

SPOR & XEVMPD Status Update

Recent & planned changes and impacts to users

08 July 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**



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**. For more information on how EMA processes your personal data when using Slido, please refer to the specific sections on Slido in this [Data Protection Notice](#).

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 #STUP080726 or by scanning the QR code here.

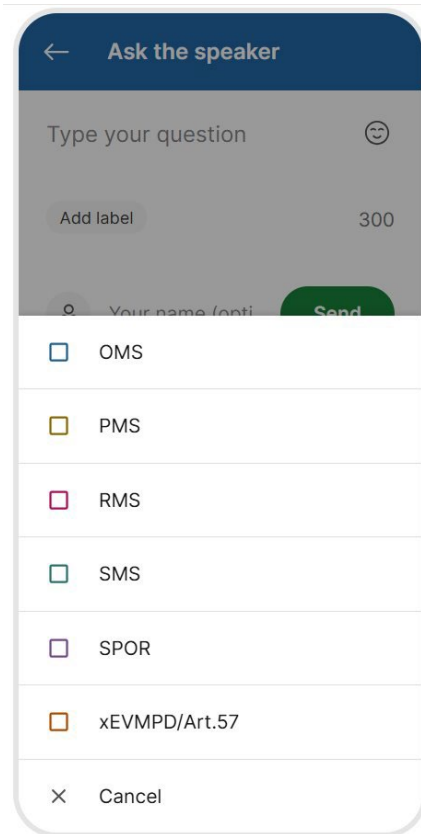


2. **Send or upvote the questions** you want to hear answered
3. **Questions will be shown on the screen** and EMA colleagues will **verbally address top 5 voted questions** in the live Q&A sessions.

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*



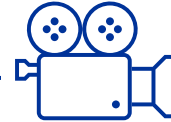
The screenshot shows a mobile application interface titled "Ask the speaker". At the top, there is a back arrow and the title. Below the title is a text input field labeled "Type your question" with a smiley face icon on the right. Underneath the input field is a label "Add label" and a character count "300". At the bottom of the input area is a "Send" button. A dropdown menu is open, showing a list of labels: OMS, PMS, RMS, SMS, SPOR, xEVMPD/Art.57, and a "Cancel" option at the bottom. Each label has a small colored square next to it.

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 + 5 mins Q&A

10:10 – 10:25

3

OMS status update

10 mins presentation + 5 mins Q&A

10:25 – 10:40

4

RMS status update

10 mins presentation + 5 mins Q&A

10:40 – 10:55

5

Coffee Break + survey info

10 mins

10:55 – 11:05

6

XEVMPD status update

10 mins presentation + 10 mins Q&A

11:05 – 11:25

7

PMS status update

10 mins presentation + 10 mins Q&A

11:25 – 11:45

8

Feature topics - OMS Subscriptions, RMS term versions in API

20 mins presentation + 10 mins Q&A

11:45 – 12:15

9

Conclusions

10 mins presentation +

5 mins Slido survey

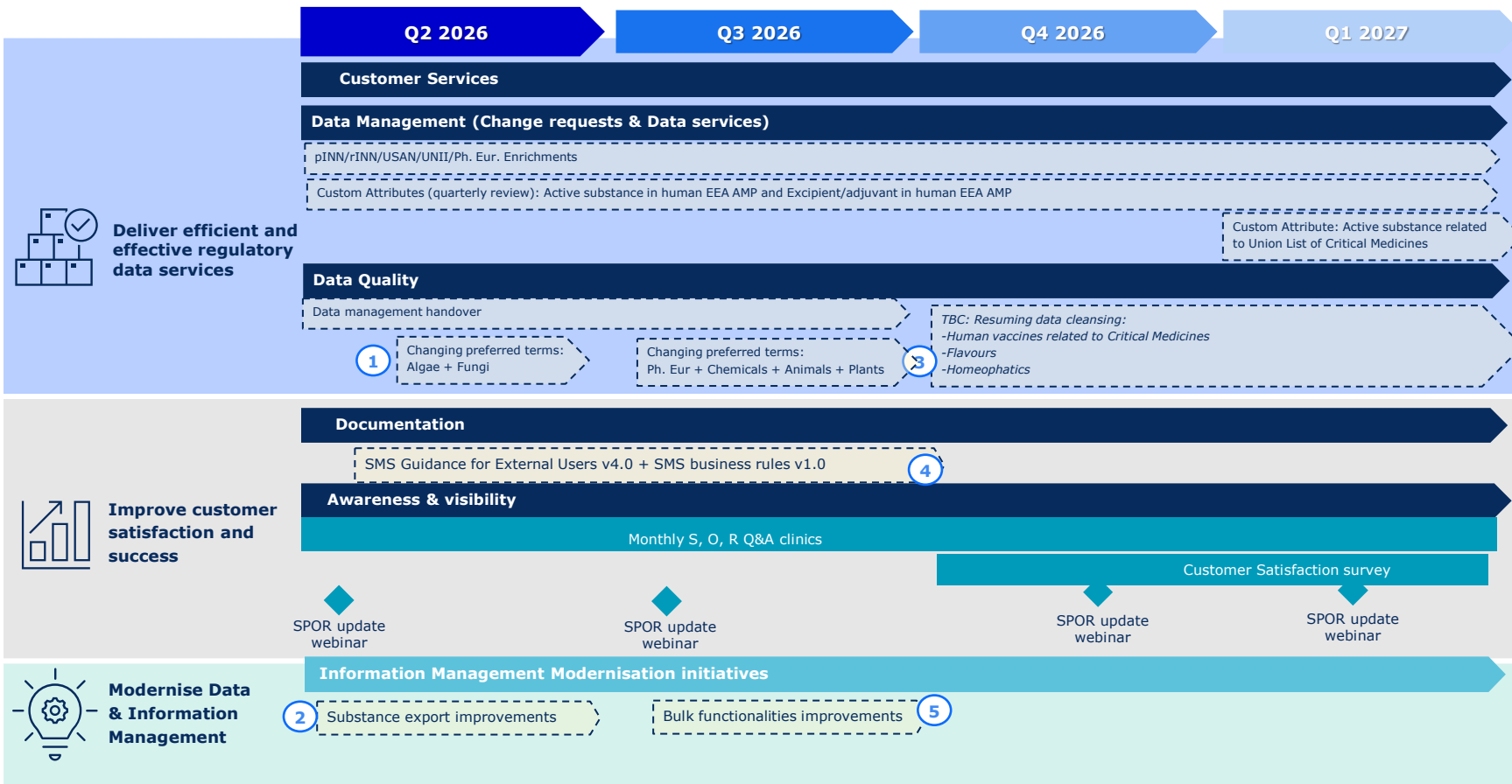
12:15 – 12:30

6

For questions: www.slido.com code: #STUP080726

SMS status update

Planned SMS Activities



Work completed – What has been done in Q2 2026



Why



How & when



Impact/ benefits to users

1

Updating outstanding preferred terms

- The SVG has identified that several substances required a change in the preferred term
- Changing substance preferred terms had an impact on ICSR recoding in Eudravigilance, so these changes have been on-hold

Technical change has been implemented in Eudravigilance to minimise impact on ICSR recoding - April 2026

Substances records with an **outstanding change in preferred term** have started to be updated in **batches by substance type/group**:

- **Algae** – completed in May 2026
- **Fungi** – completed in May 2026

- Improved data quality
- The **correct substance preferred term** is now visible in the eAF and other consuming systems

2

Substance exports improvements

- Increase access to substance data

New **columns** 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

What's next? – What will be done in Q3 2026



Why



How & when



Impact/
benefits to users

3

Updating outstanding preferred terms

- The SVG has identified that several substances required a change in the preferred term
- Changing substance preferred terms had an impact on ICSR recoding in Eudravigilance, so these changes have been on-hold

Substances records with an **outstanding change in preferred term** have started to be updated in **batches by substance type/group**:

- Ph. Eur. - planned for July 2026
- Animals - planned for July 2026
- Chemicals - planned for August 2026
- Plants - planned for September 2026

- Improved data quality
- The correct substance preferred term is now visible in the eAF and other consuming systems
- Cleansing changes recommended by the SVG can be implemented quicker

4

SMS Guidance V4.0 + SMS Business Rules V1.0

- Reacting to feedback from customer satisfaction survey where customers demanded more and faster access to information
- Following Key User Group recommendation of splitting the SMS Guidance for External Users and the SMS Business Rules into separate documents

- **Holistic review of the whole Guidance** to be started by KUG in Q2
- **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






Bulk functionalities improvements

- Several bulk functionalities are available in SMS but only for one single SMS section at a time
- All bulk functionalities trigger updates in XEVMPD and EUTCT, even if the data fields updated do not exist in these systems

- **New bulk functionality** to be developed for updating **multiple** SMS sections at once of **duplicate records**:
 - Comments
 - SVG flag 0
 - Replacement substance
- Already existing bulk functionalities will only trigger updates in systems that have the **relevant data fields**

- Outcome of data enrichment and cleansing exercises **more quickly available in SMS**
- Unnecessary updates on consuming systems **no longer triggered**

Highlights to you

 Changing preferred terms: Algae + Fungi Substance exports improvements	 Data Management team handover Finalising changes in preferred terms: Ph. Eur. + Chemicals + Animals + Plants SMS Guidance version 4.0 + SMS Business Rules 1.0 Bulk functionalities improvements	 Human vaccines cleansing Flavours cleansing Homeopathics cleansing	 SVG flag 0 cleansing
What's changed?	Ongoing work	Future changes (<i>What's next?</i>)	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**.

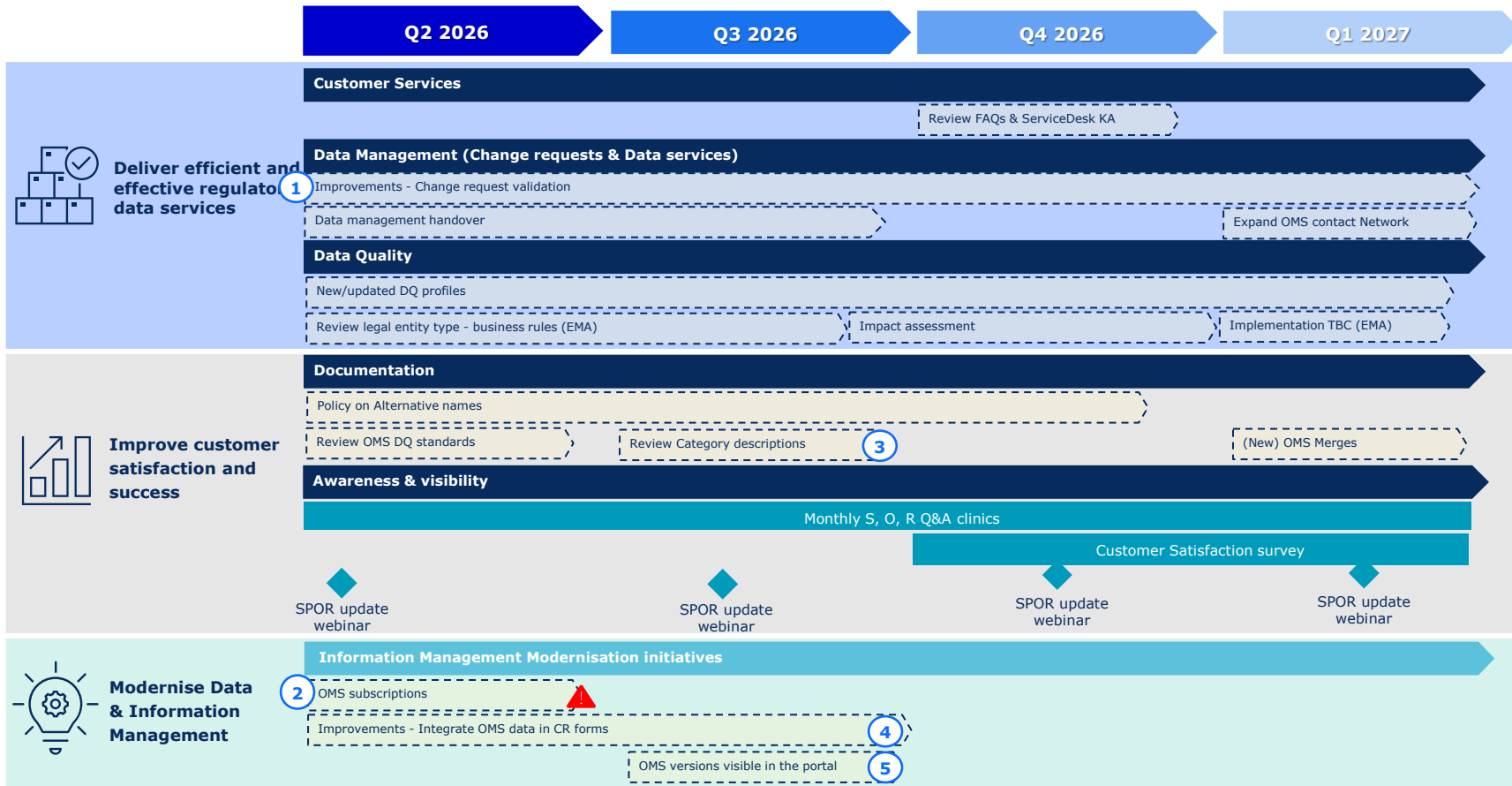
1. **Join at [slido.com](https://www.slido.com)** with the code #STUP0807426 or by scanning the QR code here.



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.

OMS status update

Planned OMS Activities



For questions: www.slido.com code: #STUP080726

Work completed – What has been done in Q2 2026



Why



How & when



Impact/ benefits to users

1 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
- If necessary, OMS Data Stewards will be able to **request more information** without having the user creating a new ServiceDesk request – **in Q2 20% decrease of rejected change requests**

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

2 OMS subscriptions

- OMS data is **updated through change request and data services** activities
- Users often do not review OMS data prior to regulatory submission, so when data, business or standardization changes occur, there may be insufficient time to clarify them

- Every Monday, user will receive a **weekly email notification**, with a summary of changes that were implemented, during last week, in the subscribed organisations
- To receive notifications, users must **select the organisation they wish to subscribe, using the newly created Preference tab** available in the OMS portal
- This feature available since **24/06/2026**

- **Improved user experience**
 - When OMS data changes occur to subscribed organisations a **weekly email notification** will be sent
 - **Support users with the preparatory work** necessary prior to regulatory submissions - **reduce** hassle associate **to last minute clarifications**

What's next? – What will be done in Q3 2026



Why



How & when



Impact/ benefits to users

3 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

4 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 Change request forms for New location, Update organisation and Update location 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






5 OMS versions visible in the portal

- **Easier and faster visibility of the latest version reason** at both organisation and location level

- When available, we will **display in the OMS portal**, under location detail's view (when you click to pen each individual record), **respective latest version** information for both organisation and location:
 - Version type – standard RMS terms
 - Version comment – further details on reason/outcome

- **Improved user experience** – details previously available only through OMS exports and OMS API are now added to the **OMS portal**

Highlights to you

What's changed?	Ongoing work	Future changes (What's next?)	On hold
 <p>Informatica MDM upgrade</p> <p>Change request validation improvement – return CR & reduction by 20% of rejected CR</p> <p> OMS subscriptions</p>	 <p>Data Management team handover</p> <p>Integrate OMS data in CR forms</p> <p>Category values/ description review</p> <p>Policy on Alternative names</p>	 <p>OMS merges guideline</p> <p>Review organisation legal entity types</p> <p>OMS versions visible in the portal</p>	 <p>OMS improvements/backlog e.g. Maintenance of NBRn via CR</p>

Acronyms

MDM: Master Data Management solution

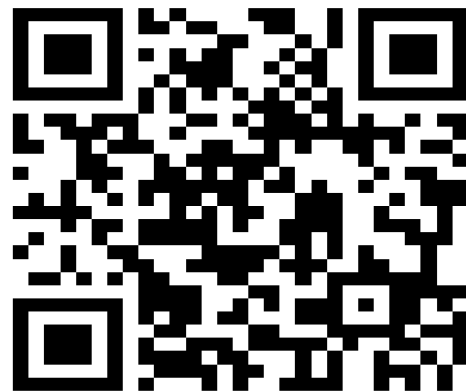
CR: Change Request

NBRn: National Business Registries number

Q&A time

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

1. **Join at [slido.com](https://www.slido.com)** with the code #STUP080726 or by scanning the QR code here.

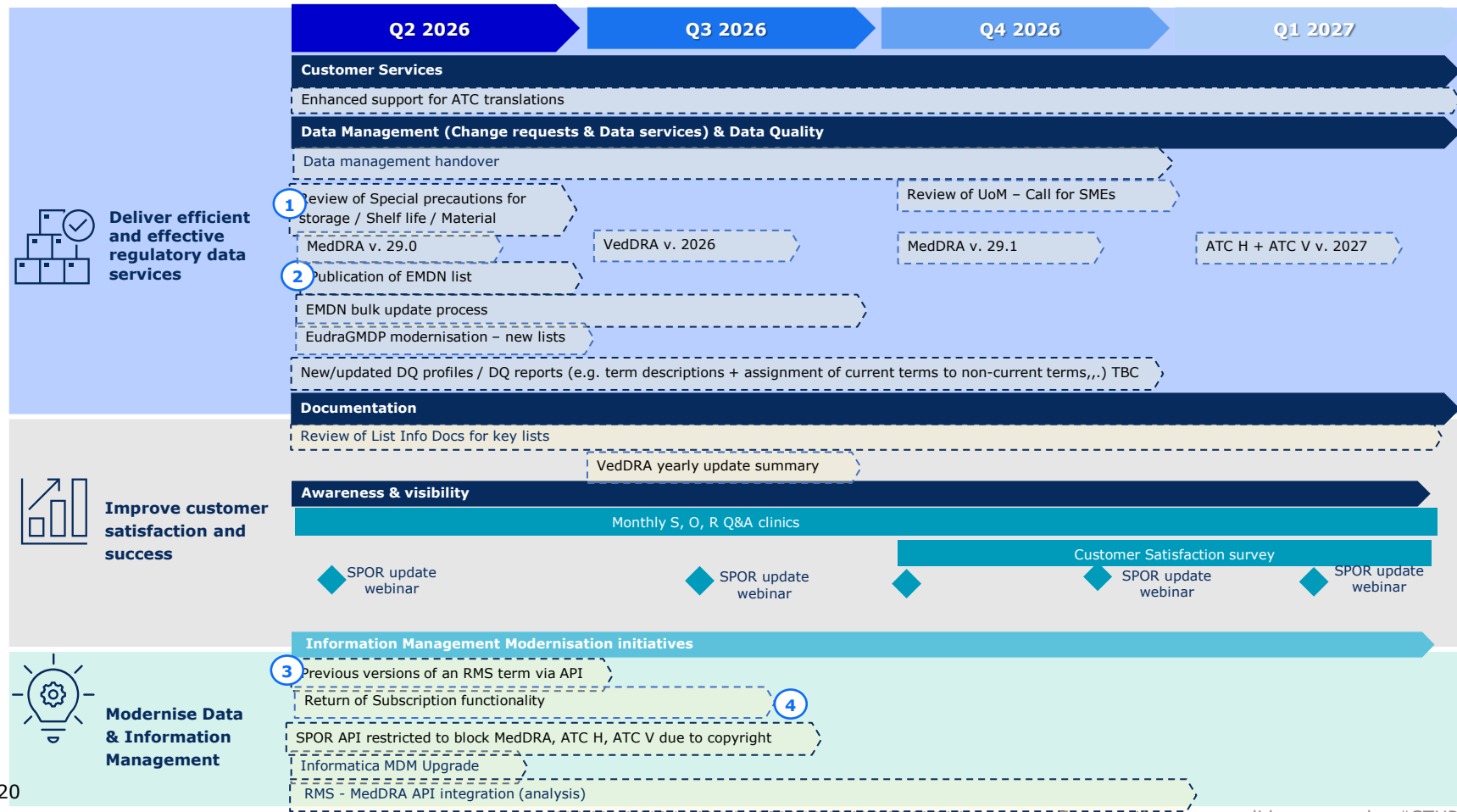


2. **Send or upvote the questions** you want to hear answered
3. **Questions will be shown on the screen** and EMA colleagues will **verbally address top 5 voted questions** in the live Q&A sessions.

*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](#).*

RMS status update

Planned RMS Activities



Work completed – What has been done in Q2 2026

Why

How & when

Impact/ benefits to users

1

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 **results** (rejected terms, new terms, revised names) by the end of Q2 2026. - Minutes of discussions available in RMS portal: Documents

- **B6**_Shelf life type_Review June 2026;
- **B7**_Special Precaution for Storage_Review June 2026;
- **B8**_Material_Review June 2026
- **Lists updated** in 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.

2

Publication of EMDN list

- Controlled vocabulary of **medical devices** is necessary in RMS for the PMS attribute "**Medical device nomenclature**".

- **EMDN** agreed as gold standard. List published in June 2026, containing **mappings** between EMDN codes and RMS IDs. List will be updated on a yearly basis

- EMDN list available in RMS for consumption by PMS users for product enrichment.

3

Previous versions of a term via RMS 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 completed 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.

What's next? – What will be done in Q3 2026



Why



How & when



Impact/ benefits to users

4






Return of subscription functionality

- Subscriptions (automated notifications of changes in RMS lists), which were temporarily disabled during the transition to the EMA Service Desk as the central point of contact for all CRs, are now being reinstated to enhance visibility and communication.

- Functionality **similar to the previous one** will be reinstated during Q3 2026.
- **E-mail address** will be required. A confirmation e-mail will be sent for confirmation by the user.
- No log in will be required.
- *Analysis will be held in Q3 to determine if/what improvements can be considered in the future.*

- Users will receive automated notifications when lists are updated, eliminating the need for manual checks and improving awareness of RMS changes.

Highlights to you

 Informatica MDM upgrade Review of Special precautions for storage/Shelf life/Material EudraGMDP modernisation – new lists Publication of EMDN list  Previous versions of a term via RMS API	 Data Management team handover EMDN bulk update process Review of List Info Docs for key lists	 Return of Subscription functionality Manuf. Activ. awareness session (Inspections & EudraGMDP) VedDRA v.2026 MedDRA v.29.1	 RMS – MedDRA API integration Review of UoM – Call for SMEs ATC H + ATC V v. 2027
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

UoM: Units of Measurement

API: Application Programming Interface

EMDN: European Medical Device Nomenclature

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 #STUP080726 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.

Coffee break

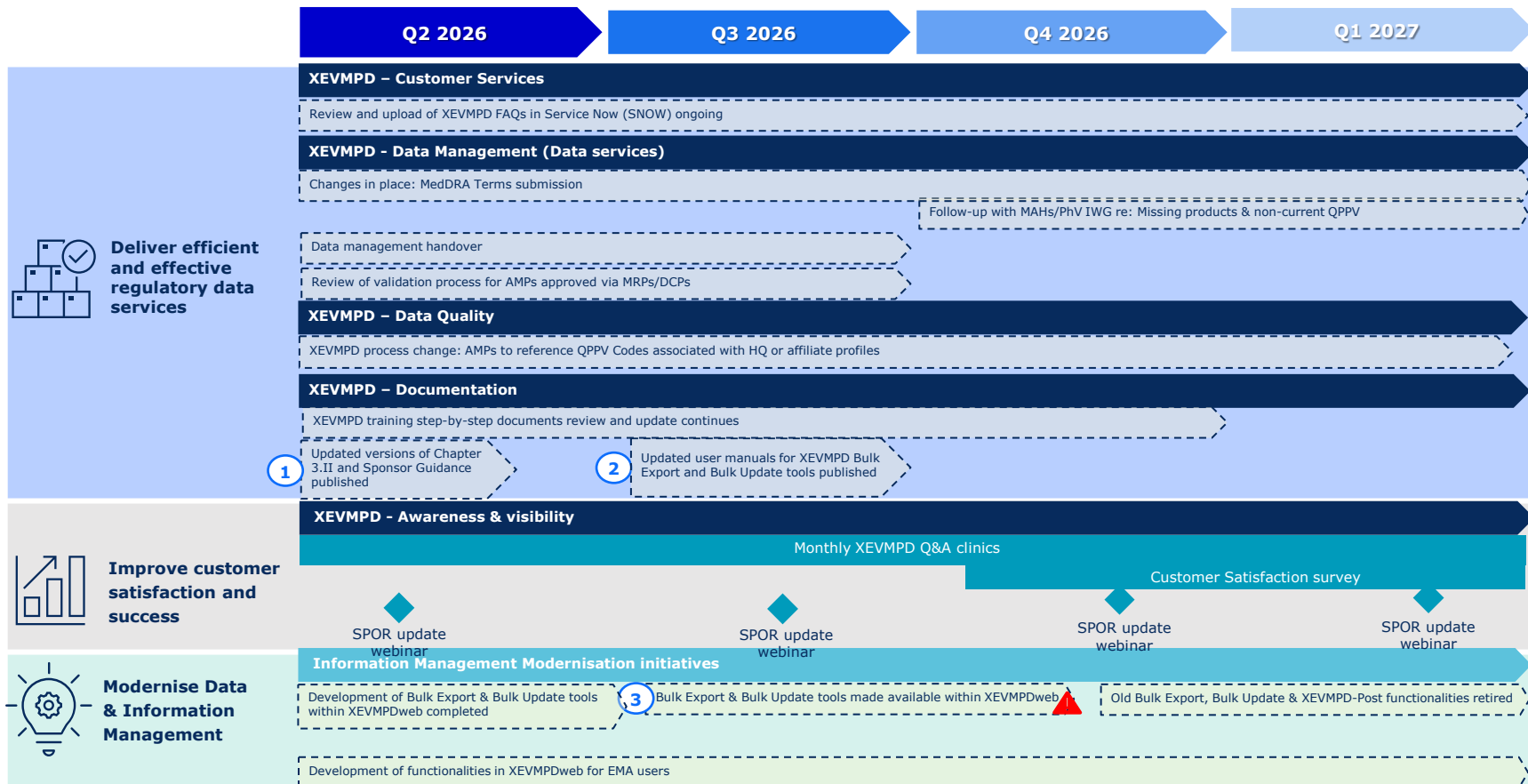


10:55 - 11:05

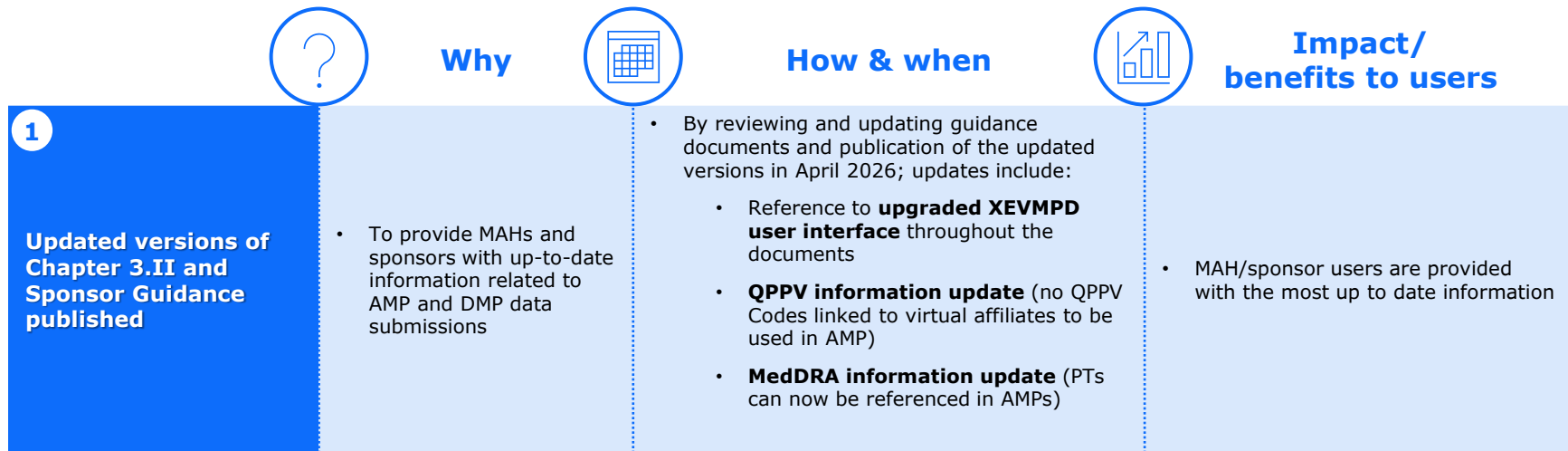


XEVMPD status update

Planned XEVMPD Activities



Work completed – What has been done in Q2 2026



What's next? – What will be done in Q3 2026



Why



How & when



Impact/ benefits to users

2

Updated user manuals for XEVMPD Bulk Export and Bulk Update tools published

- To provide MAHs with up-to-date information related to both tools following their inclusion within the upgraded XEVMPD UI (XEVMPDweb)

- By reviewing and updating the respective user manuals and the publication of the updated versions in the '**User Support**' section of the EV restricted area with details on **Bulk Export and Bulk Update tools**

- **Published on 7 July 2026**

- MAH/sponsor users are provided with the most up to date information on the use of these tools in XEVMPDweb

3

Bulk Export & Bulk Update tools made available within XEVMPDweb

- To enable XEVMPD users to export and bulk update their AMP data using the existing tools without the need for ActiveX






- By making the **tools available** within the upgraded XEVMPD user interface (XEVMPDweb)

- **Available from 7 July 2026**

- **Transition period** during which the tools will be available in EV Restricted area and in XEVMPDweb: **7 July – 7 October 2026**

- **No need for ActiveX to access and use these tools**
- Minor upgrades made to improve user experience and performance

Highlights to you

 <p>XEVMPD process change: AMPs to reference QPPV Codes associated with HQ or affiliate profiles</p> <p>Changes in place: MedDRA Terms submission</p> <p>Bulk Export & Bulk Update tools made available within XEVMPDweb </p>	 <p>XEVMPD/PMS data mapping services provided to NCAs</p> <p>Review of validation process for AMPs approved via MRPs/DCPs</p> <p>Review and update of XEVMPD training step-by-step documents</p> <p>Follow-up with MAHs/PhV IWG re: Missing products & non-current QPPV</p> <p>Data Management team handover</p>	 <p>Amendment of validation process for AMPs approved via MRPs/DCPs</p> <p>Development of functionalities for EMA users in XEVMPDweb</p> <p>XEVMPD Bulk Export and Bulk Update tools in EV Restricted area retired from 7 October</p>	 <p>Improvement on cluster validation process for updated AMPs</p> <p>Integration of product validation with review of substances with SVG flag 0</p>
<p>What's changed?</p>	<p>Ongoing work</p>	<p>Future changes (What's next?)</p>	<p>Future changes (What's later?)</p>

AMPs: Authorised Medicinal Products

XEVMPD: Extended EudraVigilance medicinal product dictionary

NCA: National Competent Authority

Acronyms

PMS: Product Management Service

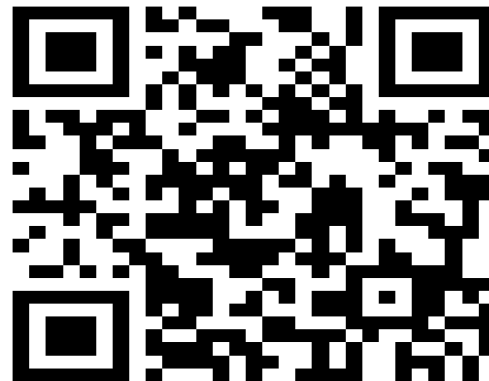
SNOW: ServiceNow

PhV IWG: PharmacoVigilance Inspectors Working Group

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 #STUP080726 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.

PMS status update

Planned PMS Activities

Q2 2026

Q3 2026

Q4 2026

Q1 2027



Deliver efficient and effective regulatory data services

PMS Customer Services (inc. Data Quality)

Strengthen ticket monitoring and improve cross-team process

Increase capacity to triage & solve DQ incidents faster (DQ SD team) **7**

Improved monitoring of DQ incidents (DQ SD team)

Customer service handover (PMS SD team)

PMS Project – Data Quality

4 CAP Sync optimization & Non-CAP product deduplication

5 Merge packages in multilingual countries + improve deltas from XEVMPD

Missing information in key fields

Implementation of DQ monitoring reports in DAP (EMA use)

DQ reports in DAP (NCA/Ind use)

Monitoring of Critical Medicines package & manufacturer compliance

PMS Project – Documentation

3

- Update of FAQ
- Chapter 1 update on Pilot Public PMS API access
- Chapter 3 update
- Chapter 1 - Annex A and Annex B (New)
- PMS Public API FAQ doc (New)
- Terms and conditions for Public API (New)

Improved cross-team process:

- Revised ticket processes
- New guideline and information to users
- Faster triage & investigation

PMS EU IG Chapter 4 - Data Quality Framework

PMS Project - Awareness & visibility

2x month PMS Q&A clinics

1

PMS Info-Day - 3rd Edition

2

System Demo

3

PMS Public Beta release

4

Managing product data quality in PMS

5

System Demo

6

System Demo

April: Adoption survey to PMS PUI/API users



Improve customer satisfaction and success

PMS Project –IT delivery

Creation of pending products for iMAA & update of AMP for CAPs to support SIAMED decommission

PUI view/write pages enhancements



2

★ **Beta release - Public PMS API**



★ **PMS Public API full Roll out (TBC)**



Work completed – What has been done in Q2 2026



Why



How & when



Impact/
benefits to users

1	Why	How & when	Impact/ benefits to users
<p>PMS Info Day - 3rd Edition</p>	<p>To enhance awareness and offer comprehensive insights into the implications of PMS for key stakeholders.</p>	<p>Hosted on Tuesday, 09 June 2026 , 09:00 - 13:00 Amsterdam time (CEST)</p> <p>Live broadcasted Event page: Link</p>	<p>Enabled direct engagement with leaders, providing insights on PMS progresses, its impacts, benefits, and EU implementation preparedness.</p>
<p>Beta release - Public PMS API</p>	<p>A trusted Public EU-Wide source of medicinal product data is a win for Healthcare</p> <p>The purpose of the Beta release is to help users become familiar with the platform, start building their connections, and gain a better understanding of how the API works and what data is available.</p>	<p>Beta release Public PMS API launched on 12 June 2026. Access details are available on the PMS webpage: Annex B to Chapter 1</p> <p>Users must register with an email and accept the Terms and Conditions of Use.</p>	<ul style="list-style-type: none"> • 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 PMS data and technology.
<p>PMS documentation updates</p>	<p>To provide updated guidance, enhance usability, and increase transparency on progresses of PMS deliveries.</p>	<p>In Q2 2026 the following updates have been published on PMS page/PUI portal:</p> <ul style="list-style-type: none"> • Ch. 3, Ch.1, Annex A to Ch.1 (update) • Annex B to Ch.1 & Public API Tech. specs. (new) • Public PMS API FAQ (new) 	<p>Supports proper use of the PUI and PMS Public API, clarifies the available public data, reduces integration and interpretation issues, and increases overall transparency and trust.</p>
<p>PMS Data Quality enhancements: CAP Sync optimization & Non-CAP product deduplication</p>	<p>CAP data quality issues persist from the original SIAMED synchronization.</p> <p>Although the root cause of duplicate products had been technically resolved, impacted products had to be fixed.</p>	<ul style="list-style-type: none"> • 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. 	<ul style="list-style-type: none"> • Ensure all authorised products are correctly displayed in PMS/PUI/eAF • MAHs see the correct number of products in PMS, eAF, etc. • Improved CAP data synchronisation, elimination of duplicate ingredients, and more accurate handling of authorization changes and MAH transfers. • Manual corrections and workload reduced.

What's next? – What will be done in Q3 2026



Why



How & when



Impact/ benefits to users

5

PMS Data Quality enhancements: Merge packages in multilingual countries + improve deltas from XEVMPD

- Products authorised in **multilingual** countries have their **packages** duplicated/triplicated in PMS (one per language) due to XEVMPD business rules.
- Some XEVPRMs are not properly handled in PMS and updates in XEVMPD are not propagated to PMS.

- Packages that have the same package description (**exact same text/language**) in XEVMPD will be merged in PMS as they will be considered the same package. (only in products authorised in **BE, LU and FI**)
- **Technical fix – Processing of Larger XEVPRMs will be improved** to handle all messages reliably.
- Data fix – Sync of messages previously missed/not processed will be analysed – *Fix expected in Q4*

- Improved data completeness and consistency.
- Reduced duplicate package records.
- Missing XEVMPD product data available in the PMS API and PUI.
- More accurate search results and easier data retrieval.

6

PMS topic-specific webinars

- Bring awareness and inform stakeholders on specific milestones and activities:
- Beta release Public PMS API
 - PMS Data Quality & Customer Service

- PMS events are hosted virtually via Webex. Registrations are open at the following links:
- **Beta release Public PMS API on 13 July 2026** (2-3:30 PM) [Register](#)
 - **PMS Data Quality & Customer Service on 21 July 2026** (2-3:30 PM) [Register](#)

- Practical guidance on using the PMS Public API.
- Overview of the 2026 PMS data quality strategy.
- Best practices for interacting with EMA via ServiceNow.
- Direct access to PMS Product Owners for Q&A and clarifications.

7

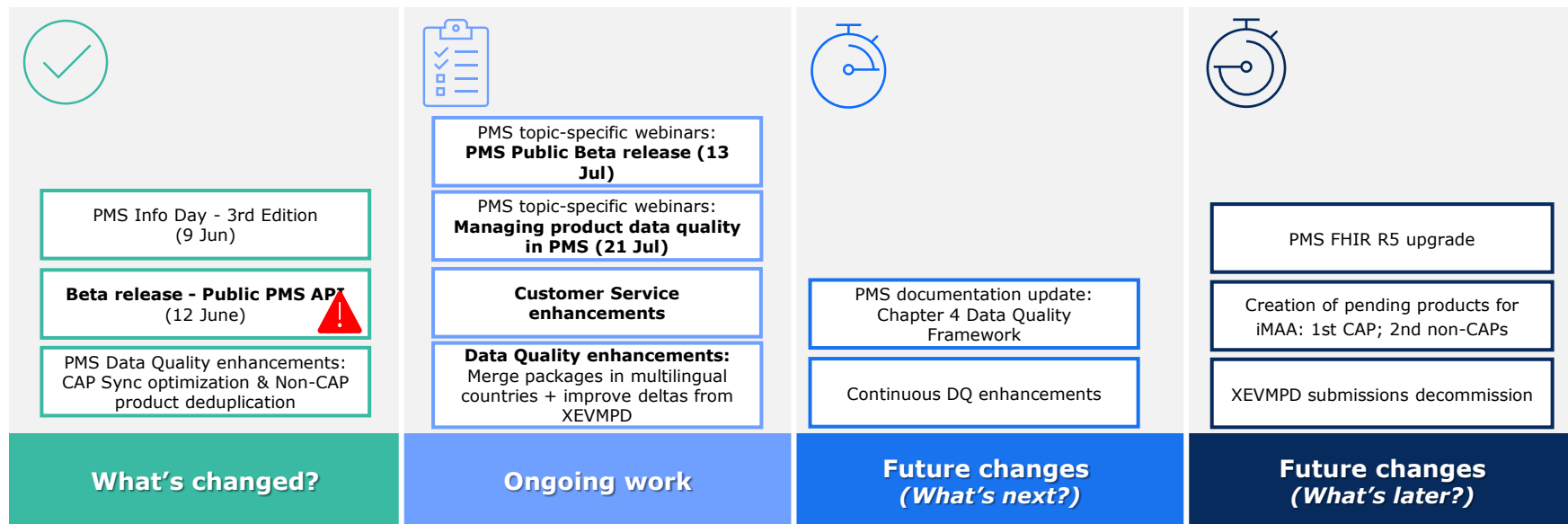
Customer Service enhancements

- Enhance customer support efficiency, consistency, and responsiveness to improve the user experience.

- During Q3 the following activities will take place:
- Scaled Customer Service training programme
 - Strengthened ticket monitoring
 - Revised ticket management processes
 - New user guidance and information
 - Faster triage and investigation procedures
 - Increased Customer Service capacity

- Faster response and resolution times
- More consistent and accurate support
- Improved communication and guidance
- Enhanced user experience and satisfaction

Highlights to you



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

Q&A time

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

1. **Join at slido.com** with the code #STUP080726 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

OMS subscriptions



OMS subscriptions

Facilitate your data updates by getting informed of changes to relevant Organisations

1. Preferences

2. Search relevant organisations

3. View subscriptions

4. Manage subscriptions

5. Get notifications

6. Update/Sync your data

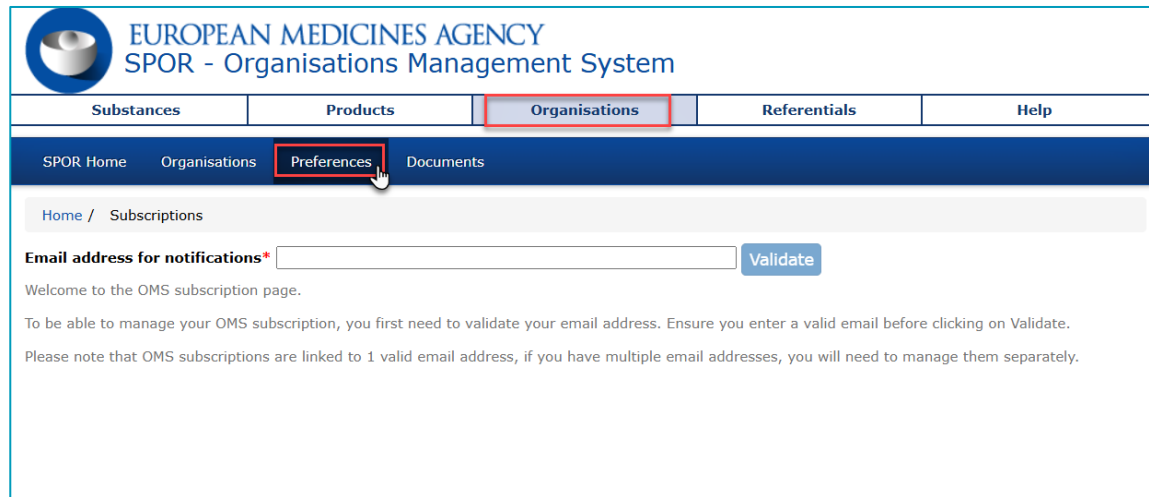
- Set your personal Preferences in the OMS portal

- Preferences will be **associated to 1 email**

- Use a **functional company email**, monitored by multiple users

RECOMMENDED 

- Email validation is required to access your preferences:
 1. Enter a valid email address
 2. Email will be sent to your inbox with the access link – 1 time use only



EUROPEAN MEDICINES AGENCY
SPOR - Organisations Management System

Substances Products **Organisations** Referentials Help

SPOR Home Organisations **Preferences** Documents

Home / Subscriptions

Email address for notifications*

Welcome to the OMS subscription page.

To be able to manage your OMS subscription, you first need to validate your email address. Ensure you enter a valid email before clicking on Validate.

Please note that OMS subscriptions are linked to 1 valid email address, if you have multiple email addresses, you will need to manage them separately.

OMS subscriptions

Facilitate your data updates by getting informed of changes to relevant Organisations

1. Preferences

2. Search relevant organisations

3. View subscriptions

4. Manage subscriptions

5. Get notifications

6. Update/Sync your data

- Set your personal Preferences in the OMS portal

- Preferences will be **associated to 1 email**

- Use a **functional company email**, monitored by multiple users

RECOMMENDED

- Email validation is required to access your preferences:

1. Enter a valid email address
2. Email will be sent to your inbox with the access link – 1 time use only

Search for organisations (only Active records will be available) using:

- **Organisation ID**

RECOMMENDED

- Organisation name + Country – combined search, otherwise it will retrieve too many results, and performance will be negatively impacted

EUROPEAN MEDICINES AGENCY
SPOR - Organisations Management System

Substances Products Organisations Referentials Help

SPOR Home Organisations Preferences Documents

Home / Subscriptions

Email address for notifications: valid@email.com Refresh

Please click Refresh if you haven't received the Validation email in the next 5 minutes, or if you wish to validate a different email.

Hide Subscriptions

Organisation ID	Organisation Name ▲	Country ▲	Org last modified date ▲	Action
No matching records found				

Search Organisation...

Page 1 of 0 Showing 5 of 0 results

Hide search

Organisation ID Contains ▾

Organisation Name Contains ▾

Country 0 Selected ▾

Reset Search

OMS subscriptions

Facilitate your data updates by getting informed of changes to relevant Organisations

1. Preferences

- Set your personal Preferences in the OMS portal

- Preferences will be **associated to 1 email**

- Use a **functional company email**, monitored by multiple users

RECOMMENDED

- Email validation is required to access your preferences:

1. Enter a valid email address
2. Email will be sent to your inbox with the access link – 1 time use only

2. Search relevant organisations

Search for organisations (only Active records will be available) using:

- **Organisation ID**

RECOMMENDED

- Organisation name + Country – combined search, otherwise it will retrieve too many results, and performance will be negatively impacted

3. View subscriptions

- View organisations currently subscribed

- In case of high number of subscriptions, use the **quick search bar** and the **number of results displayed** for a better user experience

4. Manage subscriptions

5. Get notifications

6. Update/Sync your data

EUROPEAN MEDICINES AGENCY
SPOR - Organisations Management System

Substances Products Organisations Referentials Help

SPOR Home Organisations Preferences Documents

Home / Subscriptions

Email address for notifications* valid@email.com Refresh

Please click Refresh if you haven't received the Validation email in the next 5 minutes, or if you wish to validate a different email.

Hide Subscriptions

Organisation ID	Organisation Name ▲	Country ▲	Org last modified date ▲	Action
ORG-10000011	Bayer AG	Germany	01/09/2025 10:35 AM	Unfollow
ORG-100001559	Bayer Portugal Lda.	Portugal	14/05/2026 06:09 AM	Unfollow

Search Organisation...

Page 1 of 1

Showing 5 of 2 results

Hide search

Organisation ID Contains

Organisation Name Contains

Country 0 Selected

Reset Search

OMS subscriptions

Facilitate your data updates by getting informed of changes to relevant Organisations

1. Preferences

2. Search relevant organisations

3. View subscriptions

4. Manage subscriptions

5. Get notifications

6. Update/Sync your data

The screenshot displays the SPOR - Organisations Management System interface. At the top, there are navigation tabs for Substances, Products, Organisations, Referentials, and Help. Below this, there are breadcrumb links for SPOR Home, Organisations, Preferences, and Documents. A search bar for 'Email address for notifications' is present with a 'Refresh' button. A section titled 'Hide Subscriptions' contains a table with columns for Organisation ID, Organisation Name, Country, and Org last modified date. The 'Action' column for this table contains 'Unfollow' buttons. Below this is a search bar and a 'Hide search' link. Another section contains search filters for Organisation ID, Organisation Name, and Country, with 'Contains' dropdowns and 'Reset' and 'Search' buttons. At the bottom, there is a 'Select / De-select all' section with a table showing Organisation ID, Organisation Name, Country, and a 'Subscribe' checkbox. The 'Subscribe' column for this table contains checkboxes, one of which is checked. A 'Save' button is located at the bottom right of this section.

- **Quick Unfollow action** is available under the subscriptions table
- Use the **last column of the search outcome to Subscribe or Unsubscribe** by ticking or unticking - option to select/deselect all is available on the top left hand-side to the search outcome table
- When managing your subscriptions using the search outcome table remember to **Save** your work before
- In case of high number results, use the **quick search bar** and the **number of results** displayed, for a better user experience
- Both tables are **dynamic/cumulatively updated**

OMS subscriptions

Facilitate your data updates by getting informed of changes to relevant Organisations

1. Preferences

2. Search relevant organisations

3. View subscriptions

4. Manage subscriptions

5. Get notifications

6. Update/Sync your data



OMS Subscriptions (Week 20/2026)

Dear Sir/Madam,

Please be informed that in Week 20/2026:

a) The following organisation(s) you have subscribed to have been updated:

Organisation Id	Organisation Name	Type of change	Organisation Last Update
ORG-100026210	Lo's Chemists Limited	Validation check	20/05/2026 01:24 PM
ORG-100000833	Novartis Pharma B.V.,...	New	20/05/2026 01:40 PM
ORG-100000833	Novartis Pharma B.V.,...	Standardisation update	20/05/2026 01:39 PM
ORG-100022007	Udfifar II Distribucao Farmaceutica S.A.	Validation check	20/05/2026 01:34 PM
ORG-100022007	Udfifar II Distribucao Farmaceutica S.A.	Deactivation	20/05/2026 01:34 PM

b) The following location(s) you have subscribed to have been updated:

Location Id	Organisation Id	Organisation Name	Type of change	Location Last Update
LOC-100005250	ORG-100000833	Novartis Pharma B.V.,...	Standardisation update	20/05/2026 01:49 PM
LOC-100005803	ORG-100000833	Novartis Pharma B.V.,...	Validation check	20/05/2026 01:45 PM
LOC-100005459	ORG-100001110	Teva B.V.	Deactivation	20/05/2026 01:42 PM

OMS Subscriptions (Week 22/2026)

Dear Sir/Madam,

Please be informed that in Week 22/2026:

a) The following organisation(s) you have subscribed to have been updated:

Organisation Id	Organisation Name	Type of change	Organisation Last Update
ORG-100026210	Lo's Chemists Limited	Deactivation	27/05/2026 01:34 PM

b) The following location(s) you have subscribed to have been updated:

Location Id	Organisation Id	Organisation Name	Type of change	Location Last Update
No changes in this period.				

- Email notification, sent **every Monday**, listing **all new versions/changes** of the subscribed organisations during previous week:
- **Point a)** displays all **Organisation versions/changes** of the subscribed organisations e.g.:
 - organisation undergoes a **name update** > Type of change will read *Name change*
 - organisation is set as Inactive > Type of change will read *Deactivation*
 - merge 2 organisations, as they are the same organisation/duplicate > Type of change will read *Deduplication*
- **Point b)** displays all **Locations versions/changes** of the subscribed organisations e.g.:
 - locations is set as Inactive > Type of change will read *Deactivation*
 - We add xEVMPD code to the location > Type of change will read *Mapping enrichment – external information*
- If **no changes occur** to the records you are subscribing to, the message *No changes in this period.* will be present in the email notification

IMPORTANT – Email notification acts as an alert/prompt for updates and will NOT

- Inform of **newly created organisations**
- Provide full **details on the updates/change**

- You should specifically know/search for organisations relevant to you or use the exports/OMS API to detect New Organizations or details of updates

OMS subscriptions

Facilitate your data updates by getting informed of changes to relevant Organisations

1. Preferences

2. Search relevant organisations

3. View subscriptions

4. Manage subscriptions

5. Get notifications

6. Update/Sync your data



Documentation/guidance

- Current slides – published in OMS portal
- WebUI manual will be updated to include this new feature – published in OMS portal



OMS subscription functionality has been released as MVP, to provide users with earlier access and faster visibility of the available information.

To continuously enhance this feature, **future improvements** will be shaped through discussions with KUG, as well as your valuable **feedback provided through the customer satisfaction survey**. Your input will play an important role in helping us prioritize and deliver the most impactful enhancements.

Examples of possible improvements - TBC:

- Easier access to the last Version type & comments
- Further details on merges
- Further details on location

OMS Subscriptions (Week 26/2026)

noreply@
To: User@email.com

Wed 01/07/2026 13:06

Dear Sir/Madam,

Please be informed that in Week 26/2026:

a) The following organisation(s) you have subscribed to have been updated:

Organisation Id	Organisation Name	Type of change	Organisation Last Update
ORG-100050377	Strawberry Pharma Ltd.	Business merge	30/06/2026 06:10 PM

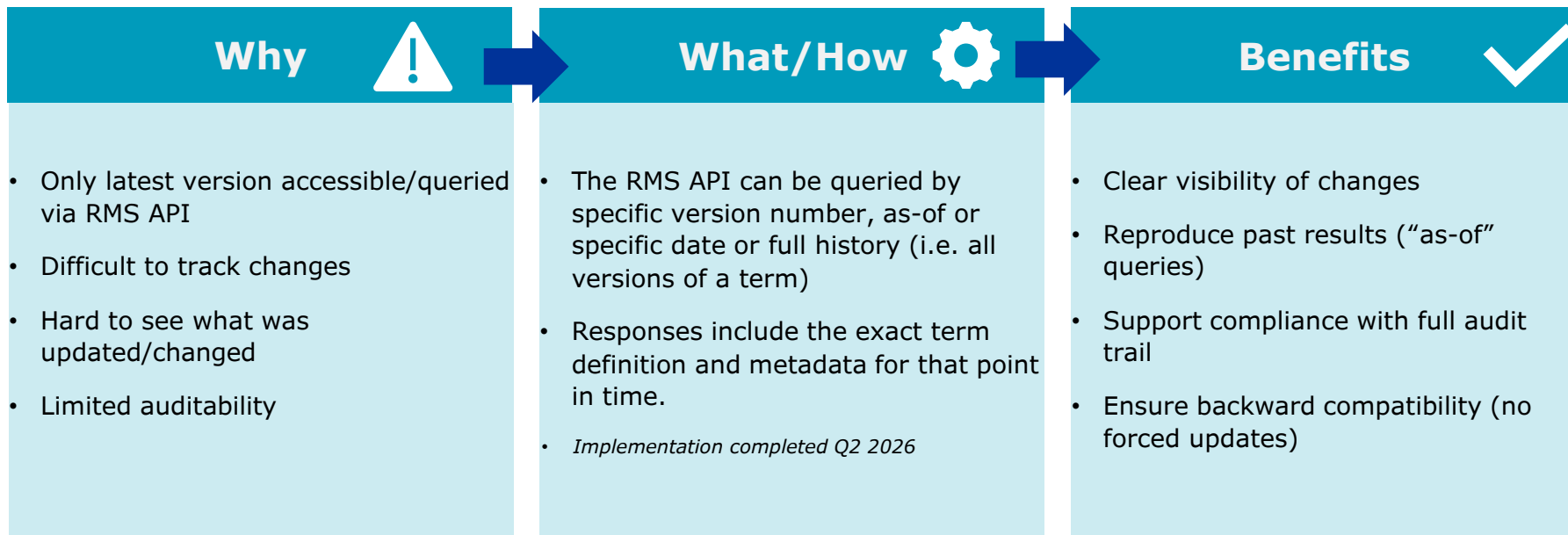
- The **periodic review of the new OMS email notification** and, analyses of respective *Type of changes* **will help you** with:

- **preparatory work necessary prior to regulatory submissions** e.g. further clarification may be required from OMS side for you to be able to process with your regulatory submission
- certain **OMS changes may require further actions at consuming system level** e.g. if a merge occurs in OMS access may be negatively impacted

Term versions in RMS API



RMS API: Accessing Term Versions



RMS API - Considerations



Requirements

- **Registration required** (see RMS documentation, slide 54)
- **API version:** All RMS & OMS queries must include API version “v1” (SMS queries are v2)



Example

- **List ID:** 100000000001
- **Term ID:** 1000000000029
- **Request:**
<http://spor.ema.europa.eu/v1/lists/100000000001/terms/1000000000029?version-number=5>



Tools

- Querying possible with different tools e.g. of **free applications:**
 - *Postman ([Sending your first request | Postman Learning Center](#))*
 - *[Dog API by kinduff](#)*
 - *[Free Dictionary API](#)*
 - *[API - RijksData \(rijksmuseum.nl\)](#)*
 - Many more (([GitHub - public-apis/public-apis: A collective list of free APIs](#)))

RMS API - Querying the latest term version 1/2



Query

- **Syntax:** GET
- **Endpoint:**
<http://spor.ema.europa.eu/v1/lists/List-ID/terms/Term-ID>
- **Returns:** Latest version of the term



Example

- **List ID:** 100000000001
- **Term ID:** 100000000029
- **Request:**
<https://spor.ema.europa.eu/v1/lists/100000000001/terms/100000000029>



Result

Example response (Postman)

GET `https://spor.ema.europa.eu/v1/lists/100000000001/terms/100000000029` Send

Query Params

Key	Value	Description	Bulk Edit
Key	Value	Description	

Body Cookies 2 Headers 13 Test Results 200 OK · 1.11 s · 3.28 KB

```
<?xml version="1.0" encoding="UTF-8"?>
<term-details schema-version="2.0" xmlns="http://ema.europa.eu/schema/spor" xmlns:spor="http://ema.europa.eu/schema/spor">
  <controlled-term spor:rowid="20268">
    <term-id id="100000000029">
      <link href="https://spor.ema.europa.eu/v1/lists/100000000001/terms/100000000029"/>
    </term-id>
  </controlled-term>
</term-details>
```

RMS API - Querying the latest term version 2/2



Result

```
1 <?xml version="1.0" encoding="UTF-8"?>
2 <term-details schema-version="2.0" xmlns="http://ema.europa.eu/schema/spor" xmlns:spor="http://ema.europa.eu/schema/spor">
3   <controlled-term spor:rowid="20268">
4     <term-id id="100000000029">
5       <link href="https://spor.ema.europa.eu/v1/lists/100000000001/terms/100000000029"/>
6     </term-id>
7     <term-names>
8       <term-name>
9         <name translation-status-code="CURRENT" modified-on="2021-11-22T12:50:22.64+01:00" lang="no" translation-id="13690028">I livmoren</name>
10      </term-name>
11      <term-name>
12        <name translation-status-code="CURRENT" modified-on="2022-03-23T10:54:40.005+01:00" lang="pt" translation-id="16290003">No útero</name>
13      </term-name>
14      <term-name>
15        <name translation-status-code="CURRENT" modified-on="2007-08-16T12:22:30+02:00" lang="en" translation-id="20054">In utero</name>
16      </term-name>
17    </term-names>
18    <short-names>
19      <short-name>
20        <name translation-status-code="CURRENT" modified-on="2021-11-22T12:50:22.77+01:00" lang="no" translation-id="13690029">I livmoren</name>
21      </short-name>
22      <short-name>
23        <name translation-status-code="CURRENT" modified-on="2007-08-16T12:22:30+02:00" lang="en" translation-id="20055">In utero</name>
24      </short-name>
25    </short-names>
26    <status code="CURRENT" modified-by="ema" modified-on="2007-08-16T12:22:30+02:00" spor:rowid="20518"/>
27    <operational-attributes version-number="6" modified-on="2023-02-23T10:45:34.052+01:00" created-on="2007-08-16T12:22:30+02:00"/>
28    <visibility code="PUBLIC"/>
```

- Only the latest version is returned
- Example: **version 6**

RMS API - Querying for a specific version of a term



Query

- Syntax: GET
- Endpoint:
`http://spor.ema.europa.eu/v1/lists/List-ID/terms/Term-ID?version-number=X`
- Returns: Requested version only



Example

- List ID: 100000000001
- Term ID: 100000000029
- Request:
`https://spor.ema.europa.eu/v1/lists/100000000001/terms/100000000029?version-number=5`



Result



- Only the requested version is returned
- Example: version 5
- Other versions are not included

RMS API - Querying for all versions term



Query

- Syntax: GET
- Endpoint:
<http://spor.ema.europa.eu/v1/lists/List-ID/terms/Term-ID?versions=true>
- Returns: All available versions of the term are returned (multiple versions exist)



Example

- List ID: 100000000001
- Term ID: 100000000029
- Request:
<https://spor.ema.europa.eu/v1/lists/100000000001/terms/100000000029?versions=true>



Result

The screenshot shows a REST client interface with the following details:

- Request:** GET <https://spor.ema.europa.eu/v1/lists/100000000001/terms/100000000029?versions=true>
- Response:** 200 OK, 1.53 s, 11.81 KB
- Body:** XML view showing the following structure:

```
1 <?xml version="1.0" encoding="UTF-8" standalone="yes"?>
2 <term-details schema-version="2.0" xmlns:spor="http://ema.europa.eu/schema/spor" xmlns="http://ema.europa.eu/schema/spor">
3   <controlled-term spor:rowid="28268">
4     <term-id id="100000000029">
5       <link href="https://spor.ema.europa.eu/v1/lists/100000000001/terms/100000000029/">
6     </term-id>
7     <term-names>
8       <term-name>
9         <name translation-status-code="CURRENT" modified-on="2021-11-22T11:50:22.648Z" lang="no" translation-id="13698828">I livmoren</name>
10      </term-name>
11      <term-name>
12        <name translation-status-code="CURRENT" modified-on="2022-03-23T09:54:40.805Z" lang="pt" translation-id="16298863">No útero</name>
```

RMS API Documentation



Documentation

- Available via **SPOR Web UI**
<https://spor.ema.europa.eu/rmswi/#/viewDocuments>
- Navigate to: Documents - **General**
- Navigate to: Documents - **Technical**

SPOR Home Lists Change Requests Translations Preferences **Documents**

Home / View Documents

General Technical NCA

Document Name ▼	Document Description ↑
Z9 - Access to SPOR API - SPOR Week 14 October 2024	Webinar - API Registration process and OMS/RMS API usage demo and tips
Z6 - SPOR API Access Request Form	SPOR API Access Request Form
Z5 - EMA - API General Terms of Service - Terms of Use	EMA - API General Terms of Service - Terms of Use
Z3 - SPOR API Access - Q&A	Process - How to request access to SPOR API - Questions and Answers

SPOR Home Lists Change Requests Translations Preferences **Documents**

Home / View Documents

General **Technical** NCA

Page 1 of 1

Document Name ▼	Document Description ↑
XSD schema	XSD schema example for the SPOR API
SPOR-API-Specification	Technical specification of the Application Programming Interface (API) which provides access to SPOR services
SPOR API sample payloads	Example of the use of API calls available in the OMS/RMS solution
RMS Logical Data Model - Documentation	Description of the elements in the RMS Logical Data Model
RMS Logical Data Model	The Logical Data Model (LDM) implemented in RMS
RMS Conceptual Data Model	The Conceptual Data Model of RMS
RMS and OMS 2.02.02 release notes	Improvements introduced with the version 2.02.02 release for RMS and OMS

Page 1 of 1

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
(CET): [access event page](#)**

PMS Public API Beta release: Technical overview and live demo

Registration open

- **13 July 2026 – 14:00–
15:30 (CEST): [access event
page](#)**

Managing product data quality in PMS: processes, known issues, current status and best practices

Registration open

- **21 July 2026 – 14:00–
15:30 (CEST): [access event
page](#)**

Upcoming SPOR & XEVMPD engagements



Q&A Clinics on SOR

- **14 Apr 2026**
- **12 May 2026**
- **10 June 2026**
- **9 Sept 2026** (15:30 – 16:00 CET): [Event page](#)
- **Other dates for 2026** (15:30 – 16:00): 9 Sep, 7 Oct, 11 Nov, 9 Dec
→ *registration available on EMA corporate website!*



Q&A Clinics on PMS

- **14 Apr 2026**
- **12 May 2026**
- **11 and 23 June 2026**
- **9 July 2026** (9:30 – 10:30 CEST): [Event page](#)
- **23 July 2026** (9:30 – 10:30 CEST): [Event page](#)
- **Other dates for 2026** (9:30 – 10:30): 10 Sep, 24 Sep, 8 Oct, 22 Oct, 12 Nov, 26 Nov, 10 Dec
→ *registration available on EMA corporate website!*



Q&A Clinics on XEVMPD

- **16 Apr 2026**
- **13 May 2026**
- **11 June 2026**
- **9 July 2026** (15:00 – 16:00 CEST): [Event page](#)
- **Other dates for 2026** (15:00 – 16:00): 10 Sep, 8 Oct, 12 Nov, 10 Dec
→ *registration available on EMA corporate website!*

Conclusions

Q2 highlights

Deliver efficient and effective regulatory data services

- Maintain the provision of S, O, R and XEVMPD/PMS data management services
 - **SMS**: Started changing substance preferred terms
 - **OMS**: Change request validation improvement – return CR capability, reduction by 20% of rejected CR
 - **RMS**: Review of Special precautions for Storage/Shelf life/Material, Publication of EMDN list, MedDRA 29.0
 - **XEVMPD/PMS**: Update of Guidance documents and start of product de-duplication

Data Management Knowledge Transfer

Improve customer satisfaction and success

- Provide increased and targeted customer engagement
- ...

Modernise data & information management

- Improve S, O, R and XEVMPD/PMS data management capabilities
 - **SMS**: New fields available in exports
 - **OMS**: Subscription feature
 - **PMS**: Beta release of Public PMS API
 - **RMS**: Previous versions of an RMS term via API



Q3 objectives

Deliver efficient and effective regulatory data services

- Maintain the provision of S, O, R and XEVMPD/PMS data management services

- **SMS:** Finalising changes in preferred terms
- **RMS:** EMDN bulk update process, VedDRA v.2026
- **PMS:** Merge packages in multilingual countries + improve deltas from XEVMPD

• Data Management Knowledge Transfer

Improve customer satisfaction and success

Provide increased and targeted customer engagement

- **SMS:** Publication of SMS Guidance v4.0 and Business Rules v1.0

Modernise data & information management

Improve XEVMPD/PMS data management services (and capabilities)

- **SMS:** Improved bulk functionalities
- **OMS:** Integrate OMS data in CR forms
- ⚠️ • **RMS:** Return of Subscription functionality
- ⚠️ • **XEVMPD:** Bulk Export & Bulk Update tools made available within XEVMPDweb





EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Thank you

More information: [SPOR Web Page](#)

Follow us

