

SPOR & XEVMPD Status Update

Recent & planned changes and impacts to users

07 October 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**.

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1. **Join at slido.com** with the code #STUP071026 or by scanning the QR code here.

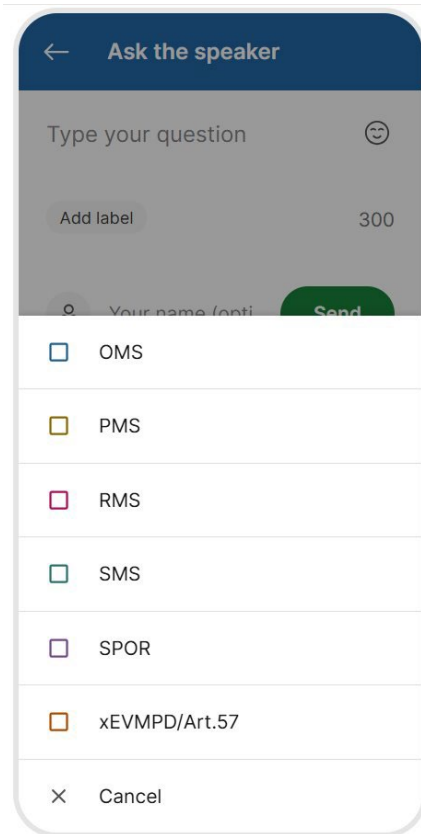


2. **Send or upvote the questions** you want to hear answered
3. **Questions will be shown on the screen** and EMA colleagues will **verbally address top 5 voted questions** in the live Q&A sessions.

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

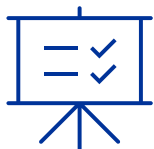
Type your question 😊

Add label 300

8 Your name (optional) Send

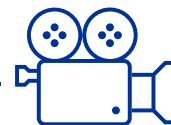
- ☐ OMS
- ☐ PMS
- ☐ RMS
- ☐ SMS
- ☐ SPOR
- ☐ xEVMPD/Art.57
- ☐ Cancel

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 + 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 versions in Portal, OMS data in CR forms

20 mins presentation + 10 mins Q&A

11:45 – 12:15

9

Conclusions

10 mins presentation +
5 mins Slido survey

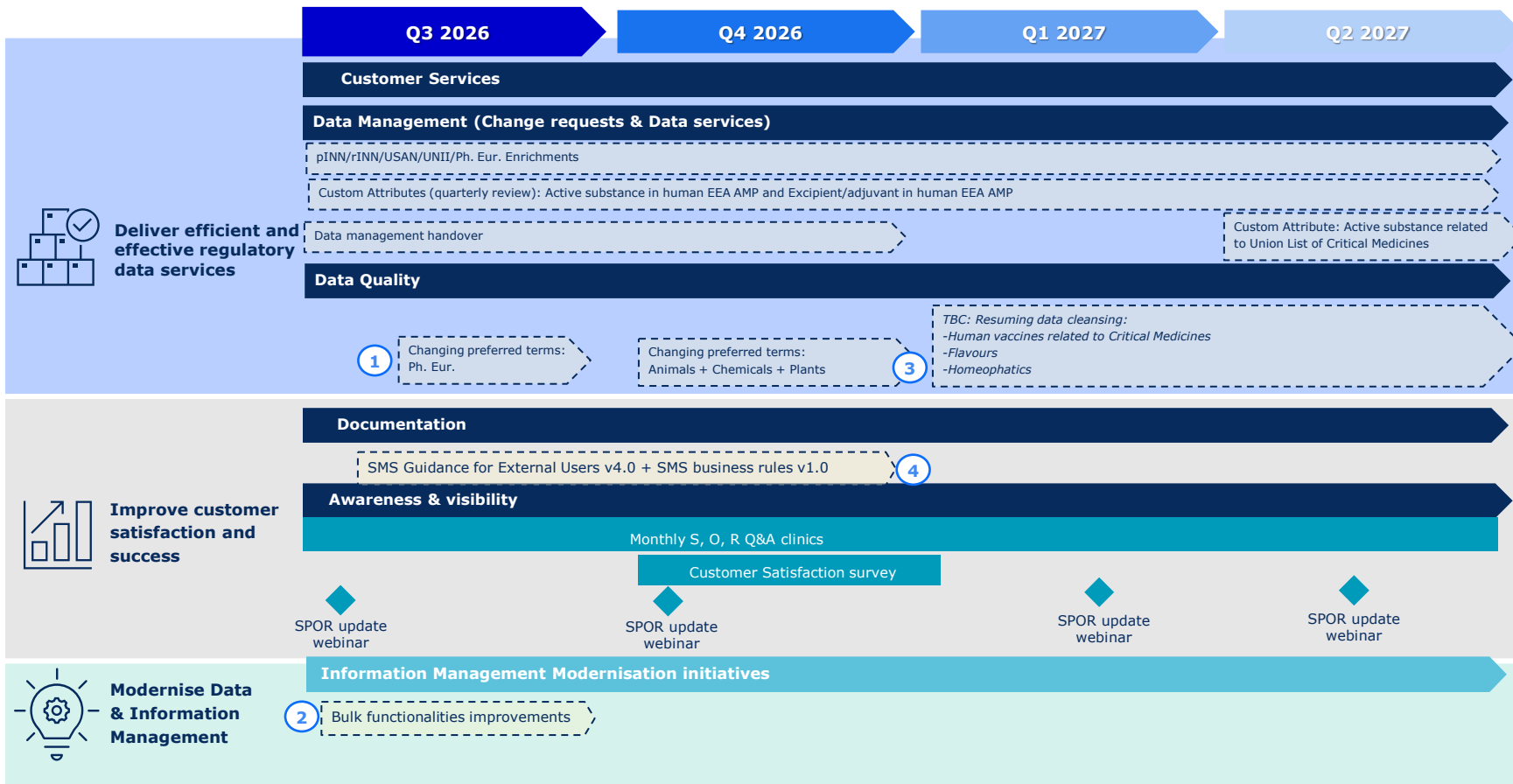
12:15 – 12:30

6

For questions: www.slido.com code: #STUP071026

SMS status update

Planned SMS Activities



Work completed – What has been done in Q3 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**:

- **Ph. Eur.** – completed in July 2026

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

2

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**

What's next? – What will be done in Q4 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**:

- Animals - planned for November 2026
- Chemicals - planned for November 2026
- Plants - planned for December 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** of SMS Guidance for Externals a new major version expected by end of November
- **Publication** of SMS Business Rules as a new document expected by end of November

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

Highlights to you

 Changing preferred terms: Ph. Eur. Bulk functionalities improvements	 Data Management team handover Finalising changes in preferred terms: Animals + Chemicals + Plants SMS Guidance version 4.0 + SMS Business Rules 1.0	 Human vaccines cleansing Flavours cleansing Homeopathics 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**.

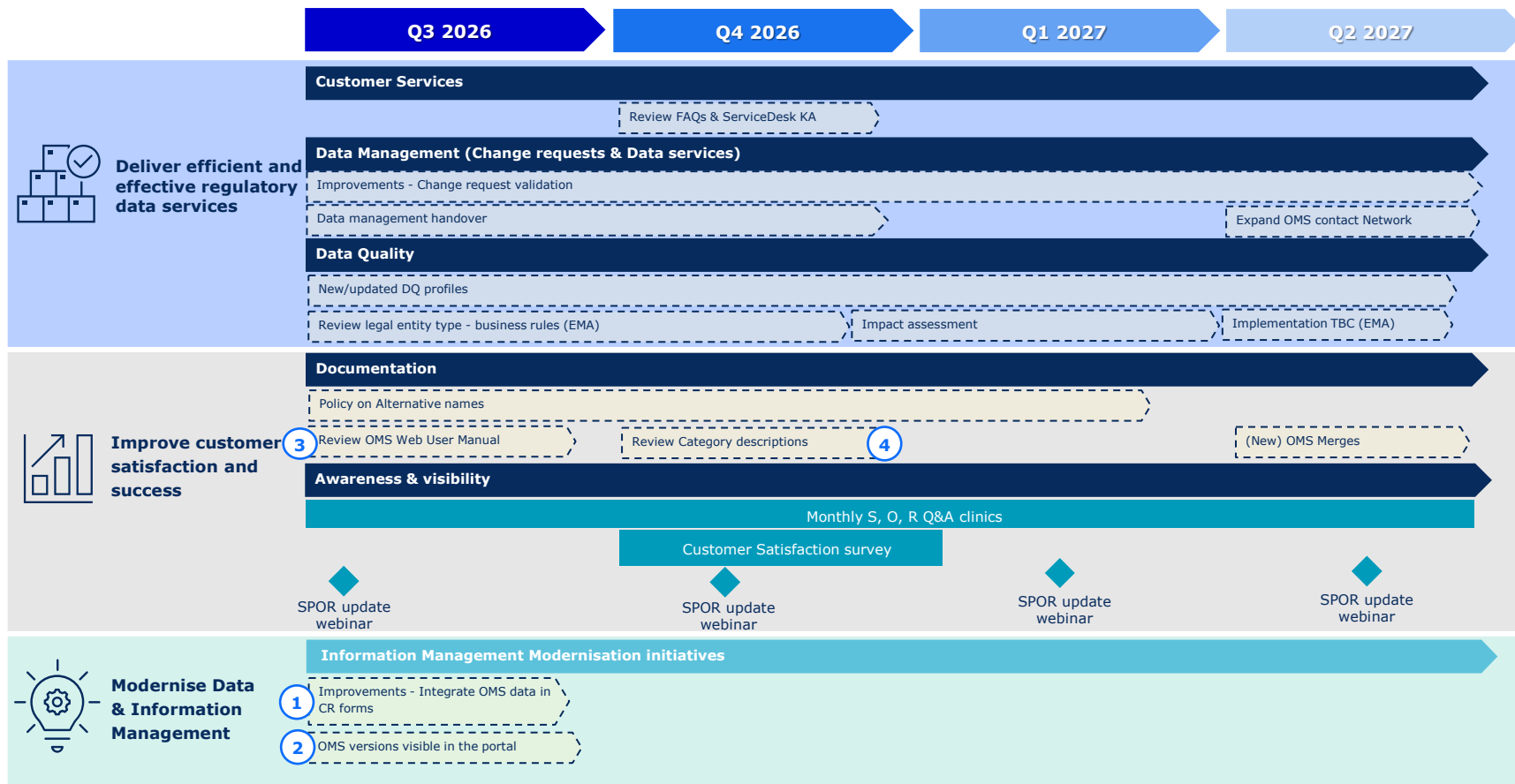
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OMS status update

Planned OMS Activities



For questions: www.slido.com code: #STUP071026

Work completed – What has been done in Q3 2026



Why



How & when



Impact/
benefits to users

1 Integrate OMS data in CR forms <i>Improvements</i>	Manually typing all fields leads to mistakes/typos, longer waiting time, further clarification required and, in some cases, <i>wrong</i> rejections	Improve OMS form accuracy through dropdown data selection, meaning user can select the organisation ID/name from an OMS dropdown list in Change request forms for New location, Update organisation and Update location	Improved user experience since users don't have to copy/paste or type all fields
2 OMS versions visible in the portal	Easier and faster visibility of the latest version reason at both organisation and location level - Version information was already available in OMS exports and OMS API but not in OMS portal	- Organisations and locations records created/updated after July/2025 will display, in the SPOR Portal the latest version information: - 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
3 Review OMS Web User Manual	- Ongoing and continuous review of OMS Web User Manual - Detailed guidance on recently implemented features	- Review current and reflect latest features implemented in SPOR portal e.g. - Inclusion of guidance on OMS subscriptions - Inclusion of details on OMS versions	Clearer and detailed guidance for current and recently implemented capabilities

What's next? – What will be done in Q4 2026



Why



How & when



Impact/ benefits to users

4 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

Highlights to you

 OMS versions visible in the portal Integrate OMS data in CR forms Review OMS Web User Manual	 Data Management team handover Category values/ description review Policy on Alternative names	 OMS merges guideline Review organisation legal entity types	 OMS improvements/backlog e.g. Maintenance of NBRn via CR
What's changed?	Ongoing work	Future changes (What's next?)	On hold 

Acronyms

MDM: Master Data Management solution

CR: Change Request

NBRn: National Business Registries number

Q&A time

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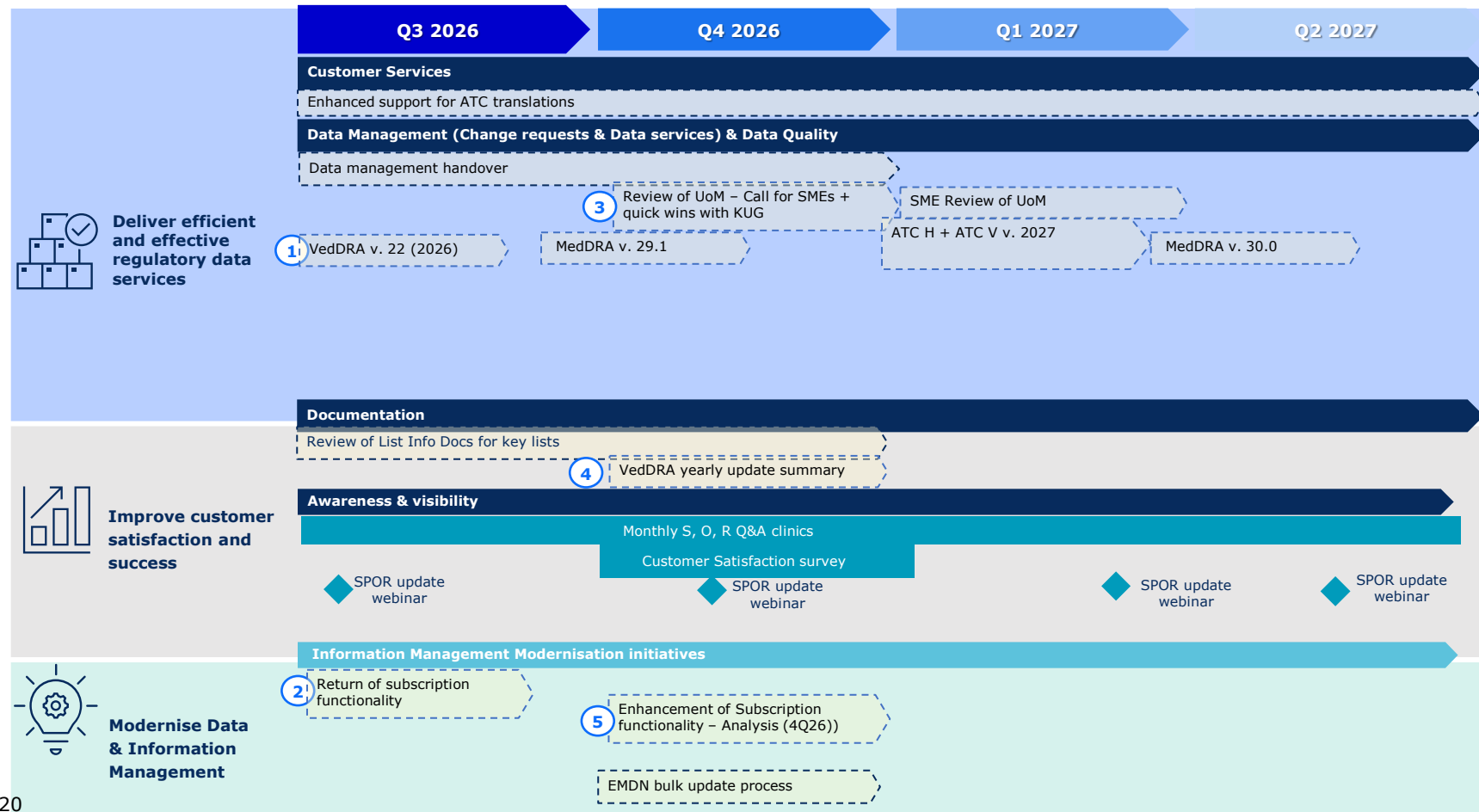


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RMS status update

Planned RMS Activities



Work completed – What has been done in Q3 2026



Why



How & when



Impact/
benefits to users

1

VedDRA v.22 (2026)

- CVMP updates **VedDRA** around **June** every year and **RMS** publishes the revised list asap thereafter.
- This list supports **standardised classification**, analysis and reporting of **adverse events**.

- The VedDRA v. 22 was **published** on the RMS website on 17 July 2026.

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

2

Return of subscription functionality

- Subscriptions (notifications of changes in RMS lists) were temporarily disabled as part of the EMA Service Desk transition and they are now being reinstated, improving visibility and communication on updates.

- Subscribers receive a **monthly e-mail** with the **lists** that have had changes the last **30 days** (advanced search is required to identify updated terms)
- **Subscription** requires an **e-mail address** and **confirmation**.
- No log is required.

- Users will receive automated notifications of list updates, reducing the need for manual checks.
- **Existing subscribers don't need to take action.**
- **New users can subscribe to start receiving notifications.**

What's next? – What will be done in Q4 2026



Why



How & when



Impact/ benefits to users

3 Review of UoM – Call for SMEs + quick wins with KUG	Responding to increased demand, enhancing list quality through review, and supporting PMS readiness.	Initial review with KUG to deliver quick wins (harmonisation and standardisation of terms and other minor corrections in Q4, followed by call for SMEs for a thorough review and optimisation (planned Q1 2027).	- Greater clarity and efficiency. - List fit for purpose, high-quality list. Up-to-date referentials to simplify selection in regulatory applications.
4 VedDRA yearly update summary	To facilitate the identification of changes performed in the yearly updates to the VedDRA list.	Following the process started in 2025, a document showing the new terms inserted, deprecated and updated with the yearly review will be published in the Documentation area of the RMS portal.	Increased transparency and awareness of list updates.
5 Enhancement of subscription functionality	To provide subscribers with expanded change notifications, offering greater detail on updates made in the last 30 days.	4Q26: Analyse enhancement opportunities. 1Q27: Implement detailed notifications showing inserted/updated terms and amended fields within subscribed lists.	- Greater transparency and awareness of lists updates. - Direct visibility of changes, removing the need for advanced searches to identify updates.

Highlights to you

 VedDRA v.22 (2026) Return of subscription functionality	 Data Management team handover EMDN bulk update process Review of List Info Docs for key lists MedDRA v. 29.1	 Review of UoM – Call for SMEs + quick wins with KUG Enhancement of Subscription functionality	 ATC H + ATC V v. 2027 MedDRA v. 30.0
What's changed?	Ongoing work	Future changes (What's next?)	Future changes (What's later?)

Acronyms

VedDRA: Veterinary Dictionary for Drug Regulatory Activities

EMDN: European Medical Device Nomenclature

MedDRA: Medical Dictionary for Drug Regulatory Activities

UoM: Units of Measurement

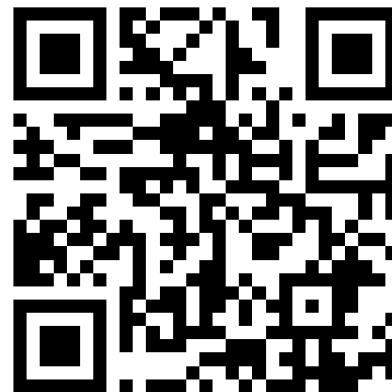
SME: Subject Matter Experts

ESMP: European Shortages Monitoring Platform

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 once a year – *open for 1 month*
- Launched during Q4 SPOR status update webinars



Target audience

SPOR & XEVMPD users



Distribution channel

Slido public link published on EMA website
Users may also receive the link via email



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: 7 November 2026



Slido code: #SPOR-SURVEY26

Coffee break

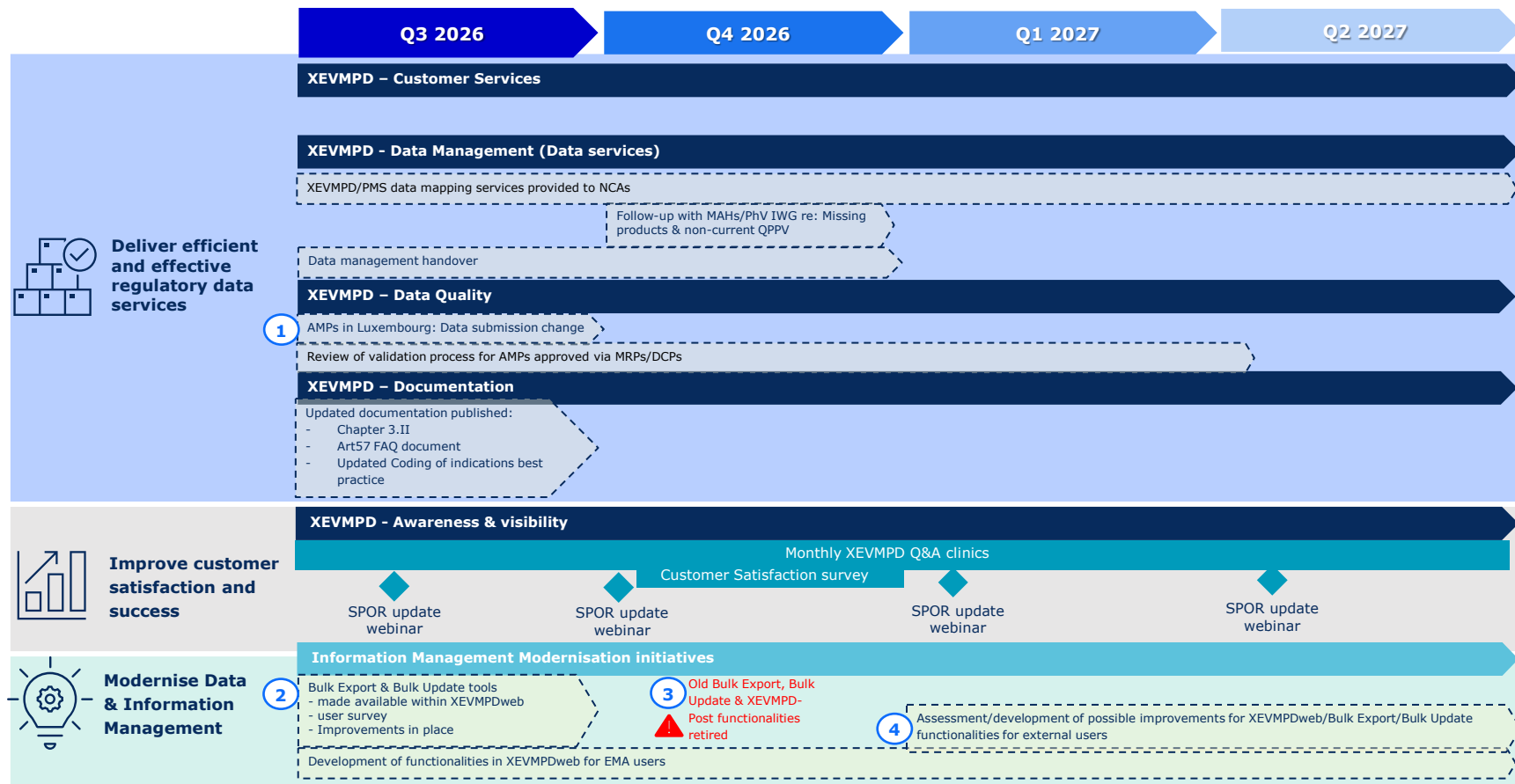


10:55 - 11:05



XEVMPD status update

Planned XEVMPD Activities



Work completed – What has been done in Q3 2026



Why



How & when



Impact/ benefits to users

1 AMPs in Luxembourg: Data submission change

- To standardise data for medicinal products authorised in Luxembourg and thus ensuring correct grouping in PMS

- By liaising with the Luxembourgish NCA and defining clear **guidance on how/where to correctly reference an MA number and package registration number** in the AMP record in XEVMPD
 - Updated **FAQ document** published in Sep 2026, users notified via email*

- Users have clear instructions on how to proceed for such products
- Medicinal products authorised in Luxembourg are correctly grouped in PMS**

2 Bulk Export & Bulk Update tools

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

- Tools now available within the upgraded XEVMPD user interface** (XEVMPDweb)
 - Available from 7 July 2026*
- By conducting a **user survey** on the use of the tools and to gather suggestions for further improvements
 - 31 August – 14 September*
- By implementing some of the **improvements** suggested via the XEVMPDweb survey
 - Upload of more than 50 results possible
 - Authorisation/Renewal date available in 'Fields' of AMP advanced queries
 - Extract of only selected AMPs into Excel possible
 - From Sep 2026*

- No need for ActiveX to access and use any XEVMPD tools**
- More user-friendly, faster processing of requests, improved look and performance

What's next? – What will be done in Q4 2026

	 Why	 How & when	 Impact/ benefits to users
3 Old Bulk Export, Bulk Update & XEVMPD-Post functionalities retired 	These tools are now obsolete/outdated, working on outdated technology (ActiveX and IE Tab)	- By removing the links to these tools from the EV Restricted area - If accessed via a direct link, a notification message with links to the upgraded version is displayed to the user - From 7 October 2026	All tools available within one location (i.e.: XEVMPDweb) No need for ActiveX to access and use these tools - Improved performance
4 Assessment/development of possible improvements for XEVMPDweb/Bulk Export/Bulk Update functionalities for external users	To further improve the functionalities and increase the usage of these tools	- By performing an assessment and development of a number of improvements suggested by survey respondents: - Links to user manuals in the respective XEVMPDweb sections - Allowing alphabetical sorting of filters - The 'Request' button in Bulk Export is highlighted <i>Assessment toward end of Q4/2026</i> <i>Development in Q1/2027</i>	- To improve access to the user manual - To improve usability of the tool

Highlights to you

 Submission of information for AMPs authorised in Luxembourg Bulk Export & Bulk Update tools made available within XEVMPDweb	 XEVMPD/PMS data mapping services provided to NCAs Review of validation process for AMPs approved via MRPs/DCPs Bulk Export, Bulk Update and Post functionality no longer available in EV Restricted area  Data Management team handover	 Follow-up with MAHs/PhV IWG re: Missing products & non-current QPPV Functionalities for EMA users in XEVMPDweb Improvements for Bulk Export and Bulk Update tools	 Improvement on cluster validation process for updated AMPs Integration of product validation with review of substances with SVG flag 0 Review and update of XEVMPD training step-by-step documents
What's changed?	Ongoing work	Future changes (What's next?)	Future changes (What's later?)

Acronyms

AMPs: Authorised Medicinal Products

PMS: Product Management Service

XEVMPD: Extended EudraVigilance medicinal product dictionary

PhV IWG: Pharmacovigilance Inspectors Working Group

NCA: National Competent Authority

Q&A time

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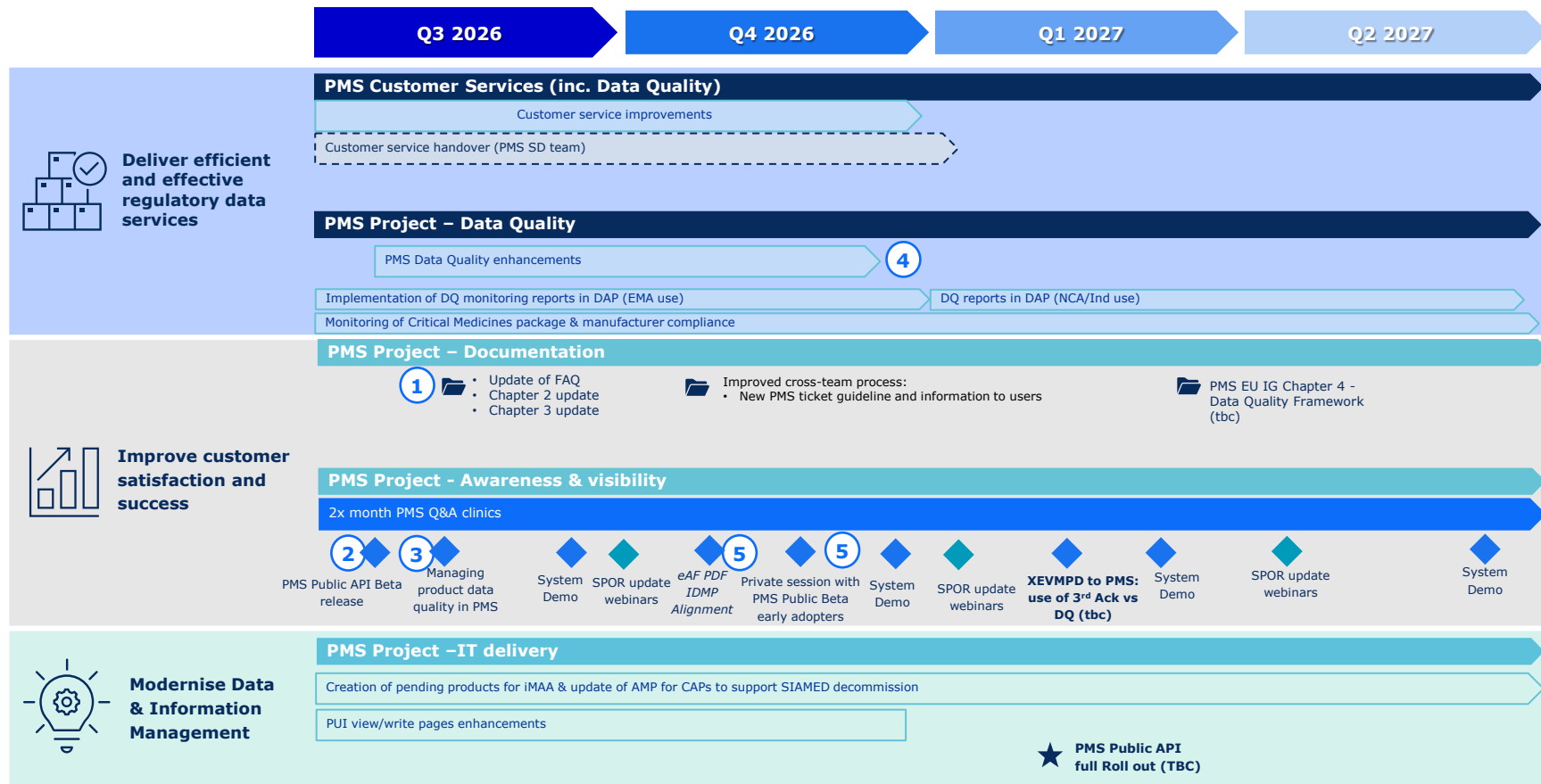
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PMS status update

Planned PMS Activities



Work completed – What has been done in Q3 2026



Why



How & when



Impact/
benefits to users

1 PMS Documentation updates	To provide updated guidance, enhance usability, and increase transparency on progresses of PMS deliveries.	In Q3 2026 the following updates have been published on PMS page/PUI portal: •Chapter 2: Updated business rules, PMS enrichment requirements and technical tables. •Chapter 3: Clarified CAP requirements, temporary MBO enrichment rules and Note 2 (enrich valid products irrespective of their marketing status). •FAQ: Added guidance on incorrect OMS data and when to open a ticket.	Users benefit from clearer and up-to-date guidance on •enrichment requirements, including how to submit manufacturer data and manufacturer operations used in CAP. •known issues and their implementation status
2 Public PMS API Beta release - Webinar	To help users understand how the API works and what data is available, and start building their connection to the API.	Public PMS API Beta release was launched on 12 June 2026. Access details are available on the PMS webpage: Annex B to Chapter 1 The Public PMS API Beta release webinar was hosted virtually via Webex, on 13 July 2026 (2-3:30 PM). Recording and material are available at the following Link.	Access authorised medicinal product data and familiarise with the system and model, to enable innovation, automation and new use cases.
3 Managing product data quality in PMS & customer service - Webinar	Raise awareness among stakeholders and provide information on identified findings, relevant data, and bug-fix activities, with the aim of improving overall data quality in PMS.	The Managing product data quality in PMS & customer service webinar was hosted virtually via Webex, on 21 July 2026 (2:30-4:00 PM). Recording and material are available at the following Link.	Users gathers clear guidance to identify PMS data quality issues, understand planned fixes and report new findings.

What's next? – What will be done in Q4 2026



Why



How & when



Impact/
benefits to users

4 PMS Data Quality enhancements (continuation)

To improve PMS data quality, ensure reliable data, and support accurate and efficient use of product data in future regulatory processes.

User-visible data quality improvements

- **Clean up and correct CAP product data**, including **duplicated** inner resources and data incorrectly reflected in PMS.
- **Improve product grouping** based on **MA numbers** to prevent duplicate products from being created in PMS.

Backend improvements in progress

- **XEVPRM processing**: Implement technical improvements to ensure larger XEVPRM messages are processed reliably and completely.
- **Multilingual package grouping**: Finalise the implementation to merge duplicate multilingual packages where the package description is identical (same text and language) for products authorised in BE, LU and FI.
- **RMS/OMS synchronisation**: Improve data synchronisation to ensure RMS/OMS information is consistently captured in products.

- 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.

5 IDMP-aligned eAF iMAA (PDF) & dedicated industry training

The MAA eAF (PDF) has been partially aligned with IDMP to support future interoperability with PMS and improve data quality.

The updated **MAA eAF v1.28.0.0** with partial **IDMP alignment** was implemented in **Q2 2026** and became **mandatory** for CAPs from **28 July 2026**. It applies to **procedures starting from 1 September 2026**. To support the transition, EMA teams are organising dedicated training and Q&A sessions for industry planning to submit MAA in Q4.

Users can learn how to **correctly complete structure product** information from the outset, supporting smoother submissions and future data flow to PMS.

6 Private session with PMS Public Beta early adopters

To gather feedback from early adopters of the Public API and identify potential enhancements and areas for improvement.

In Q4, a **private webinar via invite only** will be organised and hosted via Webex. **Active API callers** will be invited in due course.

The webinar will focus on the following key topics:

- Early adopter experience
- Feedback and key challenges
- Potential enhancements

- **Share real-world experience** with the PMS Public API
- **Learn from other early adopters** and their experiences
- **Improve API usage** through shared practices and insights

Highlights to you

 PMS Documentation updates PMS Public API Beta release - Webinar Managing product data quality in PMS & customer service - Webinar	 Private session with PMS Public Beta early adopters Continuous DQ enhancements	 PMS documentation update: Chapter 4 Data Quality Framework PMS Public API – Full roll out	 PMS FHIR R5 upgrade Creation of pending products for iMAA: 1st CAP; 2nd non-CAPs XEVMPD submissions decommission
What's changed?	Ongoing work	Future changes (What's next?)	Future changes (What's later?)

DQ: Data Quality

PMS: Product Management Service

PMS API: PMS Application Programming Interface

XEVMPD: Extended EudraVigilance medicinal product dictionary

Acronyms

Q&A time

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Feature topics

OMS versions visible in the portal



OMS versions visible in the portal

Improved transparency and reduced dependency on exports and APIs

Where



- Version information was already available in **OMS exports** and **OMS API**
- Version details are **now also visible in OMS portal**
- Only available to records with versions created after July/2025 – date of back-end version feature implementation
- Guidance is available in OMS portal in the document *F – OMS Web User Manual*

EMA | SPOR

Substances Products Organisations Referentials Help

SPOR Home Organisations Preferences Documents

Home / Search Organisations 1

Hide search

Organisation ID

Organisation name

Location ID

Address

City

Postcode

Country

Modified Since

Location status

Contains

Contains

Contains

Contains

Contains

0 Selected

yyyy-MM-dd

ACTIVE, INACTIVE

Reset Search 2

Organisation ID	Organisation Name	Country	Location ID	City	Address	Postcode	Location status	Modified	Actions
ORG-10000055	Mizar Farmaceutica S.L.	Spain	LOC-100004118	Barcelona	Gran Via De Les Corts Catalanes 764	08013	ACTIVE	2023-10-09T10:05:40	3

Showing: 20 of 1 results

Showing: 20 of 1 results

Home / Search Organisations / View Organisation Location

Organisation Details

Organisation ID:	ORG-10000055
Organisation Name:	Mizar Farmaceutica S.L.
Status:	ACTIVE
Organisation Type:	Industry Pharmaceutical company
Organisation Version:	Validation check Data Services - organisation valid as off organisation time stamp date

Location Details

Location ID:	LOC-100004118
Address:	EN Gran Via De Les Corts Catalanes 764 Barcelona 08013 Spain
GPS Location:	41.378392, 2.154027
xEVMPD Code:	ORG11447
Last Modified Date:	2023-10-09T10:05:40
Status:	ACTIVE

OMS versions visible in the portal

Improved transparency and reduced dependency on exports and APIs



What

- **Version types** – RMS list populated by Data steward

200000045065	New
200000045066	Standardisation update
200000045067	Name change
200000045068	Business merge
200000045069	Deduplication
200000045070	Mapping enrichment - external information
200000045071	Mapping enrichment - internal information
200000045072	Validation check
200000045073	Deactivation
200000045074	Unmerge

Version information have 2 fields

Organisation Details	
Organisation ID:	ORG-100000578
Organisation Name:	AqVida GmbH
Status:	ACTIVE
Organisation Type:	Industry Pharmaceutical company
SME Number:	EMA/SME/314/13/R12
SME Size:	SME
SME Size:	Medium
Organisation Version:	Mapping enrichment - external information Data Services - update SME number
Location Details	
Location ID:	LOC-100024849
Address:	EN Werkstrasse 21 Dassow 23942 Germany
GPS Location:	53.905281, 11.001480
Last Modified Date:	2025-10-08T09:22:19
Status:	ACTIVE
Location Version:	Standardisation update Data Services - State removed as per NPS

- **Version comment** – free text field populated by Data steward

➤ Origin of the change

- Data Quality
- Data Service
- Customer Service
- Change Request

➤ Summary of data changes e.g.

- Update SME number
- State removed as per NPS

Integrate OMS data in CR forms



Integrate OMS data in CR forms

Improved form accuracy by reducing error from manual data entry

New Organisation

- **No changes** to the form since the purpose is to create a new record

New Location

- Added a dropdown list of **Active OMS organisations**
- First, user must **choose** the organisation from the dropdown list by typing **part of the name or ORG ID**
- Populate address details of the location that needs to be added

Organisation Details

*Organisation ID

ORG-100000000	Avantis Sp. z o.o.
ORG-100000001	Astrazeneca UK Limited
ORG-100000002	AstraZeneca
ORG-100000003	Astellas Pharma Europe B.V.
ORG-100000004	Ayrton Saunders Limited
ORG-100000005	Abbott Laboratories d.o.o.
ORG-100000006	Allergopharma GmbH & Co. KG

Update Organisation

- Added a dropdown list of **Active OMS organisations**
- First, user must **choose** the organisation from the dropdown list by typing **part of the name or ORG ID**
- Populate organisation details that need to be updated

Organisation Details

*Organisation ID

Organisation Name

Acronym

Location Details

*Location ID

LOC-100000000	Spargelfeldstrasse 191 - Vienna
LOC-100000001	Bethovenstrasse 4 - Graz
LOC-100000002	Robert Koch-Gasse 17 - Miedling
LOC-100000003	Pöschingergasse 38 - Vienna
LOC-100000004	Trainsengasse 5 - Vienna
LOC-100000005	Zinzendorfstrasse 27 - Graz
LOC-100000006	Ernststrasse 9 - Brussels

Update Location

- Added 2 interactive dropdown list of **Active OMS organisations and locations**
- User can opt by initiating the search using either Organisation or Location search
 - If user starts with organisation search it will need to choose the applicable location under the location dropdown list - by typing **part of the name or ORG ID**
 - If user starts with location search, organisation data will be automatically populated once 1 location is selected – by typing **part of the Address line 1, City or LOC ID**
- Populate organisation details that need to be updated



Conclusions

Q3 highlights

Deliver efficient and effective regulatory data services

- Maintain the provision of S, O, R and XEVMPD/PMS data management services
 - **SMS**: Continued changing substance preferred terms
 - **RMS**: VedDRA V22
 - **XEVMPD**: Updated Art57 documentation published
 - **PMS**: Update of Guidance documents and finalise product de-duplication

Data Management Knowledge Transfer

Improve customer satisfaction and success

- Provide increased and targeted customer engagement
 - **OMS**: Review OMS Web User Manual
 - **XEVMPD**: Survey on the use of upgraded Bulk Export and Bulk Update tools

Modernise data & information management

- Improve S, O, R and XEVMPD/PMS data management capabilities
 - **SMS**: Bulk functionalities improved
 - **OMS**: Integrate OMS data in CR forms and OMS versions visible in the portal
 - **PMS**: Beta release of Public PMS API
 - **RMS**: return of subscription functionality
 - **XEVMPD**: Upgraded Bulk Export and Bulk Update tools released into production

Q4 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:** Review of UoM – Call for SMEs + quick wins with KUG
- **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)

- **XEVMPD:** Old Bulk Export, Bulk Update & XEVMPD-Post functionalities retired



Upcoming SPOR & XEVMPD engagements



Q&A Clinics on SOR

- 14 Apr 2026
- 12 May 2026
- 10 June 2026
- 8 July 2026
- 9 Sep 2026
- **7 Oct 2026 (15:30 – 16:00)**
- **11 Nov 2026 (15:30 – 16:00)**
- **9 Dec 2026 (15:30 – 16:00)**
→ *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
- 23 July 2026
- 10 and 24 Sep 2026
- **8 Oct 2026 (9:30 – 10:30)**
- **22 Oct 2026 (9:30 – 10:30)**
- **12 Nov 2026 (9:30 – 10:30)**
- **26 Nov, (9:30 – 10:30)**
- **10 Dec (9:30 – 10:30)**
→ *registration available on EMA corporate website!*



Q&A Clinics on XEVMPD

- 16 Apr 2026
- 13 May 2026
- 11 June 2026
- 9 July 2026
- 10 Sep 2026
- **8 Oct 2026 (15:00 – 16:00)**
- **12 Nov 2026 (15:00 – 16:00)**
- **10 Dec 2026 (15:00 – 16:00)**
→ *registration available on EMA corporate website!*



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Thank you

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