EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

SPOR & XEVMPD Status Update

Recent & planned changes and impacts to users

22 January 2025

Housekeeping notes – Personal Data Protection disclaimer

*Please note that **this session is being live streamed.***
It is being recorded** and **will be made available** through the **EMA Corporate Website and EMA YouTube Channel

*At certain points throughout the meeting, participants will be able to ask questions or give their input via the audience interaction tool **Slido**.*

*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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Housekeeping notes – Q&A

Join at
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- Join via **QR code** or **slido.com -** *please provide your questions and comments in Slido only*
- **Send or upvote the questions** you want to hear answered – *before raising a question check whether it has been raised already and vote for it*

Q&A Management

- Questions will be shown on the screen and managed live in the Q&A session
- EMA colleagues will **verbally address top 5 voted questions** at the end in the live Q&A session.

Unanswered questions

- This can be due to high volume of questions or assistance of a specific colleague not available today is required.
- Unanswered questions will be reviewed, and the **most relevant ones may be addressed** in other webinars or in a FAQ document.
- We may request that you ask **Questions on specific issues/cases** in Service Desk to be tracked, investigated and adequately assigned.

Housekeeping notes – Webinar materials sharing

Presentation will be available at:

- SPOR Portal Documents section
- EMA Event Web Page

Recordings will be available at:

- EMA YouTube Channel
- EMA Event Web Page

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Aim of this webinar

Today's webinar aims at sharing a short-term status update on **SMS, OMS, RMS, PMS and XEVMPD** focusing on **recent/ planned changes and impacts to users.**

This webinar format results from feedback received via Customer satisfaction survey requesting for more frequent and targeted information on changes and impacts to users

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Agenda

1. **Welcome & Housekeeping notes**
   10 mins presentation (no Q&A)
   10:00 – 10:10
2. **SPOR, XEVMPD/PMS and other processes**
   15 mins presentation + 10 mins Q&A
   10:10 – 10:35
3. **SMS status update**
   10 mins presentation + 10 mins Q&A
   10:35 – 10:55
4. **OMS status update**
   10 mins presentation + 10 mins Q&A
   10:55 – 11:15
5. **RMS status update**
   10 mins presentation + 10 mins Q&A
   11:15 – 11:35
6. **XEVMPD status update**
   10 mins presentation + 10 mins Q&A
   11:35 – 11:55
7. **PMS status update**
   10 mins presentation + 10 mins Q&A
   11:55 – 12:05
8. **Conclusions – actions & further info**
   10 mins presentation (no Q&A)
   12:05 - 12:20
9. **Q&A Session**
   10 mins Q&A
   12:20 – 12:30

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How SPOR, XEVMPD/PMS fit together

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SPOR in Processes/Systems

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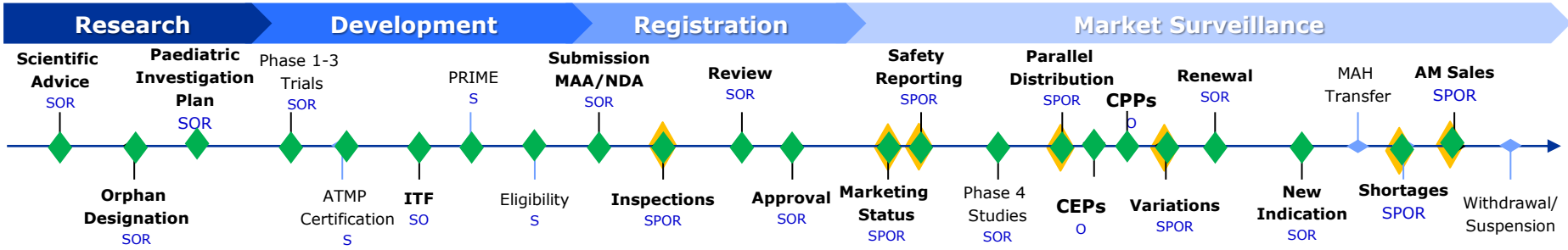
Most regulatory processes throughout the product lifecycle are using data from SPOR



System	Domain	Process	SPOR data
EMA Account Management & EV registration	**H&V**	User registration, identity and access management	O
EudraCT & **CTIS**	**H**	Phase 1-4 Trials	SOR
IRIS	**H&V** – CAPs only	Scientific Advice + Orphan Designation + ITF + Marketing Status + Inspections + Parallel Distribution + Shortage (iSPOC) + PRIME + CPP	S(P)OR
eAF (PDF) & eAF webform & PML Portal & PMS (just H)	**H&V**	Submission MAA, Variations, Renewal	S(P)OR
SIAMED via ECD	**H&V** – CAPs only	Review, Approval	SOR
UPD	**V**	Approval	SOR
EudraGMDP & CorpGXP	**H&V**	Inspections + Manufacturing Import Authorisation + Wholesale Distribution Authorisation	S(P)OR
XEVMPD & EV vet & ESVAC	**H&V**	Safety reporting	SR
ESMP	**H**	Shortages	SPOR
ASU	**V**	Anti-micriobial Sales Use	SPOR
CEP/EDQM DB	**H&V**	Certification of suitability	O

Legend

SOR in use

P in use

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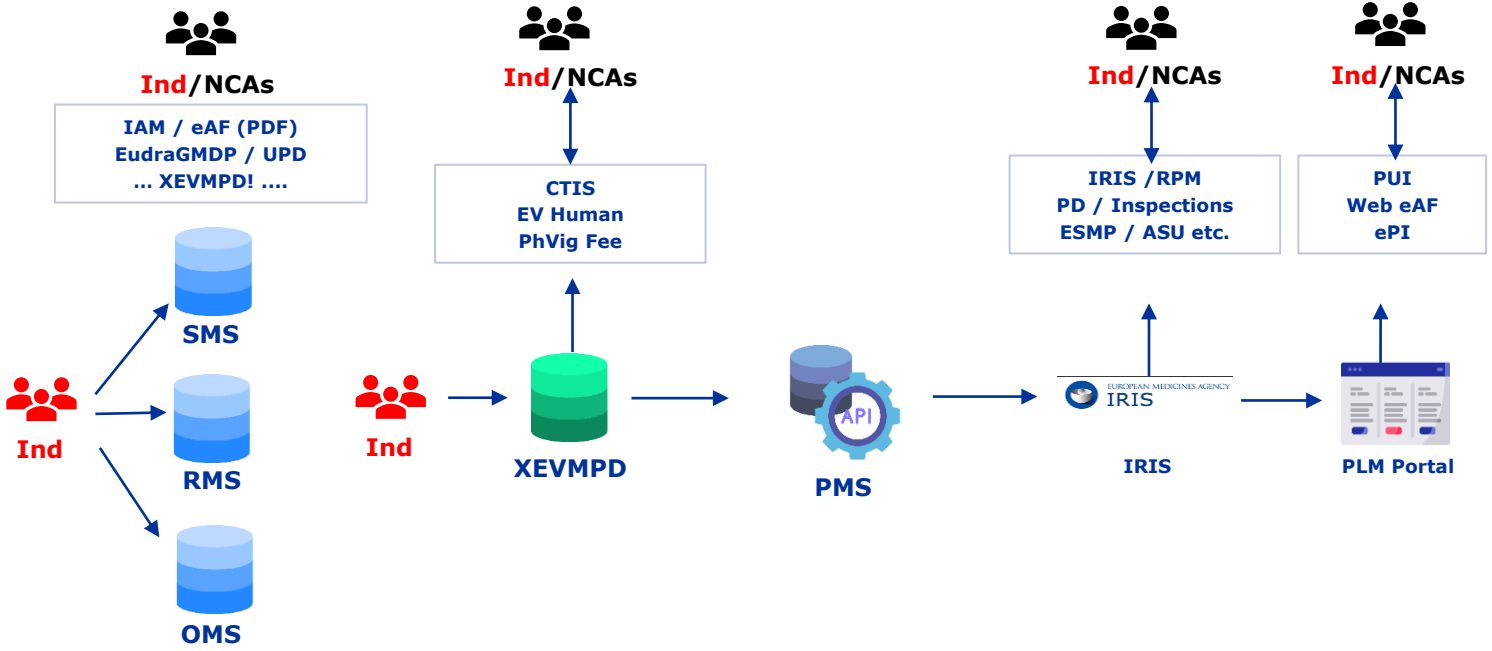
SPOR, XEVMPD/PMS and other processes

What is registered in **SMS, OMS and RMS** and **how data is mapped affects** what Industry will see in **XEVMPD, PMS and other solutions!**



- Industry should **request** Substances Terms and Organisations/locations **ahead of application**/ XEVMPD submissions
- Industry cannot update data in PMS or other solutions; **if update is required, product data must be updated in XEVMPD**
- Industry and NCAs interact with EU systems/applications where SPOR data is used, including product data

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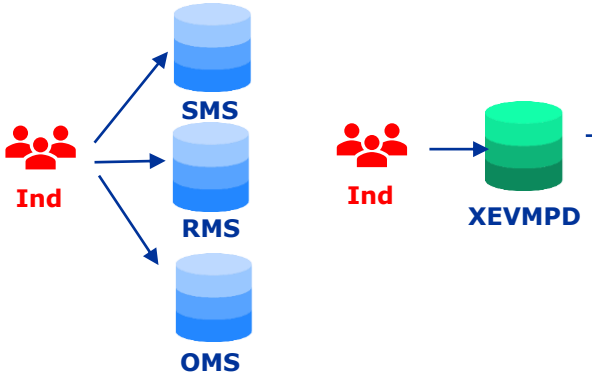
SPOR - what services will be covered in todays webinar

SMS, OMS, RMS and **XEVMPD is fully operational** whereas **PMS is ongoing**

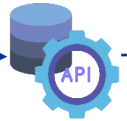
- Data Management (operational)
- Data Quality (operational)
- Customer services (operational)

- Awareness (status update webinars)
- IT modernisation (maintenance)



- Data Management (NA)
- Data Quality (NA)
- Customer services (operational)

- Awareness (Agile ceremonies)
- IT modernisation (Agile IT delivery)



PMS

Out of scope of todays webinar!

Other consuming systems:
IRIS / eAF (PDF)
EudraGMDP / UPD / CTIS / ESMP / …

- **SMS, OMS, RMS and XEVMPD** provide Data management, Data Quality and customer services. They undergo small IT improvements/IT maintenance only. Awareness is promoted via the **SPOR** quarterly **status update webinars**.
- **Product** Data management, Data Quality and customer services are mostly done in **XEVMPD**.
- **PMS** only provides **customer services** for users using PMS data in PUI/IRIS/eAF etc. PMS is following Agile practices/ceremonies. Awareness is promoted via **quarterly demos and dedicated webinars.**

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Highlights of 2024

Our biggest highlights of the year 2024

These highlights encompass a wide range of SPOR services **key milestones and achievements** that took place in 2024.

We are excited to give you a glimpse into SPOR world and offer insight into the progress we have made.

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The essential guide to SMS services

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The first-ever **SMS Guidance for External Users** is live since January!

This comprehensive guide covers key principles, system integrations, SMS API access, change request processes, and data mappings, enrichments and cleansing exercises.

It directly addresses customer feedback, **enhancing awareness and streamlining access to SMS services.**

SMS Enhances Data Quality in Development Products

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SMS successfully **replaced development substances with approved ones,** updated products and nullified outdated substances in SMS/XEVMPD in March.

This replacement **improves data quality for Development Medicinal Products** in XEVMPD and strengthens clinical trial applications in CTIS.

Improved Access to Substance Public Data

As of 1 April 2024, **public substance data** is automatically **accessible to all users,** including industry and the general public via the SMS Application Programming Interface (API).

This enhancement ensures **easier and faster access** to valuable substance information.

Enhanced substance data available

New data fields, including *Molecular Weight*, *INN Codes*, *EC List/Number*, *Salt-Parent Relationships*, *Is Active?* and *Is used in Union List of Critical Medicines?* are now **available in substance export and the SMS API** since July.

These updates:

- Aid in identifying substances for the **European Shortages Monitoring Platform**.
- Enable **conversion of strengths from salts to bases** for critical medicines and pharmacovigilance.
- Improve **data interoperability** with the European Commission and EU agencies.
- Support Health use cases (e.g. ePrescription) and Global Substance ID (GSID) generation.

OMS Enhances Legal Address Data

OMS has enriched over **13,000 EU legal addresses** with National Business Registry (NBR) numbers.

This update (OMS LOC IDs with the NBR number) ensures **clear identification** of **official legal addresses** for organizations and legal entities, improving data accuracy and reliability.

Improved EV to OMS synchronisation

Enhanced synchronisation ensures all **EV Marketing Authorisation Holders** and **Sponsors** are accurately and integrated into OMS through automation.

This upgrade supported a **smooth transition to PMS**, minimising access issues and **ensuring users can view all their products seamlessly** on the go-live date.

OMS expands support for Individuals/Entrepreneurs

OMS now registers **Individuals/ Entrepreneurs** listed in official public Entrepreneur databases, even if not in National Business Registries.

This interim solution allows these individuals to proceed with **veterinary procedures**, **EudraGMDP certificates**, and **EV MAH obligations**, ensuring continued compliance and participation.

XEVMPD enhances data quality of proposed terms

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XEVMPD implemented a **series of improvements around proposed terms**:

- A **technical restriction** now prevents the submission of proposed terms by external users.
- A **process change** ensures that MAHs request term via RMS change requests for proper standardization.
- **Data cleansing** of ATC codes, routes of administration, pharmaceutical forms ensured that EV proposed terms were mapped to standard terms, products were updated and obsolete terms nullified.

These enhancements support PMS implementation, reduce migration issues, and **prevent incorrect terms across XEVMPD, PMS, eAF, and ESMP systems**.

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PMS in 2024 - A year of progress!

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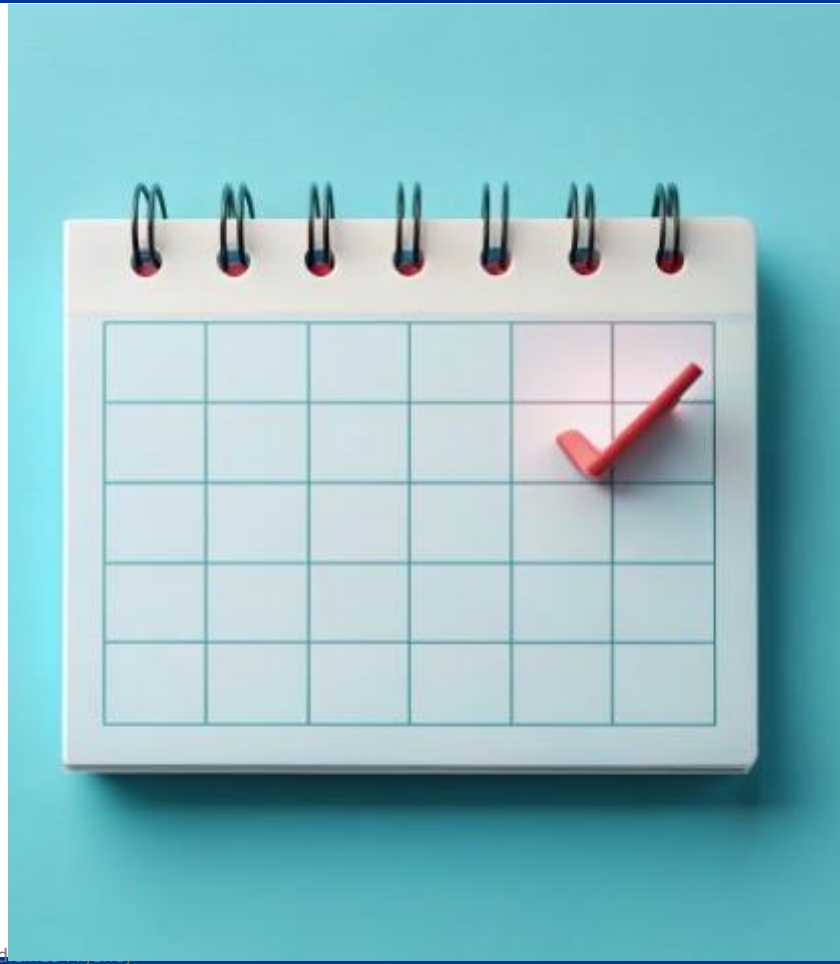
2024 marked a **transformative year for PMS,** achieving **key milestones**:

- **April:** Successful migration of CAPs and NAPs data into PMS.
- **May:** Users gained read-only access to CAPs data via the Product UI.
- **July:** Industry users unlocked API-based read-only access to CAPs and NAPs.
- **September:** NAPs were integrated into IRIS, providing UI access to both CAPs and NAPs.
- **November:** H&V NCAs received API-based read-only access to CAPs and NAPs.
- **December:** H-only NCAs were also granted API-based read-only access to CAPs and NAPs.



XEVMPD/PMS Enhances CAP Data Accuracy

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Starting Jan 2024, XEVMPD/PMS team conducts **daily checks** on **all newly authorised** or **amended** Centrally Authorised Products (**CAP**) and increased follow-up communication with MAHs.

This ensures **accurate, up-to-date data** in PMS and enhances the use of CAP data in **IRIS, eAF, ESMP** and other systems.

Enhanced NAP data validation

To support ESMP requirements for medicinal products on the Union List of Critical Medicines, **key improvements** were made:

- **Increased validation frequency** of product records from **once** to **twice a week**, reducing delays in data availability for Pharmacovigilance and other processes.
- **Cluster-based validation** boosts **process efficiency** and ensures **consistent data** across similar records.

These enhancements lead to **higher service output**, **improved data quality**, and **cost savings** per unit

Better information on XEVMPD

Throughout the year the XEVMPD has released/updated key XEVMPD information:

- Updated XEVMPD related **documentation and webpages**
- Updated **Chapter 3.II** to cover xxx
- Updated **Guidance documents for sponsors**
- Dedicated **Q&A document** on the impact of the Windsor Framework changes

This addresses feedback from customer satisfaction survey and **improves awareness** of XEVMPD services.

XEVMPD/PMS enhances NCA readiness for ESMP

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XEVMPD/PMS team supports NCAs by **mapping the products in their national databases to PMS data** and providing the relevant PMS ID/Package ID for ESMP reporting.

Additionally, the team hosts **monthly webinars** to share mapping progress and best practices.

These initiatives, identified through an NCA survey, are **crucial for ensuring NCA readiness for ESMP.**

Improved Manufacturing activities list

The RMS list **"Manufacturing activities"**, used by PMS, eAF, EudraGMDP, IRIS, and ESMP has been thouroughly **reviewed by a multidisciplinary group of experts** (QWP/ BWP/ IWG/ CMDv/CMDh).

The minutes and summary of changes are now available in the RMS portal.

MAHs can confidently use and refer to these terms, knowing the list meets a broad range of needs and has been **quality assured** by experts.

Empowering users on XEVMPD – RMS mappings

The RMS team conducted data cleansing on ATC codes, routes of administration, and pharmaceutical forms in XEVMPD, ensuring proposed terms are mapped to standard terms, outdated terms are nullified, and products are updated.

To assist users, **XEVMPD-RMS guidance documents** and **term mappings** are now available on the **SPOR Portal** and were shared during **PMS Info Day** and **SPOR webinars**, **helping users understand required actions** for their products.

RMS Now Open to All Users for Term Requests

As of May, **any user**, regardless of affiliation, is **able to request new or updated terms in RMS.**

This change **simplifies the process**, removing the previous requirement for users to be affiliated with an organization to submit RMS Change Requests (CRs), making RMS more **accessible** and **user-friendly**.

SMS status update

Planned SMS Activities

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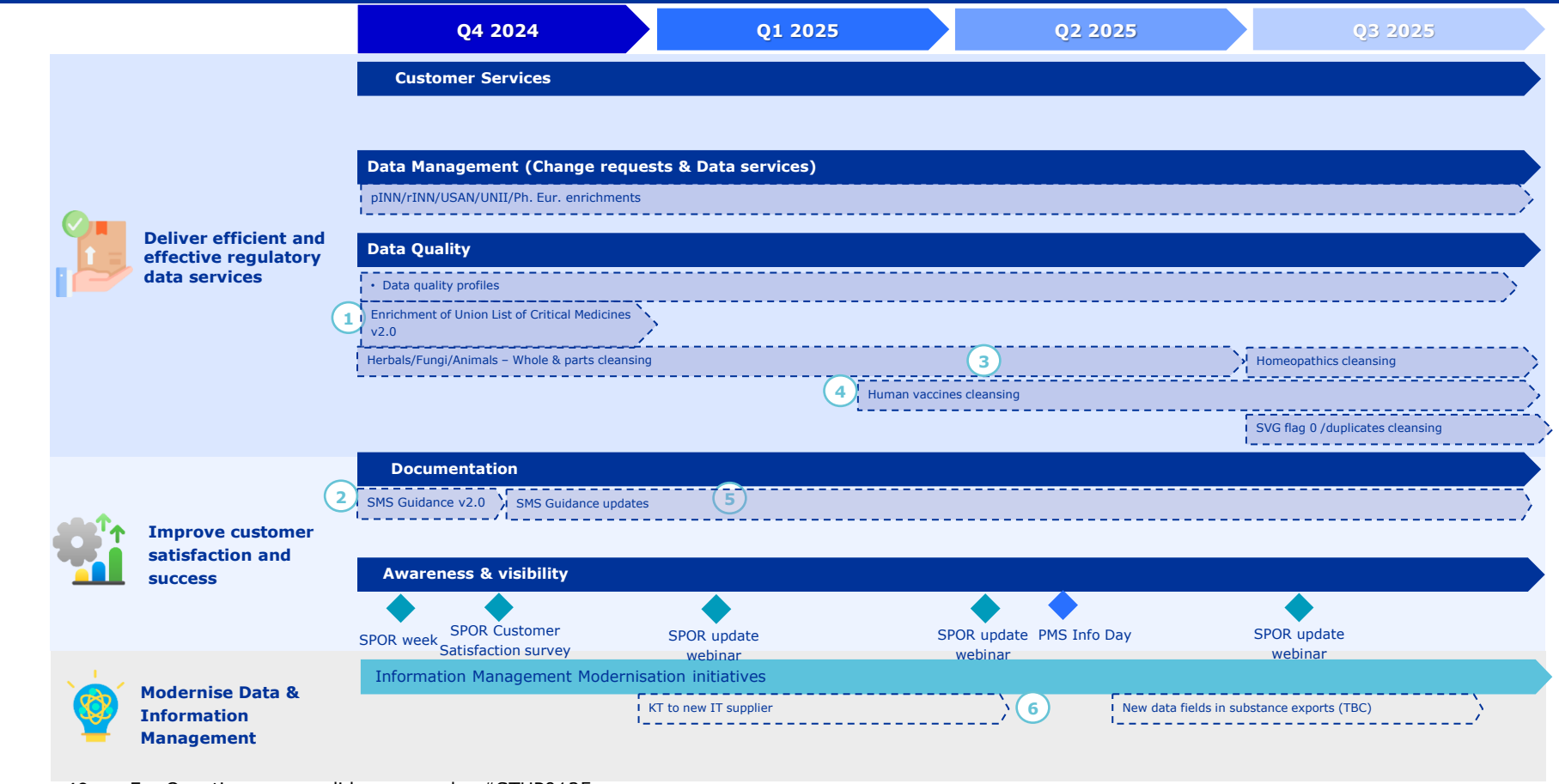

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Work completed – Highlights of what has been done in last quarter

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	 WHY	 HOW & WHEN	 IMPACT/ BENEFITS to users
Revision of Custom Attribute Critical Medicines 1 2	• New version of **Union List of Critical Medicines** published	Relevant substances have been updated in Custom Attributes "Excipient/Adjuvant in valid EEA human AMP": • Added for new ATCs/substances included in Union List version 2 • Removed for ATCs/substances no longer present in Union list version 2 This Custom Attribute is only visible via the SMS API	• Supporting identification of substances/medicines in scope for the European Shortages Monitoring Platform • Supporting Health use case e.g. ePrescription • Supporting the generation of Global Substance IDs (GSIDs)
SMS Guidance for External Users 2.0	• Reacting to feedback from customer satisfaction survey where customers demanded more/ better documentation	• Revised version describing **SMS API**, **data cleansing** and **data quality monitoring**	• Enhanced supporting documentation allowing improved awareness • Predictability of how substances will be registered and maintained

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What's next? – Highlights of what will be done in next quarter

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	WHY	HOW & WHEN	IMPACT/ BENEFITS to users
Plants/fungi/animals cleansing	3 Improve SMS Data Quality Enable the future cleansing of homeophatic substances and herbal extracts	○ SMS precleasing almost completed ○ SVG discussions to start soon	• New substance groups cleansed and business rules defined for new substances
Human vaccines cleansing	4 Complete the cleansing of substances used in Critical Medicines Improve SMS Data Quality	○ SVG cleansing is ongoing ○ **Priorisitation of human vaccines from Critical Medicines** ○ Afterwards, focus on human vaccines used in approved products	• Reliable/stable list of active substances used in Union List of Critical Medicines • New substance groups cleansed and business rules defined for new substances
SMS Guidance V2.X	5 Reacting to feedback from customer satisfaction survey where customers demanded more and faster access to information	○ **Iterative versions over the year** with updates in one section at a time	• More frequent documentation updates • Enhanced supporting documentation allowing improved awareness • Predictability of how substances will be registered and maintained
Knowledge Transfer (KT) from existing IT supplier to new IT supplier	6 Due to procurement cycles and new Framework Contract in place	• SMS IT development has been temporarily put on hold and focus is **in providing Knowledge Transfer (KT) from existing IT supplier to new IT supplier**	• Improvements in the SMS exports that were planned for Q1 are now delayed to later quarters

Highlights to you

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SMS Guidance version 2.0
(SMS API and data quality)

Revision of Custom Attribute based on Union List of Critical Medicines 2.0

What's changed?

SMS Guidance version 2.1
(Business Rules)

Plants/Fungi/Animals cleansing

Ongoing work

Human vaccines cleansing

SMS Guidance version 2.X
(Confidentiality, etc.)

Future changes *(What's next?)*

Homeophatics cleansing

SVG flag 0 cleansing

Future changes *(What's later?)*

Acronyms

API: Application Programming Interface

OMS status update

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Planned OMS Activities

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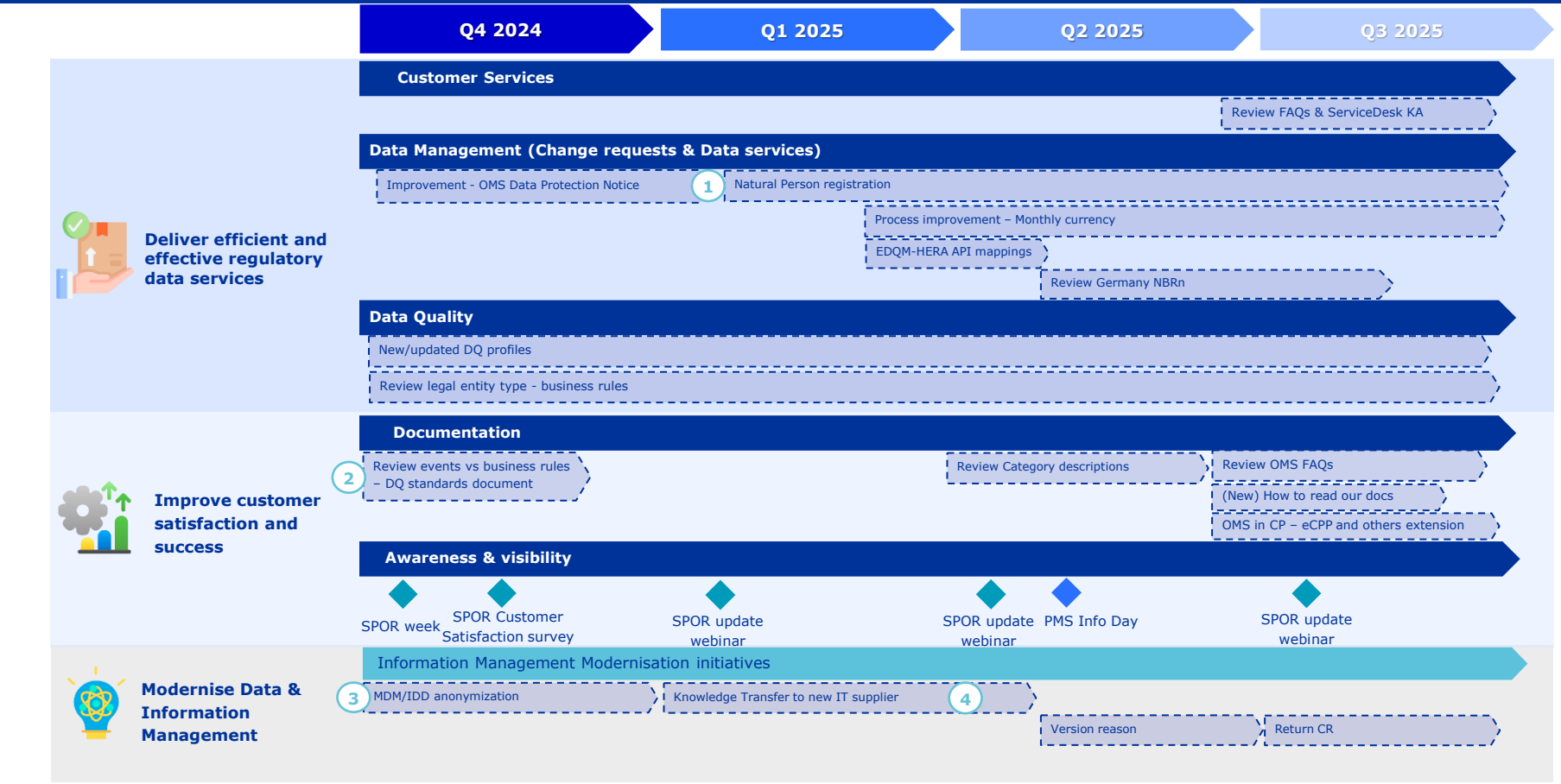

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Work completed – Highlights of what has been done in the last quarter

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	WHY	HOW & WHEN	IMPACT/ BENEFITS to users

Natural Person registration	1 Whilst a long-term solution is under assessment, **certain Natural Persons** need to be added to OMS to be able to proceed with veterinary procedures in UPD, EudraGMDP certificates and EV MAH obligations	• OMS will register **Individuals/Natural Persons** for which there is a **legal justification** and are **not registered with National Business Registry**
		• OMS Data Protection Notice (OMS DPN) provides clear information on:
		  • Justification for inclusion in OMS
		  • How data will be processed
		• **Individuals/Natural Persons** will be registered in OMS with two categories:
		  • Industry/Pharmaceutical company – to ensure downstream systems can use them
		  • Individual/Natural Person **(NEW)**
			• This is expected to lead to less CR rejections -> requests for UPD/EudraGMDP/EV MAH
			• We don't expect more users/Entrepreneurs to register in OMS!

Review events vs business rules **DQ standards document**	2 Ongoing and continuous review of old documents	Review and enrich Annex III of OMS Data Quality standards to ensure **all data changes/real world business scenarios** are accounted for and relevant **OMS process and business rules** are available	Increase transparency on the OMS business rules applicable to each event/data change
MDM/IDD anonymization	3 OMS data processing is performed outside EEA, so changes are required to comply with EU Personal data protection Regulation	Anonymization of all personal information available in MDM/IDD when processing data directly collected from Change request submission: • name, username, email, phone number (when applicable) • Q4 - Implemented	Ensures compliance with user's data protection rights and freedoms since personal data is not visible to most of EMA Data Stewards

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What's next? – Highlights of what will be done in next quarter

EUROPEAN MEDICINES AGENCY

	WHY	HOW & WHEN	IMPACT/ BENEFITS to users
4 **Knowledge Transfer (KT) from existing IT supplier to new IT supplier**	Due to procurement cycles and new Framework Contract in place	• OMS IT maintenance and support has been temporarily put on hold and focus is in providing Knowledge Transfer (KT) from existing IT supplier to new IT supplier	• Some IT capabilities (see next slides) that were planned for Q1 are now delayed to Q2-Q3

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Highlights to you

MDM/IDD anonymization

New category - Individuals (Entrepreneurs & Natural Persons)

Natural Person registration

What's changed?

Knowledge Transfer to new IT supplier

Return CR functionality

Version reason

Review organisation legal entity types

Ongoing work

Category values/description review

OMS Portal upgrade & improvements

Future changes *(What's next?)*

OMS improvements/backlog i.e Maintenance of NBRn via CR, record subscription

Block submission of duplicated requests

New Fee Regulation requires SAP codes for all Vet MAH

Future changes *(What's later?)*

Acronyms

MDM/IDD: Master Data Management solution/Informatica Data Director (user interface)

CR: Change Request

NBRn: National Business Registries number

SAP: Statutory Accounting Principles

MAH: Marketing Authorisation Holder

RMS status update

Planned RMS Activities

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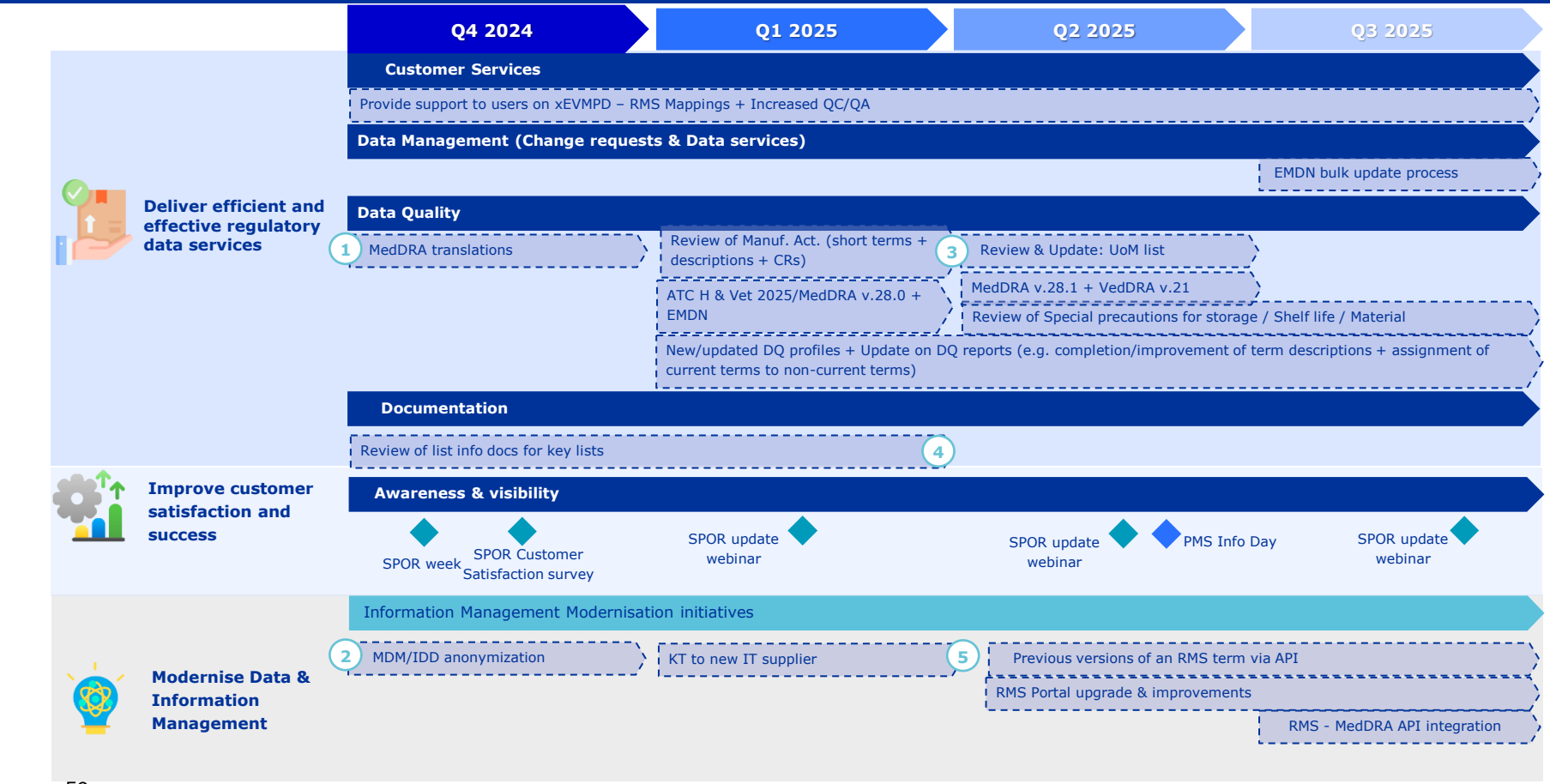

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Work completed – Highlights of what has been done in the last quarter

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		WHY	HOW & WHEN	IMPACT/ BENEFITS to users
MedDRA translations	1	MedDRA translations for 10 languages (e.g. Greek, Estonian, Korean, Latvian, Polish, Swedish, Finnish, etc.) were missing in RMS as development was needed.	• In Q4 2024 changes were made to the MedDRA upload process in RMS so that all new languages are also uploaded in the RMS database.	• Increased coverage of translations in the MedDRA list which could lead to a higher number of users and/or an increased consumption of the list.
MDM/IDD anonymization	2	RMS data processing is performed outside EEA, so changes are required to comply with EU Personal data protection Regulation	Anonymization of all personal information available in MDM/IDD when processing data directly collected from Change request submission: • name, username, email, phone number (when applicable) • Q4 - Implemented	• Ensures compliance with user's data protection rights and freedoms since personal data is not visible to most of EMA Data Stewards

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What's next? – Highlights of what will be done in the next quarter

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	WHY	HOW & WHEN	IMPACT/ BENEFITS to users
Review of Manufacturing Activities	3 Manufacturing activities list lacks information such as **short terms** and **descriptions** which are essential for PMS implementation.	• Multidisciplinary group of experts reviews the list every 6 months approximately. Current review expected to finish mid January 2025. • Final list version expected by end of January 2025.	• Descriptions will help users distinguish terms better • Short names will simplify how terms are displayed in systems such as PMS/eAF hence reducing the number of questions to EMA and/or submission errors.
Review of list information documents	4 Several list information documents are missing for some RMS lists, some others should be reviewed to contain more complete or up-to-date information.	• Documents planned for Q1 are Manuf. activity, UoM, Target Species, National classification list, Shortages Root Cause, Medicinal Product Vocabulary, Referral scopes, Conditions, Documentation, Official Name Type, Data Classification, Substance Type, Substance Name Type, Country Subdivisions.	• Improved list information documents mean improved guidance which may reduce the number of questions received for specific lists, or the number of change requests rejected due to lack of awareness for a certain list.
Knowledge Transfer (KT) to new IT supplier	5 Due to procurement cycles and new Framework Contract in place	• RMS IT maintenance and support has been temporarily put on hold and focus is in providing Knowledge Transfer (KT) from existing IT supplier to new IT supplier.	• Some IT capabilities (see next slides) that were planned for Q1 are now delayed to Q2-Q3.

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Highlights to you

MDM/IDD Anonymization

MedDRA translations

What's changed?

Review of Manufacturing Activity

New/updated DQ profiles

Review of list information documents

Knowledge Transfer to new IT supplier

Ongoing work

Consultation with SMEs for review of key lists (e.g. Special precautions for storage, Shelf life, Target Species, Material, etc.)

Previous versions of an RMS term via API

RMS Portal upgrade & improvements

Future changes *(What's next?)*

RMS – MedDRA API integration

Publication of EMDN list + EMDN bulk upload process

Future changes *(What's later?)*

Acronyms

MDM/IDD: Master Data Management solution/ Informatica Data Director (user interface)

MedDRA: Medical Dictionary for Drug Regulatory Activities

DQ: Data Quality

SMEs: Subject matter experts

API: Application Programming Interface

EMDN: European Medical Device Nomenclature

XEVMPD status update

Planned XEVMPD Activities

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	Q4 2024	Q1 2025	Q2 2025	Q3 2025
Deliver efficient and effective regulatory data services	**XEVMPD – Customer Services**			
	Review of customer services provided via Service Desk and as part of AMP validation			
	XEVMPD - Data Management (Data services)			
	Revision and improvement of current AMP validation process	4 Validation of composition in AMPs based on Module 3 information		
	Validation of AMPs in clusters			
	1 XEVMPD/PMS mapping services provided to NCAs			
	XEVMPD – Data Quality			
	Data quality review to support PMS migration			
	5 Implementation of MA transfer process notification change			
Improve customer satisfaction and success	**XEVMPD – Documentation**			
	2 Revised versions of Chapter 3.II and Art57 Q&A document published			
	XEVMPD - Awareness & visibility			
	SPOR update webinar; SPOR Customer Satisfaction survey	SPOR update webinar	SPOR update webinar; PMS Info Day	SPOR update webinar
Modernise Data & Information Management	Information Management Modernisation initiatives			
	3 Review of current XEVMPD User Interface and assessment of possible technical upgrade			
	6 Implementation of new authorisation status value in XEVMPD			

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Work completed – Highlights of what has been done in the last quarter

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	WHY	HOW & WHEN	IMPACT/ BENEFITS to users
XEVMPD/PMS mapping services provided to NCAs 1	• To support NCAs in their readiness for mapping of national product data against data in PMS	• If requested, EMA will **help NCAs with mapping data from their national databases to PMS** *Webinars held from Oct 2024 until the end of 2025*	• NCAs will be able to map products in their national databases to PMS • ESMP reporting for NCAs will be possible thanks to this mapping • Increased transparency of product data mapping efforts performed by EMA and NCAs

Revised versions of Chapter 3.II and Art57 Q&A document published 2	To reflect the below changes:
	1. Identification of the **AMP entries for France** based on the CIS number (covering all pack sizes) or the CIP number (assigned to each individual pack size)
	2. New MA status value for **pending MRPs and DCPs**
	3. Transfer of MA process change
		• By providing **details on new requirements/change** in current processes in the relevant documentation
		• *New versions of the documents published on 10 January 2025*
			• Products are available in PMS and/or consuming systems:
			  • with the correct information
			  • for the correct MAH

Review of current XEVMPD User Interface and assessment of possible upgrade 3	• To determine if XEVMPD UI could be accessed **without the need for ActiveX and IE Tab extension** and used in other supported web browsers	• EMA has identified a possible **solution for a new XEVMPD UI**, and we are currently assessing details for implementation of such solution, which depends on the strategy for XEVMPD replacement. *From Q4/2024*	• Easier access for users, browser-based solution • XEVMPD new UI could be used without ActiveX, IE Tab, in other supported browsers

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What's next? – Highlights of what will be done in the next quarter

EUROPEAN MEDICINES AGENCY

	WHY	HOW & WHEN	IMPACT/ BENEFITS to users
Validation of composition based on Module 3 information 4	• To support MAHs that wish to **provide composition within their AMP as per Module 3 dossier**	MAHs can provide composition in an AMP as per Module 3 dossier -> **for all substances** within the product -> **extract from Module 3 dossier** must be **attached** to the AMP entry to support the validation of the information *From January 2025*	• Standardisation of data • No follow-up communication is raised with the MAH if the substance information is not aligned with information in the SmPC
Implementation of MA transfer process notification change 5	• Since NAPs in PMS will contain confidential data (manufacturers) and access to the product information is controlled via XEVMPD, there's a need to increase the robustness of the process	• The **former MAH** references in the AMP record that is being **invalidated** the **new MA holder organisation** • By adding the new MAH details, the former MAH is confirming that it is ok to transfer the access to the product data in PMS • *From mid-January 2025*	• Empower MAHs to control the data and access to their products in PMS • Enriched data in PMS is kept after the MAH is changed due to a transfer of MA.
Implementation of 'Valid – pending national phase' MA status in XEVMPD 6	• To support submissions of **MRPs and DCPs approved in the Reference Member State but still under evaluation in the Concerned Member States** in the XEVMPD	• By implementing **new authorisation status value 'Valid – pending national phase'** in the XEVMPD • *From 15 January 2025*	• Pending MRPs and DCPs will be migrated to PMS and available in the web-based variation form to be used by applicants

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Highlights to you

EUROPEAN MEDICINES AGENCY

Amendment in process to notify **transfer of MAs** in XEVMPD

Possibility to report AMP **composition** as per **Module 3 dossier**

New '**Valid – pending national phase'** MA status to be used in XEVMPD

Windsor Framework in force from 1 January 2025

What has changed?

Improvement on validation process for AMPs to facilitate faster validation and grouping of records belonging to the same product **for new AMPs**

XEVMPD/PMS **mapping services** provided to NCAs

Review of current XEVMPD User Interface and assessment of possible technical upgrade

Ongoing work

Improvement on validation process for AMPs to facilitate faster validation and grouping of records belonging to the same product **for updated AMPs**

Future changes *(What's next?)*

Integration of product validation with review of substances with SVG flag 0

Future changes *(What's later?)*

Acronyms

XEVMPD: Extended EudraVigilance medicinal product dictionary
AMPs: Authorised Medicinal Products
DCP: De-Centralised Procedure
MA: Marketing authorisation
MRP: Mutual Recognition Procedure
NCA: National Competent Authority
PMS: Product Management Service
SVG: Substance Validation Group

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PMS status update

Planned PMS Activities

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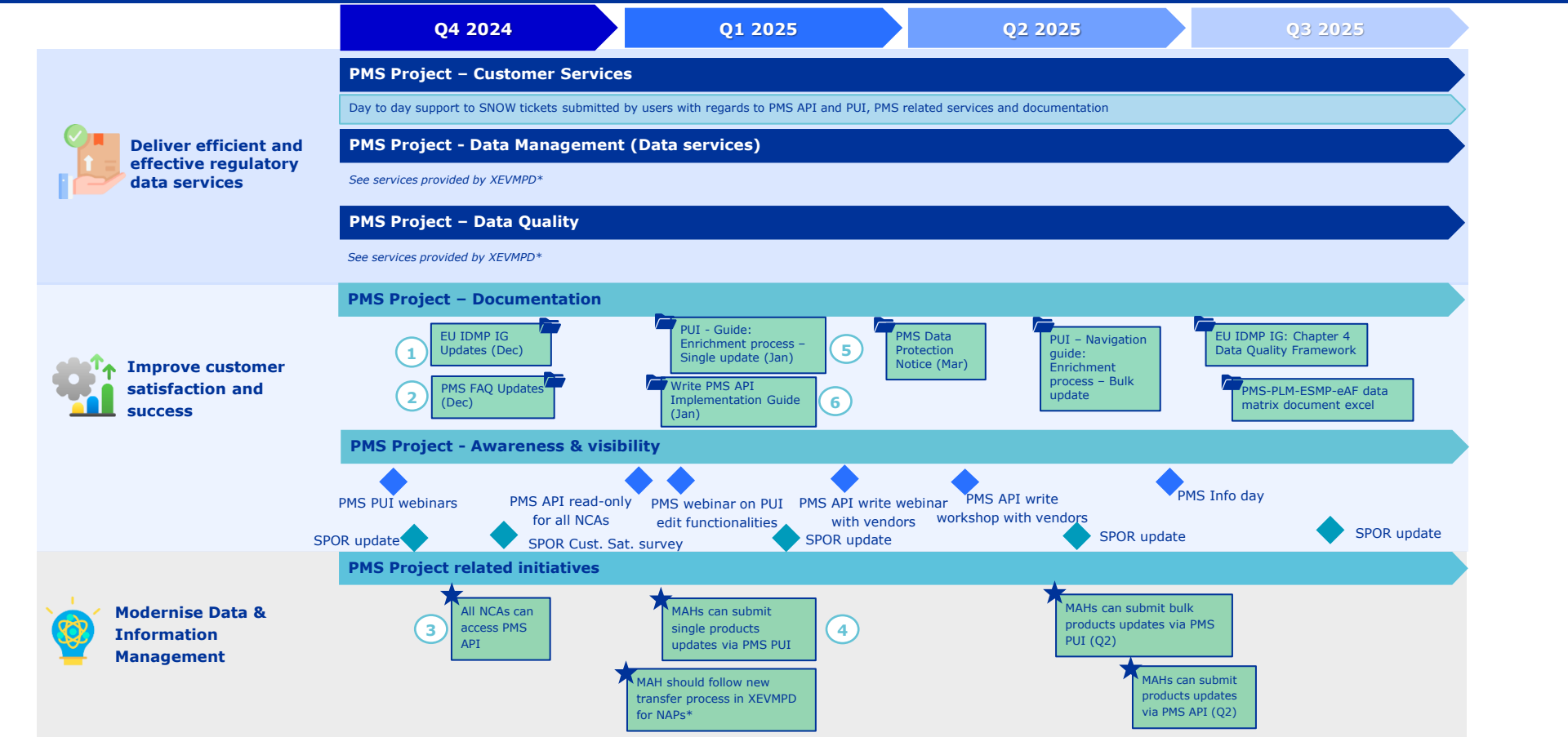

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* Link with xEVMPD status update

Document release | Milestone | SPOR update webinars | PMS webinars

Work completed – Highlights of what has been done in the last quarter

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	 WHY	 HOW & WHEN	 IMPACT/ BENEFITS to users
1 EU IDMP IG updates	Updated versions of EU IG chapters are required to support progress made in PMS at the level of the data model, business rules, accessibility and process for data submission.	• In **Dec 2024** the below listed chapters have been released on PLM PMS portal and EMA PMS webpage. • **EU IG Chapters 1, 2, 3, Annex A to chapter 5, 9** and **PMS FAQ**.	• **Preparation for PMS IDMP Compliance**: Updated guidance ensures readiness for PUI go-live with comprehensive instructions and resources. • **Enhanced Transparency and Data Quality**: The release improves visibility of PMS business rules, identifies data quality issues, and outlines data fixes (performed or planned).
2 FAQ Updates	Updated version of PMS FAQ document is needed to provide more clarity on the activities performed and planned to be excecuted to enhance the level of data quality in PMS.	• In **Dec 2024** the FAQ document have been published on PLM PMS portal and EMA PMS webpage.	• **Streamlined Submission Processes**: Clarified submission steps reduce errors, improve efficiency, and boost user confidence in compliance activities.
3 PMS API for all NCAs	As per EU IG Chapter 5 principles, full data set of authorised products data available in PMS can be accessible for NCAs (Access Level 3).	• Follow the registration requirements mentioned in EU IG Chapter 1. • As of **Dec 2024**, NCA users can register to Account Management portal to request first the administrator user role (**IRIS / PLM NCA Admin**) and then request **PMS API access**.	**Enhanced Data Accessibility:** • NCAs in Human and Vet & Human domains can access authorized product data in PMS via the API. • Enables NCAs to integrate their internal databases with EMA PMS for seamless data connectivity.

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What's next? – Highlights of what will be done in the next quarter

EUROPEAN MEDICINES AGENCY

	WHY	HOW & WHEN	IMPACT/ BENEFITS to users
4 PUI Enrichment process – Single update	• MAHs of non-CAPs from ULCM list are required to submit structured data to PMS. This is essential for fulfilling regulatory requirements and supporting ESMP. • MAHs of non-CAPs not mentioned in the ULCM list can also submit structured data to PMS.	As of **end of January 2025**, Registered non-CAPs MAH users can **submit authorized and structured product data** via PMS, including **manufacturers, pack sizes, data carrier identifiers**.	• **Improved Operational Efficiency:** Reduces manual effort, minimizes errors, and enhances workflow productivity. • **Enhanced Data Accuracy and Accessibility:** Ensures accurate product data, improving quality, decision-making, and communication with CAs. • **Streamlined Compliance with Regulatory Requirements:** Simplifies compliance by enabling seamless structured data submission, reducing non-compliance risks, and providing updated guidance.
5 PUI – Navigation Guide: Enrichment process – Single update	• Updated to include the new PUI edit functionality and guidance for submitting Enrichment Change Requests. • Clarifies that non-CAP MAHs outside the ULCM list **can submit structured data**.	As of **end of January 2025**, the updated **PUI navigation guide** will be released on PLM portal.	
6 Write PMS API Implementation Guide	To provide **technical specifications** for software developers and vendors to **build machine-to-machine connections between RIM systems and the PMS API**.	On **20th January 2025**, the relevant material has been published on the EMA PMS webpage.	• **Enables seamless integration** between RIM systems and PMS API, support development for software vendors. • **Supports automated data exchange**, ensuring accurate submissions to PMS while improving compliance and operational efficiency.

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Highlights to you

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PMS accessible via PUI and API for registered MAH and all NCA users

EU IG chapters & FAQ updated

PMS data quality improvement & data fixes performed

What has changed?

PUI Enrichment process – Single update

Implement the new transfer process for NAPs

Write PMS API Implementation Guide

Ongoing work

PUI Enrichment process – Bulk update & Guide updates

PMS API write

PMS Data Protection Notice

PMS data quality improvements & data fixes

Future changes *(What's next?)*

EU IDMP IG: Chapter 4 Data Quality Framework

PMS-PLM-ESMP-eAF data matrix excel file

PMS FHIR R5 upgrade

Future changes *(What's later?)*

Acronyms

PMS: Product Management Service
PUI: Product User Interface
MAH: Marketing Authorisation Holder
NCA: National Competent Authority
EU IG: EU IDMP Implementation Guide
FAQ: Frequently Asked Questions
NAPs: Nationally Authorised Products
PMS API: PMS Application Programming Interface

Conclusions

SPOR, XEVMPD/PMS and other processes

What is happening in **SMS, OMS, RMS** and **XEVMPD supports PMS and other solutions!**

Ind/NCAs

IAM / eAF (PDF)
EudraGMDP / UPD
… XEVMPD! ….

Ind

SMS
- Updated custom attributes in SMS API for ULCMP
- Published SMS Guidance V2.0 (SMS API and cleansing)

RMS
- 10 new languages in MedDRA
- VedDRA & MedDRA updates

OMS
- Published updated OMS Bus. rules (events and business rules)
- Natural Persons registration

Ind/NCAs

CTIS
EV Human
PhVig Fee

Ind

XEVMPD
- NEW NCA product mapping services
- NEW Transfer process
- NEW Composition based on Mod 3
- NEW submission of Pending Products

PMS
- PMS API available to all NCAs
- Published updated EU IG and FAQ
- PUI enrichment/single update in January 2025

Ind/NCAs

IRIS /RPM
PD / Inspections
ESMP / ASU etc.

IRIS

Ind/NCAs

PUI
Web eAF
ePI

PLM Portal

- Follow the instructions for **new Transfer of MA process** to avoid disruptions to access to Product data
- Optionally, align composition with Mod 3 - avoid using substances with SVG flag 0 or non-current terms where possible
- Submit **packages** for the Union List of Critical Medicinal Products (**ULCMP**) to **XEVMPD**
- Start completing **Manufacturers and structured pack sizes** for the Union List of Critical Medicinal Products (**ULCMP**) in **PUI**

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How to stay connected to work on SPOR & XEVMPD

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SPOR engagement in 2025

S, P(XEVMPD), O & R Status update Webinars

- Achievements vs what is planned;
- Key highlights for SPOR users

1) 9 April 2025
2) 9 July 2025
3) 8 October 2025

Announced via EMA's Website Events Pages

S, P(XEVMPD), O & R week of webinars

- Principles and business rules;
- key processes;
- Updates & next steps.

October 2025 (dates TBD)

Announced via EMA's Website Events Pages

SPOR customer satisfaction survey

Feedback from users

Oct-Nov 2025

Announced via SPOR webinars & email

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Upcoming event

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Thank you

SPOR Web Page

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