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

Q&A Management

- Questions will be shown on the screen and managed live in the Q&A session
- EMA colleagues will attempt to **address questions in writing throughout the session**
- EMA colleagues will **verbally address (unanswered) top voted questions** at the end in the live Q&A session

Unanswered questions

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

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Webinar materials sharing and technical recommendation

Presentations will be available at:

- SPOR Portal Documents section
- EMA Events Web Page

Recordings will be available at:

- EMA YouTube Channel
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SCIENCE MEDICINES HEALTH

Product Management Service (XEVMPD) for marketing authorisation holders

10 October 2024, 10:00 – 12:00 Central European Summer Time (CEST)

Presented by Marcos Fernandez Gomez and Veronika Baker

SPOR Webinar Series – 4-14 October 2024

SPOR Webinars

During **SPOR webinars,** EMA's Regulatory Data Management Service team talks about all aspects of regulatory data management and how it works today.

Webinar title	Date	Time
SPOR Data Governance	4 October 2024	10:00-12:00 CEST
Referentials Management Service (RMS)	7 October 2024	10:00-12:00 CEST
Substance Management Service (SMS)	8 October 2024	10:00-12:00 CEST
Organisation Management Service (OMS)	9 October 2024	10:00-12:00 CEST
Product Management Service (XEVMPD) for MAH	10 October 2024	10:00-12:00 CEST
Product Management Service (XEVMPD) for Sponsors	11 October 2024	10:00-12:00 CEST
Substance, product, organisation and referential (SPOR) application programming interface (API) - SPOR API	14 October 2024	10:00-12:00 CEST

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Goals of the session

- Re-cap of **XEVMPD submissions requirement** and **processes for AMPs**
- Share an **XEVMPD status overview**
- Provide information on the **relationship between XEVMPD and PMS**
- Remind MAHs of the **actions to be taken** on their XEVMPD data

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Agenda

1. **Welcome**
   10:00 – 10:05
2. **Introduction to XEVMPD and pre-submission requirements**
3. **Mandatory reporting requirements and XEVMPD submission process**
4. **Data stewardship – AMPs in XEVMPD**
5. **XEVMPD statistics**
6. **XEVMPD Documentation & help**
7. **XEVMPD and its relationship with PMS and eAF**
8. **Break**
   10 minutes
9. **XEVMPD Status update**
10. **Key Takeaways and Conclusions**
11. **Q&A Session**
    11:45 – 12:00

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Introduction to XEVMPD and pre-submission requirements

Presented by Marcos Fernandez Gomez

XEVMPD introduction

XEVMPD
(aka 'Article 57 database')
Centralised source** of **information on authorised and un-authorised medicines

Authorised medicinal **product data** is submitted and maintained in the XEVMPD by **marketing authorisation holders (MAHs)**

as per Article 57(2) of Regulation 726/2004

Un-authorised (referred to in the XEVMPD as 'development') medicinal product data is **submitted and maintained** in the XEVMPD by **sponsors**

as per Article 81(3) of Regulation (EU) No 536/2014

Substance records are submitted and maintained in the XEVMPD by EMA's **Substance Management Service (SMS) data stewards**

MAH and **sponsor organisation** records are submitted and maintained in the XEVMPD by **MAHs** and **sponsors**

Referential terms are submitted and maintained in the XEVMPD by **EMA's Referentials Management Service (RMS) data stewards** and **sponsors (development terms only)**

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Pre-submission requirements (1/2)

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- XEVMPD can be used by all **organisations registered with EudraVigilance** for **medicinal product reporting**

  i.e.: marketing authorisation applicants (MAA), marketing authorisation holders (MAHs), sponsors, national competent authorities (NCAs)

  - Clinical research organisations (CROs), IT vendors and third-party service providers registered in EV under MAH/sponsor organisation profiles
    - independent registration with their own EudraVigilance ID not possible
    - can only submit information on behalf of MAH/sponsors registered in EV, using the MAH's/sponsor's organisation ID
- **Organisations** must be registered in the Organisation Management System (OMS)

- **Individual users** must be registered in the EMA Account Management Portal

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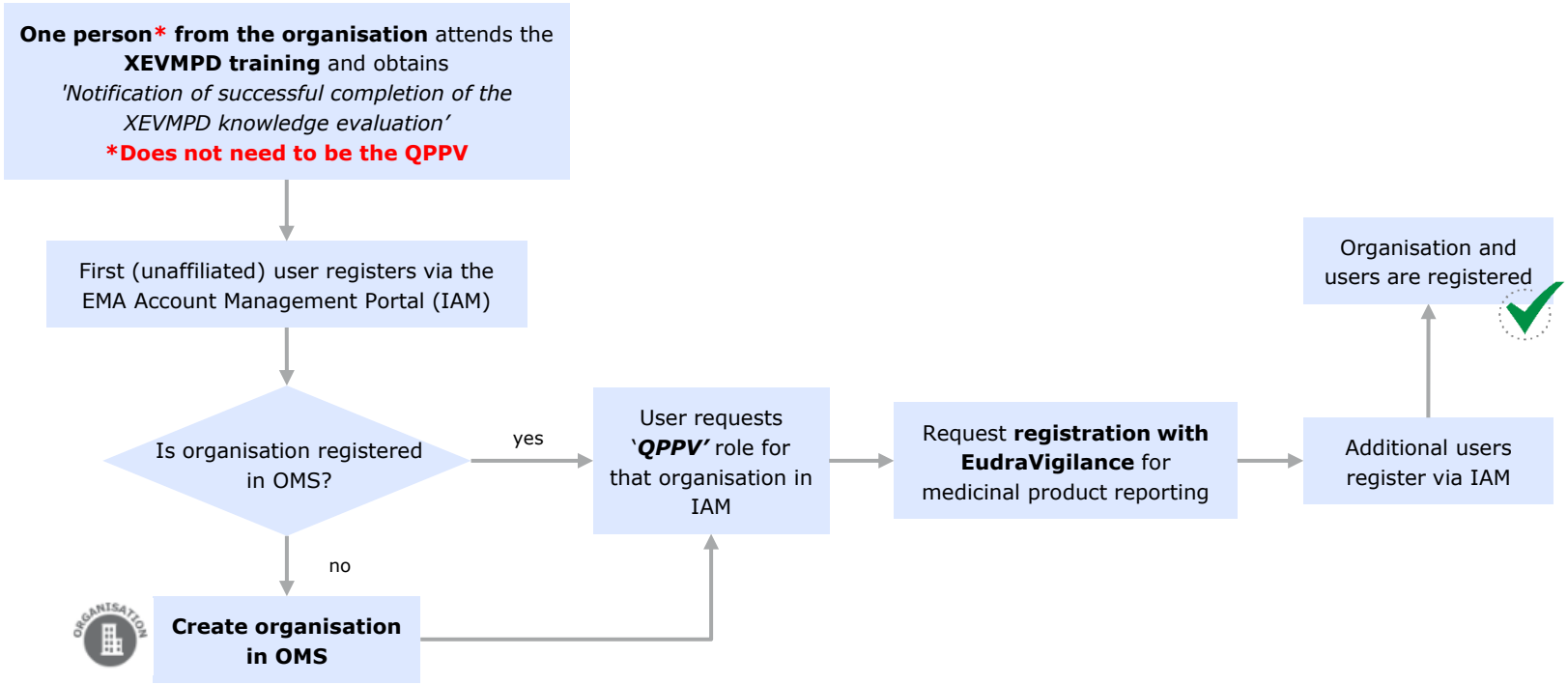
Pre-submission requirements (2/2)



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Available as:

- **Virtual** training course run by the Drug Information association (DIA)
  - Separate courses for MAHs and sponsors
  - **Paid** training course; **trainer led**, knowledge evaluation is performed by the trainers
  - No limit on the number of participants from one organisation

- **E-learning** training
  - Separate courses for MAHs and sponsors
  - **Free** training based on **self-study**; users register for knowledge evaluation via EMA Service Desk
  - Max 5 people from the same organisation
    - '*Notification of successful completion of the XEVMPD knowledge evaluation'* is requested from **one person** during the **organisation's initial registration in EV**

The holder of the notification **can train others** as part of internal knowledge transfer

XEVMPD process

Presented by Marcos Fernandez Gomez

XEVMPD Data management processes

EMA Data Steward

Business lead/ Product Owner

SPOR User **AMP submission**

Data Stewardship

Data services
- Proactive data curation (e.g., AMP validation)
- Data cleansing and corrections
- Follow-ups (FUPs) with MAHs

Data publication
Monthly publication of AMP data to share PhV contact details

Data mapping services to NCAs NEW

Customer Service

Request Information

Request Services

Report technical issues

Data Quality Management

Quality Control
Sampling & checking of performed activities

Data profiling
Monitoring & investigation across entire data

Quality Assurance
Root causes & process improvements

Service Management

Service Coordination
With Data governance & IT delivery

Performance management
- Invoicing
- KPI reporting
- Customer satisfaction

Data management processes are defined, operational and are monitored

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Data stewardship – AMPs in XEVMPD

Presented by Marcos Fernandez Gomez

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Mandatory reporting requirements for MAHs

Legal obligation from Article 57(2) of Regulation (EC) No 726/2004, the EEA Agreement and the Protocol on Ireland/Northern Ireland

MAHs **must submit** to the XEVMPD information on **medicinal products for human use authorised** under a *national, mutual-recognition, decentralised* and/or *centralised authorisation procedure in the EU*, *EEA countries and the Northern Ireland.*

- **New authorised medicinal products** must be submitted as soon as possible and no later than **15 calendar days** from the date of authorisation
- **Amendments to the terms of the marketing authorisations** following variation, transfer, renewal, suspension, revocation or withdrawal of the marketing authorisation must be submitted no later than **30 calendar days** from the date of which the amendments have been authorised

Voluntary reporting requirements for MAHs

MAHs **may submit** to the XEVMPD **information on:**

- **Herbal medicinal products** - Art. 16a Dir No 2001/83/EC (traditional use registration application)
- **Homeopathic medicinal products** - Art 14 Dir No 2001/83/EC (simplified registration application)
- **'Named patient use' and 'EU Distribution Procedure'** - Art 5(1) and Art 5(2) Dir 2001/83/EC
- **Parallel Distributed/Imported medicinal products** - Art 76(3) and (4) Dir No 2001/83/EC]
- Medicinal products authorised **outside the EEA** or following a non-EU procedure
- Products **without a marketing authorisation in the EU/EEA**, which are **approved under emergency use, compassionate use or other national schemes**

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Qualified person responsible for pharmacovigilance (QPPV)

Legal obligation from Directive 2001/83/EC Article 103: *The marketing authorization holder shall have permanently and continuously at his disposal an appropriately qualified person responsible for pharmacovigilance*

- MAHs must have an **EU QPPV** registered in EV at the HQ level
  - **Trusted deputy** or **additional QPPV** (e.g., at national level) may also be registered
- A **QPPV must be referenced in the relevant AMPs** in the XEVMPD
  - A QPPV Code referenced in their AMPs must be a **valid QPPV Code** referring to a **current QPPV**
- In case of a **change of a QPPV (as a person)**:
  - the MAH must nominate a **new QPPV within 10 calendar days**;
  - AMPs must be updated to reference the new QPPV immediately and **no later than 30 calendar days.**

Pharmacovigilance system master file location (PSMFL)

Requirement as per Guideline on good pharmacovigilance practices (GVP): Module II – Pharmacovigilance system master file

- **Since 2 July 2015**, MAHs must submit PSMFL information to the Article 57 database
- The assigned **PSMFL EV Code must be referenced in the relevant AMPs**
- **Changes to the PSMFL information** must be reflected in the XEVMPD immediately and no later than **30 calendar days since the change applies**
  - Incl. PSMFL amendment in AMPs

AMP: Initial submission process

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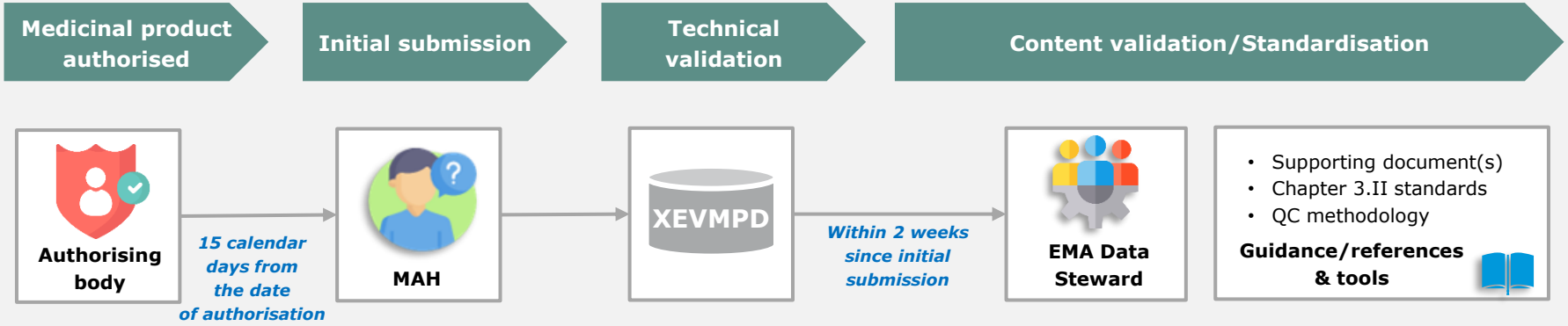

Submit AMP data in XEVMPD:

- **Insert AMP information**, including MAH/PSMFL/QPPV information reference
- Insert and reference in the AMP record(s) **supporting document(s)** (e.g. SmPC/PIL)

Check if mandatory data is provided in accordance with technical and business rules in place

- Chapter 3.I: Technical specifications
- Chapter 3.II: business guidance

1st and 2nd XEVPRM ACK generated

Perform validation based on

- Information provided in documents
- Chapter 3.II describing the business rules/approach for entering AMP data
- Data quality control methodology
- Rational assessment of the submitted information

AMP: Validation process

Content validation outcome - AMP validated/flagged for follow-up (FUP)

Product **entry is validated** (with or without changes made as part of the validation)

AMP record data (except for MFL and QPPV details) **become visible** to other users in EVWEB, not just the owner organisation and EMA. AMP record is used to support PhV activities

If MAH disagrees with the changes made as part of the validation/in case of additional questions, submit a ticket via the EMA Service Desk portal

MAH receives validation related XEVPRM ACK
(3rd XEVPRM ACK)

Product **entry not assessed**, FUP communication triggered

MAH receives FUP communication
(Emails are sent on weekly basis)

MAH amends product entry as required/provides additional documents
As per the timelines specified in the FUP communication (i.e.; 15 or 30 calendar days)

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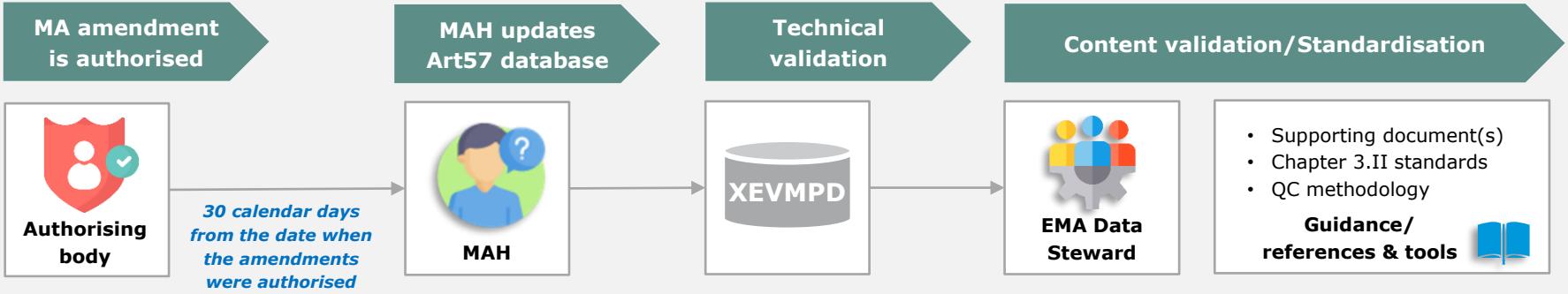
AMP: Amendments following a regulatory procedure process



Insert/update/invalidate AMP data in XEVMPD as applicable

- Based on processes described in Chapter 3.II: business guidance
- Insert and reference in the AMP record(s) **supporting document(s)**

1st and 2nd XEVPRM ACK generated within 24 hours since submission

Perform follow-up validation

- *Re-validation is performed as needed and max within 2 years since last validation*

AMP CAP submission compliance check

Regular check performed by the EMA

New CAPs	Transferred, renewed, revoked, withdrawn and expired CAPs

• **Number of presentations** in EMA DB (SIAMED) is **compared** with XEVMPD entries
• **Product information** is entered in:
  • EMA's scientific group table
  • European Pharmacovigilance Issues Tracking Tool (EPITT)
• *If CAP data is not inserted in XEVMPD by the MAH **within 15 calendar days since authorisation** -> the QPPV is contacted*
	• **XEVMPD entry check** is performed on:
	  • **transferred MAs**
	  • **renewed MAs**
	  • **revoked/withdrawn/expired MAs**
	  • *If MA changes related to the above procedures were not notified correctly in the XEVMPD by the MAH **within 30 calendar days since MA amendment** -> the QPPV is contacted*

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Data Publication

Monthly

List of medicinal products authorised in the EU/EEA published on EMA web page: Public data from Article 57 database | EMA (europa.eu) **to share MAH's pharmacovigilance contact details (phone number and e-mail)**

This will be replaced by a PMS dynamic report when the functionality is ready in the Product User Interface (PLM Portal)

Quarterly

XEVMPD controlled vocabulary lists published on: Guidance documents | European Medicines Agency (europa.eu)

This publication has been discontinued in 2023; information is available in the relevant SPOR services

Ad-hoc

Updates of documentation (Guidance docs, Q&A docs, other) as required

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Data mapping services

- **EMA** will provide **data mapping services to NCAs** to facilitate the **initial implementation** and mapping of national product data against PMS data.
- **One off service** based on EMA capacity, budget availability and executed in **order of submission**. *Not a continuous EMA service.*

NCAs to **implement a process to maintain data mappings in the future** to cover both legacy and newly authorised products.

Monthly webinars

- **EMA** will host a series of **follow-up webinars from Q4 2024 (as of October) until end of 2025** to*:*
  - **Report mapping progress** (number of NCAs who submitted product data to EMA, number of NCAs mapping their product data, status of the service provided by EMA, reporting and monitoring main identified issues etc.).
  - **Facilitate lessons exchanges** among NCAs.
  - **Q&A session** to address NCA data mapping queries.

Benefits

- **Reduced NCA burden** and therefore **facilitate NCA initial implementation** and mapping of national product data against PMS data
- **Continuous support** and **enhanced collaboration** through NCA mapping activities
- Increased **transparency of product data mapping efforts** performed by EMA and NCAs

XEVMPD Statistics

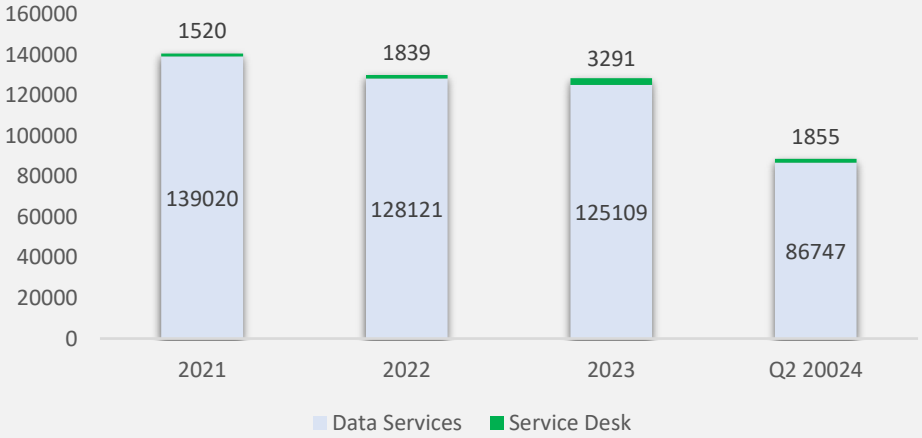
Presented by Marcos Fernandez Gomez

 For Questions: www.slido.com code: #SWOCT1024

XEVMPD Statistics

- The amount of **new products validation has been increased** this year due to the submission of new EV codes to support eAF and ESMP projects.
- **Service Desk numbers are consistent** with other years

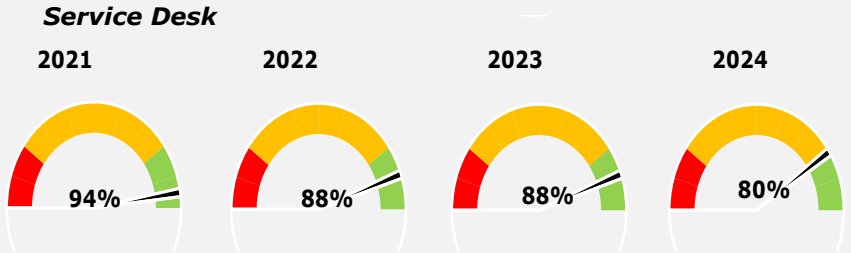
xEVMPD Activities



**2024 up to Q2 cumulative*

- **SLA overall compliance is within the target score**
- Lower overall compliance due to more time needed to reply to DMP request tickets and more incidents requiring more than 5 days to be solved. The reason being that different systems and teams should be contacted to resolve the incidents.

Overall Compliance



Documentation overview & help

Presented by Marcos Fernandez Gomez

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EMA corporate website

- Overview of reporting requirements **for MAHs**, links to guidance documents
- Information on how to register with EV for product reporting

EMA Account Management Portal

- Guidance on to obtain access to EMA systems (including SPOR & XEVMPD)
- Create a new EMA account and request SPOR user role

Training opportunities

- @emainfo channel contains Videos of SPOR webinars with tips/tricks and questions raised from users
- XEVMPD Training webpage contains overview of available training courses, training documents & step-by-step guides

EV Restricted Area

- Access to EV Services (EVWEB, XEVMPD Export and Bulk update tools etc.)
- User Support section– technical documentation

EMA Service Desk

- To request information, support with XEVMPD data management, report technical issues
- Managed through the ServiceNow Portal

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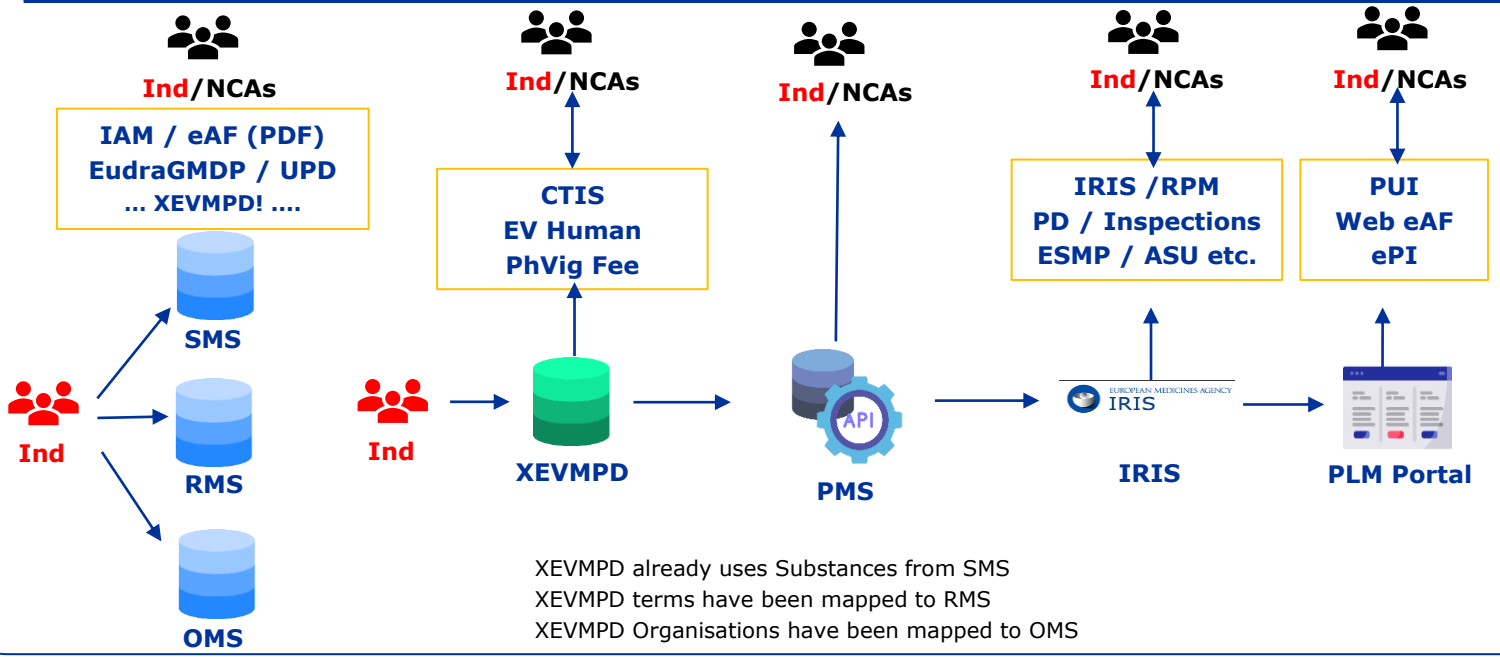
XEVMPD and its relationship with PMS, eAF & ESMP

Presented by Marcos Fernandez Gomez

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



XEVMPD already uses Substances from SMS
XEVMPD terms have been mapped to RMS
XEVMPD Organisations have been mapped to OMS

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

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What does this mean for you and XEVMPD?

Medicinal products from XEVMPD available in Product UI and PMS API

- MAHs and NCAs can access their products and the product data through the PMS API and the Product UI.
- Registration process explained in Chapter 1 of EU IG.

Web-based variation form using PMS products.

- The web-based variation form can be already be used for CAPs and will be available soon for non-CAPs as well: MRPs, DCPs and pure NAPs.
- Notification will be sent by the eAF colleagues as soon as the form is ready for non-CAPs

ESMP consuming data from PMS

- ESMP is also using the products from PMS.
- Please, make sure you follow the requirements from XEVMPD to have the correct products and pack sizes in PMS.

AMP submissions

- XEVMPD submissions are still mandatory and are the only way to keep PMS updated.

Same long-term goal

- Replace XEVMPD submissions with direct submissions to PMS for CAPs and NAPs

Actions for MAHs to take (1/3)

To support eAF, MAHs are required to:

- Submit to XEVMPD **herbal and homeopathic products** that are required for the web-based variation form.

- Submission of **MRPs and DCPs** approved in the Reference Member State but still **under evaluation** in the Concerned Member States will be allowed in Q1 2025.
    - This **pending MRPs and DCPs** are a specific use case for eAF.
    - **Pending pure NAPs** should not be submitted to XEVMPD as variations are not allowed for NAPs that are still under evaluation.

- Check that **non-CAPs have been migrated correctly in PMS** so there are no issues when trying to submit a variation.

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Actions for MAHs to take (2/3)

To support ESMP, MAHs are required to:

- Submit **pack sizes** for the products under the ULCM before or on 31st Jan 2025. Instructions can be found in Chapter 3.II and the 'pack size submissions' webinar.
  - Include meaningful information at package description: National IDs
  - General rule: update the existing EV code for multiple pack sizes to the lowest pack size and insert the rest of the packs as new.

- For medicinal **products with several official names**, use the same package description (same language and info). This will allow us to **merge EV codes under the same packaged medicinal product** in Q1 2025.

- Start compiling **manufacturers and manufacturing business operations** for non-CAP products under the ULCM. Capability to submit this information through the Product UI and PMS API will be released in 2025.

Actions for MAHs to take (3/3)

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To enhance the data quality of products, MAHs are advised:

- **Not to reference substances with SVG flag 0 and the comment "Duplicate" in any new or existing owned product records in the XEVMPD**
- **MAHs can update their AMPs**; if any substances denoted by an SVG flag "0" and the comment "Duplicate" is referenced -> MAHs can replace them with the replacement substance provided.
    - *If no review is performed, the EMA will make the replacements in the product entries in 2025.*

- **Not to reference terms to be nullified in new product record submissions or updates in the XEVMPD**
- **MAHs to review XEVMPD-RMS data mapping files** and, if their AMPs reference a term/data for which an action is required -> MAHs can perform the required action/update of AMP.

- Enter **MAH details in XEVMPD as per OMS**
    - Include the LOC ID in the 'Comment' field of the MAH entity.

See SMS/RMS/OMS webinar for further details

- Review **3rd ACKs and follow-up communication (FUP) emails** from the EMA and perform the required actions/amend data in their internal database.

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Break (10 minutes)

Let's have a short break!

XEVMPD status update

Presented by Veronika Baker

Planned XEVMPD Activities

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	Q3 2024	Q4 2024	Q1 2025	Q2 2025
Deliver efficient and effective regulatory data services	**XEVMPD – Customer Services**			
	XEVMPD - Data Management (Data services)			
	1 Validation of new AMP entries due to pack size additions			
		3 Revision and improvement of current AMP validation process		
	NEW	4 XEVMPD/PMS mapping services provided to NCAs		
	XEVMPD – Data Quality			
	2 Data quality review to support PMS migration			
Improve customer satisfaction and success	**XEVMPD – Documentation**			
		Revision and update of published Article 57(2) data Q&A document		
	XEVMPD - Awareness & visibility			
	SPOR update webinars	SPOR week; SPOR Customer Satisfaction survey	SPOR update webinars	SPOR update webinars
Modernise Data & Information Management	Information Management Modernisation initiatives			
		5 Review of current XEVMPD User Interface and assessment of possible technical upgrade		
			6 New authorisation status value in XEVMPD	

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

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	 WHY	 HOW & WHEN	 IMPACT/ BENEFITS to users

1 **Validation of new AMP entries due to pack size additions**	• To ensure that validation is performed shortly after the initial submission and is consistent for all product records for the same medicinal product	• MAHs to submit information on AMPs down to the **pack size level for <u>critical medicines</u>**
		  • *By 31 January 2025*
		• EMA to validate newly submitted records
		  • *On weekly basis*
			• Proactive measure to support management of shortages in the EU and the European Shortages Monitoring Platform (ESMP) project
			• No delay in making newly submitted product data available for Pharmacovigilance and other business processes

2 **Data quality review to support PMS migration**	• To ensure high quality of data in XEVMPD and PMS	• Frequent **review of key fields** that impact the XEVMPD to PMS migration such as Auth numbers, EU numbers, Auth country, etc. • **Improvement of the terms used in XEVMPD** by checking proposed terms and where necessary, update to standard terms or nullify if not used in any product	• Minimise migration issues and risk that product may not be available for use in IRIS/eAF/ESMP

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

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	WHY	HOW & WHEN	IMPACT/ BENEFITS to users
Revision of current AMP validation process 3	• Due to **increased volume** of product data submitted to XEVMPD • To ensure **consistent validation of product records in the same cluster**	• By identifying **validation process improvements** • By using **available/new tools** • *By Q2/2025*	• Consistent validation is performed for clusters of product records
XEVMPD/PMS mapping services provided to NCAs 4	• To support NCAs in their readiness for mapping of national product data against data in PMS	• If requested, EMA will **help NCAs with mapping data from their national databases to PMS** • *Dedicated webinars held from Oct 2024 until end of 2025*	• NCAs will be able to map products in their national databases to PMS • ESMP reporting for NCAs will be possible thanks to this mapping • Increased transparency of product data mapping efforts performed by EMA and NCAs
Review of current XEVMPD User Interface and assessment of possible technical upgrade 5	• To determine if XEVMPD UI could be accessed without the need for ActiveX and IE Tab extension and used in other supported web browsers	• EMA is **assessing** if/how XEVMPD UI can be improved whilst there is no major impact on current users (no need to re-train users, no loss in functionality, same secure access, look and feel etc.) • *From Q4/2024*	• Easier access for users, browser-based solution • XEVMPD new UI could be used without ActiveX, IE Tab, in other supported browsers
New authorisation status value in XEVMPD 6	• To support **submissions of MRPs and DCPs** approved in the Reference Member State but **still under evaluation in the Concerned Member States** in the XEVMPD	• By implementing new authorisation status value 'Valid – pending national phase' in the XEVMPD • *In Q1/2025*	• Pending MRPs and DCPs will be migrated to PMS and available in the web-based variation form to be used by applicants

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Highlights to you

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- More frequent validation of product entries since MAHs started to submit information on AMPs down to the **pack size level** and **to support PMS migration**

What has changed?

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

Review of **XEVMPD** related **documentation and webpages**

Ongoing work

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

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

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

Future changes *(What's next?)*

Reminder for MAHs: **Windsor Framework** coming into force (foreseen for 1 January 2025)

Future changes *(What's later?)*

Acronyms

XEVMPD: Extended EudraVigilance medicinal product dictionary
MFA: Multi-factor authentication
XCOMP: XEVMPD test environment
QPPV: Qualified person responsible for Pharmacovigilance
RP: Responsible person
AMPs: Authorised Medicinal Products
PhV: Pharmacovigilance
CAP: Centrally Authorised Product
FUP: Follow-Up
MRP: Mutual Recognition Procedure
DCP: De-Centralised Procedure
DMP: Development Medicinal Product

Key Takeaways and Conclusions

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Conclusions

This presentation explained what are the **submission requirements** for marketing authorisation holders and **how authorised medicinal product data is currently managed in the XEVMPD**

XEVMPD status update was shared:

- *AMP validation process revision*
- *Mapping services to NCAs, review of current XEVMPD User Interface (EVWEB)*

It was explained how the data from XEVMPD is consumed by PMS, eAF and ESMP and which are the actions for MAHs to take support these projects

The XEVMPD team also highlighted actions to be completed by MAHs:

- *Submit herbal and homeopathic products and pending MRPs and DCPs in XEVMPD*
- *Check that non-CAPs have been migrated correctly in PMS*
- *Submit pack sizes for products under the ULCM before 31st Jan 2025 and use the same package description for products on multilingual countries*
- *Review substances with SVG flag '0' and the comment 'Duplicate' and the XEVMPD-RMS data mapping files*
- *Review received 3rd ACKs and communication from EMA and perform the required product amendments*

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Quiz Time

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Any questions on the webinar?

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SPOR Webinars

During **SPOR webinars,** EMA's Regulatory Data Management Service team talks about all aspects of regulatory data management and how it works today.

Webinar title	Date	Time
SPOR Data Governance	4 October 2024	10:00-12:00 CEST
Referentials Management Service (RMS)	7 October 2024	10:00-12:00 CEST
Substance Management Service (SMS)	8 October 2024	10:00-12:00 CEST
Organisation Management Service (OMS)	9 October 2024	10:00-12:00 CEST
Product Management Service (XEVMPD) for MAH	10 October 2024	10:00-12:00 CEST
Product Management Service (XEVMPD) for Sponsors	11 October 2024	10:00-12:00 CEST
Substance, product, organisation and referential (SPOR) application programming interface (API) - SPOR API	14 October 2024	10:00-12:00 CEST

For Questions: www.slido.com code: #SWOCT1024

Further information

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Glossary

Glossary (1/4)

EUROPEAN MEDICINES AGENCY

Acronym	Name
API	Application Programming Interface
Art. 57	Article 57 of Regulation (EU) 726/2004, which requires marketing authorisation holders to electronically submit to the Agency information on all medicinal products for human use authorised in the EU
CAP	Centrally Authorised Product
CR	Change request
CTIS	Clinical Trials Information System
DADI	Digital Application Dataset Integration
DMP	Development Medicinal Product
DCP	De-centralised Procedure
DQ	Data Quality
eAF	Electronic Application Form
ePI	Electronic Product Information
eCTD	Common Technical Document in electronic format
EMA DB	European Medicines Agency Data Board
EMRN	European Medicines Regulatory Network
Epic	An epic is a container with one common objective, for a development initiative large enough to require analysis, definition of a minimal viable product (MVP) and financial approval before implementation. An epic usually takes more than one Programme Increment to complete and is broken into multiple Features. Business epics are large initiatives that deliver Solutions needed by the business/customers Enabler epics are pieces of work that extend the architectural infrastructure of the solution under development or improve the performance of the value stream

Glossary (2/4)

EUROPEAN MEDICINES AGENCY

Acronym	Name
ESMP	European Medicines Shortages Monitoring Platform
ESMDP	European Medicinal Devices Shortages Monitoring Platform
EURS	European Review System for eCTDs
EU-SRS	European Substance Reference System
EUTCT	European Union Telematics Controlled Terms
FHIR	Fast Healthcare Interoperability Resources
HMA	Heads of Medicines Agencies
IAM	Identity and Access Management
ICSR	Individual Case Safety Report
IDMP	The ISO IDMP standards specify the use of standardised definitions for the identification and description of medicinal products for human use
INN	International Nonproprietary Names
IRIS	A secure online platform for handling product-related scientific and regulatory procedures with EMA (iris.ema.europa.eu)
KUG	Key User Group
KPI	Key Performance Indicator
MAA	Marketing Authorisation Application
MAH	Marketing Authorisation Holder
Mon	Monitoring Value Stream

Glossary (3/4)

EUROPEAN MEDICINES AGENCY

Acronym	Name
MRP	Mutual Recognition Procedure
NAP	Nationally Authorised Product
NCA	National Competent Authority
NDB	Network Data Board
NICTAC	Network ICT Advisory Committee represents the network IT community
NPAG	Network Portfolio Advisory Group represents the Management Board and HMAs
OD	Orphan Designation
OMS	Organisation Management Service
PB	Portfolio Board
PI	Programme Increment, a three month period of work
PI Planning ceremony	A quarterly event to plan work for the entire Value Stream in the next quarter, ensuring that teams and stakeholders have a shared mission and vision
PIP	Paediatric Investigation Plan
PLM	Product Lifecycle Management Value Stream
PMS	Product (Data) Management Service
PO	Product Owner (PO) is the Agile team member primarily responsible for maximizing the value delivered by the team by ensuring that the team backlog is aligned with customer and stakeholder needs.
RMS	Referential Management Service
R&D	Research and Development Value Stream

Glossary (4/4)

Acronym	Name
SAFe	Scaled Agile Framework
SIAMED	An Information System for the management of regulatory procedure for centrally authorised products
SLA	Service Level Agreement
SPOR	Substance, Product, Organisation and Referential
SmPC	Summary of product characteristics
SMS	Substance Management Service
SQI	Service Quality Indicator (metric)
SVG	Substance Validation Group
UNII	Unique Ingredient Identifier
USAN	United States Adopted Names
Value Stream	Value Streams represent the series of steps that an organization uses to implement Solutions that provide a continuous flow of value to the Business/Customer
VSM	EMA Value Stream Manager (VSM) is a "Servant Leader and Coach" for the Value Stream teams
VSO	EMA Value Stream Owner (VSO) has the primary responsibility for the business outcomes, including the delivery of business outcomes, in their Value Stream
XEVMPD	eXtended EudraVigilance Medicinal Product Dictionary