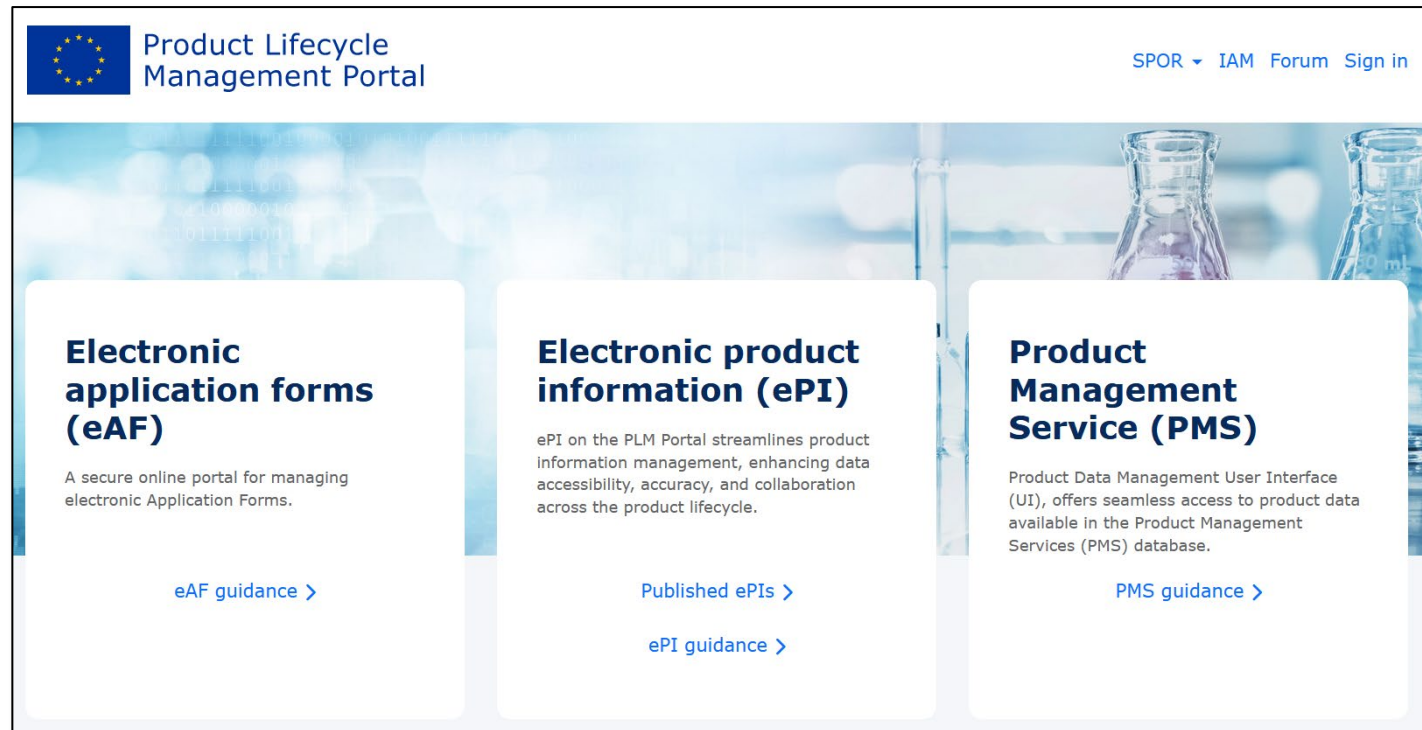


<https://youtu.be/sfdsWxuz9Uc?list=UUBsNj4B33Q7-50XTXdqAGlg>

Conclusions



PLM Portal – “a door to the world”



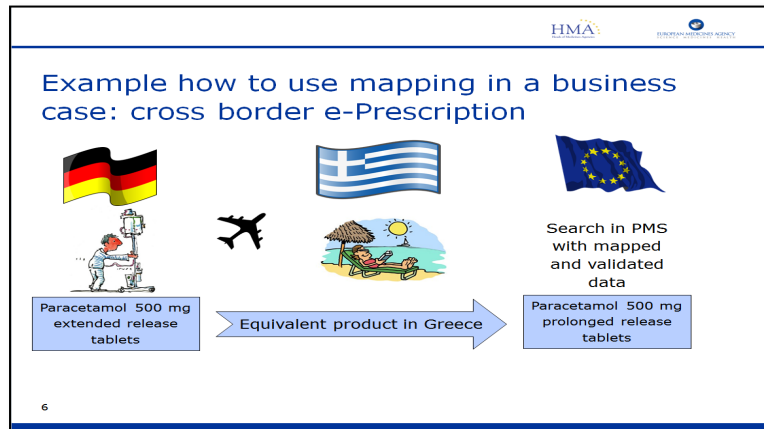
The screenshot shows the homepage of the Product Lifecycle Management Portal. At the top left is the European Union flag and the text "Product Lifecycle Management Portal". At the top right are navigation links: "SPOR", "IAM", "Forum", and "Sign in". The main content area features three white cards on a blue background with laboratory glassware. The first card is titled "Electronic application forms (eAF)" and describes it as a secure online portal for managing electronic Application Forms, with a link for "eAF guidance". The second card is titled "Electronic product information (ePI)" and describes it as streamlining product information management, with links for "Published ePIs" and "ePI guidance". The third card is titled "Product Management Service (PMS)" and describes it as a Product Data Management User Interface (UI) for accessing product data, with a link for "PMS guidance".



Interoperability

The success of the next digitalisation steps depends on the degree of **interoperability of data, processes and IT systems** and next data consumers/scenarios are already waiting for trustworthy data

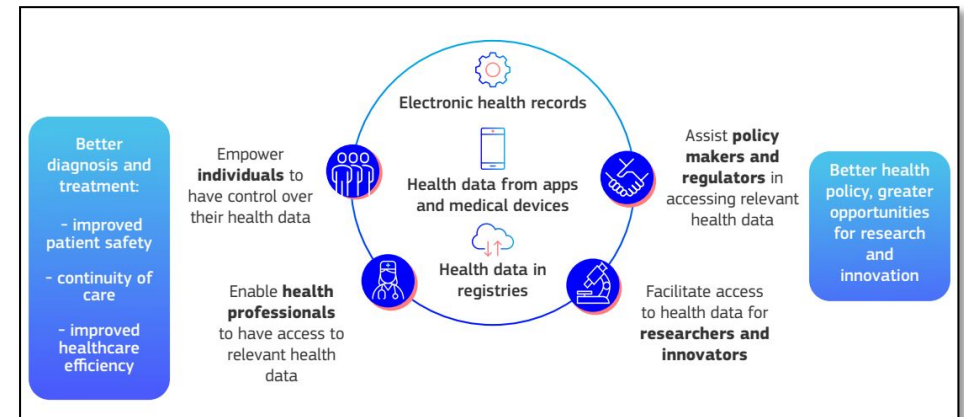
Empowering patients



Source: EMA

e.g. "Master data of medicinal products are a central prerequisite for cross-border activities, EU-Patient-Summary

European Health Data Space



Source: EC, <https://www.european-health-data-space.com/>

**The EMRN is one source for trusted master data
For primary and secondary use of data**

Take Home Message

- **XEVMP data is now becoming relevant for regulatory activities**
 - e.g. for medicinal product masterdata in eAFs; might delay applications!
 - Please check your data quality in XEVMP

- **Consider resources for data enrichments**
 - Packages, Pack sizes/units needs to be enriched in XEVMP and PMS
 - Manufacturer data needs to be enriched in PMS for ESMP

- **Consider interoperability measures at your level to ensure consistent data (flows)**
 - ISO-IDMP and EU implementation guides
 - FHIR for data exchange
 - Usage of SPOR OMS, RMS, SMS

Questions and Contact



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