

# SPOR & XEVMPD Status Update

Recent & planned changes and impacts to users

13 April 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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# Housekeeping notes – Q&A

You can ask questions or give your input via the audience interaction tool **Slido**.

1. **Join at [slido.com](https://www.slido.com)** with the code #STUP130426 or by scanning the QR code here.

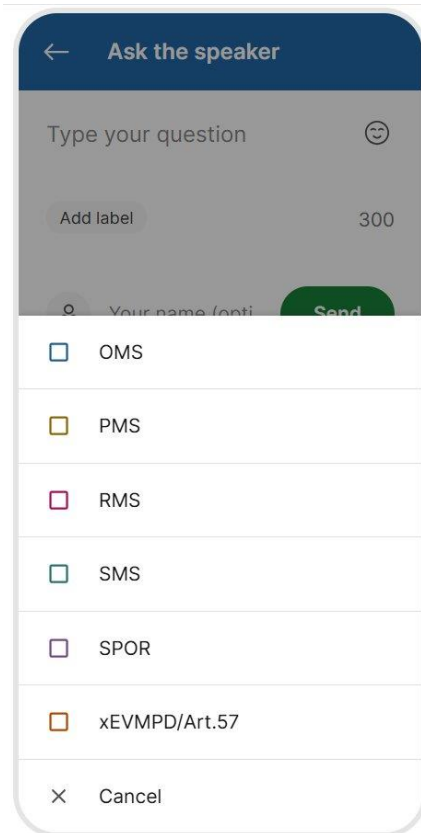


2. **Send or upvote the questions** you want to hear answered
3. **Questions will be shown on the screen** and EMA colleagues will **verbally address top 5 voted questions** in the live Q&A sessions.

# 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*



Ask the speaker

Type your question

Add label 300

Your name (optional) Send

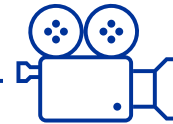
- OMS
- PMS
- RMS
- SMS
- SPOR
- xEVMPD/Art.57
- Cancel

# 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

# 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.**

# 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, Data management handover

15 mins presentation + 5 mins Q&A

12:00 – 12:20

9

## Conclusions

5 mins presentation +

5 mins Slido survey

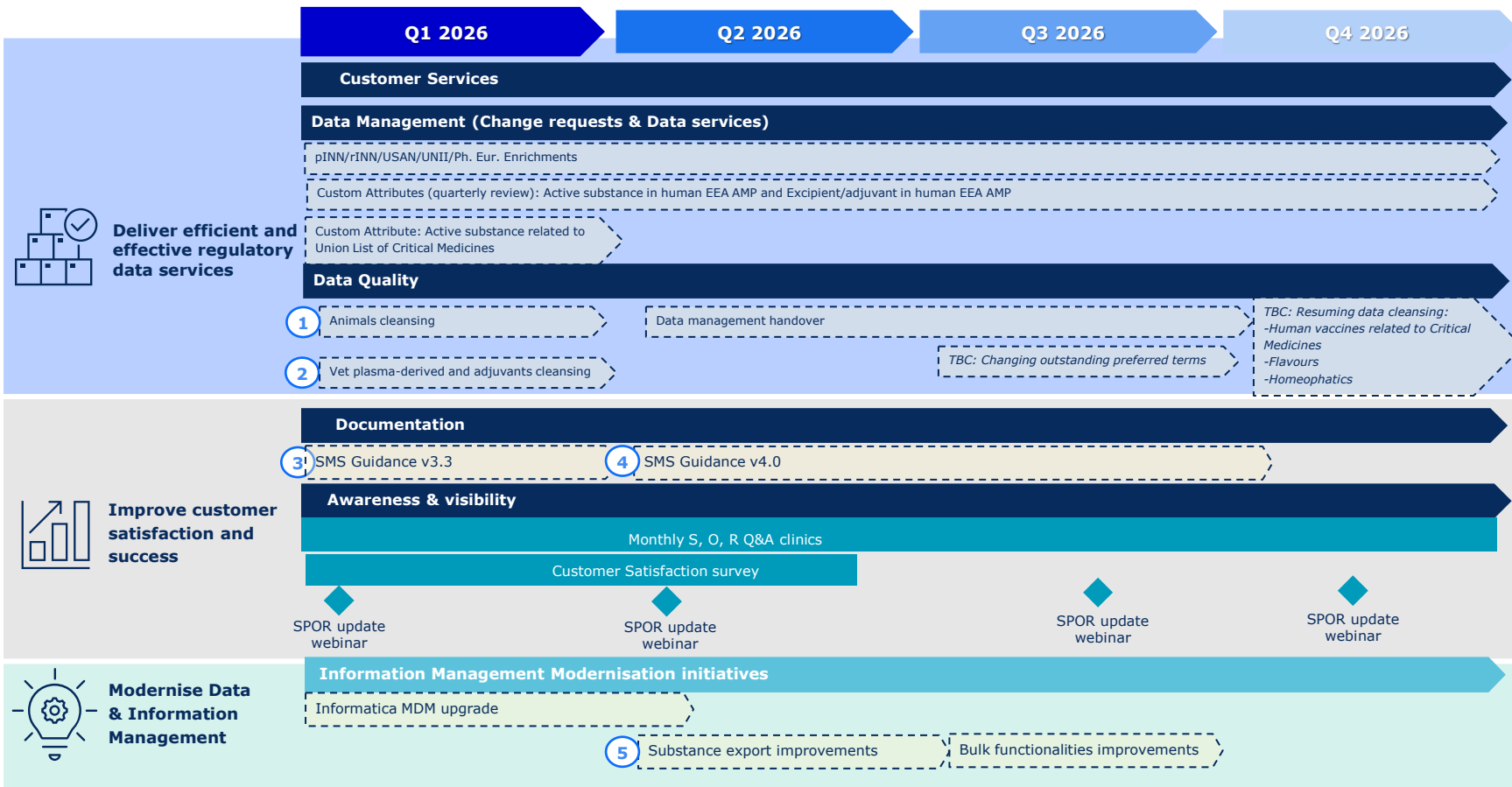
12:20 – 12:30

6

For questions: [www.slido.com](http://www.slido.com) code: #STUP130426

# SMS status update

# Planned SMS Activities



# Work completed – What has been done in Q1 2026



## Why



## How & when



## Impact/ benefits to users

	Why	How & when	Impact/ benefits to users
<b>1</b> <b>Animal cleansing</b>	<ul style="list-style-type: none"> <li>Quick win, easy to cleanse and outsource</li> </ul>	<ul style="list-style-type: none"> <li>Business rules agreed by the SVG in March</li> <li><b>All animal records</b> (whole and part) <b>cleansed in SMS</b> in March</li> <li>Outsourcing of this substance group started in March</li> <li>Business rules published in SMS Guidance v3.3</li> </ul> <p>Note: allergen extracts (Structurally Diverse – Allergens) are not included in this substance group</p>	<ul style="list-style-type: none"> <li><b>Improved Data Quality</b></li> <li>New substance group (within Structurally Diverse - Other) cleansed and business rules defined for new substance records</li> <li>Prevention of pharmacovigilance change requests by proactive registration of animals and animal parts</li> <li>Increased scope of outsourcing</li> </ul>
<b>2</b> <b>Vet plasma-derived and adjuvants cleansing</b>	<ul style="list-style-type: none"> <li>Quick win, easy to cleanse and outsource</li> </ul>	<ul style="list-style-type: none"> <li>Business rules agreed by the SVG in March</li> <li><b>All Vet plasma-derived and adjuvant records cleansed in SMS</b> in March</li> <li>Business rules to be published in the next SMS Guidance version</li> </ul>	<ul style="list-style-type: none"> <li><b>Improved Data Quality</b></li> <li>New substance group cleansed and business rules defined for new substance records</li> </ul>
<b>3</b> <b>SMS Guidance V3.3</b>	<ul style="list-style-type: none"> <li>Reacting to feedback from customer satisfaction survey where customers demanded more and faster access to information</li> </ul>	<ul style="list-style-type: none"> <li><b>New version</b> containing business rules for <b>Animal records</b></li> </ul>	<ul style="list-style-type: none"> <li>Enhanced supporting documentation allowing improved awareness</li> <li><b>Predictability</b> of how substances will be registered and maintained</li> </ul>

# What's next? – What will be done in Q2 2026



## Why



## How & when



## Impact/ benefits to users

### 4 SMS Guidance V4.0

- Reacting to feedback from customer satisfaction survey where customers demanded more and faster access to information

- **Holistic review of the whole Guidance** to be started by KUG in Q2
- Addition of business rules for Vet plasma-derived and adjuvants
- **Publication as** a new major version expected by **end of Q3**

- More frequent **documentation** updates
- Enhanced supporting documentation allowing improved awareness
- **Predictability** of how substances will be registered and maintained






### 5 Substance exports improvements

- Increase access to substance data

- New **columns** to be added in the **substance exports** in the SPOR Portal:
- Export of Current substances
    - **Replacement SMS ID** (for duplicates with SVG flag 0)
    - Ph. Eur. Number (external code)
  - Export of Non-current substances
    - Substance domain

- Additional data available
- Replacement substance in case of duplicates more easily accessible

# Highlights to you

 Animals cleansing cleansing Vet plasma-derived and adjuvants cleansing SMS Guidance version 3.3 (Business Rules for animal records)	 Data Management team handover preparation Substance exports improvements SMS Guidance version 4.0 (Holistic review and business rules for Vet plasma-derived and adjuvants)	 Data Management team handover Changing outstanding preferred terms	 Homeopatics cleansing Human vaccines cleansing SVG flag 0 cleansing
What's changed?	Ongoing work	Future changes (What's next?)	On-hold 

## Acronyms

**SMS:** Substance Management Services

**SVG:** Substance Validation Group

# Q&A time

You can ask questions or give your input via the audience interaction tool **Slido**.

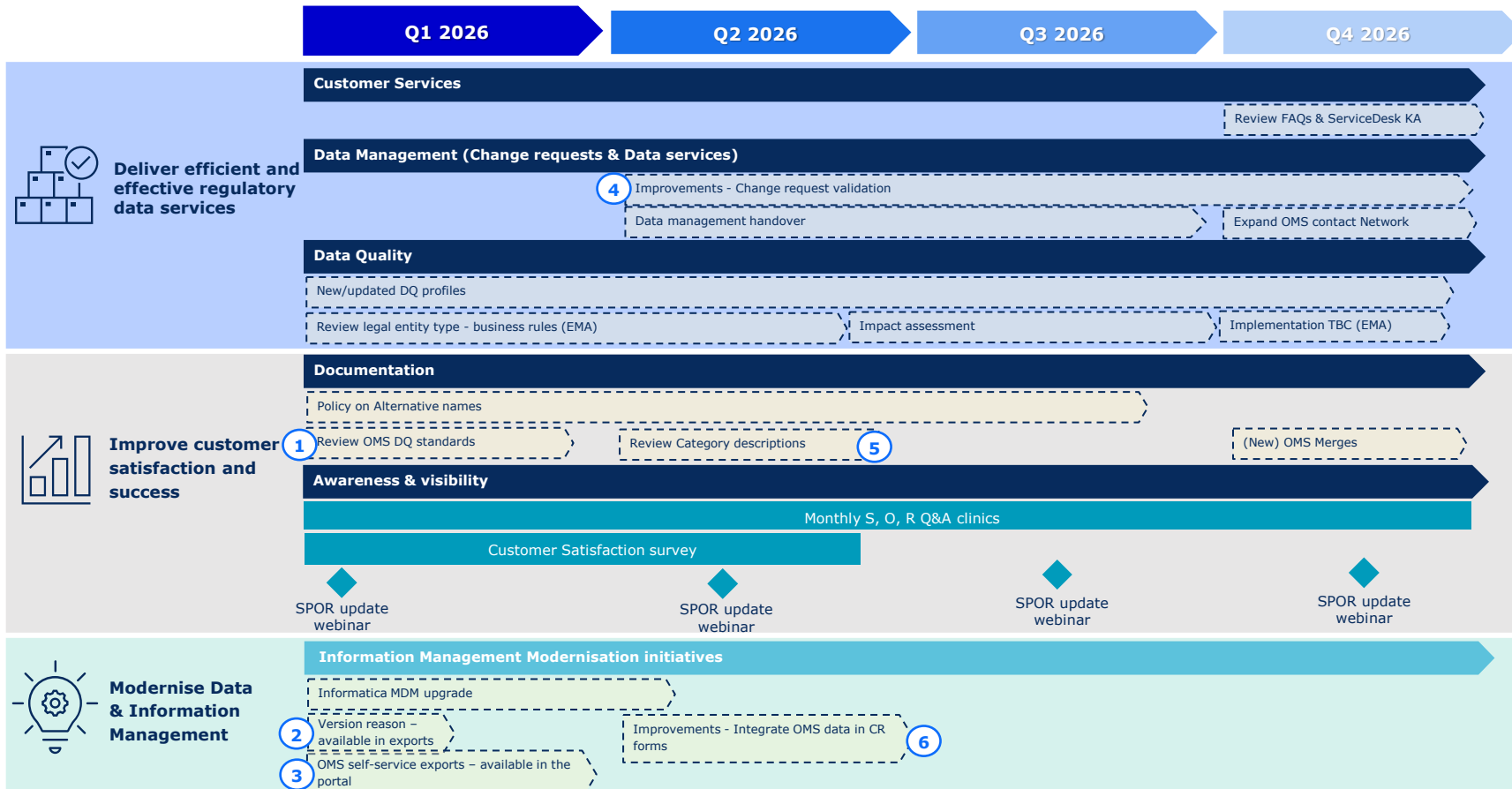
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# OMS status update

# Planned OMS Activities



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# Work completed – What has been done in Q1 2026



## Why



## How & when



## Impact/ benefits to users

### 1 Review OMS DQ standards

- Ongoing and continuous review of **OMS Data Quality standards used by OMS**
- **Transparency** on the standards used during maintenance of OMS data

- Review current and publish new standards adopted by OMS e.g.
  - Inclusion of business rules to maintain entrepreneurs & natural persons records
  - Inclusion/review of organisation validation sources (national business registry) for Monaco, Jordon, India, China

- Clearer standards, business rules and organisation/locations validation sources used as part of the maintenance of OMS data

### 2 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**

### 3 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

# What's next? – What will be done in Q2 2026



## Why



## How & when



## Impact/ benefits to users

### 4 Change request validation *Improvement*

- Continued effort of process **harmonization** across different SPOR domains – RMS have return CR capability
- High number of **rejected** change request ~ 40%
- Slight increase of **SLAs**

- Triage and **validation** to take place in ServiceDesk and
- If necessary, OMS Data Stewards will be able to **request more information** without having the user creating a new ServiceDesk request

- **Improve user experience**
  - **Reduce** the current **waiting time**
  - Reduce rejections, as we introduce the **return change request capability**

### 5 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

- Clearer categorization of OMS records facilitates filtering/usage of data






### 6 Integrate OMS data in CR forms *Improvements*

- Manually typing all fields leads to **mistakes/typos**, longer waiting time, further clarification required and, in some cases, *wrong* rejections

- Improve **OMS form accuracy through dropdown data selection**, meaning allow OMS New location, Update organisation and Update location Change request forms to be populated with OMS data i.e. user will be able to select the organisation ID/name from a dropdown list

- **Improved user experience** since users don't have to copy/paste or type all fields

# Highlights to you

 <p>Version reason - available in the exports</p> <p>OMS exports - available in the portal</p>	 <p>Informatica MDM upgrade</p> <p>Category values/ description review</p> <p>Policy on Alternative names</p> <p>Change request validation improvement</p> <p>Integrate OMS data in CR forms</p>	 <p>Data Management team handover</p> <p>OMS merges guideline</p> <p>Review organisation legal entity types</p>	 <p>OMS improvements/backlog e.g. Maintenance of NBR via CR, return CR</p> <p>Record subscription</p>
<b>What's changed?</b>	<b>Ongoing work</b>	<b>Future changes (What's next?)</b>	<b>On hold</b> 

## Acronyms

**MDM:** Master Data Management solution

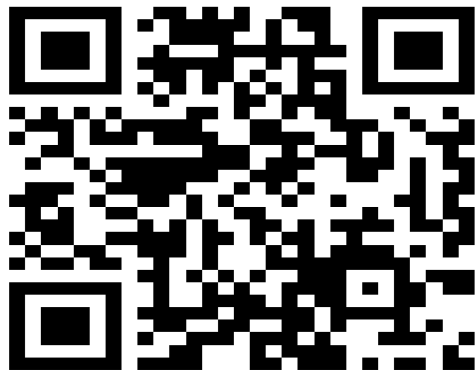
**CR:** Change Request

**NBRn:** National Business Registries number

# Q&A time

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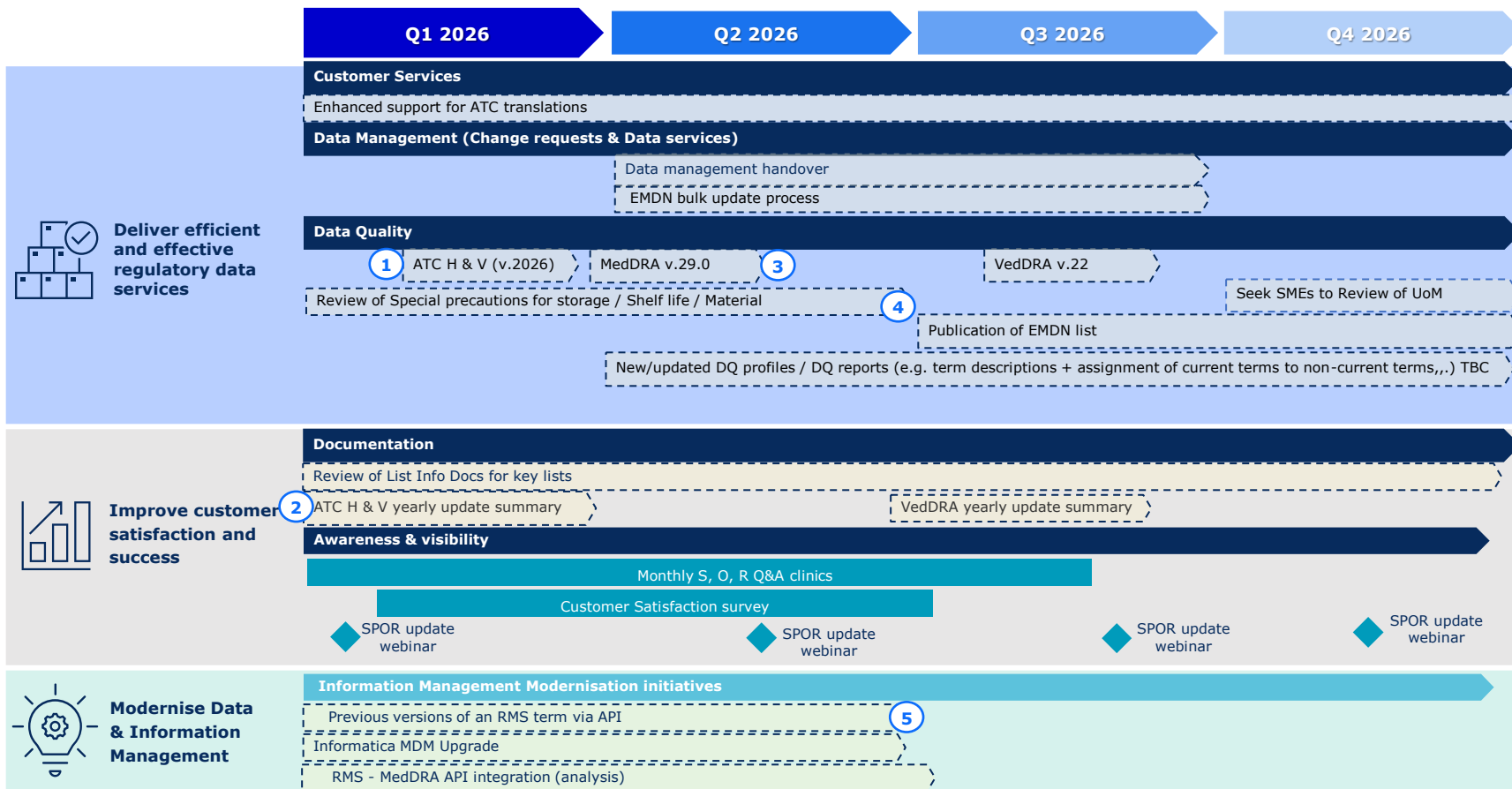


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# RMS status update

# Planned RMS Activities



# Work completed – What has been done in Q1 2026



## Why



## How & when



## Impact/ benefits to users

### 1 ATC H & V (v.2026)

- **ATC H & V** are updated by WHO CC every year around January and they need to be reflected in SPOR RMS.

- Both lists were received from WHO CC end of Feb and the RMS portal was updated accordingly early March.

- **Process efficiency** - Up to date lists should **reduce the number of change requests** to add new terms/codes.

### 2 ATC H&V yearly update summary

- There is **no easy way to identify within the SPOR portal what exactly has changed with the yearly updates.**

- In parallel to the publication of the 2026 version of the ATC H&V lists, a **document showing the new terms inserted and the terms updated with the yearly review** was published in the **Documentation area** of the **RMS portal.**

- Increased **transparency** and **awareness** of lists updates.

# What's next? – What will be done in Q2 2026



Why



How & when



Impact/  
benefits to users

## 3 MedDRA v.29

- MedDRA is updated every March & September by MSSO, RMS publishes the updates asap afterwards.

- MSSO published the new MedDRA v. 29 on 15<sup>th</sup> March and this update was **published** in the RMS portal early April.

- Complete and up to date list in RMS may increase usage and awareness of the list.

## 4 Review of 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 started 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.

## 5 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 early Q2 2026.

- Greater **clarity and transparency of changes**, stable integrations, **improved synchronisations** through flexible version identification and selection, and compliance-readiness for regulated environments.

# Highlights to you



ATC H & V (v.2026)

ATC H&V yearly update summary



Review of Special precautions for storage/Shelf life/Material

Review of List Info Docs for key lists

Informatica MDM upgrade



MedDRA v.29

Data Management team handover

Previous versions of an RMS term via API



RMS – MedDRA API integration

EMDN bulk upload process

**What's changed?**

**Ongoing work**

**Future changes  
(What's next?)**

**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

# Q&A time

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# SPOR & XEVMPD satisfaction survey updates

From 8 October 2025 until 8 March 2026, SPOR & XEVMPD satisfaction survey was publicly available on Slido for users to provide their feedback on services' performance:



## Feedback highlights

Positive feedback on the **supporting documentation** for all SPOR services. Suggestions include consolidating information into a single, synchronised documents when possible.

For all services, more than half of the feedback on **Service Desk support** is fully positive, while most of the remaining comments are neutral.

For SMS, RMS, OMS, and XEVMPD users are generally satisfied with **data quality**. For PMS, open comments highlight concerns about issues with data quality – the team is aware of these and is actively working on it.

Concerning **System/ IT capabilities**, most respondents are fully satisfied with the PMS user interface, SPOR portal, SPOR API and Service Desk portal.

Most respondents are fully satisfied with the processing of **change requests** in OMS and RMS.

Most respondents expressed high satisfaction with **SPOR and XEVMPD engagement activities**, e.g. Q&A clinics and surveys, as well as informational initiatives such as webinars, demos, and newsletters.



**Next survey** will be launched during the **Q4 2026 status update webinar**, and remain open for one month.

# Coffee break

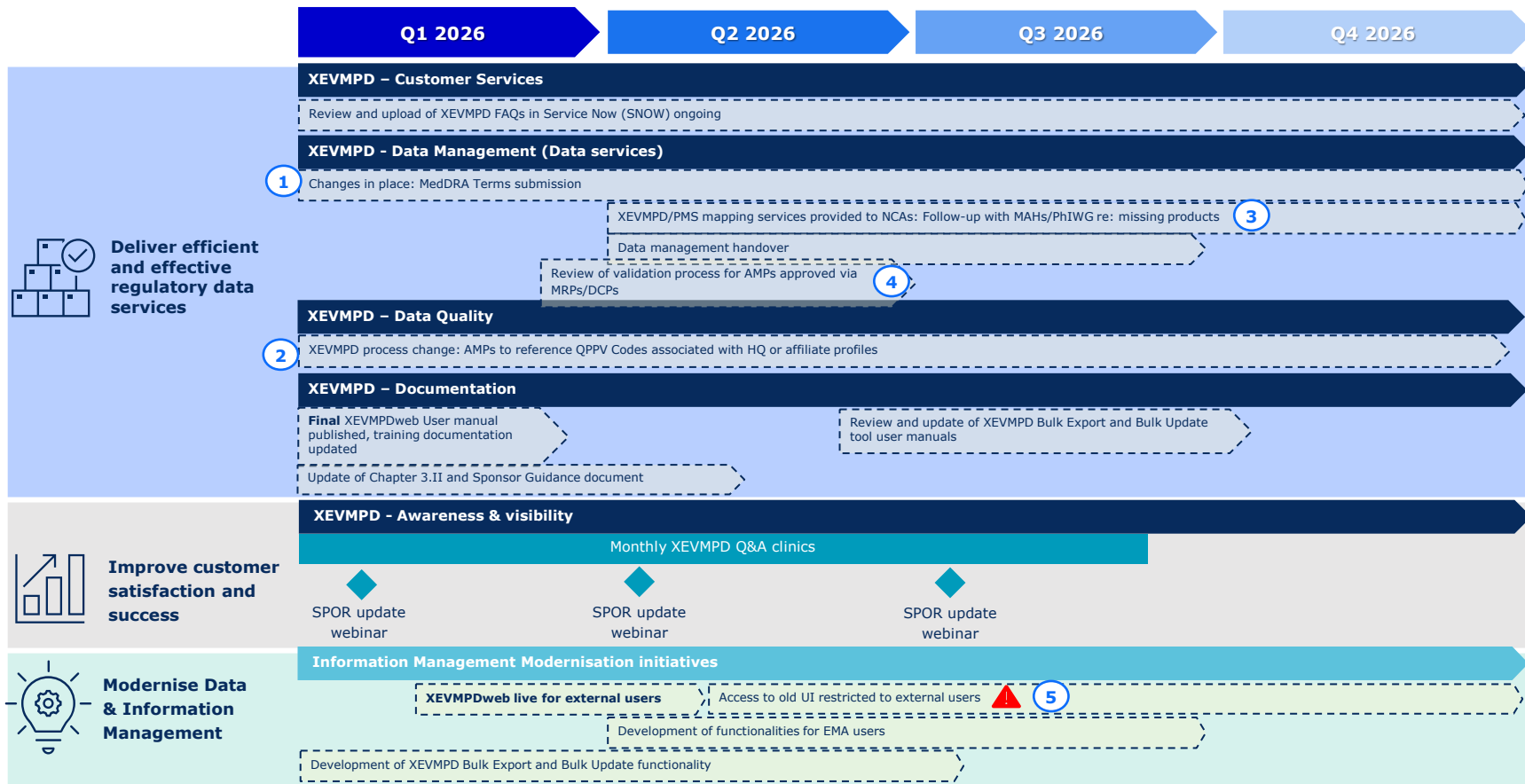


10'



# XEVMPD status update

# Planned XEVMPD Activities



# Work completed – What has been done in Q1 2026



## Why



## How & when



## Impact/ benefits to users

### 1 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 and/or Low Level Terms (LLTs):
  - 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 consistent for all products in a cluster

### 2 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

# What's next? – What will be done in Q2 2026



## Why







## How & when



## Impact/ benefits to users

	Why	How & when	Impact/ benefits to users
3	<p><b>XEVMPPD/PMS mapping services provided to NCAs: Follow-up with MAHs/PhIWG re: missing products</b></p> <ul style="list-style-type: none"> <li>To ensure alignment of data in XEVMPPD/PMS with data in NCAs' databases</li> </ul>	<ul style="list-style-type: none"> <li>By establishing a process of <b>following-up with an MAH when AMP information is missing in XEVMPPD</b> <ul style="list-style-type: none"> <li><i>Discussion planned with PhIWG in June 2026</i></li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Product data in NCA databases is aligned with data in XEVMPPD/PMS</li> <li>Missing data in XEVMPPD/PMS is <b>not raised during PhV inspection</b> with MAH</li> </ul>
4	<p><b>Review of validation process for AMPs approved via MRPs/DCPs</b></p> <ul style="list-style-type: none"> <li>To <b>improve consistency across RMS/CMS data</b> in MRP/DCP products</li> </ul>	<ul style="list-style-type: none"> <li>By discussing the option of validating all products for the <b>same procedure</b> together with NCAs and <b>aligning data of a set of common fields</b> across all records with the <b>data in the RMS record</b></li> <li><b>Preliminary discussions</b> started in March 2026, 'common fields' to be defined and agreed with NCAs</li> <li><i>Further information at next Status update webinar or PMS Info day</i></li> </ul>	<ul style="list-style-type: none"> <li><b>Common data</b> for AMPs approved via MRP/DCP is the <b>same in across all records in XEVMPPD/PMS</b></li> <li>Data is consistent for all products in the same MRP/DCP procedure</li> </ul>
5	<p><b>Access to old UI restricted to external users</b></p> <ul style="list-style-type: none"> <li>To facilitate the decommissioning of the current UI (XEVMPPD EVWEB)</li> </ul>	<ul style="list-style-type: none"> <li><b>From 11 May 2026</b>, external users (MAH, sponsor, NCAs) can access XEVMPPD via the <b>upgraded UI (XEVMPPDweb) only</b> <ul style="list-style-type: none"> <li><b>Access via the current XEVMPPD UI (XEVMPPD EVWEB) no longer possible</b></li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>All external users use the upgraded UI for their submissions           <ul style="list-style-type: none"> <li><b>No need for IE Tab</b></li> <li><b>ActiveX needed only for Bulk Update tool</b></li> </ul> </li> </ul>

# Highlights to you

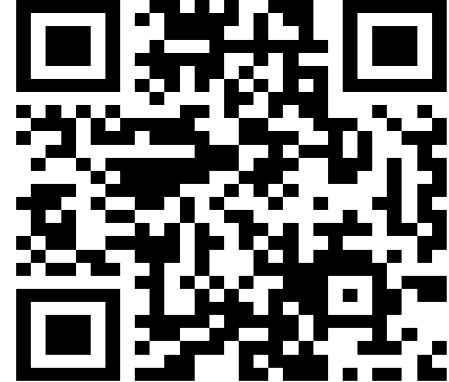
What's changed?	Ongoing work	Future changes (What's next?)	Future changes (What's later?)
 <p>Upgraded <b>XEVMPD UI</b> (XEVMPDweb) made available to non-EMA users in February</p> <p><b>MAHs not able to reference QPPV Codes</b> associated with <b>virtual affiliate</b> profiles in AMPs</p> <p>MAHs can referenced <b>MedDRA PTs, as well as LLTs, in AMPs</b></p>	 <p>XEVMPD/PMS <b>data mapping services</b> provided to <b>NCAs</b></p> <p>Development of <b>XEVMPD Bulk Export</b> functionality in XEVMPDweb</p> <p>Development of XEVMPD Bulk Update functionality in XEVMPDweb</p> <p><b>Review</b> of validation process for AMPs approved via MRPs/DCPs</p>	 <p><b>XEVMPD access for external users via upgraded UI (XEVMPDweb) only</b></p> <p>Data Management team handover</p> <p>Development of functionalities for EMA users in XEVMPDweb</p> <p><b>Amendment</b> of validation process for AMPs approved via MRPs/DCPs</p>	 <p>Improvement on <b>cluster validation process for updated AMPs</b></p> <p>Integration of product validation with review of substances with SVG flag 0</p>

Acronyms	
<b>AMPs:</b> Authorised Medicinal Products	<b>PMS:</b> Product Management Service
<b>FAQs:</b> Frequently Asked Questions	<b>SNOW:</b> ServiceNow
<b>XEVMPD:</b> Extended EudraVigilance medicinal product dictionary	<b>UAT:</b> User Acceptance Testing
<b>NCA:</b> National Competent Authority	

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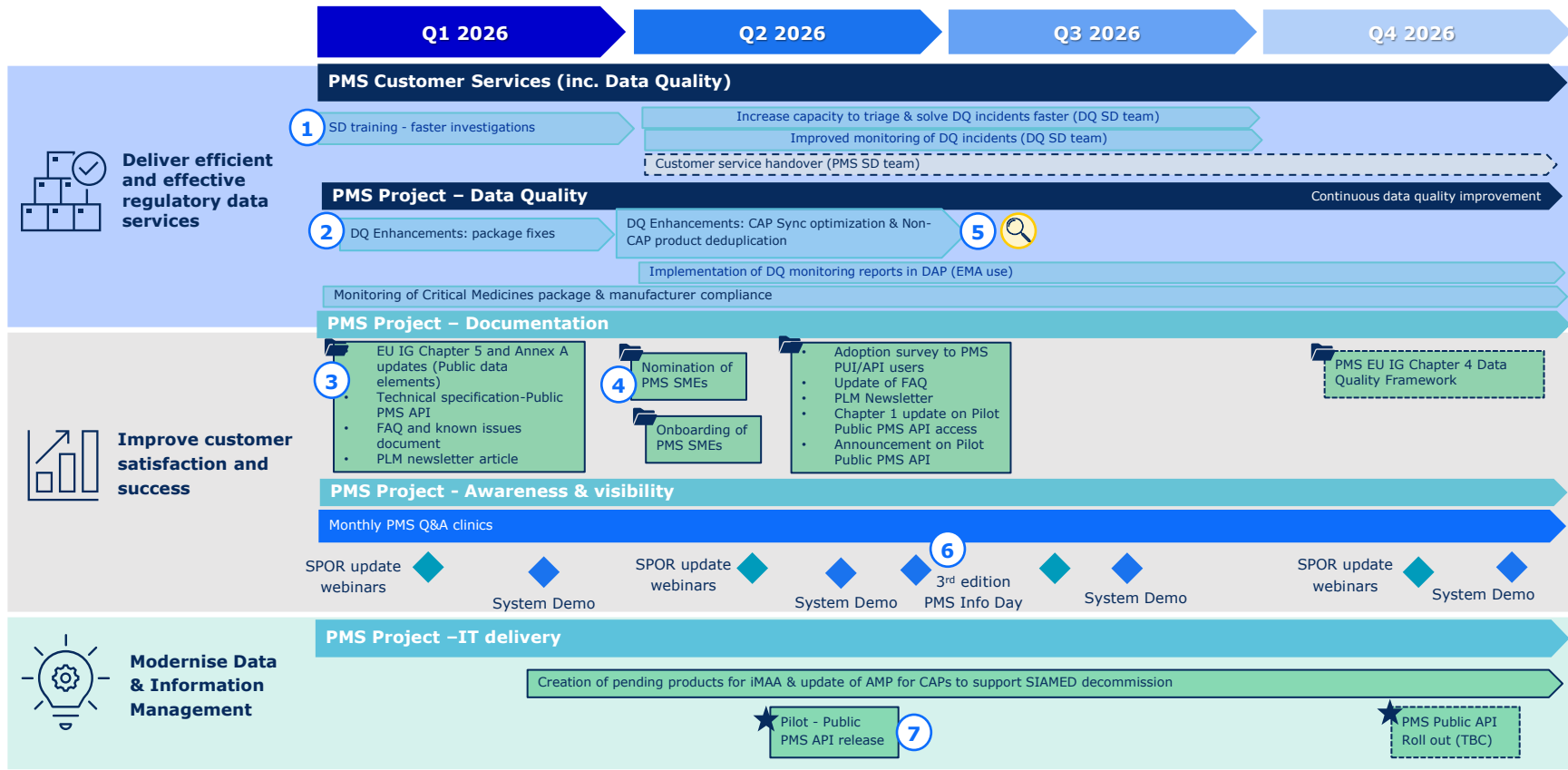
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# PMS status update

# Planned PMS Activities



# Work completed – What has been done in Q1 2026




Why



How & when



Impact/  
benefits to users

<p><b>1 SD training - faster investigations</b></p>	<p>Lengthy investigation of issues across multiple teams.</p>	<p>Training Fist Line Support to investigate/collect info across multiple systems.</p>	<p>Shared workload, faster investigation of issues, leading to faster triage.</p>
<p><b>2 DQ Enhancements: package fixes</b></p> 	<p>Although the root-cause has been technically fixed, previously corrupted data still needs to be corrected.</p>	<ul style="list-style-type: none"> <li>• <b>Transferred pack sizes:</b> In some transferred products, all the EV Codes were created under the same package. We have now created one packaged medicinal product per each EV Code in those cases.</li> <li>• <b>Cleanup of Duplicated non-CAP packages:</b> For each pair, one record is retained and the other nullified on a case-by-case basis.</li> </ul>	<ul style="list-style-type: none"> <li>• Ensure <b>all authorised packages are correctly displayed in PMS/PUI/EAF</b></li> <li>• MAH will see all authorised packages submitted via XEVMPD upon MA transfer in PUI and API (around 27K packages now available).</li> <li>• <b>MAHs should verify package availability and close any remaining open tickets</b></li> </ul>
<p><b>3 PMS documentation updates</b></p>	<p>To provide updated guidance, enhance usability, and increase transparency on data quality status and required fixes.</p>	<p>In <b>Q1 2026</b> the following updates have been published on <b>PMS page/PUI portal</b>:</p> <ul style="list-style-type: none"> <li>• EU IG Chapter 5 and Annex A updates (Public data elements)</li> <li>• Technical specification-Public PMS API</li> <li>• FAQ and known issues document</li> <li>• PLM newsletter article</li> </ul>	<p>Supports <b>proper use of the PMS Public API</b>, clarifies the available public data, reduces integration and interpretation issues, and increases overall transparency and trust.</p>
<p><b>4 Nominations of PMS SMEs</b></p>	<p>The current SME mandate ends in March 2026. A new call was launched to ensure continued collaboration between regulators and industry.</p>	<p>The Network call for expressions of interest was extended until February. Candidate evaluation followed immediately after. EMA is now informing candidates of the results so onboarding can begin promptly.</p>	<p>Ensures <b>continued expert input</b> into regulatory work. Avoids gaps in SME participation. Supports efficient and consistent decision-making. <b>Strengthens stakeholder engagement.</b></p>

# What's next? – What will be done in Q2 2026



## Why



## How & when



## Impact/ benefits to users

### 5 DQ Enhancements: CAP Sync optimization & Non- CAP product deduplication



CAP data quality issues persist from the original SIAMED synchronization.

Although the root cause of duplicate products has been technically resolved, the previously affected data still requires correction.

- **CAP synchronisation optimization** (SIAMED ETL): technical fix is being implemented to prevent future synchronisation issues, including duplicate ingredients and incorrect handling of authorization changes and MAH transfers.
- **Cleanup of duplicated Non-CAP products:** For each pair, one record is retained and the other nullified on a case-by-case basis.

- Ensure **all authorised products are correctly displayed in PMS/PUI/EAF**
- MAHs see **only products needing enrichment** with correct info in the web-based eAF.
- **Improved CAP data** synchronisation, elimination of duplicate ingredients, and more accurate handling of authorization changes and MAH transfers.
- Manual corrections and workload reduced.

### 6 3rd edition PMS Info Day

To enhance awareness and offer comprehensive insights into the implications of PMS for key stakeholders.

Tuesday, **09 June 2026**, 09:00 - 13:00  
Amsterdam time (CEST)

Live broadcast Event page: [Link](#)

Enables direct engagement with leaders, providing insights on PMS progresses, its impacts, benefits, and EU implementation preparedness.

### 7 Pilot - Public PMS API release

A trusted Public EU-Wide source of medicinal product data is a win for Healthcare

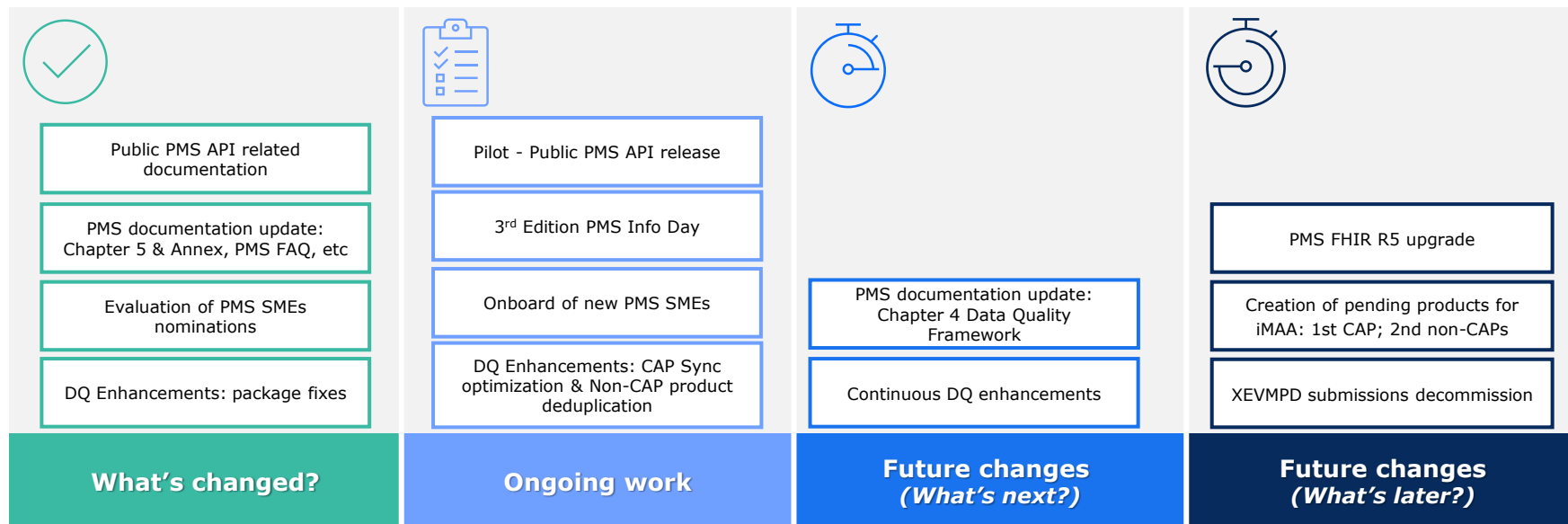
Releasing an early **pilot** makes the PMS Public API **benefits available sooner**, while also allowing **learning and improvements** ahead of the full release.

Pilot Public PMS API launches in **Q2 2026** (May–June). Access details will be on the PMS webpage.

Users must register with an email and accept the terms and conditions.

- Easy access to structured, authorised Public Product data
- Faster integration and automation of workflows
- Enables innovation and new use cases with PMS data
- Empowers users to build, automate, and innovate using our data and technology.

# Highlights to you



**Acronyms**

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

# Adoption survey for PMS users open until 17 April



Objective: Assess users' level of satisfaction with PMS PUI & API use, their experience with user support resources and communication, as well as potential concerns or challenges.



## Cadence

Conducted every year (first survey distributed in 2025)



## Target audience

PMS PUI & API users



## Distribution channel

Direct email to registered users with EUsurvey link received on 1 April 2026



## Question type

Questions on PMS user experience



## Time needed

5 minutes

# Q&A time

You can ask questions or give your input via the audience interaction tool **Slido**.

1. **Join at [slido.com](https://www.slido.com)** with the code #STUP130426 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.

# Feature topics

# New XEVMPDweb UI is live since 10 February 2026!

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



## Satisfaction survey numbers

356 respondents



272 (76%)  
used XEVMPDweb

**Over 80%** think:

- XEVMPDweb is easy to navigate
- XEVMPDweb performs reliably
- Prefer XEVMPDweb compared to EVWEB

**71%** know where to find user manual



## Satisfaction survey Feedback highlights

*"Fast and more user-friendly interface"*

*"Better search functionality,  
no need to use wildcards"*

*"Referencing and posting  
attachments is much easier"*

*"Amazing, no IE tab, no Active X!"*

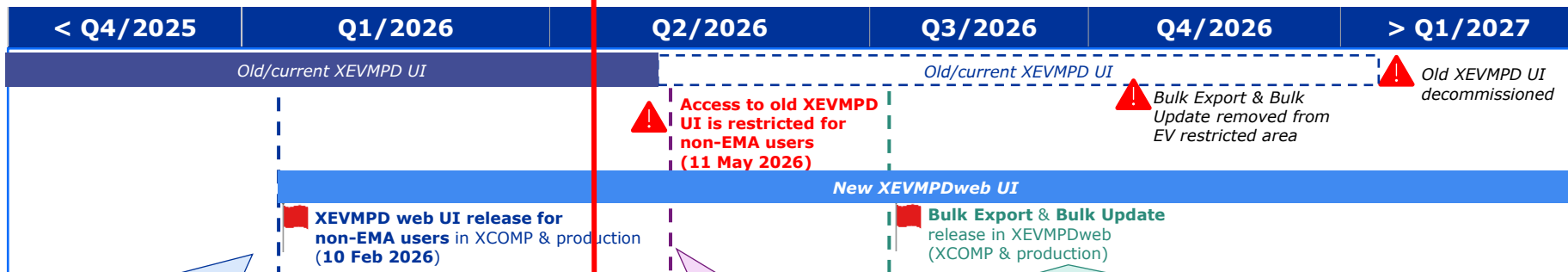
*"Love the possibility to switch between  
organisations without logging off"*

*"Time-out warnings are  
much appreciated"*

*"Easier search for messages  
in Inbox and Outbox"*

# XEVMPDweb UI upgrade plan

We are here



## From 10 Feb to Q2 2026:

- 'Go live' date (10 Feb) and URLs shared with registered users via **email**; URLs to new UI 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 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**

## As of 11 May 2026:

- MAH, sponsor and NCA users **cannot use the old XEVMPD UI (XEVMPD EVWEB)**
  - URL link to old UI is removed from restricted area for external users
  - When direct link is used, a pop-up message with XEVMPDweb link is presented
- MAH, sponsor and NCA users **must use the new XEVMPDweb UI** for their searches and submissions
- The **Bulk Export and Bulk Update tools** are still available in **EV restricted area and ActiveX is still needed to use them** -> foreseen implementation of Bulk Export & Bulk Update tools in XEVMPDweb is in Q3; exact date will be communicated via email to all registered users
- XML files generated via Bulk Update tool can be retrieved from new XEVMPDweb UI

# XEVMPDweb UI useful information

## Access



### URLs to new XEVMPDweb:

- shared via email communication ([production](#), [XCOMP](#)) and
- made available in **EV restricted area, under 'EV Services'** on 11 Feb 2026

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)

# Data Management handover

*Delivering stability today, strengthening services for tomorrow*

## Transition to a new EU-based service supplier

- Align with EU legal and regulatory requirements
- Strengthen personal data protection
- Enhance security for commercially sensitive information
- Meet evolving data sovereignty expectations

## What this means for you

### No disruption to ongoing services

- *Existing service levels will be fully maintained*
- *All existing support channels and points of contact remain unchanged*

### Temporary pause on new enhancements

- *Focus on stability and continuity during the transition period*

## Our commitment

- Controlled, well-structured transition across the coming quarters.
- Fresh perspectives may help to identify improvement opportunities
- A stronger foundation for future capabilities once transition is complete



**We appreciate your partnership and remain available for any questions.**

# Upcoming webinars



## **SPOR & XEVMPD status update webinar**

### ***Registration open***

- **8 July 2026 — 10:00–12:30  
(CEST): [access event page](#)**
- **7 October 2026 — 10:00–12:30  
(CEST): [access event page](#)**

## **PMS Info-day 2026 (3<sup>rd</sup> edition)**

### ***Public broadcast***

- **9 June 2026 — 9:00–13:00  
(CEST): [access event page](#)**

# Upcoming SPOR & XEVMPD engagements



## Q&A Clinics on SOR

- **14 Apr 2026** (11:00 – 12:00 CEST): [Register here](#)
- **12 May 2026** (11:00 – 12:00 CEST): [Register here](#)
- **New dates for 2026** (15:30 – 16:00): 10 Jun, 8 Jul, 9 Sep, 7 Oct, 11 Nov, 9 Dec  
→ *registration available soon on EMA corporate website!*



## Q&A Clinics on PMS

- **14 Apr 2026** (15:00 – 16:00 CEST): [Register here](#)
- **12 May 2026** (15:00 – 16:00 CEST): [Register here](#)
- **New dates for 2026 2x month** (9:30 – 10:30): 11 Jun, 25 Jun, 9 Jul, 23 Jul, 10 Sep, 24 Sep, 8 Oct, 22 Oct, 12 Nov, 26 Nov, 10 Dec  
→ *registration available soon on EMA corporate website!*



## Q&A Clinics on XEVMPD

- **16 Apr 2026** (15:00 – 16:00 CEST): [Register here](#)
- **13 May 2025** (15:00 – 16:00 CEST): [Register here](#)
- **New dates for 2026** (15:00 – 16:00): 11 Jun, 9 Jul, 10 Sep, 8 Oct, 12 Nov, 10 Dec  
→ *registration available soon on EMA corporate website!*

# Conclusions

# Q1 highlights

## Deliver efficient and effective regulatory data services

- Maintain the provision of S, O, R and XEVMPD/PMS data management services
  - SMS: Animals and Vet plasma-derived cleansing
  - RMS: ATC H & V (v.2026) updates + Yearly Update summaries
  - 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
  - OMS: OMS DQ standards updated

## Modernise data & information management

- Improve S, O, R and XEVMPD/PMS data management capabilities
  - SPOR: Informatica MDM Upgrade
  - **OMS: exports available in the portal**
  - **XEVMPD: Upgraded XEVMPD UI (XEVMPD web) available to non-EMA users from 10 Feb 2026**



# Q2 objectives

## Deliver efficient and effective regulatory data services

- Maintain the provision of S, O, R and XEVMPD/PMS data management services
  - SMS: process improvements for team handover
  - OMS: Change request validation improvement (triage, SLA & return)
  - RMS: MedDRA V29 updates

## ⚠️ Data Management Knowledge Transfer

## Improve customer satisfaction and success

Provide increased and targeted customer engagement

## Modernise data & information management

Improve XEVMPD/PMS data management services (and capabilities)

- SMS: Substance export improvements
- OMS: Integrate OMS data in CR forms
- RMS: Previous version via API
- XEVMPD:

⚠️ • **Access to old XEVMPD UI is restricted for non-EMA users from 11 May 2026**

- Development of Bulk Export and Bulk Update tools

⚠️ **PMS : Pilot PMS Public API**





EUROPEAN MEDICINES AGENCY  
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# Thank you

More information: [SPOR Web Page](#)

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