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Heads of Medicines Agencies

PMS Info-Day 2026

Medicinal product data for Europe's public health

9 June 2026 - Morning session

8:45 – 13:00 (CEST)

Welcome

Speakers:

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

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

Opening remarks

Opening remarks

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)

Runa Hauksdottir Hvannberg
Co-chair of Regulatory Optimisation Group (ROG) and Executive Director of the Icelandic Medicines Agency (IMA)

Speakers:

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

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

What do we want to achieve today?

Inform

Enable stakeholders to gain a common baseline knowledge, reducing confusion and supporting more effective participation.

Align

Bring different stakeholders onto the same page on common goals, expectations and coordinated contributions enabling a smoother and more effective implementation.

Engage

Provide an opportunity for active dialogue and collaborative ecosystem that supports adoption and buy-in.

Agenda: Morning session

1. **Welcome and opening remarks**
   8:45 – 9:05
2. **Session 1: PMS, a strategic catalyst**
   9:05 – 9:45
3. **Session 2: PMS, bringing data and process together**
   9:45 – 10:45

Coffee break (*30 min*)

4. **Session 3: From strategy to reality – How we are implementing it**
   11:15 – 11:55
5. **Session 4: From build to public healthcare benefits**
   11:55 – 12:40
6. **Conclusions and closing remarks**
   12:40 – 13:00

Lunch (*60 min*)

Session 1:
PMS a strategic catalyst

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Chairs:

Runa Hauksdottir Hvannberg
Co-chair of Regulatory Optimisation Group (ROG) and Executive Director of the Icelandic Medicines Agency (IMA)

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

Speakers:

Georgia Gavriilidou
Head of Legal Department, EMA

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

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Speakers:

Georgia Gavriilidou
Head of Legal Department, EMA

Topic:

Legal drivers for the EU Network

New Pharmaceutical Legislation (NPL)

The first **comprehensive revision** of EMA's founding regulation and the Community Code on medicinal products for human use since 2004 aims to bring about the **following key changes**

New Pharmaceutical Legislation (NPL) key changes (1/2)

A **simpler** regulatory environment

Streamlined committee structure: from five to **two scientific committees (CHMP & PRAC)**
Stronger expert, patient and healthcare professional involvement

Reduced assessment timelines (210 → 180 days)

Marketing authorisation valid for an **unlimited period** by default, unless safety concerns arise

Mandatory **digital submissions** and electronic product information (ePI)

More **support** and **improved** conditions for **innovation**

Extended **scientific advice** with HTA bodies and expert panels & strengthened **PRIME support**

Regulatory sandbox for innovative medicines supervised by the competent authorities

Adapted frameworks for non-standard medicines (e.g. personalised therapies)

Improved **efficiency** of the process for **studying medicines for children**, including the formalisation of an iterative paediatric investigation plan (PIP)

New Pharmaceutical Legislation (NPL) key changes (2/2)

Stronger **safeguards** against **medicine shortages**

- Stronger **supply obligations** for companies
- **Obligation** to **notify** shortages and withdrawals in **advance** and to have shortage **prevention plans**
- Monitor of **expected** and **actual shortages** by both EMA and NCA
- EU list of **critical medicines** and **supply-chain vulnerability** assessments

Enhanced **environmental protection** & focus on **antimicrobial resistance**

- Enhanced **environmental risk assessment**
  - including specific methodologies to assess antimicrobial resistance risks from antimicrobial manufacturing
- **Prudent use** of antimicrobials, including:
  - mandatory prescriptions for all antimicrobials
  - enhanced product information (package leaflet and awareness card)
  - required antimicrobial stewardship plans

Critical Medicines Act (CMA) overview

Key measures

- **Boost EU manufacturing capacity** for critical medicines, active substances, and key inputs through **strategic projects** informed by MSSG vulnerability assessments.
- **Enable flexible public procurement (award criteria)** to strengthen resilience and diversify supply chains for critical medicines and other medicines of common interest (e.g., rare diseases, antibiotics).
- **Leverage joint procurement** by combining Member States' demand and buying power to improve access to critical medicines and medicines of common interest
- **Develop strategic international partnerships** to diversify sourcing and enhance security of supply for critical medicinal products and their key components.

Tasks for EU Network

- **MSSG (tasks enshrined in NPL):** update Union list of critical medicines, vulnerability evaluations, and issue recommendations on common procurement initiatives; MSSG and CMG may hold joint meetings.
- **Provide regulatory and scientific support to manufacturers (Strategic Projects promoters)** on innovative manufacturing processes.

Biotech Act overview

Description

- Biotech Act is the expected new legal proposal from the EC aiming to strengthen EU competitiveness by improving conditions for biotechnology and biomanufacturing.
- It focuses on health sector, with key focus to amendments to the Clinical Trials Regulation (CTR).

Tasks for EU Network

- As part of the CTR revision, EC will aim to reduce CT authorisation timelines, improve MSs coordination, encourage the uptake of AI, introduce certain CT application harmonisation, increase flexibility for CT substantial modifications etc.

European Health Data Space (EHDS) overview

Key measures

- Empower patients to freely **access and manage their electronic health data**, while also enabling secure **sharing of such data for the provision of healthcare**, in order to **assess, maintain or restore the state of health of the natural person to whom those data relate** (= primary use)
- Enable **access and reuse of electronic health data for research, innovation and regulatory activities** in safe and secure way (= secondary use)
- Create a single market for electronic health records (EHRs) systems, supporting both primary and secondary use

Tasks for EU Network

- From **March 2029** EHDS enters into application for primary use data and some categories of secondary use.
  - Patients can use **heath data across EU** (patient summary, ePrescriptions, e_dispensatins, etc) including their **medication data**
  - EMA/NCAs obtain a right to **request electronic health data** via EHDS upon fee to support its regulatory activities.
  - EMA/NCAs are obliged to **comply with access requests for data that they hold**, incl. data from EHRs and data from registries for medicinal products such as PMS.
- From **March 2031** the scope of EHDS to be extended to all data categories (e.g. clinical trial data, genomics, medical imaging).
  - Member States are expected to be fully compliant and **cross-border infrastructure fully operational**

Medicinal product data: the backbone of regulatory success

Reliable data today powers compliance, collaboration, and tomorrow's regulatory transformation

Rising regulatory demands: significant **mobilisation in next 2-3 years** ahead!

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Speakers:

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

Topic:

Implementation of EU strategic drivers in the Network portfolio

PMS at the centre of Digital transformation

Portfolio Vision

Transform our stakeholders experience during the interaction with the regulatory Network by providing ***an integrated customer and data digital journey through medicines*** **regulatory processes*, to the benefit of public and animal health in EU***

Portfolio drivers

- ***Legislative Priorities***
- ***Data Driven Network***
- ***Operational Efficiency***
- ***Cybersecurity & Technology Modernisation***

Portfolio IT products enabled by PMS today

PMS — **Shared repository of trusted medicinal product data in the EU**

- **RPM**
- **Product UI**
- **eAF**
- **ePI**
- **ESMP**
- **ASU**

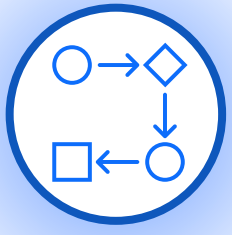
PMS Vision

PMS Vision

Public health empowered by a shared repository of comprehensive trusted structured data on medicines in the EU

Key changes

ISO IDMP-compliant data

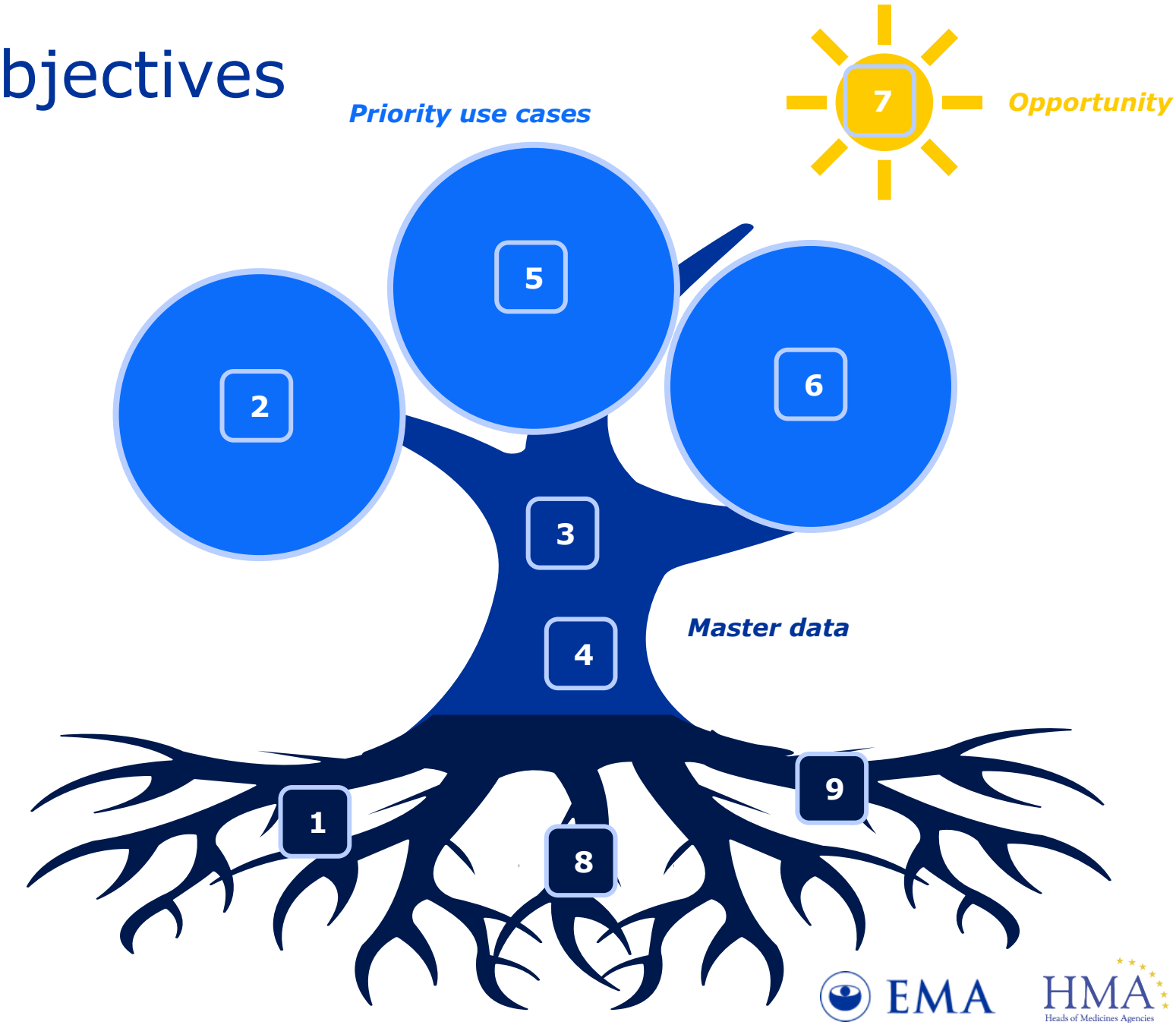


Integrated data journey with regulatory procedures

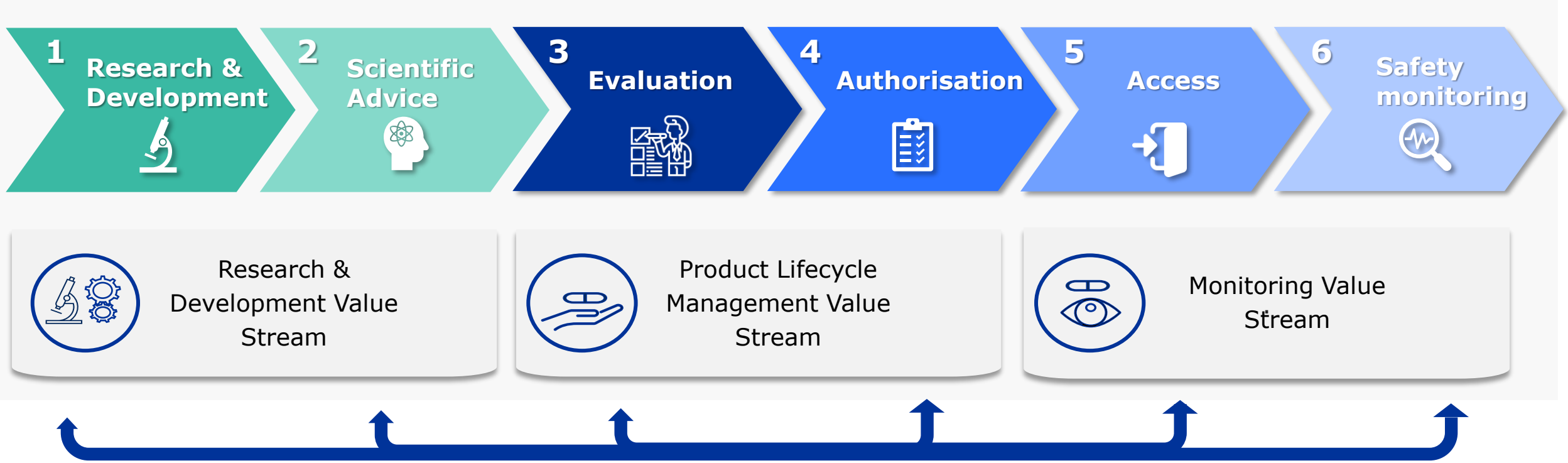
Trustworthy and quality data in one shared source

Network Portfolio Objectives

1. **Information security**
2. **Clinical trial authorisation**
3. **Veterinary medicines info mngt**
4. **ISO-IDMP master data management**
5. **Medicines lifecycle management**
6. **Shortages**
7. **Evidence-based AI and advanced analytics**
8. **Corporate back-office**
9. **Legacy systems**



PMS supporting the full Medicinal Product Lifecycle



- **SPOR Master Data Management (Substances, Product, Organisations, Referentials)**
- **PMS: Product Management Services**

Session 2:
PMS, bringing data and process together

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Chairs:

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

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

Speakers:

Isabel Chicharo
PMS Epic Owner and Head of Regulatory Data Management

Dino Soumpasis
PMS Network Product Owner and member of Regulatory Optimisation Group (ROG) PMS Operational Group, Bfarm

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Speakers:

Isabel Chicharo
PMS Epic Owner and Head of Regulatory Data Management

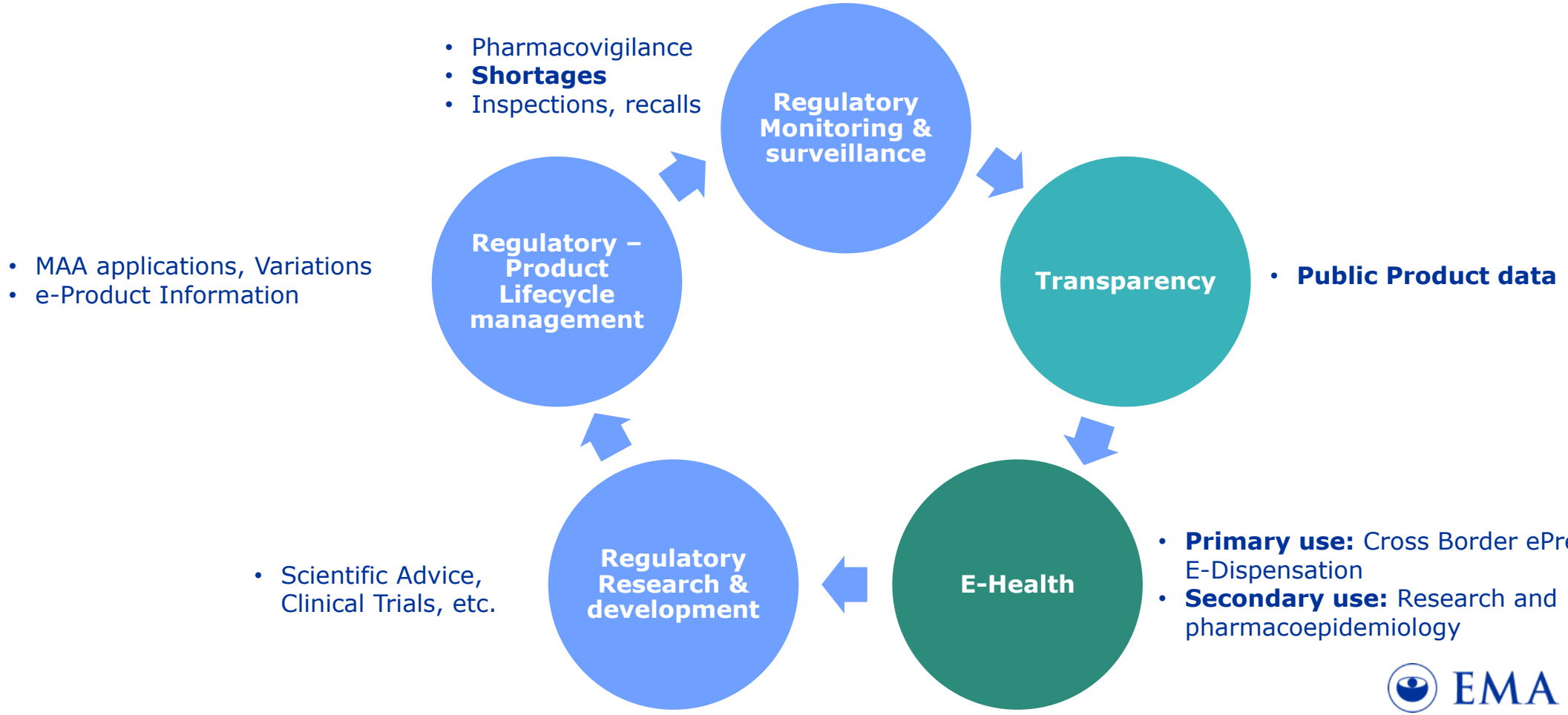
Topic:

Product data supporting use cases

What use cases does product data support?

A win for Regulators and e-Health:

- *Product data is critical to support Regulatory activities through the medicinal product lifecycle.*
- *Healthcare Professionals and Patients need clear visibility of product information and regulatory outcomes.*
- *A trusted Public EU-wide product data source is a win for Healthcare (Regulators, Marketing Authorisation Holders, Healthcare Professional and Patients, Researchers)*



- Pharmacovigilance
- **Shortages**
- Inspections, recalls

- **Public Product data**

- **Primary use:** Cross Border ePrescription/ E-Dispensation
- **Secondary use:** Research and pharmacoepidemiology

- Scientific Advice, Clinical Trials, etc.

- MAA applications, Variations
- e-Product Information

Monitoring of shortages

PMS product data: anticipating shortages before they occur

Using standardised product data facilitates collection and analysis of supply and demand data, to monitor and prevent shortages. It enables to access the supply chain for vulnerabilities and recommend measures to mitigate and address shortages

1. A **product shortage** is identified in country A

2. **NCAs report shortages** and demand for medicinal products

2. **MAHs report shortage** and supply of medicinal products

3. **Shortages Monitoring**
Matching supply data against demand to identify gaps

Analysis:
- Search for similar products available in other countries
- Identify therapeutic alternatives
- Assess MAHs supply capacity and potential to scale up production
- Explore regulatory support measures

4. **Regulatory coordination** (SPOC WP, MSSG, and EC) to agree on **measure to prevent, monitor and manage shortages**.

Decisions and relevant information are communicated to MAHs and NCAs

5. **Shortage resolved** through product import or approved alternatives

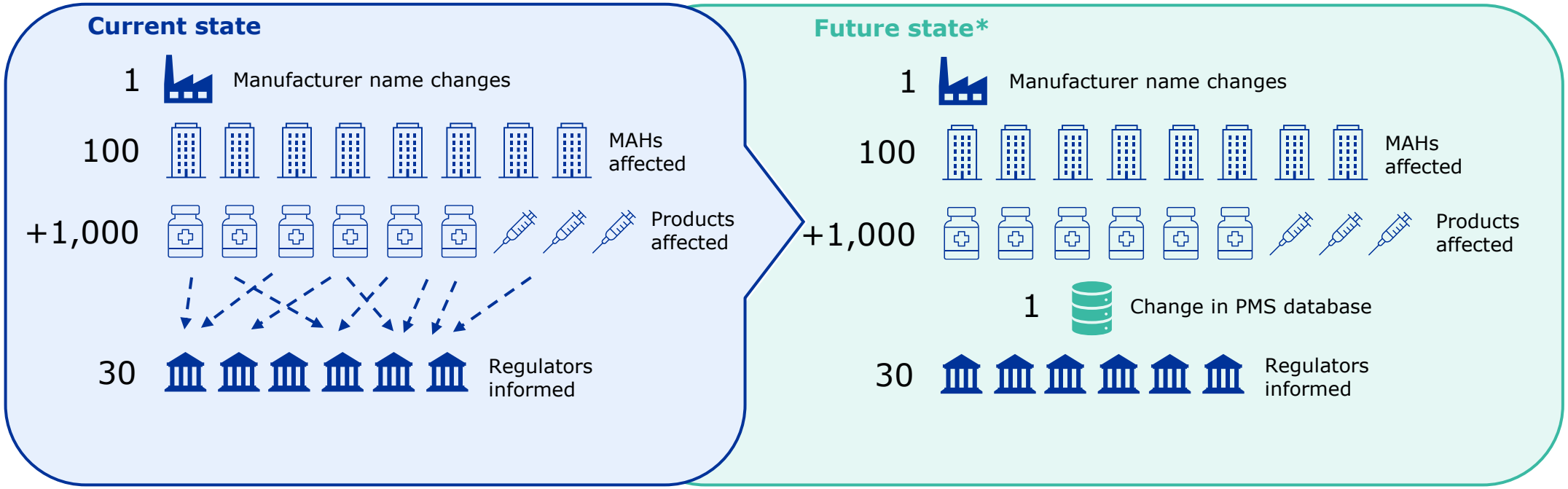
Data readiness	
IDs	
Name	
Pharm. Form	
ATC code	
AS & Strength	
Route of admin.	
MAH	
Marketing Auth.	
Indications	
Packages	
Manufacturer	
Data carriers	

Legend – PMS data readiness to support the different use cases:
Blue: PMS has/will have more data/extra data that could create new opportunities
Green: PMS data quality acceptable, supports the use case even if with workarounds
Amber: Significant issues (e.g. missing data) and actions required
Red: PMS doesn't support the basic need of the use case
White: Data not needed for use case

NPL Variations type IA optimisation through data submissions

NPL supports data submissions only!

- *The precedent and success of XEVMPD in handling QPPV reporting demonstrates the value of structured data-driven approaches in regulatory affairs*
- *Implementing digital, data-driven PMS submissions leveraging structured data eliminates the burden of variation submission and tracking for all stakeholders.*



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*The precise future state will be determined through comprehensive assessment and refinement of the Proof of Concepts and work of the ROG.

EHDS – cross border e-Prescription/ e-Dispensation

PMS: the foundation for seamless cross-border e-Prescription and e-Dispensation

Standardised PMS data bridges the gap between national formularies, enabling safe, accurate prescribing and dispensing for patients across EU borders. Critical improvement compared to current substance based cross-border dispensing.

1

E-Prescription

The patient is prescribed a medication in Country A

2

E-Dispensation

The patient collects their medication from pharmacy in Country A

3

Patient travels abroad…

…and forgets to bring their medication!

He visits a doctor in Country B, explains his condition, but s unsure of the medication's brand name and substances contained

4

Cross-Border e-prescription

The doctor retrieves *Patient Summary* from Country A, confirming medication details.

The doctor prescribes appropriate equivalent medication available in Country B

5

Cross-Border e-Dispensation

The patient goes to pharmacy to collect the medication, but the product is not in stock due to shortage in Country B

Pharmacist substitutes the prescribed medication with a suitable alternative and dispenses the available equivalent

Data readiness	
IDs	
Name	
Pharm. Form	
ATC code	
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Overview PMS use cases – is data fit for purpose?

PMS data supports **key use cases**

Data Quality monitoring focuses on **specific data fields/rules** required to support key use cases

PMS Data Quality planed improvements **target highest impact problem** (on relevant use case & data field)

Use case	Data readiness												Data readiness Improvements
	IDs	Name	Pharm. Form	ATC code	AS & Strength	Rout of admin	MAH	Marketing Auth.	Indications	Packages	Manufacturers	Data carriers	
Pharmacovigilance processes											(4)		• (1) Correction of duplicate Products & packages – Q2-Q3 • (2) Correction of out-of-date information in products (mostly packages) - Q3 • (3) Correction of Missing information in products (Key fields: AS, DF, MAH, ...) - Q4 • (4) Package/manufacturing enrichments (UCL by June 2026 and remainder by end 2027) • (5) Optional data carrier enrichment
Shortages Monitoring & Vulnerability assessment	(1)	(2)	(2)		(2)		(3)			(1) (2) (4)	(4)		
EHDS – primary use (ePrescription & eDispensation)	(1)	(2)	(2)		(2)		(3)			(4)			
NPL Type IA Var simplification – eg Manufacturer name changes											(4)		
NPL e-PI creation Opportunity: box scanner & ePI reader												(5)	

Legend – PMS data readiness to support the different use cases:

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Speakers:

Dino Soumpasis
PMS Network Product Owner and member of Regulatory Optimisation Group (ROG) PMS Operational Group, Bfarm

Topic:

Legacy Data Qualification

ROG PMS operational group - Data qualification feasibility study

Stepwise approach towards trusted data in PMS

Data Qualification Goal: The data submitted by MAHs *[stored and published in PMS]* is aligned with the data approved by the NCAs *[stored and published at national level]* **i.e. data across MAH-PMS-NCAs is aligned.**

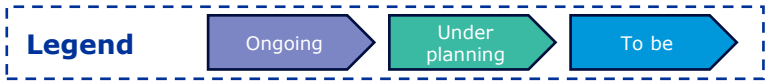
AS-IS
MAH creates/ updates in PMS

Dedicated effort
Same product/ packages in PMS and EMA/ NCA databases
- EMA provides mapping support to NCAs

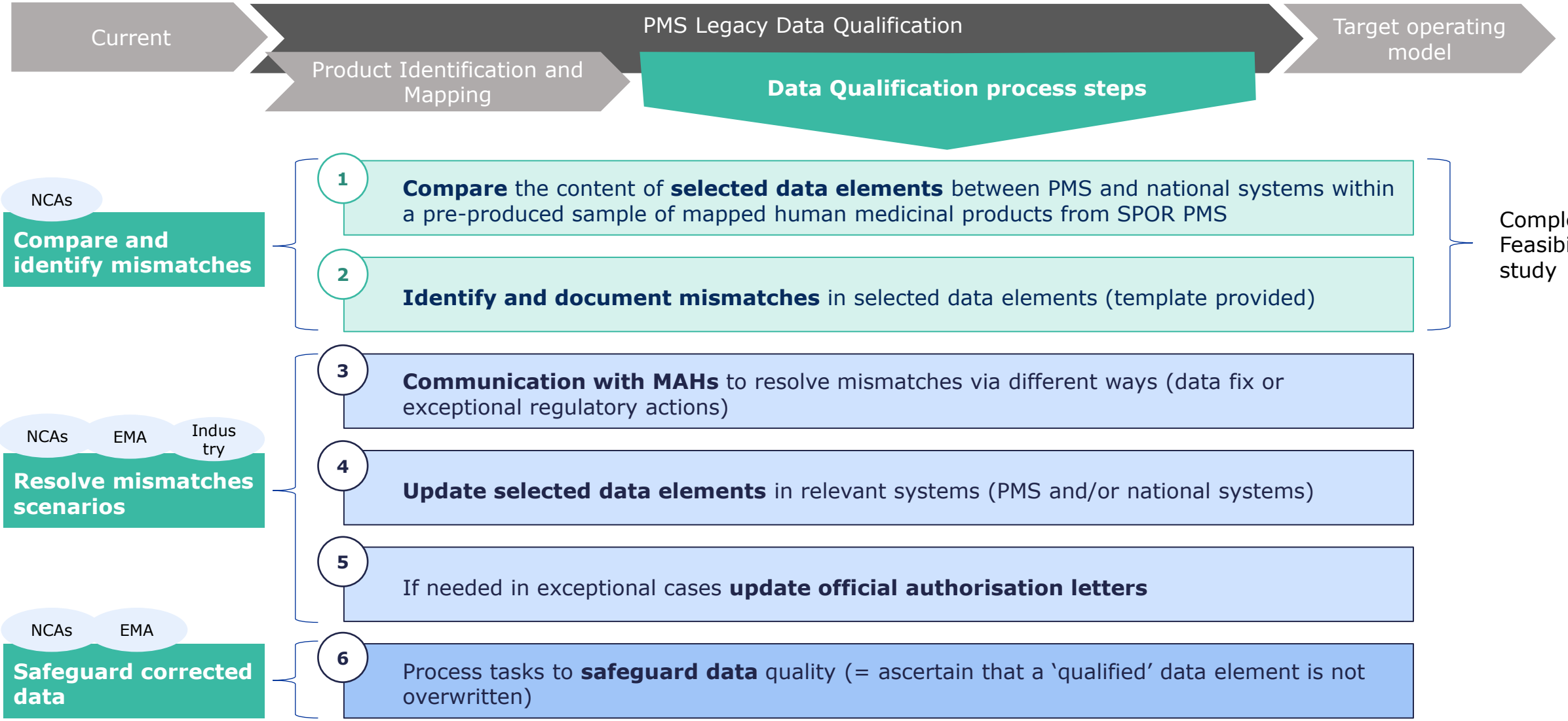
Dedicated effort
Identical data-elements in PMS and NCA databases
- Data-elements stored in PMS is aligned with the data approved by the NCA

Continuous model
Execution of Data Quality Framework – data submission, data validation/stewardship and Data Quality monitoring

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



Data Qualification process steps



Feasibility study – key outcomes

Data elements recommended to start with

Based on matching rate and efforts required, the group recommends the step-wise approach:

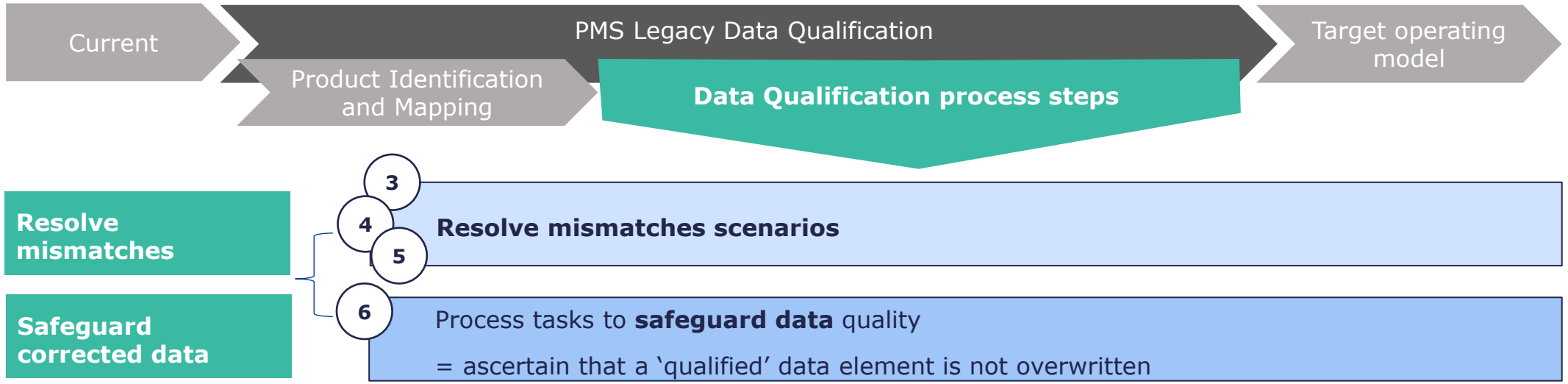
- **Subset 1**: Core PMS data elements that are already available in PMS and minimal effort for data qualification
  - Data elements: Product name, MAH name and address, authorisation number, procedure number, ATC code, pharmaceutical form, manufacturer responsible for batch certification, route of administration
- **Subset 2:** PMS data elements that fall within the scope of ESMP-related data enrichment
  - Data elements: All other manufacturers, packages information
- **Subset 3:** PMS data elements with dependencies, such as those that require XEVMPD decommissioning as a prerequisite
  - Data elements: Active substance and strength (and others)

- Time spend on average: 45 minutes, Subset 1 in 9 minutes

Catalysts

- IDMP ready systems supplemented by further IT tools are essential for efficient data qualification by NCAs
- In MRP/DCP, data qualification of common data elements by the RMS increases efficiency and reduces Network workload

Key elements of a full qualification process



Designing a first detailed qualification process*

Proposal to agree on:

- the procedure and tasks
- definitions and rules for identifying and for correcting mismatches in relevant industry/regulatory data systems
- inclusion and roles of various stakeholders

* for subset 1

First Draft proposal*

- PMS data is compared with national data,
  - Alternative 1: NCAs inform EMA
  - Alternative 2: NCAs send information to EMA

  on identified mismatches to EMA for correction
- EMA data stewards implement the changes required
- Industry is informed of changes via XEVMPD acknowledgement system
- Data is safeguarded by XEVMPD current processes and data versioning management

* for subset 1

Next steps

- Within ROG PMS OG: Test the proposed data qualification process **for subset 1**
- **Industry consultation and engagement** on the proposed process foreseen for 2Q’26 onwards
- **XEVMPD decommissioning** is acknowledged as a priority and a need for a full data qualification process to run subset 3
- Detailed process and roles and responsibilities (operational level) to be included as part of the **PMS Data Quality Framework**

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Speakers:

Isabel Chicharo
PMS Epic Owner and
Head of Regulatory Data
Management

Topic:

Stepwise approach towards trusted data

Stepwise approach towards trusted data in PMS – a network effort

Product Data Quality Framework - Strong foundations, shared data, seamless continuity

Data Stewardship & Data Quality Management

Current measures already in place

- Ensuring data quality at data entry point
- Unified guidance and controlled vocabularies
- EMA validation process and feedback.

Dedicated effort

- EMA provides mapping support to NCAs
  - ✓Strong progress with most NCAs close to completion
  - ✓Clear positive momentum across the network
  - ✓Strong foundation for harmonised PMS data integration

Dedicated effort

EMA supports NCAs and MAHs to align the data by a centralised coordination/validation

Continuous model

Foreseen to evolve more into DQ oversight, managing by exception.
Validation on behalf of NCAs who cannot do so

Current

PMS Legacy Data Qualification

Product Identification and Mapping

Data Qualification

Working operating model

AS-IS

MAH creates/ updates in PMS

Dedicated effort

Same product/ packages in PMS and EMA/ NCA databases

Dedicated effort

Identical data-elements in PMS and NCA databases

Continuous model

Product data is re-used in regulatory processes

Network collaboration towards fit for purpose PMS data

ROG Feasibility study + recommendations

- Subgroup of ROG (PMS ROG OG) piloting and advising on data qualification process
- Advising on process, tools and recommendations with regards to legacy data
- Aiming for a common shared repository of trusted data – with data aligned between PMS and member states database

PMS Data Quality Framework

- Document following the Agency's framework of documenting and improving Data Quality management
- Focused on describing the processes, metrics, maturity of DQ processes (in detail)
- Documents the detailed roles and responsibilities – clear expectations

EMRN working arrangements

- Deliverable on NDSG workplan
- Proposes a short-term and a long term approach to ensuring fit for purpose product data
- Aim to include a high-level TOM overview

Target Operating Model (TOM)

- Generally understood as the end-state of management of structured product data, with product data re-used in regulatory processes
- Once in place, a revision of proposed arrangements will be needed

Session 3:
From strategy to reality – How we are implementing it

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Chairs:

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

Marta Marcelino
Chair of Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), Head of Regulatory Strategy and Innovation Unit (INFARMED)

Speakers:

Anne-Marie van Nederkassel
Product Lifecycle Management (PLM) Value Stream Owner

Veronica Lipucci Di Paola
PMS Product Owner

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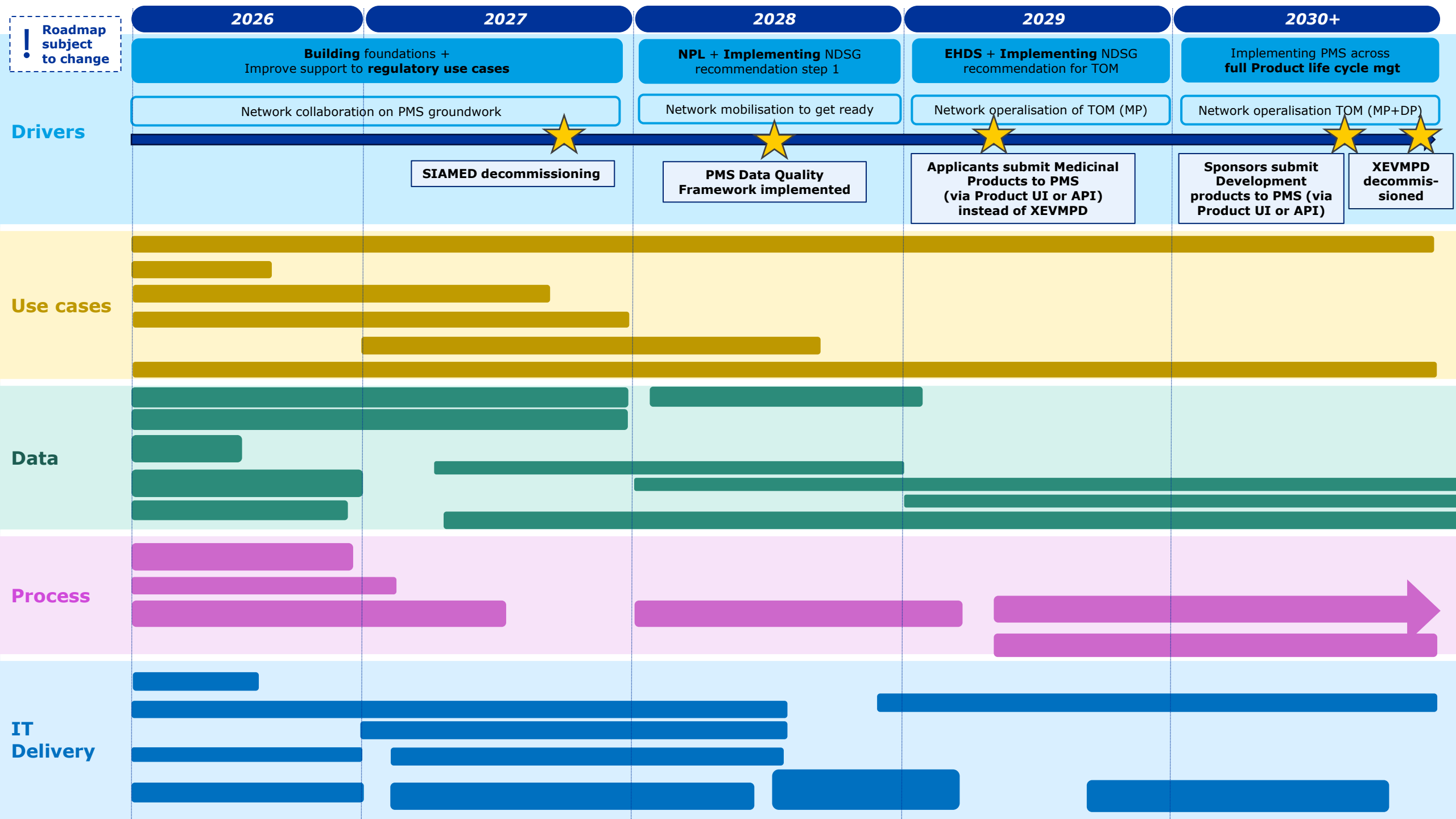
Speakers:

Anne-Marie van Nederkassel

Product Lifecycle Management (PLM) Value Stream Owner

Topic:

PMS roadmap Long-term view


Roadmap subject to change
2026
2027
2028
2029
2030+
Building foundations + Improve support to regulatory use cases
NPL + Implementing NDSG recommendation step 1
EHDS + Implementing NDSG recommendation for TOM
Implementing PMS across full Product life cycle mgt
Drivers
Network collaboration on PMS groundwork
Network mobilisation to get ready
Network operalisation of TOM (MP)
Network operalisation TOM (MP+DP)
SIAMED decommissioning
PMS Data Quality Framework implemented
Applicants submit Medicinal Products to PMS (via Product UI or API) instead of XEVMPD
Sponsors submit Development products to PMS (via Product UI or API)
XEVMPD decommis-sioned
Use cases
Data
Process
IT Delivery

Roadmap subject to change

2026	2027	2028	2029	2030+

Drivers

Building foundations + Improve support to **regulatory use cases**

NPL + **Implementing** NDSG recommendation step 1

EHDS + **Implementing** NDSG recommended TOM

Implementing PMS across **full Product life cycle mgt**

Network collaboration on PMS groundwork

Network mobilisation to get ready

Network operalisation of TOM (MP)

Network operalisation TOM (MP+DP)

- **SIAMED decommissioning**
- **PMS Data Quality Framework implemented**
- **Applicants submit Medicinal Products to PMS (via Product UI or API) instead of XEVMPD**
- **Sponsors submit Development products to PMS (via Product UI or API)**
- **XEVMPD decommis-sioned**

Use cases

PharmacoVigilance processes

CAP Procedure management

- iMAA CAPs (Sept '26)

PhVig processes use PMS data for Authorised medicinal products

PhVig processes use PMS data for Development products

Shortage and Security of Supply (Shortage management and vulnerability assessment to feed ESMP)

- June '26 ULCM enrichment Manuf. & packages
- Dec '26 All EU medicines enriched for Manufacturers
- June '27 All EU medicines enrichment

NPL Variation simplification Type IA pilot

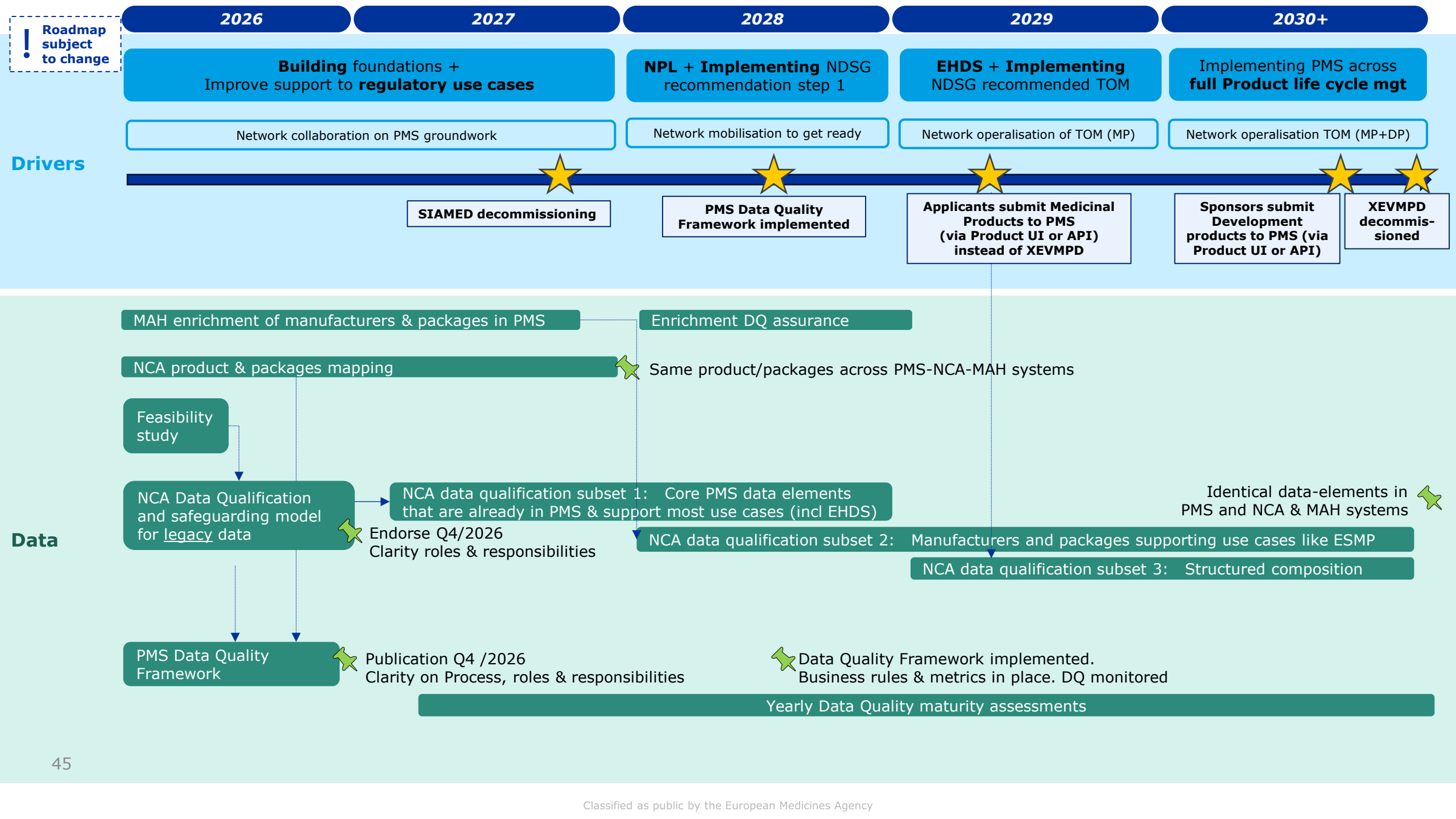
- Industry submits product data updates to PMS for some type IA variations (Date TBC)

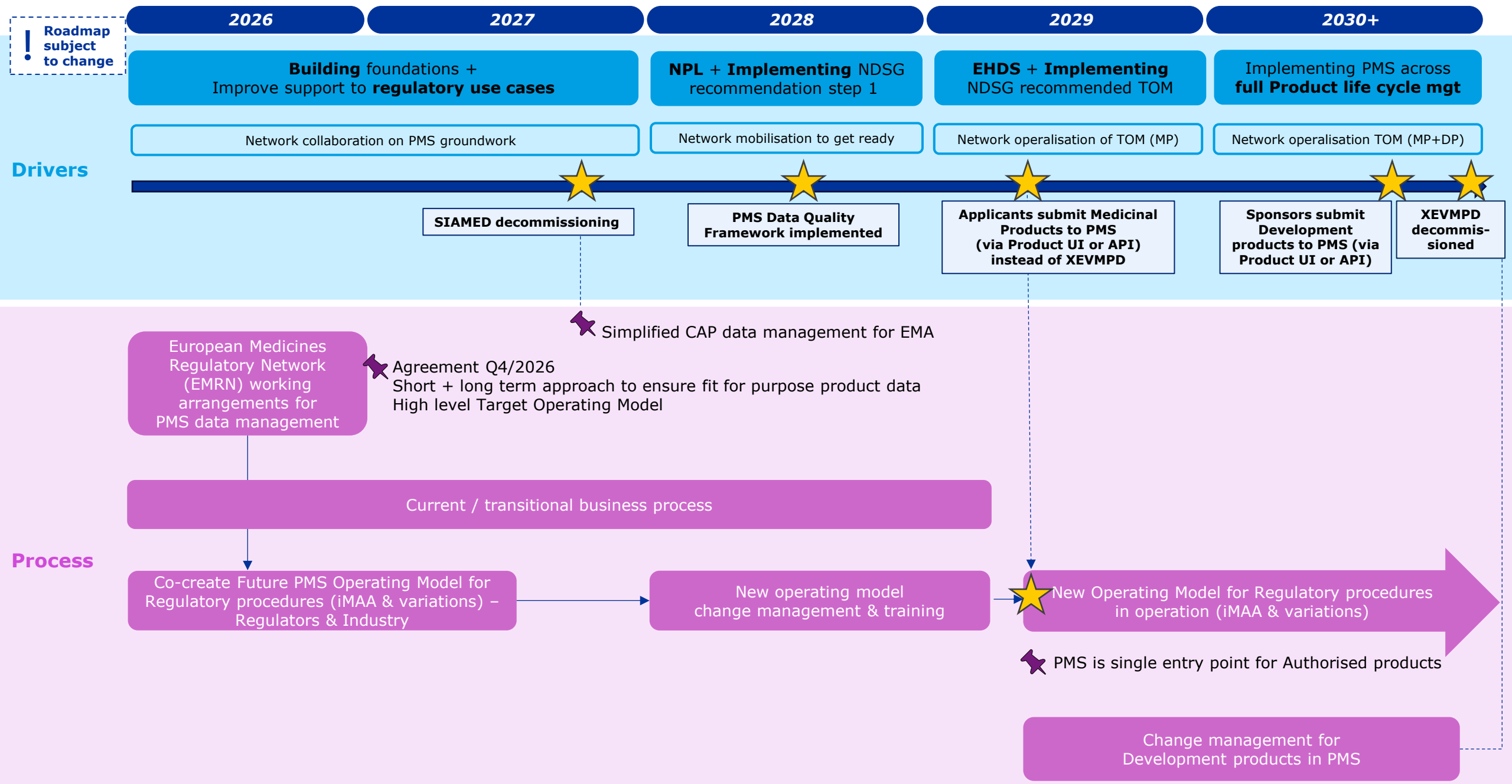
NPL e-PI roll out CAPs, followed by Non-CAPs

- ePI mandatory date TBC
- PMS enrichment: Data carrier

European Health Data Space (EHDS)

- Publication Implementing Act for Art. 15 (European electronic health exchange format (date tbc Q3/2026)
- March '29 Entry into application Primary use
- March '31 Entry into application Secondary use





Roadmap subject to change

2026	2027	2028	2029	2030+
Building foundations + Improve support to **regulatory use cases**		**NPL** + **Implementing** NDSG recommendation step 1	**EHDS** + **Implementing** NDSG recommended TOM	Implementing PMS across **full Product life cycle mgt**

Drivers

- Network collaboration on PMS groundwork
- Network mobilisation to get ready
- Network operalisation of TOM (MP)
- Network operalisation TOM (MP+DP)

- **SIAMED decommissioning**
- **PMS Data Quality Framework implemented**
- **Applicants submit Medicinal Products to PMS (via Product UI or API) instead of XEVMPD**
- **Sponsors submit Development products to PMS (via Product UI or API)**
- **XEVMPD decommis-sioned**

IT Delivery

DATA ACCESS & IMPORT

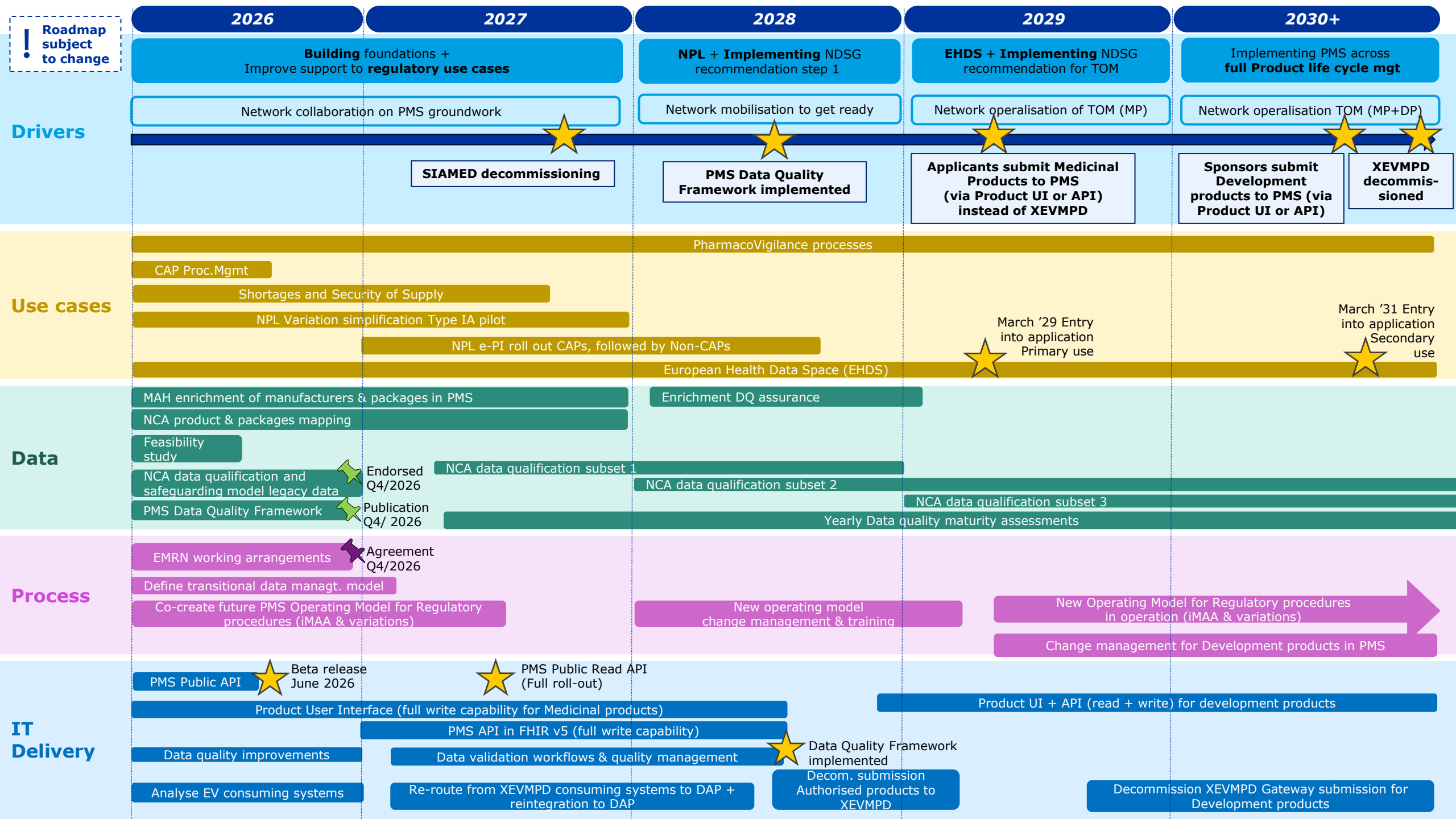
- PMS Public Read API — Beta release June 2026
- PMS Public Read API (Full roll-out)
- Product User Interface (full write capability for Medicinal products)
- PMS API FHIRv5 (full write capability Med. products)
- Product User Interface + PMS API (read + write) for Development products

DATA QUALITY

- Data quality improvements
- PMS-OMS integration improvements — Needed for future Type IA updates in PMS
- DQ reports for NCA & Industry
- Versioning and Meta data
- Data validation workflows & quality management — Data Quality Framework implemented

XEVMPD DECOMMISSIONING

- Analyse XEVMPD consuming systems
- Re-route XEVMPD consuming systems to Data Analytics Platform (DAP) + reintegration to DAP
- Decom. submission Authorised products to XEVMPD
- Refactor: DAP to consume Development products from PMS instead of XEVMPD
- Decommission XEVMPD Gateway submission for Development products
- Migrate Development products from XEVMPD to PMS
- **XEVMPD decommissioned**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XEVMPD decommis-sioned
Use cases
PharmacoVigilance processes
CAP Proc.Mgmt
Shortages and Security of Supply
NPL Variation simplification Type IA pilot
NPL e-PI roll out CAPs, followed by Non-CAPs
March '29 Entry into application Primary use
March '31 Entry into application Secondary use
European Health Data Space (EHDS)
Data
MAH enrichment of manufacturers & packages in PMS
Enrichment DQ assurance
NCA product & packages mapping
Feasibility study
NCA data qualification and safeguarding model legacy data
Endorsed Q4/2026
NCA data qualification subset 1
NCA data qualification subset 2
NCA data qualification subset 3
PMS Data Quality Framework
Publication Q4/ 2026
Yearly Data quality maturity assessments
Process
EMRN working arrangements
Agreement Q4/2026
Define transitional data managt. model
Co-create future PMS Operating Model for Regulatory procedures (iMAA & variations)
New operating model change management & training
New Operating Model for Regulatory procedures in operation (iMAA & variations)
Change management for Development products in PMS
IT Delivery
PMS Public API
Beta release June 2026
PMS Public Read API (Full roll-out)
Product User Interface (full write capability for Medicinal products)
Product UI + API (read + write) for development products
PMS API in FHIR v5 (full write capability)
Data quality improvements
Data validation workflows & quality management
Data Quality Framework implemented
Analyse EV consuming systems
Re-route from XEVMPD consuming systems to DAP + reintegration to DAP
Decom. submission Authorised products to XEVMPD
Decommission XEVMPD Gateway submission for Development products

EMA
EUROPEAN MEDICINES AGENCY

Speakers:

Veronica Lipucci Di Paola
PMS Product Owner

Topic:

PMS activities in 2026

4 Data Quality related activities

Three main Data Quality activities will be carried out throughout 2026 :

Technical fixes and resolution of system bugs and root causes driving data quality issues

Data correction of corrupted or inaccurate data to ensure reliability

Monitoring ongoing issues to their resolution, through Data Quality reports/dashboards.

Resulting in the following improvements:

Q1

- Corrected **Missing/ merged packages** due to **MA transfer**

Q2

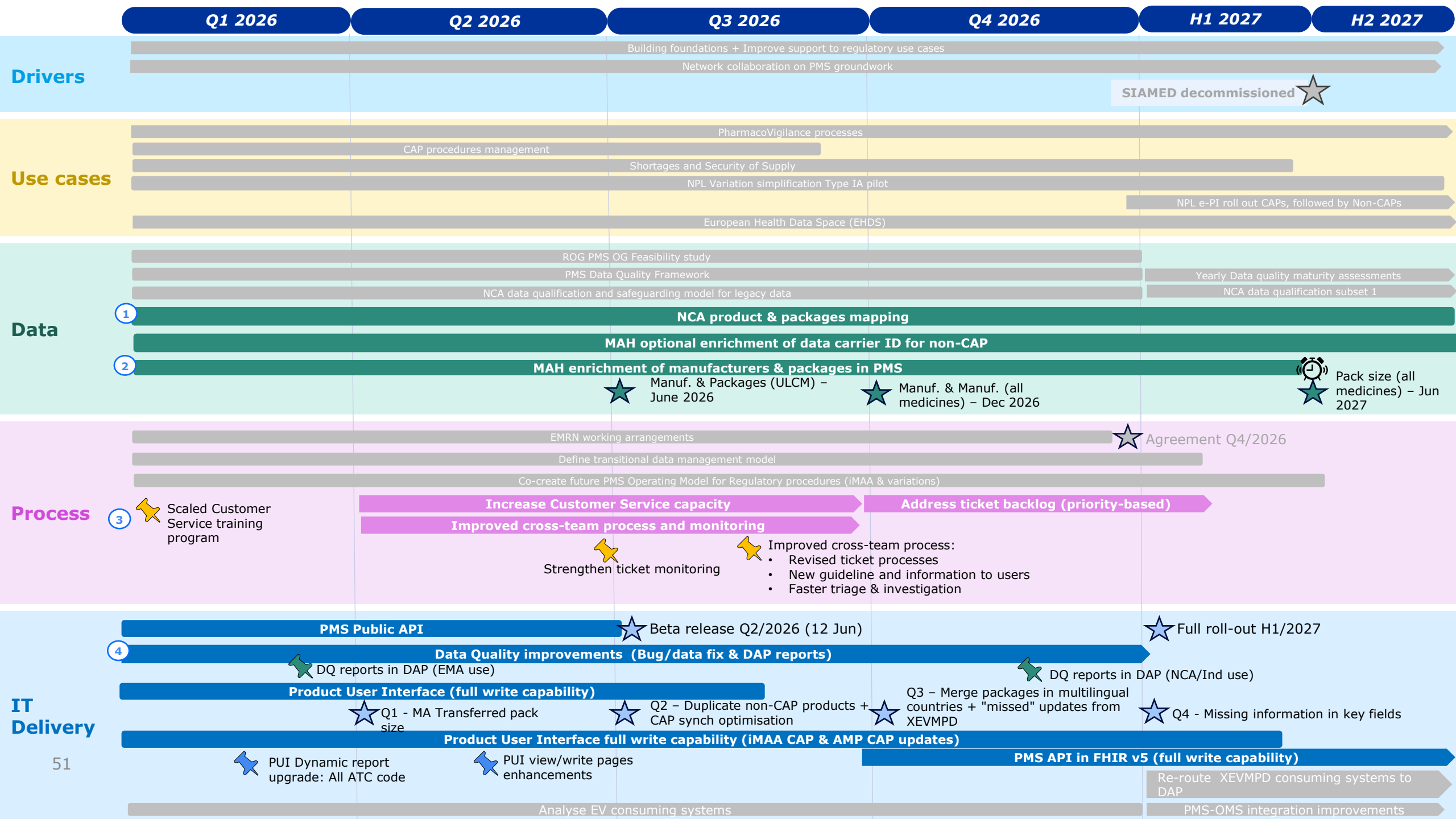
- Corrects **Duplicate Non-CAP** product
- Resolves and prevents **Duplicate CAP products** by improving CAP synchronisation rules

Q3

- Resolves and corrects **duplicate packages in multilingual countries**
- Resolves and corrects **"missed" updates from XEVMPD** by adding missing packages and/or information changes on the products

Q4

- Resolves and corrects **gaps of information in key fields** e.g. missing units in strength, missing terms in Dosage Forms and some MAH (these are very rare).


Q1 2026
Q2 2026
Q3 2026
Q4 2026
H1 2027
H2 2027
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ROG PMS OG Feasibility study
PMS Data Quality Framework
Yearly Data quality maturity assessments
NCA data qualification and safeguarding model for legacy data
NCA data qualification subset 1
1
NCA product & packages mapping
MAH optional enrichment of data carrier ID for non-CAP
2
MAH enrichment of manufacturers & packages in PMS
Manuf. & Packages (ULCM) – June 2026
Manuf. & Manuf. (all medicines) – Dec 2026
Pack size (all medicines) – Jun 2027
Process
EMRN working arrangements
Agreement Q4/2026
Define transitional data management model
Co-create future PMS Operating Model for Regulatory procedures (iMAA & variations)
3
Scaled Customer Service training program
Increase Customer Service capacity
Address ticket backlog (priority-based)
Improved cross-team process and monitoring
Strengthen ticket monitoring
Improved cross-team process:
• Revised ticket processes
• New guideline and information to users
• Faster triage & investigation
IT Delivery
PMS Public API
Beta release Q2/2026 (12 Jun)
Full roll-out H1/2027
4
Data Quality improvements (Bug/data fix & DAP reports)
DQ reports in DAP (EMA use)
DQ reports in DAP (NCA/Ind use)
Product User Interface (full write capability)
Q1 - MA Transferred pack size
Q2 – Duplicate non-CAP products + CAP synch optimisation
Q3 – Merge packages in multilingual countries + "missed" updates from XEVMPD
Q4 - Missing information in key fields
Product User Interface full write capability (iMAA CAP & AMP CAP updates)
PUI Dynamic report upgrade: All ATC code
PUI view/write pages enhancements
PMS API in FHIR v5 (full write capability)
Re-route XEVMPD consuming systems to DAP
Analyse EV consuming systems
PMS-OMS integration improvements

Q1 2026	Q2 2026	Q3 2026	Q4 2026	H1 2027	H2 2027

Stakeholder engagement

Topic-specific Events

- PMS Info-day (3rd edition) — *9 Jun*
- Webinar on Beta PMS Public API — *13 Jul*
- Webinar on PMS Data Quality — *21 Jul*

Update sessions

- SPOR update webinar — *28 Jan*
- System Demo — *26 Mar*
- SPOR update webinars — *28 Apr*
- System Demo — *25 Jun*
- SPOR update webinars — *8 Jul*
- System Demo — *17 Sep*
- SPOR update webinar — *7 Oct*
- System Demo — *10 Dec*

User support Sessions

PMS Q&A Clinics

10 Feb; 10 Mar; 14 Apr; 12 May; 11 Jun; 25 Jun; 09 Jul; 23 Jul; 10 Sep; 24 Sep; 08 Oct; 22 Oct; 12 Nov; 26 Nov; 10 Dec

User surveys

- Adoption survey
- Adoption survey

General Info & Announcements

- PLM Newsletter article
- PLM Newsletter article *(routine update)*
- PUI Release notes (***New***)
- Nomination & onboarding of PMS Industry & Network SMEs
- Announcement - PMS Public API Beta release
- PLM Newsletter article *(routine update)*
- PUI Release notes
- PLM Newsletter article *(routine update)*
- PUI Release notes
- Announcement - PMS Public API full release (tbc)

Training materials

Business guidance

- EU IG Chapter 5 and Annex A updates (Public data elements)
- PMS FAQ (Update)

PMS FAQ (Update)

- EU IG Chapter 1 PMS PROD API (Update)
- Annex A to Ch.1 PMS UAT API (Update)
- Annex B to Ch.1 PMS Public API Beta (***New***)
- Chapter 3 (Update)
- PMS FAQ (Update)

PMS EU IG Chapter 4 Data Quality Framework

Technical guidance

Technical specification-Public PMS API to support UAT in Q2

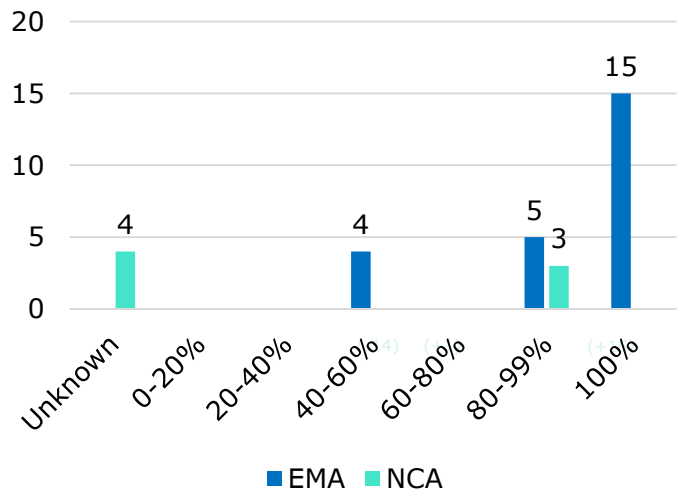
- Technical specification-PMS Public API Beta release (***New***)
- Service Desk SNOW service guide (***New***)

1 NCA readiness

On-Going Activities

- **Mapping** products across NCA database and PMS is ongoing
- **Monthly webinars** to share progress, experiences, lessons learnt and raising topics of interest
- Monthly survey on **topics of interest**
- Periodic **surveys on progress**
- Collaboration with **PhVig IWG**

Data Mapping Status



100%

EMA - ES, AT, HR, FI, CZ, NL, LU, IE, SI, HU, BG, PL, LV, EE, SK

80-99%

EMA – BE, FR, NO, DE (BfArM), LT

NCA - SE, DK, IS

60-80%

Not Applicable

40-60%

EMA – PT, DE (PEI), IT, CY

Due to differences in data models and underlying structures, automation is limited, and a managed, ongoing manual mapping process is taking place.

20-40%

Not Applicable

0-20%

Not Applicable

Unknown

GR, LI, MT, RO

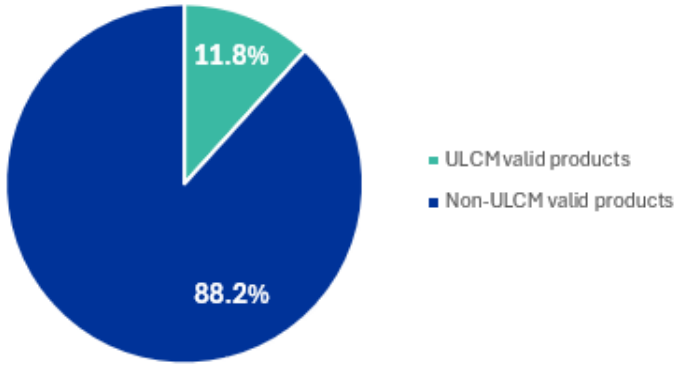
Data mapping currently at product level *(package level data mapping currently in progress)*

Progress Highlights

- **Strong progress with most NCAs at advanced stages** (15 NCAs with 100% data mapping completion)
- **≈ 1.3 % critical medicines not matched** → Follow-up coordinated with PhVig IWG
  - Investigation ongoing with NCA data mapping delegates and PhVig IWG
  - MAHs can be contacted by EMA/NCAs in due course
  - Regulatory actions can be taken by NCAs if/as applicable

2 MAH readiness

Overview of PMS products

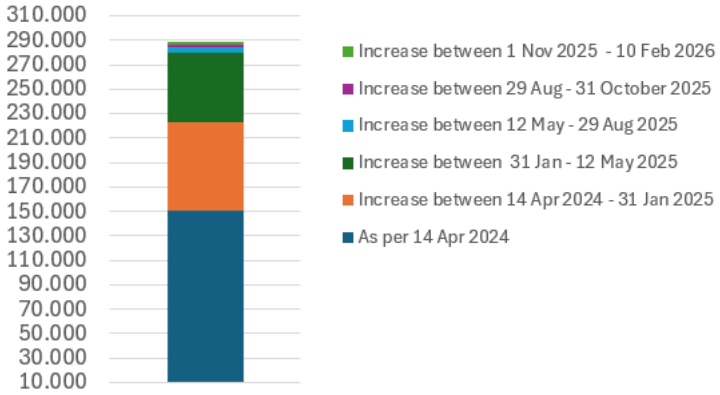


Total valid products in PMS: 289.520

Calculation is based on ULCM v2 and as of 1 June 2026

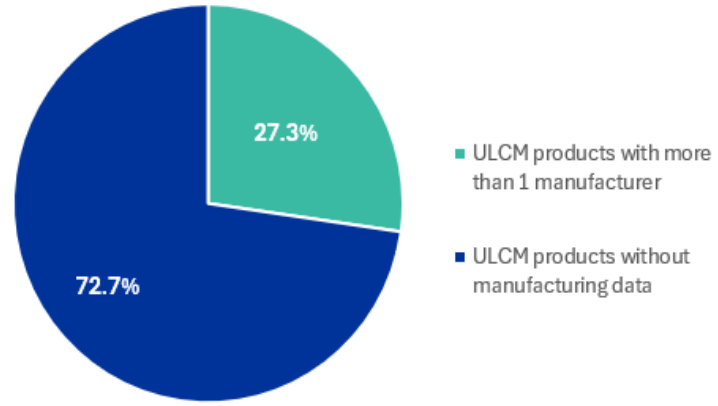
Packages of ULCM-products in XEVMPD

+ 9056



Total packages as per 1 June 2026: 274.970

ULCM-products: status of manufacturers data in PMS



Calculation is based on ULCM v2 and as of 1 June 2026

Call to action for MAHs:

- **Complete submission of:**
  - **Manufacturers and structured package details** for **non-CAPs** in **ULCM list** by end of **June 2026**
  - **Manufacturers** for **all other non-CAPs** by end of **December 2026**
  - **Package sizes and structured package details** for **all other non-CAPs** by end of **June 2027**

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3 Customer Service

Meeting growing demand and committed to better customer services by:

Increased Customer service capacity

- **Recruit, train and onboard**
- **Structured onboarding programme** (May–October 2026), including training, mentoring and continuous knowledge updates.

Improve cross-team processing

- Faster triage & aligned ticket prioritisation
- Faster allocation and resolution
- Increased monitoring
- Aligned SLAs

Address ticket backlog

- Close and inform users of resolved tickets
- Resolve old tickets
- Explain tickets put on hold - clarify priorities and expected resolution for users

Guideline and information to users

- Clarify how best to submit tickets based on the type of issues
- Explain ticket prioritisation and handling/resolution process

Resulting in the following improvements:

Q1

- Prompt investigation and improved triage

Q2

- Strengthen ticket monitoring

Q3

- Increased customer service capacity
- Revised ticket processes
- New guidelines and information to users
- Faster triage & investigations

Q4

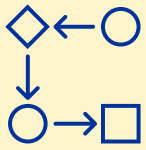
- Address ticket backlog

4 Data Quality priorities

Focused Data Quality: Prioritising High-Impact enhancements for Critical Use Cases

*Data quality efforts focus on **resolving high-impact issues** (such as duplicate, missing products and packages) that directly affect key regulatory and operational processes.*

*Actions are **prioritised around critical use cases** and the **specific data elements they rely on.***



Priority use cases

The main priority use cases being supported by product data are:

- **Pharmacovigilance** processes
- **Shortages** monitoring
- NPL related activities such as vulnerability assessment
- NPL **Type IA variation simplification** (manufacturer name changes)
- NPL ePI creation opportunities (box scanner and ePI reader functionalities
- E-Health **primary use** (ePrescription and eDispensation)

Priority fields

Overall, remediation targets the **PMS data fields with the greatest regulatory and operational impact** to ensure effective and efficient processes.

- Identifiers
- Product full name
- Pharmaceutical dose form
- ATC code
- Active substance & strength*
- Route of administration
- Marketing Authorisation Holder
- Marketing Authorisation information*
- Therapeutic indication
- Packages*
- Manufacturers data*

* Class of PMS data elements

4 Data Quality incidents and ticket handling

Users can help reduce unnecessary workload by limiting submissions to relevant, prioritised incidents, enabling faster resolution of the most critical issues

Data Quality incidents and Ticket handling

To **ensure efficient handling** of data quality incidents, users should align ticket submissions with the following **prioritisation criteria:**

- **Priority findings:** missing products/packages > duplicate products > duplicate packages > missing/incorrect information on priority fields
- **Volume of products:** Highest > lower number of impacted products
- **Impacted fields:** priority data fields > others

Tickets resolution

- Tickets will not be resolved individually as they come in, rather will be addressed **in phases/batches** following the established priority
- As a result, **non-priority tickets** may be placed on **hold** for extended periods

Session 4: From build to public healthcare benefits

EMA
EUROPEAN MEDICINES AGENCY

HMA
Heads of Medicines Agencies

Chairs:

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

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

Speaker:

Marcos Fernandez Gomez
PMS Product Owner

EMA
EUROPEAN MEDICINES AGENCY

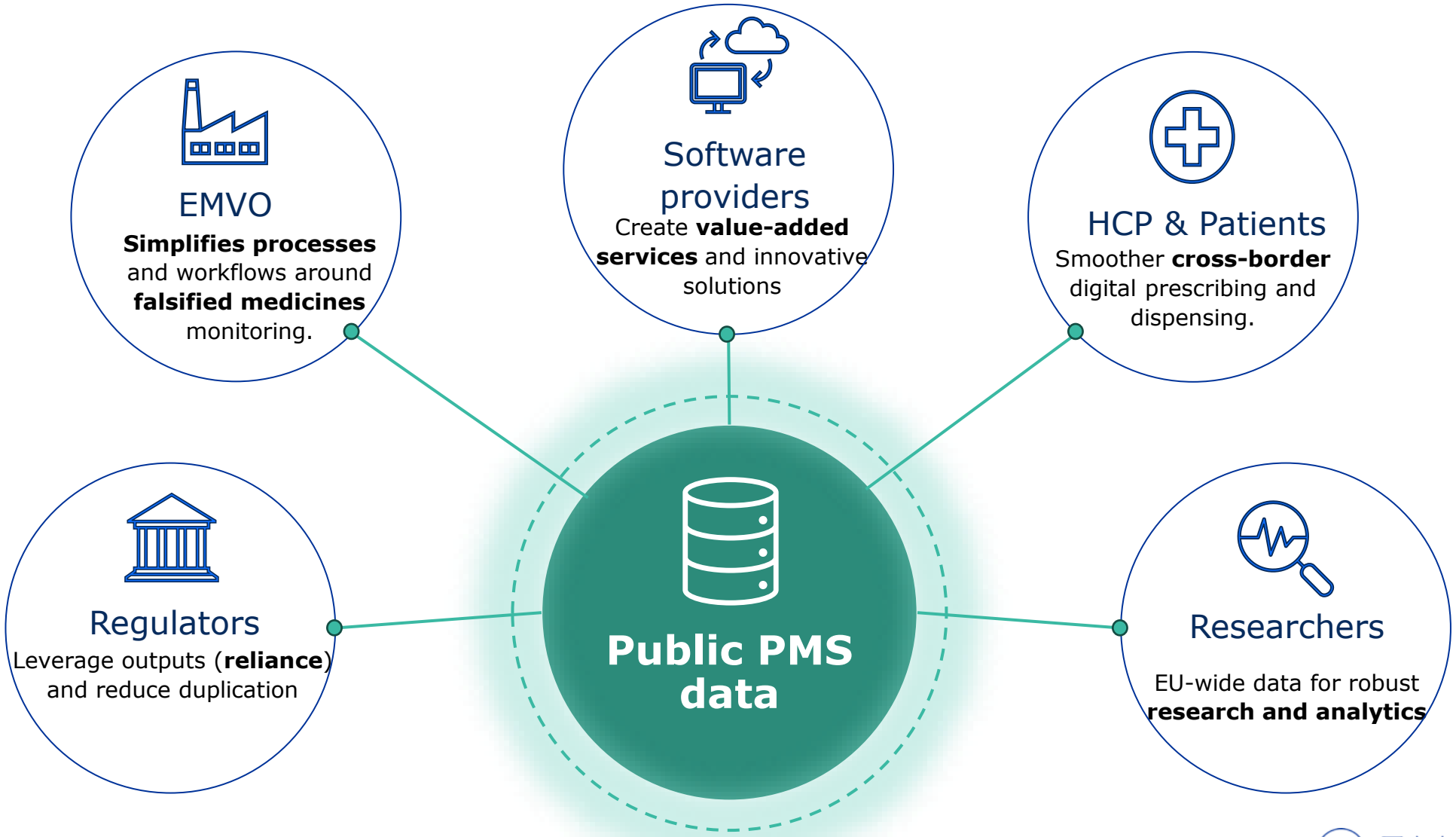
Speakers:

Marcos Fernandez Gomez
PMS Product Owner

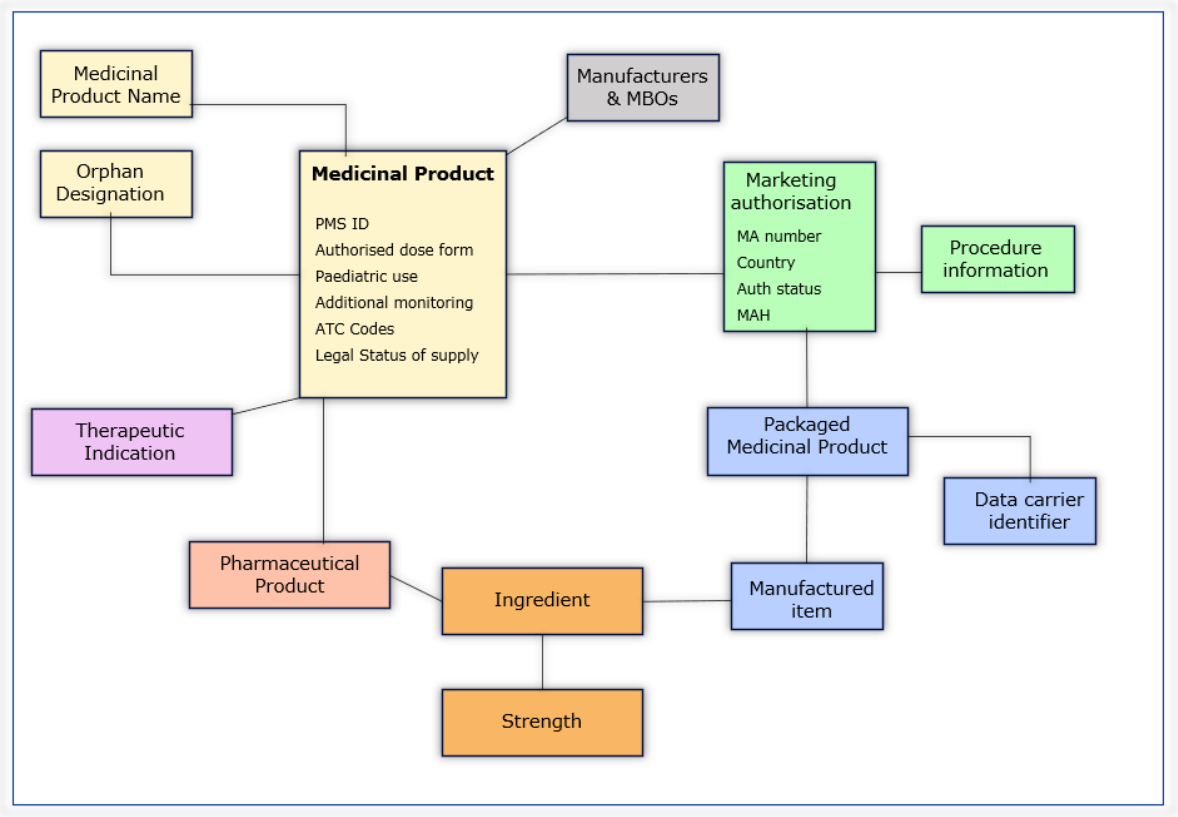
Topic:

Product data – Public PMS API demo

Value of a Public EU wide product data source



What product data is made available to the Public?



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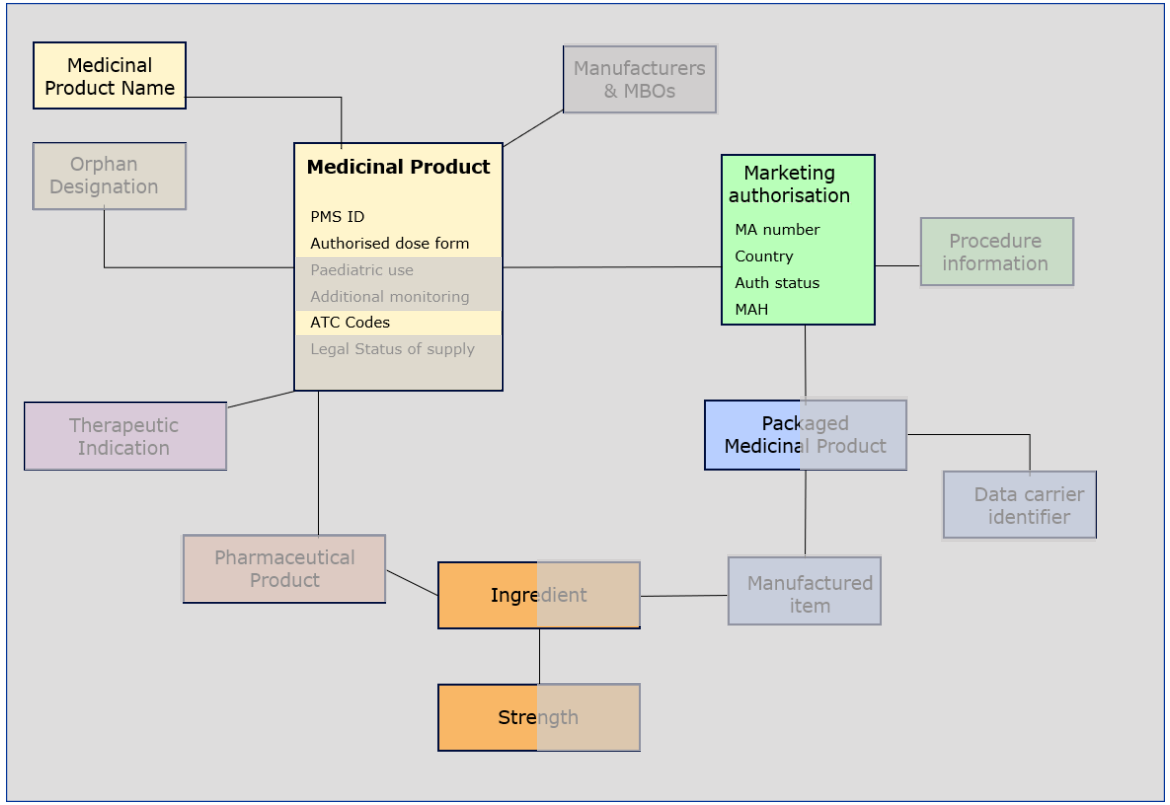
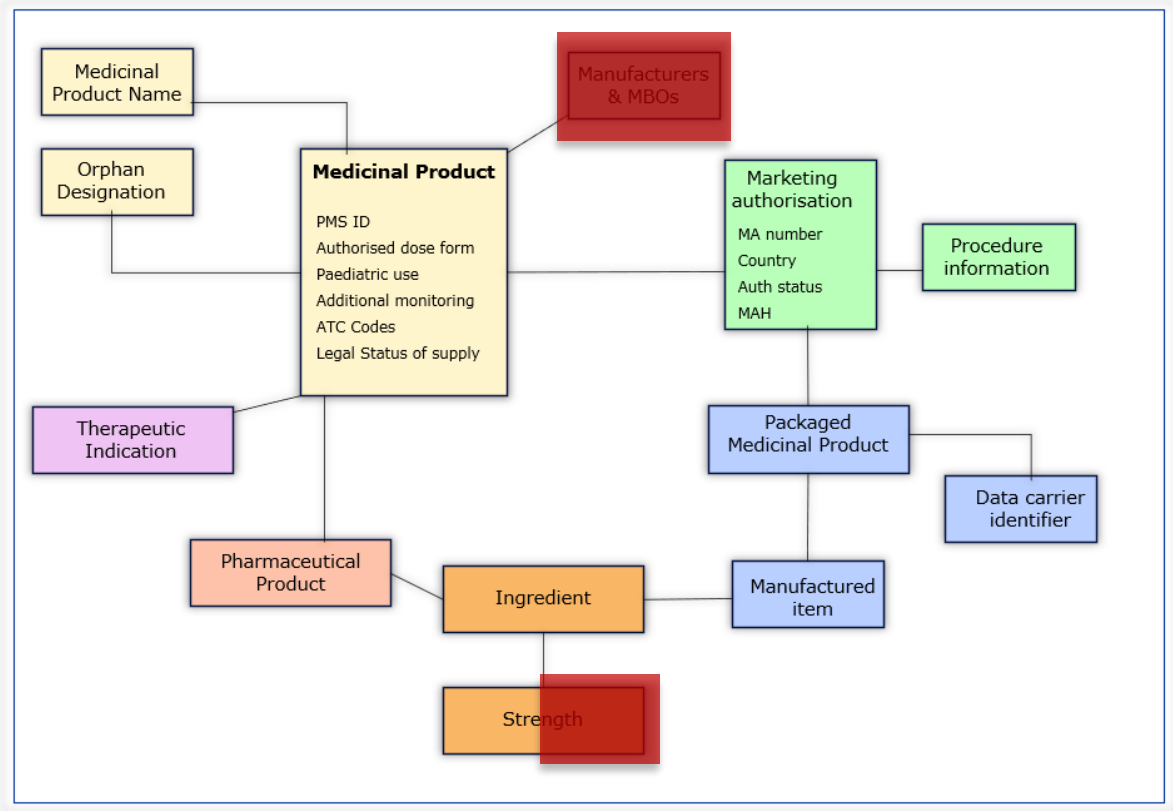


Product UI

Public **can search and view limited** public product data from Product UI

- **No export or download** functionality
- **Restricted interoperability** and reuse of data

What product data is made available to the Public?



Product UI

Public **can search and view limited** public product data from Product UI

- **No export or download** functionality
- **Restricted interoperability** and reuse of data

Public PMS API

Public **can search, view, export all public*** product data from PMS API

- **Machine-to-machine access**
- Access to a **significantly larger dataset**
- **Improved interoperability** for analysis, integration, and reuse

*As per Annex A of EU IG Chapter 5

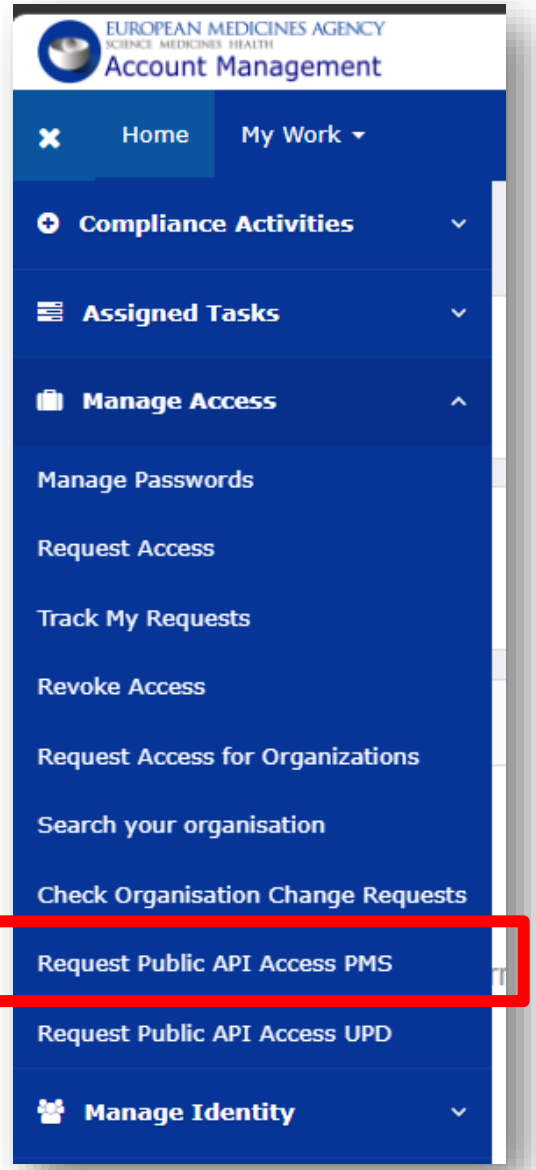
Access to Public PMS API

Request access through EMA Account Management → no need to belong to any organisation. Free access.

After accepting Terms and Conditions of Use a set of credentials are provided via email.

Users can start using the Public PMS API

Information can be found in EU IG Chapter 1



Public PMS API: Beta release approach

EMA is planning the release of the Beta Public PMS API through a deliberately controlled and collaborative approach, based on:

Controlled selection of available data: use of data already available via public PUI and data classified as public in EU IG Chapter 5 – Annex A

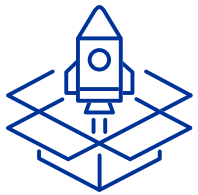
Introduction of access controls: monitoring and oversight of who accesses and uses the available data

Explicit acceptance of EMA's API General Terms and Conditions of use: covering aspects as envisaged purpose and use of API, source of data, roles and responsibilites in sharing and managing data, how to address and resolve any identified data quality errors, intellectual property, and reproduction rights

Collaboration across stakeholder groups: ongoing close collaboration with NDSG, ROG, and Industry to refine and implement data quality processes

Continuous data quality monitoring: application of the PMS Data Quality Framework, including PMS data quality monitoring through DAP reports

From Beta to production



This release follows a **beta** approach in order to:

- Enable **early integration** and **benefit realisation**
- Allow **EMA to build experience** in this domain
- Support **incremental data quality and functional improvements** ahead of full production readiness

FHIR/API expected to remain stable

→ users can integrate and develop with confidence

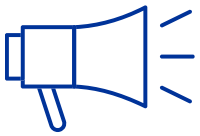
Products and fields shared expected to remain stable

→ including clear separation of public and non-public information

Improvements expected

→ **Data content -** focusing on data quality, completeness and synchronisation

→ **New capabilities -** Additional search parameters and new export functionalities (bulk export of all medicinal products)

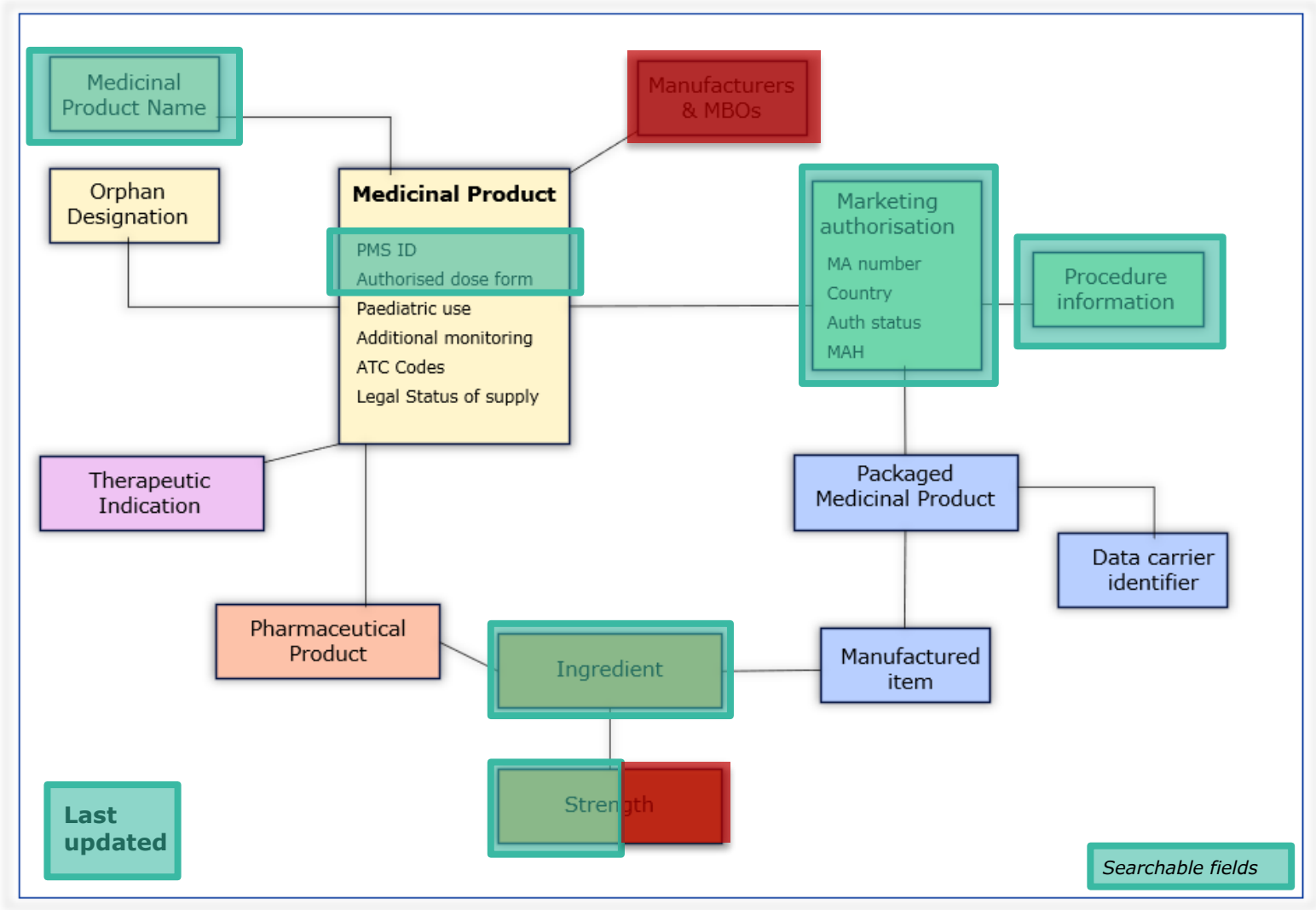


Public users **can**:

- ✓ **explore** PMS API structure, formats, and available medicinal product data
- ✓ **evaluate beta release integration** into their systems and processes

Current search capabilities

- Public API supports searches across multiple fields, either independently or in combination.
  - This search returns list of PMS IDs with matching criteria
- Get everything endpoint by PMS ID
  - This search returns full FHIR bundle containing all public product data



Public PMS API - Demo

Felkarid 100 mg tablete

PMS ID: 600001783988
Authorisation number: H/21/02828/002
Presentation: 30 tablets
Authorisation country: Slovenia

Public PMS API - Demo

Felkarid 100 mg tablete

PMS ID: 600001783988
Authorisation number: H/21/02828/002
Presentation: 30 tablets
Authorisation country: Slovenia

Which products with this active substance are approved in EU?

This active substance can be found in:

- Tablets
- Prolonged-released tablets
- Solution for injection

Different indications and posology depending on the authorised dose form.

Public PMS API - Demo

Felkarid 100 mg tablete

PMS ID: 600001783988
Authorisation number: H/21/02828/002
Presentation: 30 tablets
Authorisation country: Slovenia

Which products with this active substance and authorised dose form are approved in EU?

Two different strengths are authorised for this combination of active substance and dose form:

- 50 mg
- 100 mg

Public PMS API - Demo

Felkarid 100 mg tablete

PMS ID: 600001783988
Authorisation number: H/21/02828/002
Presentation: 30 tablets
Authorisation country: Slovenia

Which products with this active substance, authorised dose form and strength are approved in EU?

Public PMS API - Demo

Felkarid 100 mg tablete

PMS ID: 600001783988
Authorisation number: H/21/02828/002
Presentation: 30 tablets
Authorisation country: Slovenia

Is there any equivalent product in Spain and in Denmark that a patient could be prescribed?

MedicinalProductDefinitions

MPD ID	Product Name
600001438944	Flecainida Amneal100 mg comprimidos EFG
600001518627	Flecainida Aurovitas 100 mg comprimidos EFG
600001691926	Flecainida Apotex 100 mg comprimidos EFG
600001693565	Flecainida Apertos 100 mg comprimidos EFG
600001714796	Flecainida Normon 100 mg comprimidos EFG
600001799849	Apocard 100 mg, comprimidos
700000174785	Apocard 100 mg, comprimidos

MedicinalProductDefinitions

MPD ID	Product Name
600001496157	Flecainid "Stada", tabletter
600001513735	Flecainid "Actavis", tabletter
600001636202	Flecainid "Sandoz", tabletter 100 mg
600001824517	Tambocor

Public PMS API - Demo

Felkarid 100 mg tablete

PMS ID: 600001783988
Authorisation number: H/21/02828/002
Presentation: 30 tablets
Authorisation country: Slovenia

Is there any equivalent presentation (package) in Spain and in Denmark that a patient could be prescribed?

Public PMS API - Demo

Felkarid 100 mg tablete

PMS ID: 600001783988
Authorisation number: H/21/02828/002
Presentation: 30 tablets
Authorisation country: Slovenia

Flecainida Normon 100 mg comprimidos EFG

PMS ID: 600001714796
Authorisation number: 704661.5
Presentation: 30 tablets
Authorisation country: Spain

Flecainid "Sandoz", tabletter 100 mg

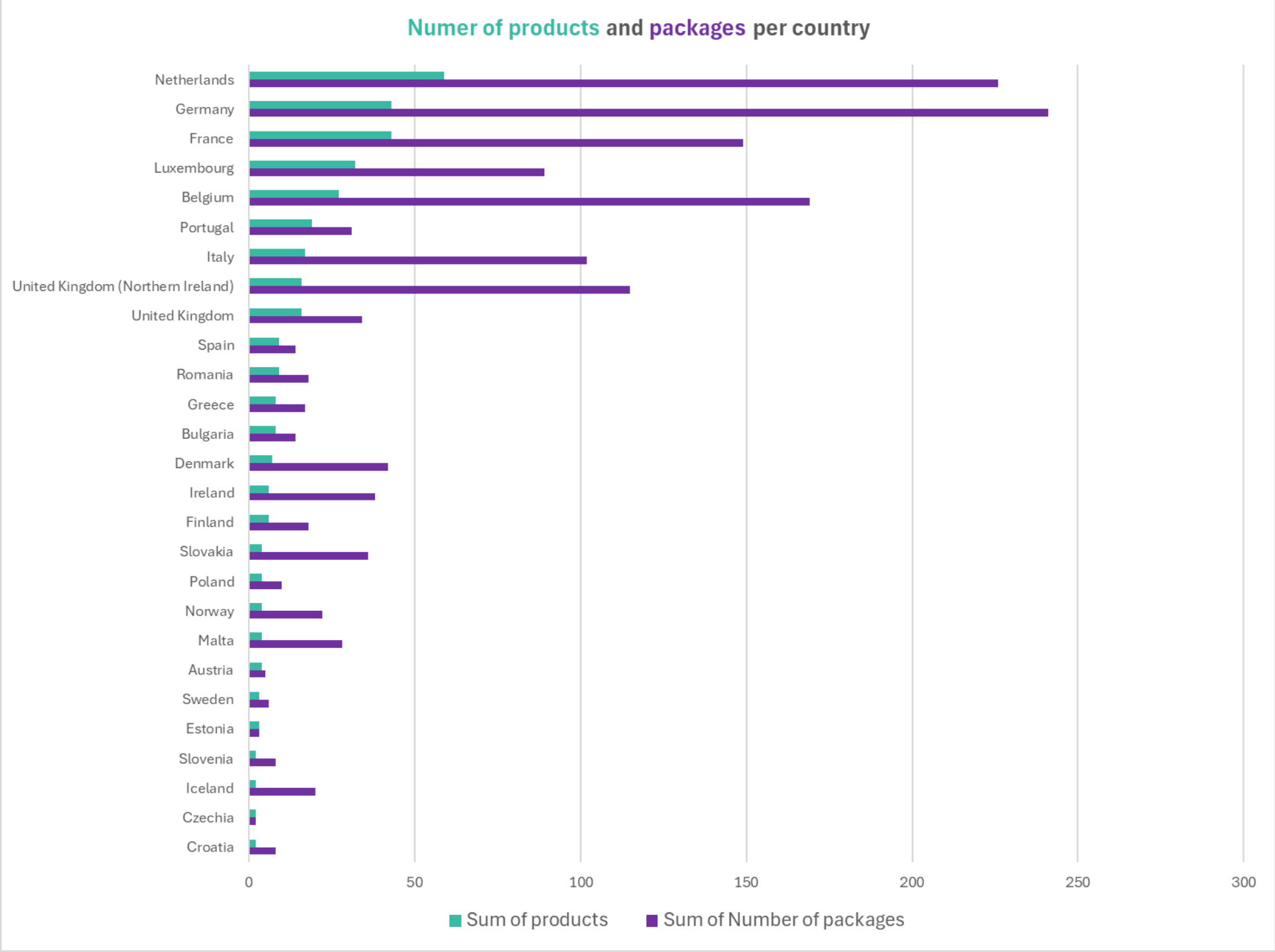
PMS ID: 600001636202
Authorisation number: 39283
Presentation: 30 tablets
Authorisation country: Denmark

Public PMS API - Demo

Felkarid 100 mg tablete

PMS ID: 600001783988
Authorisation number: H/21/02828/002
Presentation: 30 tablets
Authorisation country: Slovenia

Slovenia only has two products authorised for this active substance. If applicable, which other EU countries have equivalent or comparable products?



The API only supplies product data. Any reporting or visualisation activities are to be carried out outside the tool.

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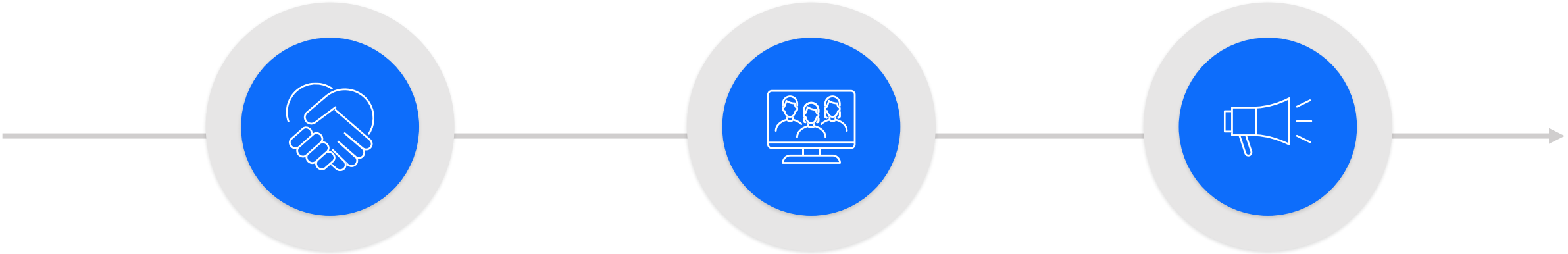
Beta Public PMS API go-live
is coming on 12 June 2026!

Public PMS API - Next steps



Users are encouraged to:

- explore PMS API structure, formats, and available medicinal product data
- evaluate beta release integration into their systems and processes

Early adopters/ registered users will be invited to an event in H2 2026 to **collect feedback and help EMA prioritise improvements**

The **transition to full public release** will be announced to registered users and general public via **official EMA channels**

Conclusions and closing remarks

Conclusions and closing remarks

Chairs:

Runa Hauksdottir Hvannberg
Co-chair of Regulatory Optimisation Group (ROG) and Executive Director of the Icelandic Medicines Agency (IMA)

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

Additional reflections:

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

What did we cover today?

1 Strategic Outlook

- PMS enables **compliance** with upcoming legal changes
- Positions PMS as a **strategic enabler** for digital health

2 Network alignment

- Aligns EMA, NCAs, and Industry on **fit-for-purpose data**
- MAHs enrich data for **completeness** (e.g. shortages)
- NCA legacy data qualification ensures **data consistency** across MAHs-NCAs-PMS

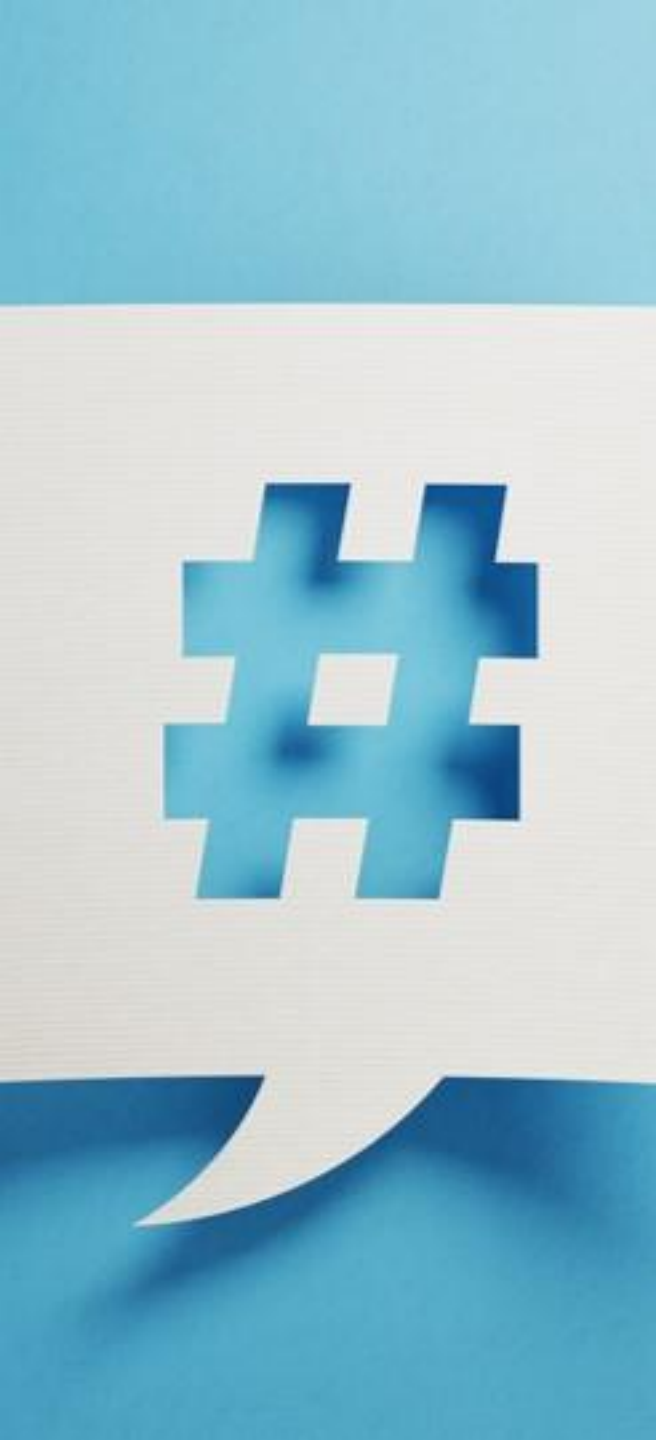
3 Portfolio delivery

- Clear roadmap aligning **use cases, data, processes, and IT**
- 2026 focus: **public access, data quality, network mobilisation**

4 Practical use & value

- Launch of **beta PMS Public API** for wider access

Strengthening alignment and shared understanding across stakeholders



Key takeaways & conclusions

1. **Regulatory Readiness and Strategic enabler:** PMS enables the network to confidently meet upcoming legal and policy changes while serving as a strategic digital foundation for future regulatory use cases and digital health innovation.

2. **Shared Commitment to Data Quality:** EMA, NCAs, and industry stakeholders are aligned on delivering high-quality, fit-for-purpose product data.

3. **Critical Role of MAHs and NCAs:** Marketing Authorisation Holders enhance data completeness (especially for shortages), while NCA legacy data qualification improves overall alignment across systems.

4. **Strong Governance and Collaboration:** A structured Data Quality Framework and coordinated working arrangements (via NDSG) ensure trusted, consistent, and usable product data across the network.

5. **Accelerated Delivery and Public Value:** The evolving PMS roadmap—especially the 2026 focus—drives expanded access, improved data quality, and tangible public benefits, highlighted by the upcoming beta public API increasing transparency and usability.

Thank you

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