EMA
EUROPEAN MEDICINES AGENCY

SPOR & XEVMPD Status Update

Recent & planned changes and impacts to users

28 January 2026

Housekeeping notes – Personal Data Protection disclaimer

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

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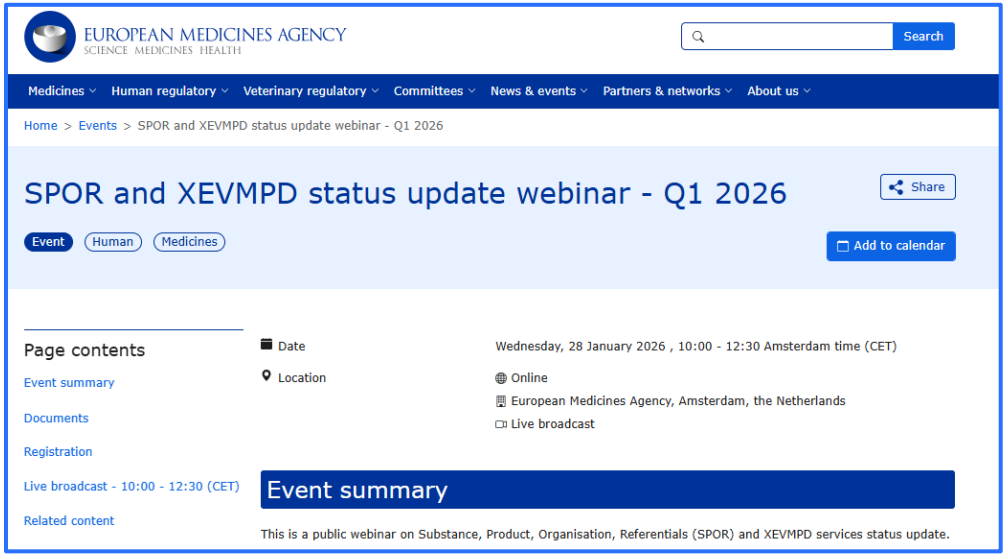
Live broadcast available from event page

- As the WebEx session has a capacity limit of 1,000 participants, you are welcome to watch the live broadcast from the event page
- Link to event page available on Slido in the highlighted comment



 For questions: www.slido.com code: #STUP280126

Housekeeping notes – Q&A

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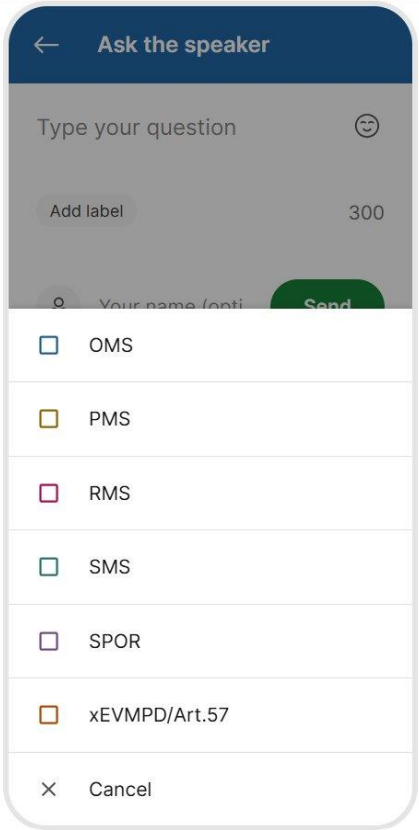
2. **Send or upvote the questions** you want to hear answered
3. **Questions will be shown on the screen** and EMA colleagues will **verbally address top 5 voted questions** in the live Q&A sessions.

Housekeeping notes – Q&A labels

Before sending your question, please **use one of the following labels** to get your question answered in the relevant Q&A session:

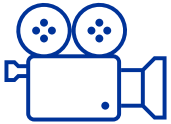
- *OMS*
- *PMS*
- *RMS*
- *SMS*
- *SPOR*
- *XEVMPD/ Art 57*



Housekeeping notes – Webinar materials

Presentation will be available at:

- SPOR Portal Documents section
- EMA Event Web Page



Recording will be available at:

- EMA YouTube Channel (also in SPOR webinars playlist)
- 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.**

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Agenda

1. **Welcome & Housekeeping notes**
   10 mins presentation (no Q&A)
   10:00 – 10:10
2. **SMS status update**
   10 mins presentation + 10 mins Q&A
   10:10 – 10:30
3. **OMS status update**
   10 mins presentation + 10 mins Q&A
   10:30 – 10:50
4. **RMS status update**
   10 mins presentation + 10 mins Q&A
   10:50 – 11:10
5. **Coffee Break + survey**
   10 mins
   11:10 – 11:20
6. **XEVMPD status update**
   10 mins presentation + 10 mins Q&A
   11:20 – 11:40
7. **PMS status update**
   10 mins presentation + 10 mins Q&A
   11:40 – 12:00
8. **Feature topics - XEVMPD web UI upgrade, SPOR Service changes**
   15 mins presentation + 5 mins Q&A
   12:00 – 12:20
9. **Conclusions**
   5 mins presentation +
   5 mins Slido survey
   12:20 - 12:30

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SMS status update

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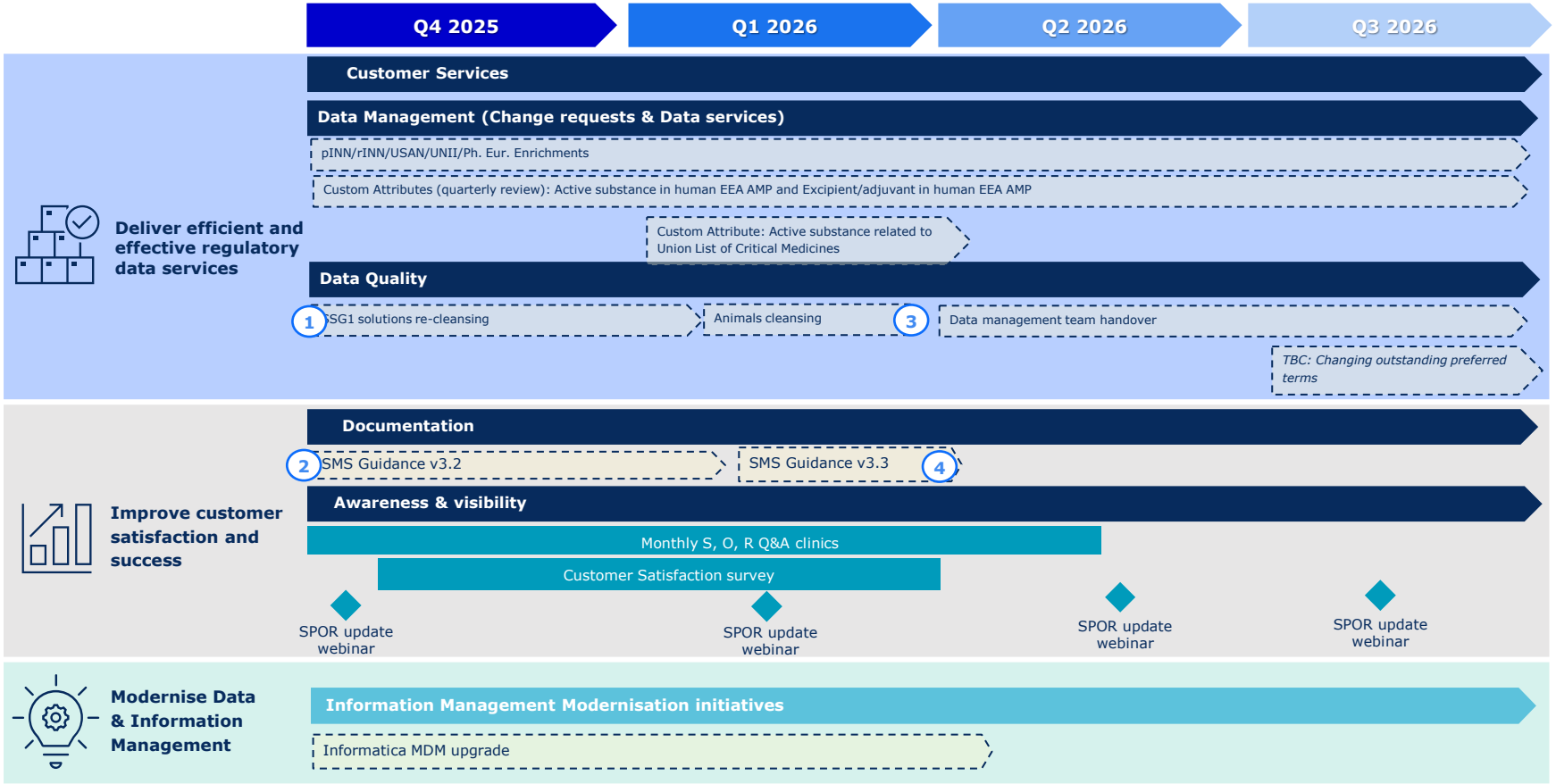
Planned SMS Activities



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Work completed – What has been done in Q4 2025

	Why	How & when	Impact/ benefits to users
1 SSG1 solutions re-cleansing	• SSG1 solutions had been cleansed in 2024 by the Substance Validation Group (SVG). At that stage, only SSG1 solutions with a related Ph. Eur. monograph were considered valid records (SVG flag 1). • However, this caused concerns with some NCAs and Industry users, since it did not cover all SSG1 solutions required for product registration.	• The business rules for SSG1 solutions were revised by the SVG. There are **three identified scenarios** for a SSG1 solution to be considered **valid** (SVG flag 1): ▪ Related to a Ph. Eur. monograph ▪ Related to another EEA pharmacopoeia monograph (e.g. German Pharmacopoeia) ▪ Other exceptions identified by the SVG • All the **valid records are listed in SMS Guidance for External Users** • Taking into account the new business rules defined by the SVG: ▪ Some **new** SSG1 solutions records were **created** ▪ Some SSG1 solutions records had the cleansing flag **reverted** from SVG flag 0 to SVG flag 1 ▪ The **replacement records** of several SSG1 solutions **considered invalid (SVG flag 0) have been reviewed.**	• **All required SSG1 solutions needed for product registration cleansed** and available in SMS • Improved Data Quality
2 SMS Guidance V3.2	• Reacting to feedback from customer satisfaction survey where customers demanded more and faster access to information	• **New version** containing business rules for **SSG1 solutions**	• Enhanced supporting documentation allowing improved awareness • **Predictability** of how substances will be registered and maintained

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What's next? – What will be done in Q1 2025

	Why	How & when	Impact/ benefits to users
3 **Animal cleansing**	• Quick win, easy to cleanse and outsource	• SMS pre-cleansing completed for animals whole and animal parts • SVG discussions to start in February • Planned SVG cleansing completion in Q1 Note: allergen extracts (Structurally Diverse – Allergens) are not included in this substance group	• **Improved Data Quality** • New substance group (within Structurally Diverse - Other) cleansed and business rules defined for new substance records • Prevention of pharmacovigilance change requests by proactive registration of animals and animal parts • Increased scope of outsourcing
4 **SMS Guidance V3.3**	• Reacting to feedback from customer satisfaction survey where customers demanded more and faster access to information	• **New version** containing business rules for **Animals**	• More frequent **documentation** updates • Enhanced supporting documentation allowing improved awareness • **Predictability** of how substances will be registered and maintained

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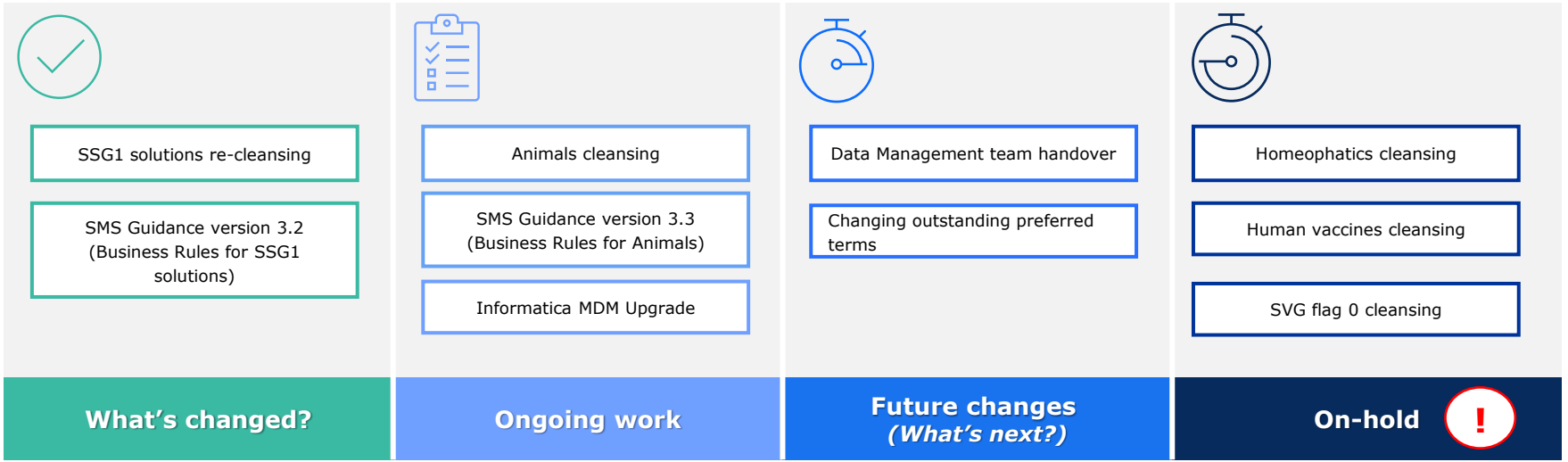
Highlights to you



Acronyms

SMS: Substance Management Services

SVG: Substance Validation Group

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Q&A time

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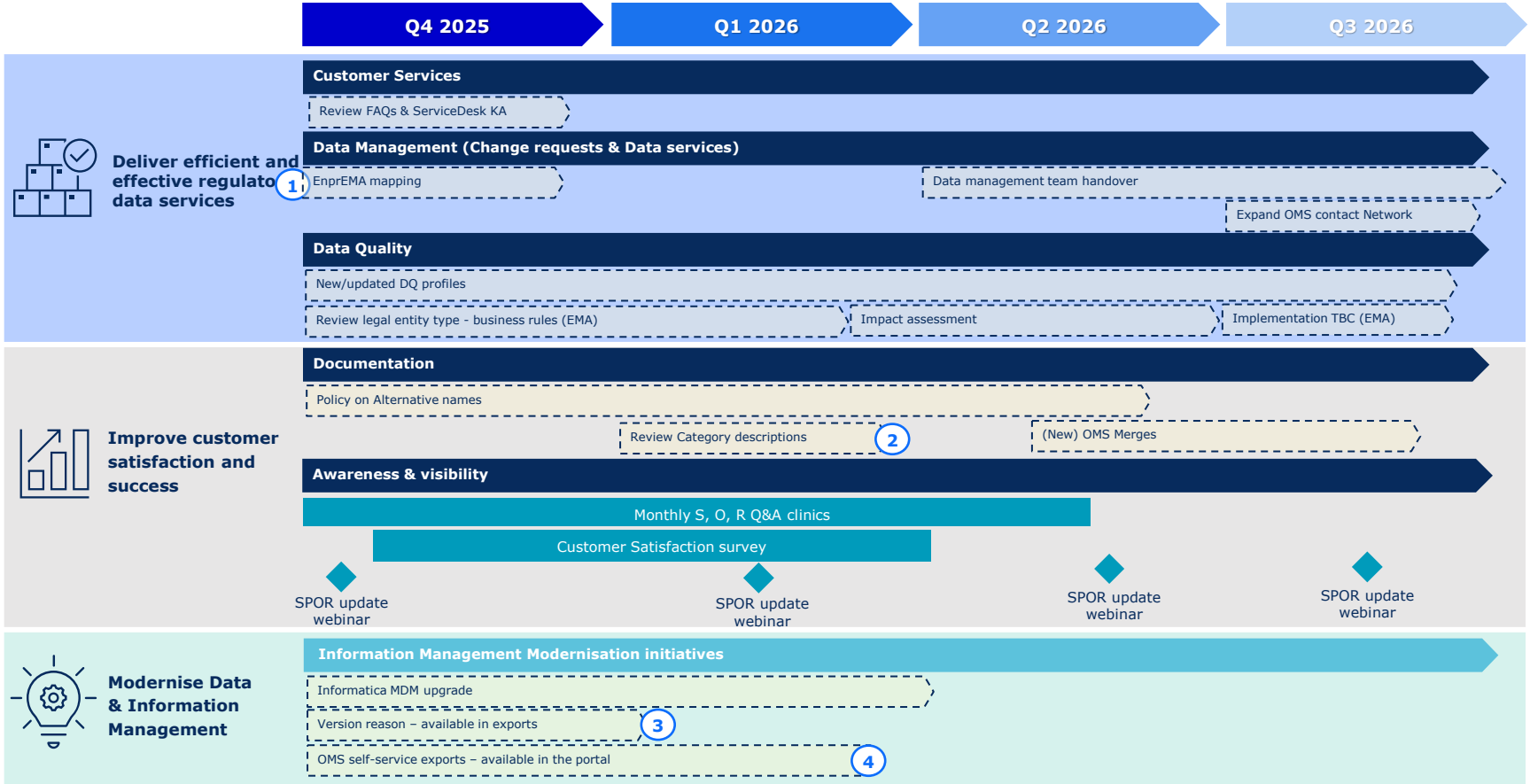
OMS status update

Planned OMS Activities



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Work completed – What has been done in Q4 2025

	Why	How & when	Impact/ benefits to users
1 Enpr-EMA mapping	• To **expedite communication when sharing good practices** within and outside the European Union (EU), OMS data will be used on a mandatory bases by the new **European network of paediatric research at the European Medicines Agency** database	• OMS mapped all research networks and centres with recognised expertise in performing clinical studies in children available in the old Enpr-EMA database	• **Improved Data Quality** – all entities registered in the new database will follow the OMS data quality rules • **Improve user experience** – all entities previously registered in EnprEMA are now available in OMS

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What's next? – What will be done in Q1 2026

	Why	How & when	Impact/ benefits to users
2 **Category values/ description review**	• Ongoing and continuous review of **Controlled vocabulary used by OMS** • Improve data profiling	• Review current categories available and possible expansion to accommodate new requirements and/or recent system integrations - Q1 2026	• Clearer categorization of OMS records facilitates filtering/usage of data

3 **Version reason** ***available in the exports***	• **Transparency** on the reason to create a **new version** at organisation and location level	• For each new version OMS maintains 2 fields:
		  • Version type – standard RMS terms
		  • Version comment – further details on reason/outcome
		• This feature has been implemented previously through API and is available in the **OMS exports** since 14/01/2026
			• **Improved user experience** – details previously available only through API are now added to the **OMS exports** allowing **easier use of the information**

4 **OMS self service exports** ***available in the portal***	• With the transition of change requests to ServiceDesk, **OMS exports were temporarily impacted**: Full organisation exports were made accessible in the Documents section of the OMS portal, and any specific or historical exports were obtained through a ServiceDesk request.	• All exports will be available in the OMS portal in self service at the end of Q1 2026	• **Improved user experience**
			  • user can access any export on a self-service bases
			  • no waiting time

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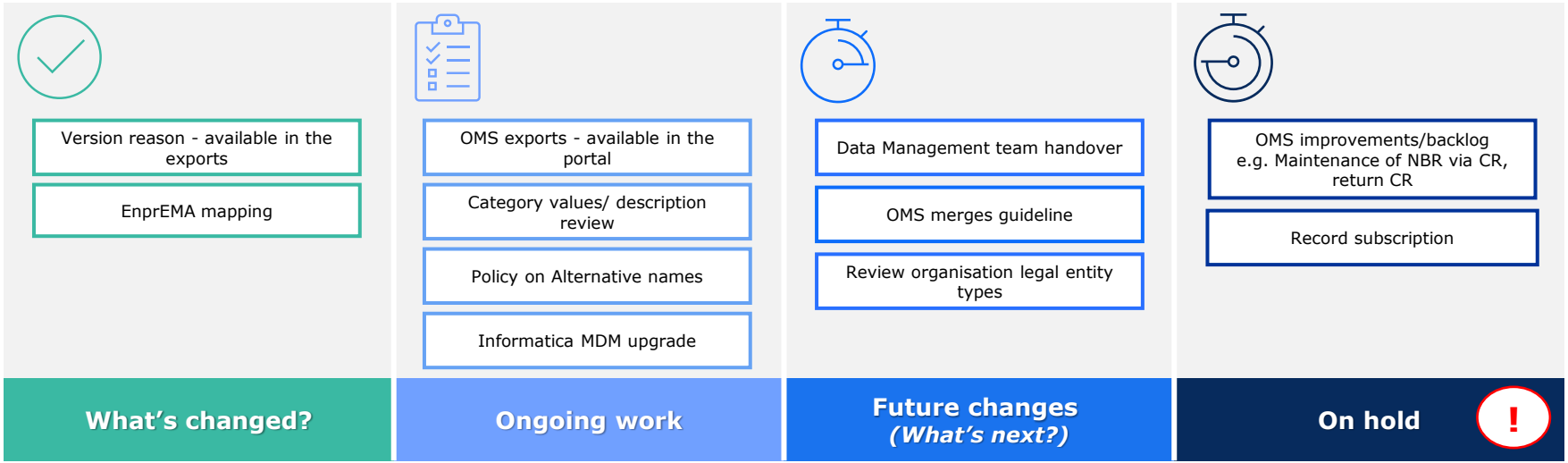
Highlights to you



Acronyms

MDM: Master Data Management solution

CR: Change Request

NBRn: National Business Registries number

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Q&A time

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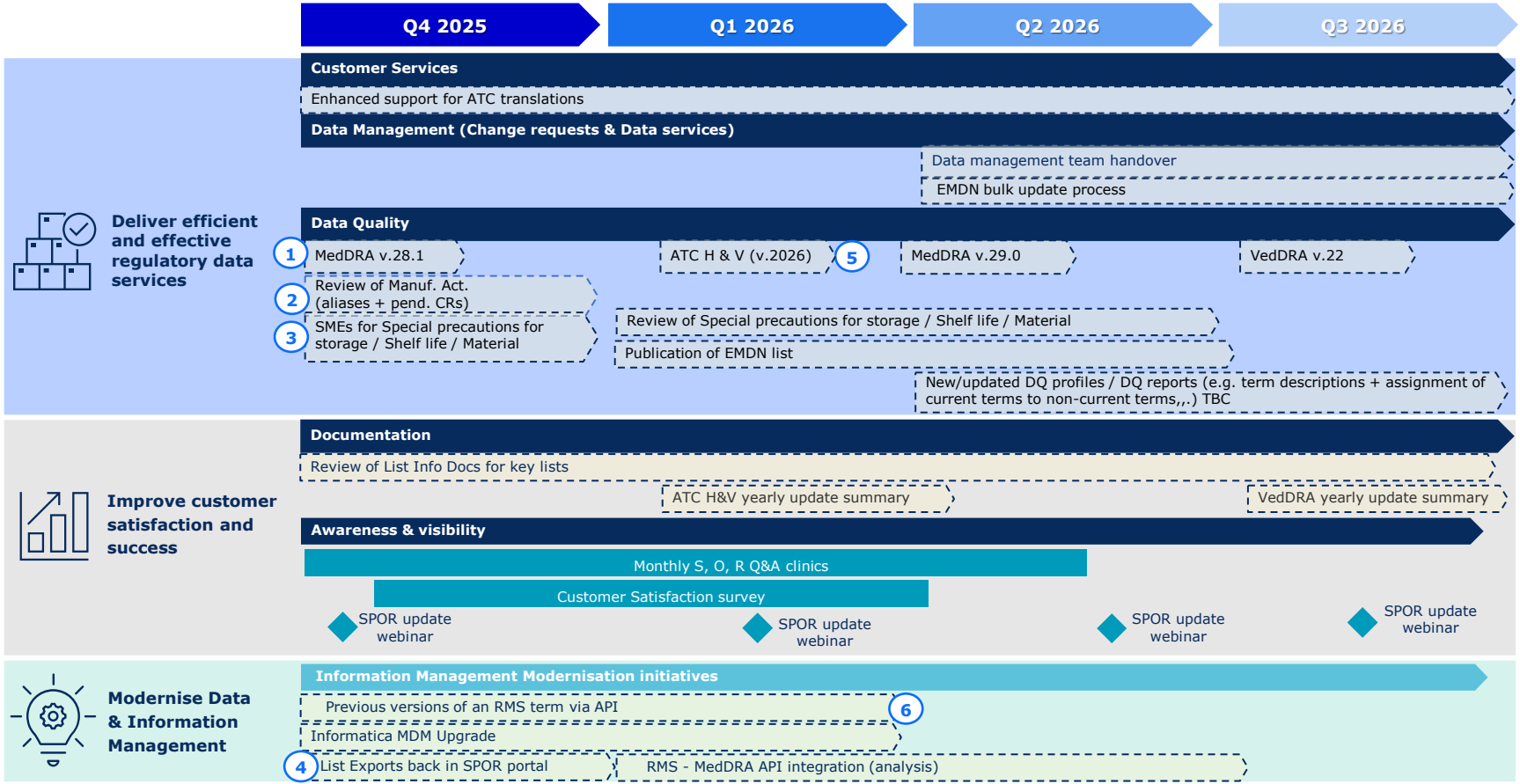
RMS status update

Planned RMS Activities



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Work completed – What has been done in Q4 2025

	Why	How & when	Impact/ benefits to users
1 **MedDRA v 28.1**	• MedDRA is updated every March & September by MSSO, RMS publishes the updates asap afterwards.	• MSSO published the new MedDRA v.28.1 on 15th September and this update was **published** in the RMS portal on **10 October 2025.**	• Complete and up to date lists in RMS may increase usage of terms and reduce the number of requests for new or updated terms.
2 **Review of Manufacturing Activities (aliases + pending CRs)**	• Only few terms contain **aliases/other names**, creating confusion/questions from users.	• **Consultation** with the multidisciplinary group took place in **Q4 2025**. • List was updated with several new aliases and two new terms and **minutes** were **published in the RMS portal.**	• **Improved clarity and process efficiency** • Aliases will help with understanding of the terms and reduce the number of questions to EMA or the number of CRs rejected due to lack of awareness of the list.
3 **SMEs for Special Precautions for Storage/Shelf Life/Material**	• **Increasing number of requests** and the need to have the lists ready for PMS implementation.	• **SMEs** were **identified** in **Q4 2025**. • Review planned to start in Q1 2026 and implementation by the end of Q2 2026.	• **Improved clarity and process efficiency** • Lists fit for purpose. • Complete and up to date lists will ensure that the selection of referentials in regulatory applications is straightforward.
4 **List exports back in SPOR portal**	• With the transition of change requests to ServiceDesk, **exports of RMS lists from the RMS portal were temporarily impacted**, and these could only be obtained through a ServiceDesk request.	• As of December 2025, **exports of RMS lists are available again** in the RMS portal • Exception: ATC H, ATC V, MedDRA (copyright protected), these should be requested through a ServiceDesk request.	• **Improved user experience** • user can access any export on a self-service basis • no waiting time

 For questions: www.slido.com code: #STUP280126

What's next? – What will be done in Q1 2026

	Why	How & when	Impact/ benefits to users
5 **ATC H & V (v.2026)**	• ATC H & V are updated by WHO CC every year around January. RMS publishes the updates asap afterwards.	• Both lists are expected to be **updated by the end of January approx**. and therefore the changes are expected to be replicated within one month after publication by WHO CC).	• Complete and up to date lists in RMS may increase usage of terms and should reduce the number of requests for new or updated terms.
6 **Previous versions of an RMS term via API**	• Versioning enables auditability, reproducibility, and backward compatibility by **letting users see what changed, recreate past results, and query specific versions without forced updates.**	• The API can be queried by **version number, as-of date, or to list all versions of a term**. Responses include the **exact term** definition and metadata **for that point in time.** • Implementation expected by end of Q1 2026.	• Greater **clarity and transparency of changes**, stable integrations, i**mproved synchronisations** through flexible version identification and selection, and compliance-readiness for regulated environments.

Highlights to you

- MedDRA v.28.1
- Review of Manuf. Activ. (aliases + pending CRs)
- SMEs for Special precautions for storage / Shelf life / Material
- List exports back in SPOR portal

What's changed?

- Review of Special precautions for storage/Shelf life/Material
- Review of List Info Docs for key lists
- Informatica MDM upgrade

Ongoing work

- ATC H & V (v.2026)
- Data Management team handover
- Previous versions of an RMS term via API

Future changes *(What's next?)*

- RMS – MedDRA API integration
- EMDN bulk upload process

Future changes *(What's later?)*

Acronyms

MedDRA: Medical Dictionary for Drug Regulatory Activities
SME: Subject Matter Experts
DQ: Data Quality
CR: Change Request
API: Application Programming Interface
EMDN: European Medical Device Nomenclature

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Q&A time

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SPOR & XEVMPD satisfaction survey now available

The survey monitors services' performance, analysing improvement areas and trends

Cadence	• Conducted every 6 months – *open for 5 months* • Launched during Q2 & Q4 SPOR status update webinars
Target audience	SPOR & XEVMPD users
Distribution channel	Slido public link published on EMA website
Question type	• Recurring questions on satisfaction levels on different services' aspects • Ad hoc questions to gather feedback on specific topics
Time needed	5 minutes

Complete the survey here!

Closure date: 8 March 2026

Slido code: #SPOR-SURVEY

Coffee break

10’

Use this time to give us feedbak. Complete the SPOR Customer satisfaction survey here!

Slido code: #SPOR-SURVEY

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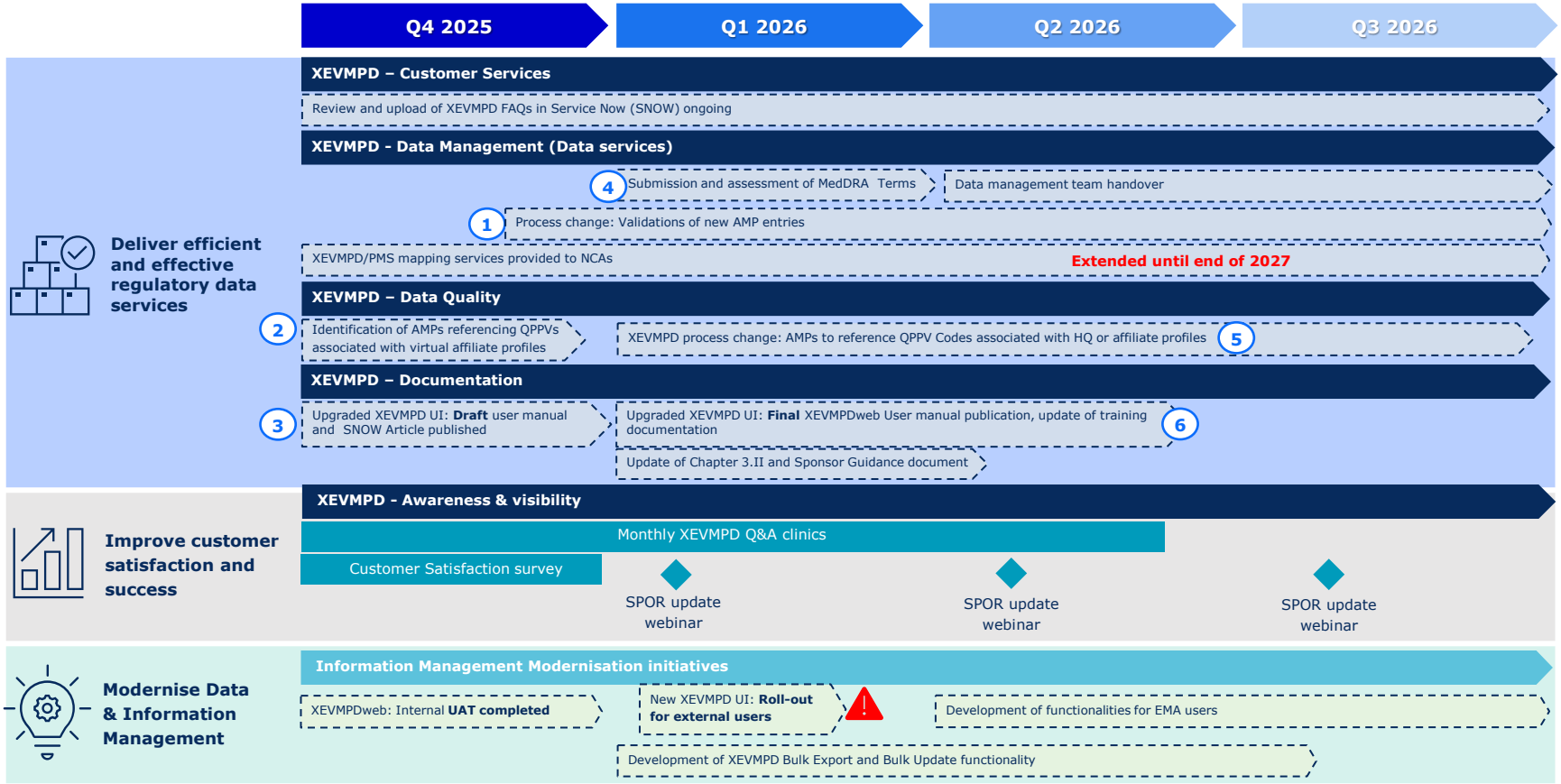
XEVMPD status update

For questions: www.slido.com code: #STUP280126

Planned XEVMPD Activities



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Work completed – What has been done in Q4 2025

	Why	How & when	Impact/ benefits to users
1 Process change: Validations of new AMP entries	• To cope with increased workload and manage the validations of newly authorised product entries submitted for each pack size more efficiently	• By prioritizing **new products** over **new pack sizes** during validation: • All AMP records for **new products** (critical/non-critical medicines) are validated first • New **package records related to critical medicines** and containing **inconsistent data** are validated afterwards • New **package records** with **consistent data** are validated in due course • *From November 2025*	• Benefit: there is no delayed validation of new/critical product records • Impact: MAHs should be aware that validation of New package records with consistent data may take longer
2 Identification of AMPs referencing QPPVs associated with virtual affiliate (VA) profiles	• To ensure that 24/7 contact number for a QPPV is always provided (which was not the case for QPPVs associated with VA)	• By **contacting MAHs with AMPs referencing VA QPPV Code** with request to review and update such products • *Before 26 January 2026*	• Impact: Contacted MAHs should update their AMPs to reference QPPV Codes linked to HQ or genuine affiliate profiles where 24/7 contact must be provided
3 Upgraded XEVMPD UI: Draft user manual and SNOW Article published	• To increase transparency of upcoming upgraded XEVMPD UI	• By publishing DRAFT version of the XEVMPDweb User Manual • Making available a new SNOW Article • Contacting all registered users • *December 2025*	• Benefit: early visibility and awareness of users • Users can **preview the upcoming changes** (based on screenshots and information in Annex I) • Review **additional information** related to the upgraded UI

What's next? – What will be done in Q1 2026

	Why	How & when	Impact/ benefits to users

4 Submission and assessment of MedDRA Terms	• To simplify MedDRA coding and avoid corrections/disputes between MAH and EMA	• MAHs can reference Preferred Terms (PTs) in AMPs:
		  • No need to update existing records; LLTs can continue to be referenced
		  • PTs to be entered for new products or during the next product info update
		  • EMA to correct/update MedDRA coding only if PT is incorrect
		  • No validation performed on LLTs
			• **Decreased burden** for EMA and MAHs with regards to coding of indications - MedDRA coding is simplified and consitent for all products in a cluster

5 XEVMPD process change: AMPs to reference QPPV Codes associated with HQ or affiliate profiles	• To ensure QPPV code associated with HQ/legal affiliate profile is referenced in AMPs and 24/7 contact number for a QPPV is provided	• By **introducing new technical rule** preventing the use of virtual affiliate (VA) linked QPPV Codes in AMPs • *From 26 January 2026* • 24/7 QPPV phone number must be provided	• **Negative ACK** is received **if QPPV Code referenced in an AMP is linked to a VA** • PhV inspectors raise missing 24/7 contact number with MAH
6 Final XEVMPDweb User manual publication, update of training documentation	• To deliver the most up to date versions of the existing documentation to users	• Final version of the User Manual to be published *in February 2026* • Updated versions of training presentations to be published *by end of February 2026* • Step-by-step guides to be updated *by end of Q2/2026*	Users are provided with updated documentation prior to new UI roll-out to: • view screenshots from the new UI; • note main differences; • become familiar with the look/feel of the new UI.

 For questions: www.slido.com code: #STUP280126

Highlights to you

What's changed?	Ongoing work	Future changes *(What's next?)*	Future changes *(What's later?)*
Upgraded **XEVMPD UI** (XEVMPDweb) to be made available to non-EMA users in February	XEVMPD/PMS **data mapping services** provided to **NCAs**	Submissions of **MedDRA PTs in AMPs**	Improvement on **cluster validation process <u>for updated AMPs</u>**
MAHs not able to reference QPPV Codes associated with **virtual affiliate** profiles in AMPs	Development of **XEVMPD Bulk Export** functionality in XEVMPDweb	Data Management team handover	Integration of product validation with review of substances with SVG flag 0
Validation priority given to new products over new pack sizes	Update of XEVMPD training documentation	Development of functionalities for EMA users in XEVMPDweb	
XEVMPD submission related FAQs available as articles in SNOW	Conversion of XEVMPD related FAQs into SNOW articles		

Acronyms

AMPs: Authorised Medicinal Products

FAQs: Frequently Asked Questions

XEVMPD: Extended EudraVigilance medicinal product dictionary

NCA: National Competent Authority

PMS: Product Management Service

SNOW: ServiceNow

UAT: User Acceptance Testing

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Q&A time

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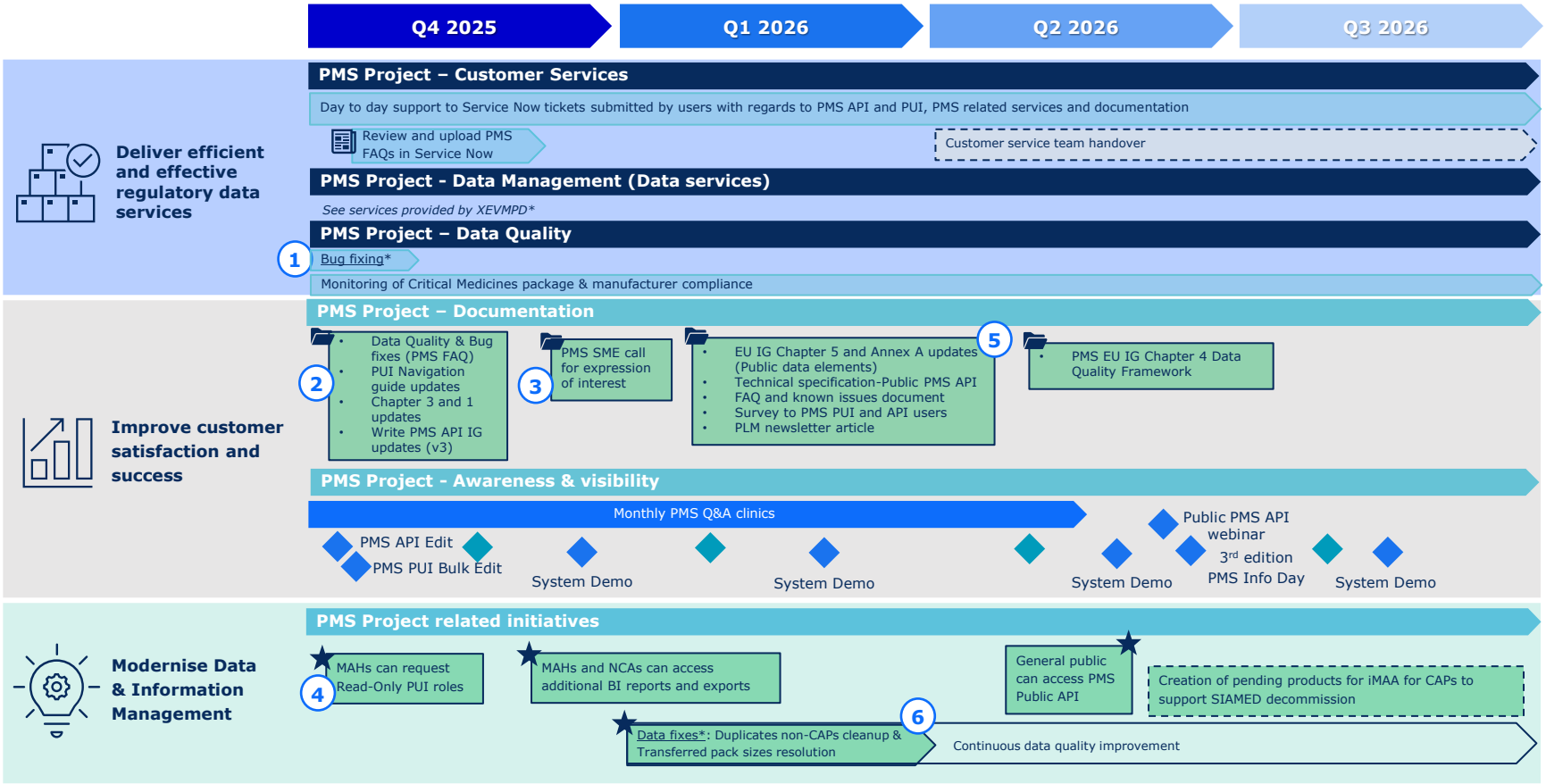
PMS status update

Planned PMS Activities



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* Link with xEVMPD status update

Document release | Milestone | SPOR update webinars | PMS webinars

Work completed – What has been done in Q4 2025

	Why	How & when	Impact/ benefits to users
1 **Bug fixing: MA number at product level, units of presentation on the pharmaceutical product and duplicated products**	To enhance the level of products data quality, specific synchronisation bugs were fixed.	MA number at product level: If all packages have the same MA number, this will also reflect at product level, otherwise, it will be blank. Units of presentation: the system did not include the units of presentation in the pharmaceutical product. This has been fixed. Duplicated products: The fix avoids the generation of multiple products in PMS when only one product should be created.	The correct data will be captured when creating new products in PMS or when updating the existing ones. Additionally, no duplicated products will be generated in PMS. This allows MAHs to know which products to enrich or to use the web-based eAF as no duplicates will be generated.
2 **PMS documentation updates**	To provide updated guidance, enhance usability, and increase transparency on data quality status and required fixes.	Updates published over **Q4 2025** on the **PMS webpage** and **PLM portal**, including:PMS FAQ, EU IG chapter 3, PUI Navigation guide, Chapter 1 PROD and UAT, Write PMS API IG updates (v3) online page.	Easier access and use of PMS production and test environments. Clarifies data quality status and required fixes over time.
3 **PMS SME call for expression of interest**	The current SME mandate runs until March 2026 and the call is launched to ensure continued collaboration between regulators and industry.	The call was open in **December 2025**, via official EMA channels for National Regulatory Authorities and Industry (ie. Industry Trade Organisations, HMA, Network portfolio website et) and will be **closed on 31 January 2026**.	Ensures **continued expert input** for regulatory work. Prevents gaps in SME participation. Supports efficient and consistent decision-making. Strengthens engagement with stakeholders.
4 **PUI Industry Read vs Write roles**	The previously released **PUI** required **system enhancements** to enforce more granular read-only functionality.	**Starting mid October 2025**, users can request relevant **Read-Only (RO) roles** via the EMA Account Management portal: PUI Industry Read/ Qualifier Read user	Users can be assigned either **Read-Only (R)** or **Read + Write (R+W)** access, providing more flexibility and security. All **previously registered users retain their Read + Write capabilities.**

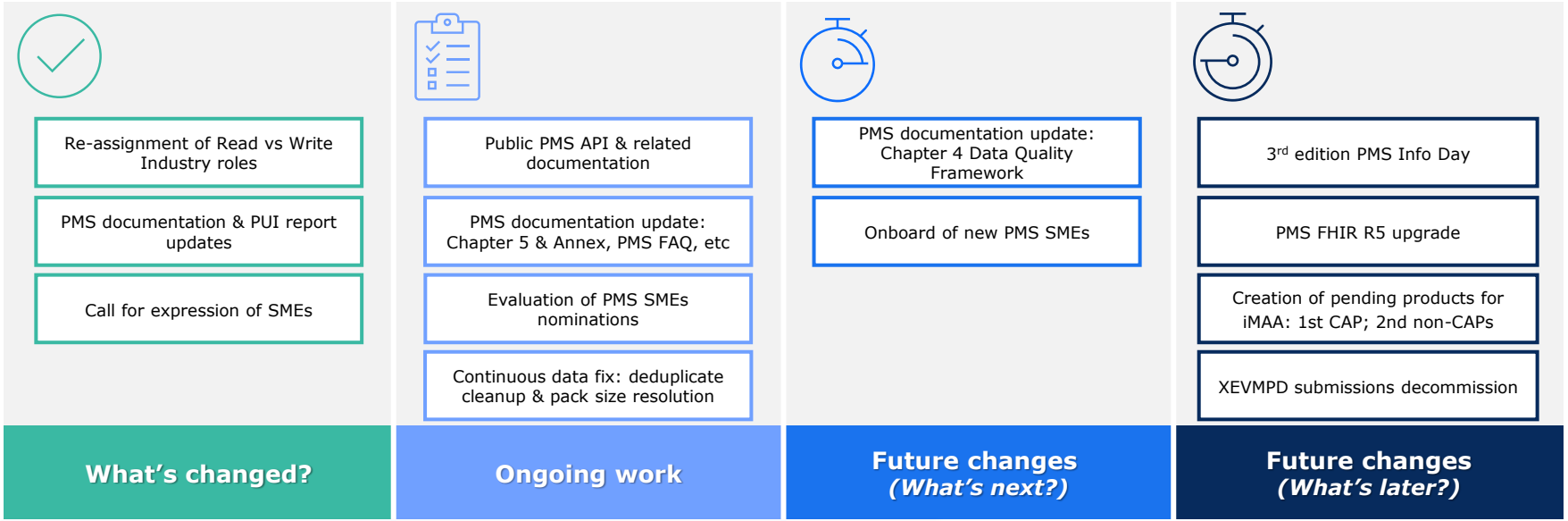
What's next? – What will be done in Q1 2026

	Why	How & when	Impact/ benefits to users

5 PMS documentation updates	• In preparation of the PMS Public API go live in Q2	• Updates to be published by **end Q1 2026** on **PMS webpage** and **PLM portal**, including:
		  • Chapter 5 and Annex A updates (Public data elements)
		  • Technical specification to access Public PMS API
		  • Update of FAQ and known issues document
			• Facilitates **correct and efficient use of the PMS Public API**, improves understanding of available public data, reduces integration and data interpretation issues, and enhances transparency and trust for all users.

6 Data fixing: Duplicates non-CAPs cleanup & transferred pack sizes resolution	• **Following the bug fix**, it is deemed necessary:
	- remove all previously created duplicated non-CAP records, to improve the level of consistency and data quality between XEVMPD and PMS
	- ensure all authorised pack sizes are correctly displayed in PMS
		• **Duplicate non-CAP product and package** records will be removed in **Q1 2026**. One of the duplicates will be nullified and the other one will remain active. Which product is nullified will be decided case by case (no rule can be implemented).
		• **Transferred pack sizes:** For transferred EV Codes that were included under one packaged medicinal product instead of under specific packages in PMS, each EV Code has been included in newly created packaged medicinal products.
			• Following the data fix:
			  • when **all duplicated** products are **fixed** MAHs will only see the products requiring enrichment, and the **correct product displayed** in the **web-based eAF**.
			  • **all authorised packages** submitted via XEVMPD upon MA transfer are now visible in PUI and API (around 27K packages now available). **MAHs should verify package availability** and **close any remaining** open tickets.

Highlights to you



Acronyms

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

For questions: www.slido.com code: #STUP280126

Q&A time

You can ask questions via the audience interaction tool **Slido**.

1. **Join at slido.com** with the code #STUP280126 or by scanning the QR code here.

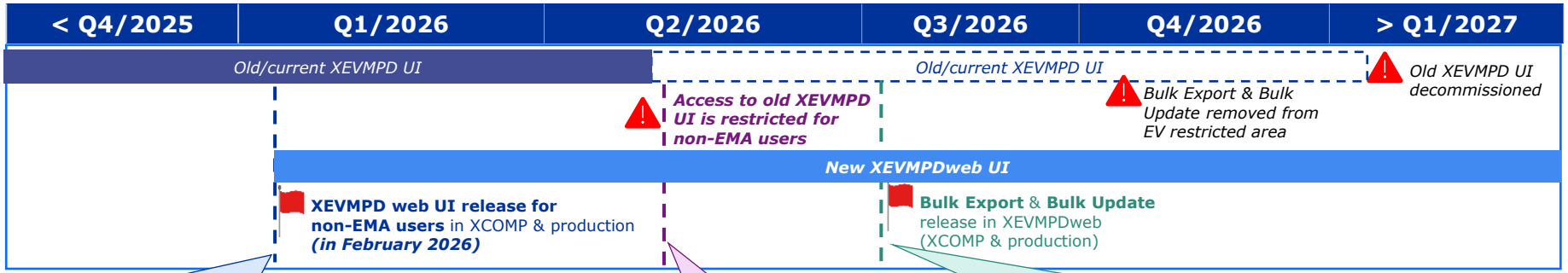
2. **Send or upvote the questions** you want to hear answered
3. **Questions will be shown on the screen** and EMA colleagues will **verbally address top 5 voted questions** in the live Q&A sessions.

*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.*

Feature topics

XEVMPDweb UI upgrade

The new XEVMPD web UI provides **improved user experience** thorough **easier access** without the need for ActiveX or IE Tab, similar look and feel and **no need for (re)training**.



From 'Go live' to Q2 2026:

- 'Go live' date and URLs shared with registered users via **email**; URLs to new UI will be made available in EV restricted area
- MAH, sponsor and NCA users are **encouraged to start using the new XEVMPDweb UI** for their searches and submissions
  - ✓ *All functionalities supporting MAH & sponsor submissions available*
  - ✓ *Search functionalities for NCA users available*
  - ✓ *'Post' functionality available*
- MAHs and sponsors can use the **Post functionality** from EV restricted area and/or from within XEVMPDweb.
- XML files generated via Bulk Update tool can be retrieved in both UIs and submitted from both UIs
- There is **no impact on Gateway users**

As of Q2 2026:

- MAH, sponsor and NCA users **cannot use the old XEVMPD UI (XEVMPD EVWEB)**
- MAH, sponsor and NCA users **must use the new XEVMPDweb UI** for their searches and submissions
- The **Bulk export and Bulk update** are still available in **EV restricted area and ActiveX is still needed to use them.**
- XML files generated via Bulk Update tool can be retrieved from new XEVMPDweb UI

As of Q3 2026:

- MAH, sponsor and NCA users **must use the new XEVMPDweb UI** for their searches and submissions as well as **Post, Bulk Export** and **Bulk Update capabilities** from within the **new XEVMPDweb**.
- **ActiveX is no longer needed**

For questions: www.slido.com code: #STUP280126

XEVMPDweb UI useful information

Access

URLs to new XEVMPDweb:

- will be shared via email communication and
- made available in **EV restricted area, under 'EV Services'**

Existing access used for current UI is valid for new UI

Info and training

Information available:

- XEVMPDweb User Manual
- ServiceNow Knowledge Base Article KB0014045

e-learning:

- Updated training presentations and user manual available on XEVMPD training webpage from **February**
- Step-by-step guides from **Q2/2026**

Virtual training (DIA organised) from **11 March**

Customer service

Questions:

- Request for Information
    - *Service: **SPOR** Service Offering: **XEVMPD/Art.57***

Issues with XEVMPD UI (current or new):

- Report an Issue: Specify if related to old UI (XEVMPD EVWEB) or new UI (XEVMPDweb)

SPOR service improvements

Self-service

Managed services

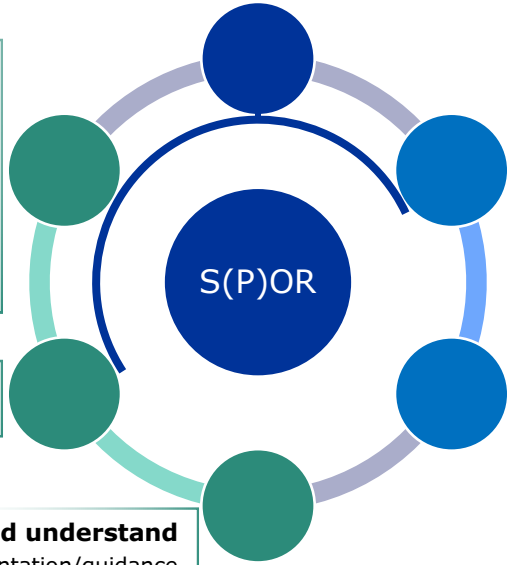
4. Access, browse, download data – Machine to machine
No changes to the **API** access/use

SPOR portal

3. Export and use data
SMS export – main landing page
NEW! RMS exports – view lists page since Q4/2025
OMS All Active organisations export – documentation
Planned: OMS self-service export & history in the OMS portal – Q1/2026
Planned: OMS & RMS manage subscriptions – Q4/2026

2. Access and Browse data
SMS, OMS and RMS Dictionary

1. Learn and understand
General SPOR documentation/guidance



Service Desk portal

5. Request Data
Change requests
OMS, SMS and RMS
Planned: Reduce data manual entry with direct link to SPOR data – > Q3/2026

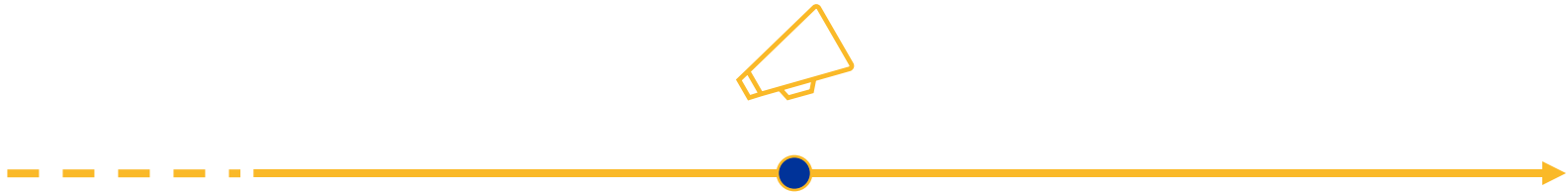
6. Request services and Customer support
SMS, OMS and RMS Question, Issues and requests
Request/manage RMS translations
Temporarily: Request OMS search specific or with history exports

Key messages

Self-service capabilities in SPOR portal: some already re-introduced, others planned, including new capabilities

Managed services in Service Desk:
- CRs will not go back to SPOR portal but expect improvements in Service Desk
- RMS translations – will be best supported as a managed service

Upcoming SPOR & XEVMPD engagements (1/2)



SPOR & XEVMPD status update webinars

Registration open

- **13 April 2026 — 10:00–12:30 (CET)**: access event page
- **8 July 2026 — 10:00–12:30 (CEST)**: access event page
- **7 October 2026 — 10:00–12:30 (CEST)**: access event page

44

Upcoming SPOR & XEVMPD engagements (2/2)



Q&A Clinics on SOR

New dates for 2026 available!

- **10 February 2026** (11:00 – 12:00 CET): Register here
- **10 March 2026** (11:00 – 12:00 CET): Register here
- **14 April 2026** (11:00 – 12:00 CEST): Register here
- **12 May 2026** (11:00 – 12:00 CEST): Register here

Q&A Clinics on PMS

New dates for 2026 available!

- **10 February 2026** (15:00 – 16:00 CET): Register here
- **10 March 2026** (15:00 – 16:00 CET): Register here
- **14 April 2026** (15:00 – 16:00 CEST): Register here
- **12 May 2026** (15:00 – 16:00 CEST): Register here

Q&A Clinics on XEVMPD

New dates for 2026 available!

- **12 February 2026** (15:00 – 16:00 CET): Register here
- **12 March 2026** (15:00 – 16:00 CET): Register here
- **16 April 2026** (15:00 – 16:00 CEST): Register here
- **13 May 2025** (15:00 – 16:00 CEST): Register here

SPOR & XEVMPD customer satisfaction survey - link

(open until 8 March 2026)

Conclusions

 For questions: www.slido.com code: #STUP280126

Q4 highlights

Improve customer satisfaction and success

- Provide increased and targeted customer engagement
  - SMS guidance V3.2
  - New Customer satisfaction survey launched

Deliver efficient and effective regulatory data services

- Maintain the provision of S, O, R and XEVMPD/PMS data management services
  - SMS: SSG1 re-cleansing
  - OMS: EnprEMA mapping
  - RMS: MedDRA V28.1
  - XEVMPD/PMS: XEVMPD UI docs updated; Validation priority given to **new products over new pack sizes**
- **Evaluate** Data Management Tender

Modernise data & information management

- Improve S, O, R and XEVMPD/PMS data management capabilities
  - OMS: **Version reason - available in the exports**
  - ⚠ RMS: **List exports back in SPOR portal**
  - XEVMPD: New XEVMPD UI UAT; XEVMPD UI go-live Q1 2026

Q1 objectives

Deliver efficient and effective regulatory data services

- Maintain the provision of S, O, R and XEVMPD/PMS data management services
  - SMS: Animals cleansing
  - OMS: Category values/description review
  - RMS: ATC H & V (v.2026) updates
  - XEVMPD/PMS: mapping NCA-PMS data services **extended to end 2027**; **MAHs not able to reference QPPV Codes associated with virtual affiliate profiles in AMPs**; **Submissions of MedDRA PTs in AMPs**
- **Launch** Data Management Framework Contract and **prepare for Knowledge Transfer**

Improve customer satisfaction and success

Provide increased and targeted customer engagement

- SMS Guidance V3.3

Modernise data & information management

Improve XEVMPD/PMS data management services (and capabilities)

- SPOR: Informatica MDM Upgrade
- **OMS: exports available in the portal**
- XEVMPD: **Upgraded XEVMPD UI (XEVMPDweb) available to non-EMA users**

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2025 highlights

SMS guidance for external users updated

The **version v3.0** enhances **clarity on Data Enrichments** (INN, USAN, Custom Attributes, etc.) and **Business Rules** (for chemicals and veterinary vaccines)

The **version v3.1** elaborates on **business rules for Herbals and Veterinary vaccines**, improving user awareness and predictability in substances registration and maintenance.

Substance data quality continues to be improved

All herbal substance records (**~4.000** , 6% of all substances) were **cleansed in Q3 2025** and enriched with all UNII codes available, all names from the Ph. Eur. and several names from the Chinese Pharmacopoeia.

This will enable outsourcing of herbals in 2026 improving operational efficiency.

It also contributed to achieving the key milestone of **over 50% of all substance records cleansed**.

OMS monthly currency

Since February 2025, OMS conducts **monthly checks on organisations** not updated for over two years to keep OMS data current and prevent the use of inactive organisations in regulatory processes.

OMS improved versioning

From 16 July 2025 the OMS system and API made available to users clearer **information on the reason for creation of a new version** to improve transparency and traceability of changes.

For each new version, 2 fields maintained in OMS:

- **Version type:** standard RMS terms on what changed
- **Version comment:** further details on reason/outcome (e.g. which ID will become the master/prevail)

OMS mandatory in Spain

As of 15 July 2025, the **Spanish NCA (AEMPS) made OMS mandatory for:**

- applications for new registrations and MA variations for nationally registered medicines
- applications for national codes for centrally authorised medicines and their variations

Update of manufacturing activity

Manufacturing Activity list is used across **inspections/ EudraGMPD, eAF** and now also in **PMS**, specifically for the required enrichment of manufacturers to support shortages analysis.

RMS led review by Network experts of **short names**, **other names** and **descriptions** improved clarity of terms in the **Manufacturing Activity list**, enhancing PMS interface and reducing errors from unclear terminology.

Publication of summaries of yearly updates for ATC Human, ATC Vet and VedDRA lists in RMS

RMS publishes a **summary of yearly changes** for the **ATC H, ATC V** and **VedDRA lists** in the Documents section of the RMS portal containing the **mappings** between the **ATC/VedDRA codes** and the **RMS IDs**.

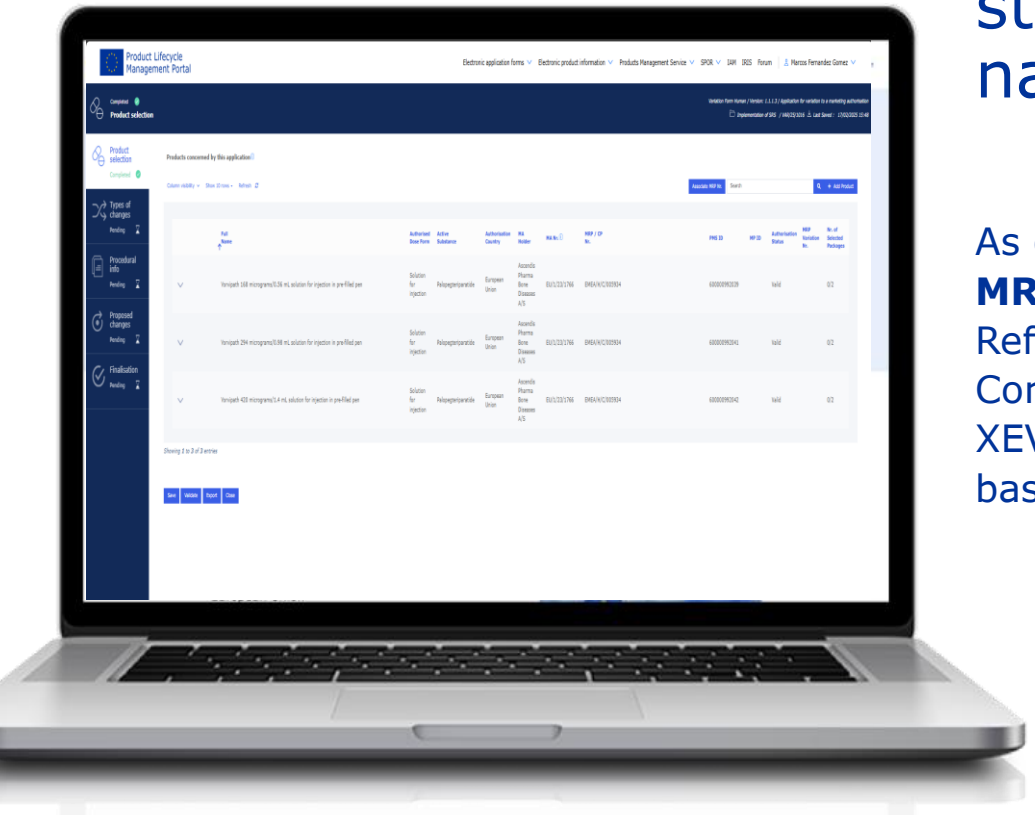
This is to increase **transparency** and enable the **quick identification** of **new** and **updated** terms.

Strengthening our lists content with SME expertise

We have successfully established our **SME network** for 3 key lists (**Special Precautions for Storage**, **Shelf-life**, **Materials**).

This will result in a stronger governance, more accurate and up-to-date lists, reduced rework, clearer decision making and greater confidence for users.

XEVMPD new authorisation status: Valid – pending national phase

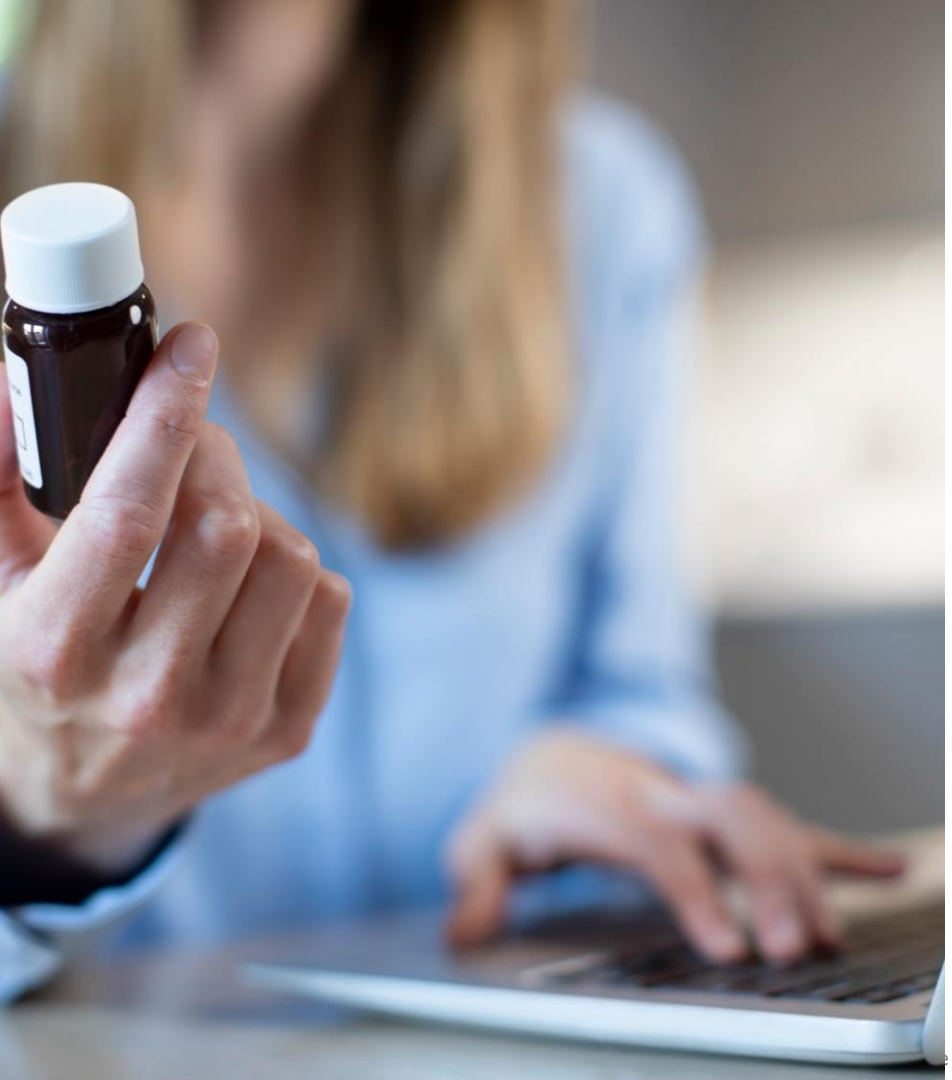


As of January 2025, MAHs can **submit MRP/DCP products authorised** by the Reference Member State (RMS) but still under Concerned Member State (CMS) evaluation to XEVMPD, ensuring availability in the web-based eAF when needed.

QPPV and CCI information data-masked in XEVMPD

As of January 2025, QPPV and CCI information in XEVMPD was data masked for most EMA staff and contractors to further **reduce internal access and minimise risk of unintended disclosure**.

This information is only disclosed to selected members on well-justified, need-to-know basis.



Voluntary submission of composition as in M3 in XEVMPD

As of January 2025, MAHs can **submit**, on voluntary basis, **the medicinal product composition** as stated in **Module 3** instead of as stated in the SmPC.

That allows web-based variation form to capture the same information as stated in the dossier.

Validation of XEVMPD newly submitted product records improved

To cope with increased demand for validation of new products records in XEVMPD key improvements were introduced:

- simpler checks against OMS/SMS/RMS resulting in **increased 30% process efficiency;**
- **prioritisation of new products over new packages** resulting in more targeted validations.
- validation in clusters allowed to increase validation volumes without increasing operational cost.

The team is able validate the additional package submissions required for shortages while reducing effort, time and cost.

PMS Info-Day - 21 May 2025

Scope of the event:

- ✓ Connect stakeholders with senior leaders on PMS and Network strategy
- ✓ Showcase EMRN digital transformation and seamless product data interaction
- ✓ Share knowledge and align for successful EU PMS implementation

Key takeaways:

1. Improve data quality
2. Simplify submissions and data flows
3. Update roadmap with clear milestones
4. Address national implementation speeds
5. Implement bulk and API enrichment feature

Link to PMS Info-day webpage

PMS API write and PUI bulk update releases

As of January 2025, Product User Interface (PUI) users are able to submit updates to individual medicinal products.

Since September 2025, the PMS API write and PUI bulk update functionalities enable MAHs to **submit high volumes of structured pack sizes, manufacturer details and data carrier identifiers for non-CAPs**, supporting the ESMP and ePI.

Data management tender

Throughout 2025 RDM launched and evaluated the Data Management Tender that underpins **next 6 years of data services provision**.

Driving PMS Quality with Data Mapping, Automation & Community Alignment

Successfully enhanced PMS data quality and regulatory readiness by **engaging 28 NCAs** in product data mapping activitie sthat produced only limited findings, implementing **automated mapping for 25 NCAs**, and fostering alignment through **monthly community-driven meetings**.

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Revitalizing SOR collaboration with new KUG

Successfully re-established in **Q4 2025**, the **SOR Key User Group** brings together **EMA, Network, and Industry representatives** to advise on S/O/R data management changes, consolidate user feedback, and cascade key messages across the community.

NDSG recommendations for human Product Master Data implementation and data management

- NDSG recommendations for human Product Master Data implementation and data management adopted by NDSG (April 2025) and endorsed by HMA and EMA Management Board (June 2025).
    - includes guiding principles, operational recommendations to support effective and efficient execution, and a step-wise approach for delivery and benefits delivered by human medicinal product master data.
    - These principles and recommendations will serve as the foundation upon which a model for the EMRN working arrangements for PMS data qualification and use can be agreed by end of 2025.
- Available at: Medicinal Product master data for better regulation and better health - NDSG recommendations for human Product Master Data implementation and data management
- Publication is in progress: Data in regulation: Big data and other sources | European Medicines Agency (EMA)

HMA
Heads of Medicines Agencies

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SCIENCE MEDICINES HEALTH

15 May 2025
EMA/135628/2025

Medicinal Product master data for better regulation and better health

NDSG recommendations for human Product Master Data implementation and data management

This paper provides the NDSG recommendations for human Product Master Data implementation and data management and includes operational recommendations from the Regulatory Optimisation Group (ROG) to support effective and efficient execution. A programme of work with Marketing Authorisation Holders (MAH) and Sponsors is being undertaken to understand their views and identify the steps they will need to take.

The goal is to achieve a **shared centralised repository** of human medicinal product information at EU level, supporting the product data lifecycle via a **unified entry point** for initial and subsequent product data submissions.

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Thank you

More information: SPOR Web Page

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