EMA
EUROPEAN MEDICINES AGENCY

Unlocking PMS API potential: Edit functionality training for MAHs

16 October 2025

10:00 – 11:30 CET

Presented by Marcos Fernández Gómez
and Veronica Lipucci Di Paola

PMS Product Owners

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

*At certain points throughout the session, 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** as explained in the EMA Data Privacy Statement for Slido.*

Housekeeping – Q&A

Join at
slido.com
#APIWRITE

- 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*

- 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** 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 the PMS FAQ document.
- We may request that you ask **Questions on specific issues/cases** in Service Desk to be tracked, investigated and adequately assigned.

Housekeeping – Webinar materials sharing

Presentation will be available at:

- EMA Event Web Page

Recordings will be available at:

- EMA YouTube Channel
- EMA Event Web Page

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Aim of this webinar

Today's webinar aims at **exploring** Product Management Service (PMS) **Application Programming Interface (API) Write functionality in PMS** for Marketing Authorisation Holders (MAH).

DEEPEN YOUR KNOWLEDGE ABOUT THE PMS API WRITE

Gain information and step-by-step guidance on accessing, navigating, and utilising API environments (production and testing) including where to find the right resources.

UNDERSTAND THE IMPORTANCE OF CONSISTENT DATA ENRICHMENT

Explore the core principles behind the implementation of the MVP enrichment process and identify the PMS data elements included in its scope.

COLLECT FEEDBACK & CLARIFY QUESTIONS

Address any questions to ensure you are fully prepared for the submission of structured product data via API.

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Agenda

1	**Welcome** *5 min*	**Veronica Lipucci Di Paola**, PMS Product Co-Owner, EMA **Marcos Fernandez Gomez**, PMS Product Co-Owner, EMA	4	**Demo** *15 min*	**Andrei Idu**, SPOR platform architect, EMA
2	**PMS API environments, functionalities, accesses** *20 min*	**Veronica Lipucci Di Paola**, PMS Product Co-Owner, EMA **Marcos Fernandez Gomez**, PMS Product Co-Owner, EMA	5	**Q&A** *30 min*	**Moderator: Greta Salerno,** PMS Change Management Team
3	**Write PMS API Knowledge sharing** *15 min*	**Rik Smithies**, FHIR Specialist **Luis Gouveia**, **Marco Oliveira** Web & Azure Cloud Experts	6	**Closing** *5 min*	**Veronica Lipucci Di Paola**, PMS Product Co-Owner, EMA

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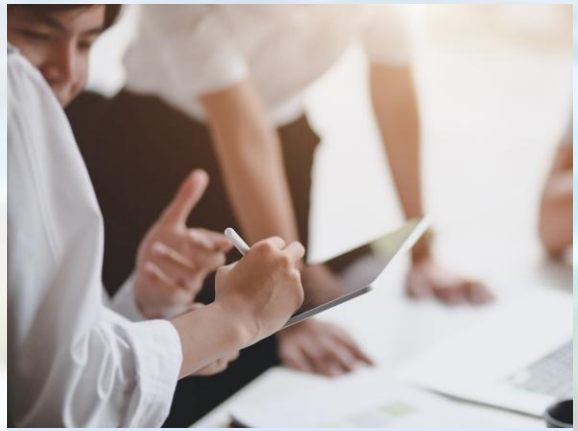
PMS API Write functionality is live!

The PMS API Write functionality **went live on 25 September 2025**



- **Go-live communications**:
- PLM Portal news
- PLM Newsletter (October issue)
- PMS EMA website

- **Questions and support:**
- The PMS team is available to answer your questions during Q&A sessions (currently planned until December 2025)

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PMS API functionalities: READ vs WRITE

Read functionality

- Available in production from **July 2024**
- Allows users to **retrieve product master data** from the EMA PMS database into external system and **read** it.
- Enables data retrieval for compliance, mapping, and alignment with regulatory systems.
- Accessible upon registration to:
  - National Competent Authorities (NCAs)
  - Marketing Authorisation Holders (MAHs)

Write functionality

- Available in production from **September 2025**
- In addition to reading, it allows users to **update and submit structured product dataset** from the user's external system **to the PMS** ie. Manufacturer(s), pack size(s) and data carrier identifier(s).
- Enables real-time data submission, product updates, and two-way data integration.
- Accessible upon registration to: Marketing Authorisation Holders (MAHs) only

Together, these enable full bi-directional integration with external systems

Supporting document & guide

updated

PMS EU IG Chapter 1: Registration

Outlines how organisations and users can register to access PMS via API, including role-based access and availability of write endpoints.

Technical Notes:

- Current write API version: **v5-Alpha**
- Protocol: **HTTPS only**
- Authentication: **OAuth2 Client Credentials**
- Supported FHIR version: **4.4.0 (R5 Preview 2)**
- Endpoint access is **role-restricted and phased**

updated

WRITE PMS API Implementation Guide

Provides a comprehensive FHIR-based framework for developers to implement the PMS Write API, enabling secure and structured data exchange for medicinal product information.

Version 1.2.0 Highlights:

- **FHIR Version:** Updated to FHIR 5.0.0.
- **Validation:** Profiles now enforced for incoming messages.
- **Error Handling:** Enhanced structured logging for both successful and erroneous requests.
- **Health Checks:** Introduced lightweight, proactive internal health check endpoints.

PMS EU IG Chapter 5 & Annex A: Data access

Defines access rules for medicinal product data in PMS, balancing transparency with data confidentiality.

Access Levels:

- **Level 1:** Public – read-only access to basic product info
- **Level 2:** Marketing Authorisation Holders – access to owned products
- **Level 3:** Authorities (EMA, EC, National) – full access to all data

PMS EU IG Chapter 7: Data migration

Outlines the rules and processes for migrating medicinal product data from XEVMPD and SIAMED into PMS, ensuring compliance with ISO IDMP standards

Key Points:

- **Data Sources:** XEVMPD and SIAMED
- **Migration Rules:** Defines match-merge and transformation rules
- **Data Mapping:** Specifies Art.57-SIAMED II-PMS data mapping

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PMS environments overview: Production vs Test

Production Environment (PROD)		Test Environment (UAT)
• Submission of updated product data to EMA • Access to the most up-to-date, ISO IDMP-compliant authorised product data	**Scope of Use**	• Familiarisation with PMS API functionalities in a safe, isolated setting • No risk of unintentional data submission to EMA
Operational use for regulatory compliance and official data exchange	**Purpose**	Training, testing, and integration without regulatory consequences
• **Read-only**: since **July 2024** • **Read & Write**: from **September 2025**	**Availability**	Read & Write available from **November 2025**
Authority and Industry	**Access**	Authority and Industry

Value for Stakeholders

The **Production** environment ensures secure, compliant data exchange with EMA, while the **Test** environment provides a safe space to explore PMS features and prepare for smooth integration.

Access to PMS Production

Admin roles

User	Admin role names
Industry user(s)	IRIS/PLM Industry Admin
NCA user(s)	IRIS/PLM NCA Admin

Industry roles

Function	Role names	PMS Access Level (*EU IG Ch.5*)
Read + Write	PMS Industry API User	Level 2a (active)

NCA roles

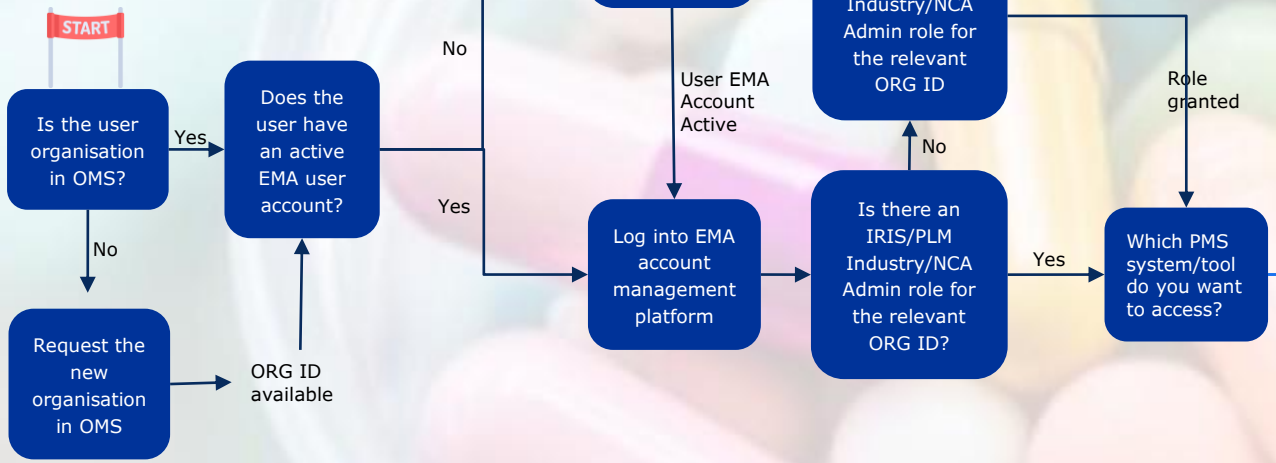
Function	Role names	PMS Access Level (*EU IG Ch.5*)
Read	API Competent Authority User	Level 3 (active)

Key role characteristics and recommendations

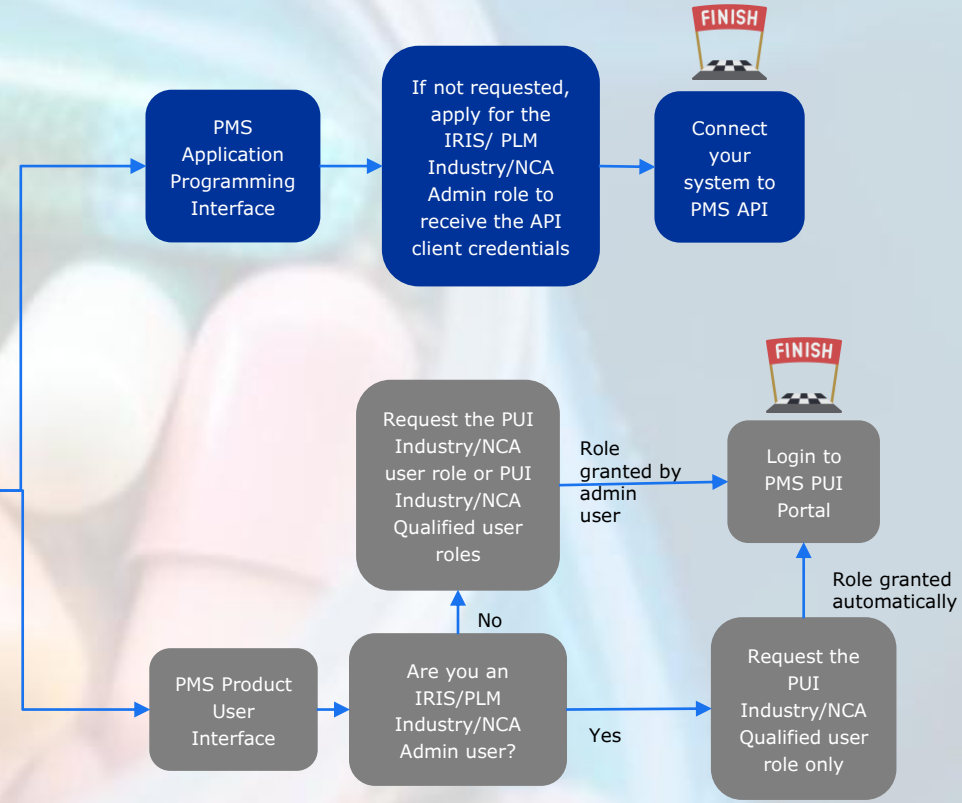
IRIS/PLM Admin	API User
• **No direct READ/WRITE access to PMS API** • **1st Admin** of Organisation is **approved by IRIS / PLM EMA Admin;** from 2nd Admin onwards, Org Admin can approve it • Each organisation recommended to have **at least two Admin users**	• Approved IRIS/PLM user can request **API Competent Authority User** role via IAM account • **PMS API Client Credentials are** generated only upon request by the Admin users to **READ/WRITE PMS API**

PMS Production - Registration process

Step 1: Check/Request Admin role



Step 2: Role application-based request



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How to access PMS Production as of September 2025?

If you have already an PMS API Industry role at the time of the PMS API WRITE MVP release:

- ✓ WRITE privileges will be added to your existing user role
- ✓ No further actions on the EMA Account management portal are required
- ✓ Your PMS API role name will remain unchanged
- ✓ You will have full **read and write** MVP access to all PMS data for your affiliated ORG ID

If you do NOT have access to PMS API as industry at the time of the PMS API WRITE MVP release:

- ✓ Follow the instructions in **EU IG Chapter 1** (will be updated to include WRITE endpoints)
- ✓ The same registration process for PMS API full read will apply to the PMS API WRITE MVP
- ✓ Your PMS API role name will remain unchanged

Access to the SPOR V1 API for OMS and RMS, or the SMS API, does not automatically grant access to the PMS API. A separate access request must be submitted for PMS API access

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Access to PMS Test

1. **Register** your account on EMA Access Management (EAM) portal **Production** environment
2. **After 1hr** from the registration login to EAM portal **Test** environment
3. Request **PMS Industry Super User** Role: select your Organisation and the PMS Industry Super User role
4. Complete the registration and submit
5. An **EMA Administrator** will evaluate and approve your request. User will be **notified via email**.
6. Upon approval of the PMS Industry Super User role, **request API access** in EAM Test environment
7. Accept the EMA API General Terms and Conditions of Use
8. **Fulfil the digital form**: PMS application, ORG ID, API Technical contact email, PMS Industry API role
9. The request will be **automatically approved**, and the user will receive an **email with the access details**.

PMS UAT API Registration Process document will be published on PMS webpage by 3rd November

Note: External industry users and internal EMA users will continue to share the test environment until a dedicated external environment is available.

Access to PMS for Developers & Vendors

Who can access

Developers and software vendors **working independently (UAT only) or on behalf of registered authorities or industry (MAHs) (UAT and PROD)**

Environment access

- Access to **Production** (Prod) and **Test** (UAT) environments
- UAT testers from Q3 2025 already have the required credentials. There is no need to request them again
- PMS API Level 2a/3 Access *(Ref. EU IG Chapter 5 & Annex A)*
- Only allowed on behalf of a client (MAH or NCA) for security reasons

Credentials requirement

- Secret credentials must be obtained from a registered Industry/NCA admin user
- Requires sharing of client's registered secret credentials

Important notes

- Only **registered admin users at ORG-ID level** can request/generate credentials *(Ref. EU IG Chapter 1)*
- **Access is always linked to the organisation (ORG-ID)** the user is registered with

Timelines for master data entry in PMS

Drivers

EMA considered challenges brought up by Industry vs PMS delivery

- **PUI Single product update** available as of 31 January 2025
- **PUI Bulk update and PMS API write** capabilities available from end **Q3 2025**
- Industry requires **6-9 months to set up their RIM** systems to submit data via PMS API

- Industry **heaviest workload** is on preparing/submitting **package sizes** to XEVMPD
- *Industry delays in submitting package sizes impacts overall **NCA mapping** efforts at package level*

Actions

EMA agreed to extend the milestones for submission

- Enrichment of **Manufacturer's & structured pack size data** for non-CAPs on the **ULCM** using Product UI and API

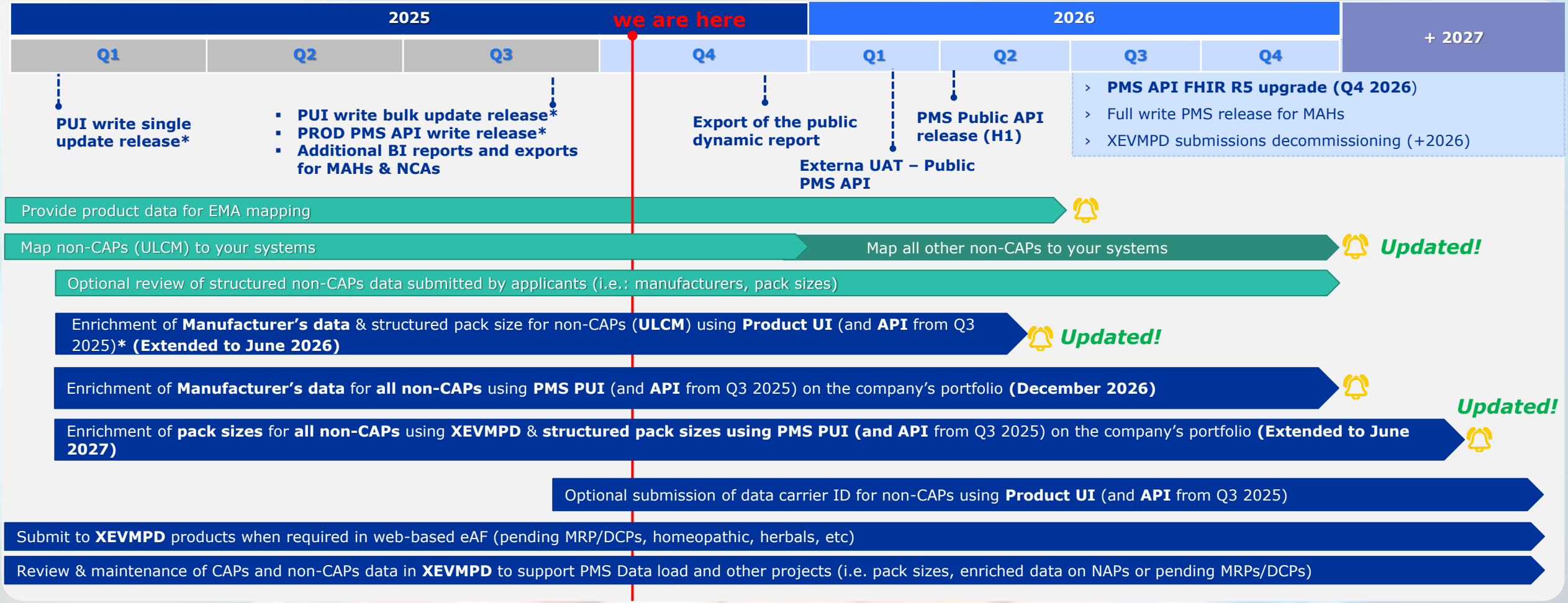
→ **Extended to June 2026**

- Enrichment of **pack sizes** for **all non-CAPs on the company's portfolio** using XEVMPD & **structured pack sizes** using PMS PUI and API
- *NCAs will map all other non-CAPs to their systems*

→ **Extended to June 2027**

EMA requires **actionable assurances** from industry associations to comply with new deadlines (i.e. ISG in Dec)

Product Management Service roadmap



* (MVP) limited to structured pack size, manufacturers and MBOs data for non-CAPs

Acronyms

- **API:** Application Programming Interface
- **ASU:** Antimicrobial Sales and Use
- **CAPs:** Centrally Authorised Products
- **DCP:** Decentralised Procedures
- **eAF:** electronic Application Form
- **MAHs:** Marketing Authorisation Holders
- **MRP:** Mutual Recognition Procedure
- **MVP:** Minimum Viable Product
- **NCAs:** National Competent Authorities
- **PUI:** Product User Interface
- **UAT:** User Acceptance Testing
- **ULCM:** Union List of Critical Medicines

Legend

NCA action | MAH action | Milestone | Deadline

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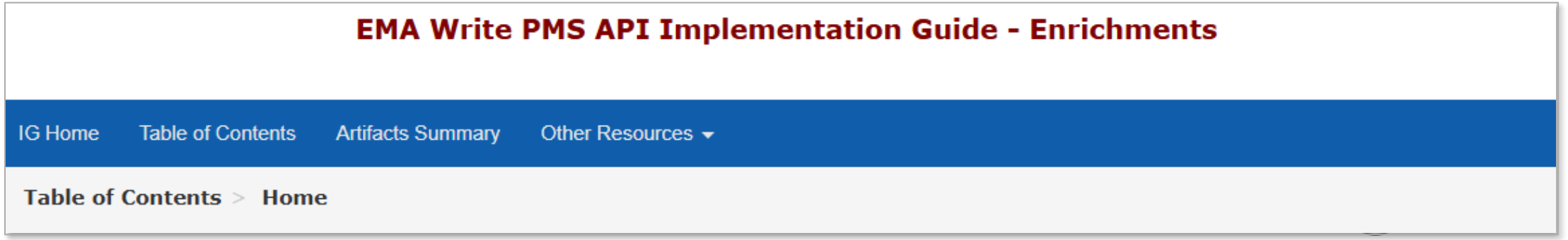
Write PMS API
Knowledge sharing

The Write API is documented in a FHIR "Implementation Guide"

- Version 1.2.0 of the "IG" was published recently
- Currently a downloadable zip, but will be web pages in future
- A FHIR IG has certain purpose, about the more technical parts of the data interface
- It is a technical document including details of the way this API uses the standard FHIR resources
- It is an international standard format (similar to the publication format of FHIR itself)



What is a FHIR Implementation Guide?

- A technical document, and it does need some FHIR technical knowledge to read it fully
  - The notation and layout may be unfamiliar at first
  - But it matches all other similar IGs (EMA, and everywhere)
  - It is very detailed
  - The less left to chance the better
  - To be read with the more business focussed Chapter 2

- A lot of the benefit comes from the *machine-readable* parts.
  - It can be used to validate that your FHIR data matches the specification

What's inside

The main focus is:

- Overview of the API (what to send and when)
- *Profiles* of FHIR resources
- Extensions (special cases added by EMA for PMS)
- Value Sets and Code Systems (FHIR versions of parts of RMS)
- Example XML files (added after first release)

The profiles are the main assets, and use the extensions, value sets and code systems

What else?

What it typically does **not** have (but are definitely needed elsewhere):

- General FHIR Training material/references
- Overview of the project (better in PPTs/webinars)
- Lists of actual deployment API URLs
- Service levels, response times etc.
- Decisions made, rationale, future plans etc.

FHIR Profiles

These are machine-readable/processable files, that have two purposes:

- To describe the specifics of this FHIR interface, item by item
- To allow validation of data against this interface

As well as being in the IG, the profiles are now built into the actual deployed API.

This helps to assure the data is correct.

The profiles are also available for users' own testing.

Ensure your FHIR submissions are correct, before you send them.

FHIR Profiles

3.4.1.1 Formal Views of Profile Content

Key Elements Table | Differential Table | Snapshot Table

Name	Flags	Card.	Type
MedicinalProductDefinition			
extension		1..*	EmaCoding
Slices for identifier		*0..3*	*Identifier*
identifier:eurdId		0..1	EmaEurdIdentifier
system		1..1	uri
identifier:mpId		0..1	EmaMpIdentifier
system		1..1	uri
identifier:apiv2Id		0..1	EmaApiV2Identifier
system		1..1	uri

How to use the profiles

“Off the shelf”, and open source, FHIR tooling includes ways to use profiles.

FHIR provides validators, as downloadable programs, and as source code.

These can read EMA FHIR profiles and automatically apply the correct rules.

For information see:

https://hl7.org/fhir/profiling.html

https://hl7.org/fhir/validation.html

Profile Validation Error Messages

A few Regulated Authorization examples:

- *"Only one of the three data carrier identifiers (GS1, Pharmacy, National Trade) may be present"*
- *"If there is a Manufacturing Identifier, then the regulator is mandatory"*
- *"If there is a Manufacturing Identifier, then the validity period is mandatory"*

These will be presented in:

- Bundle.entry.resource.OperationOutcome.issue

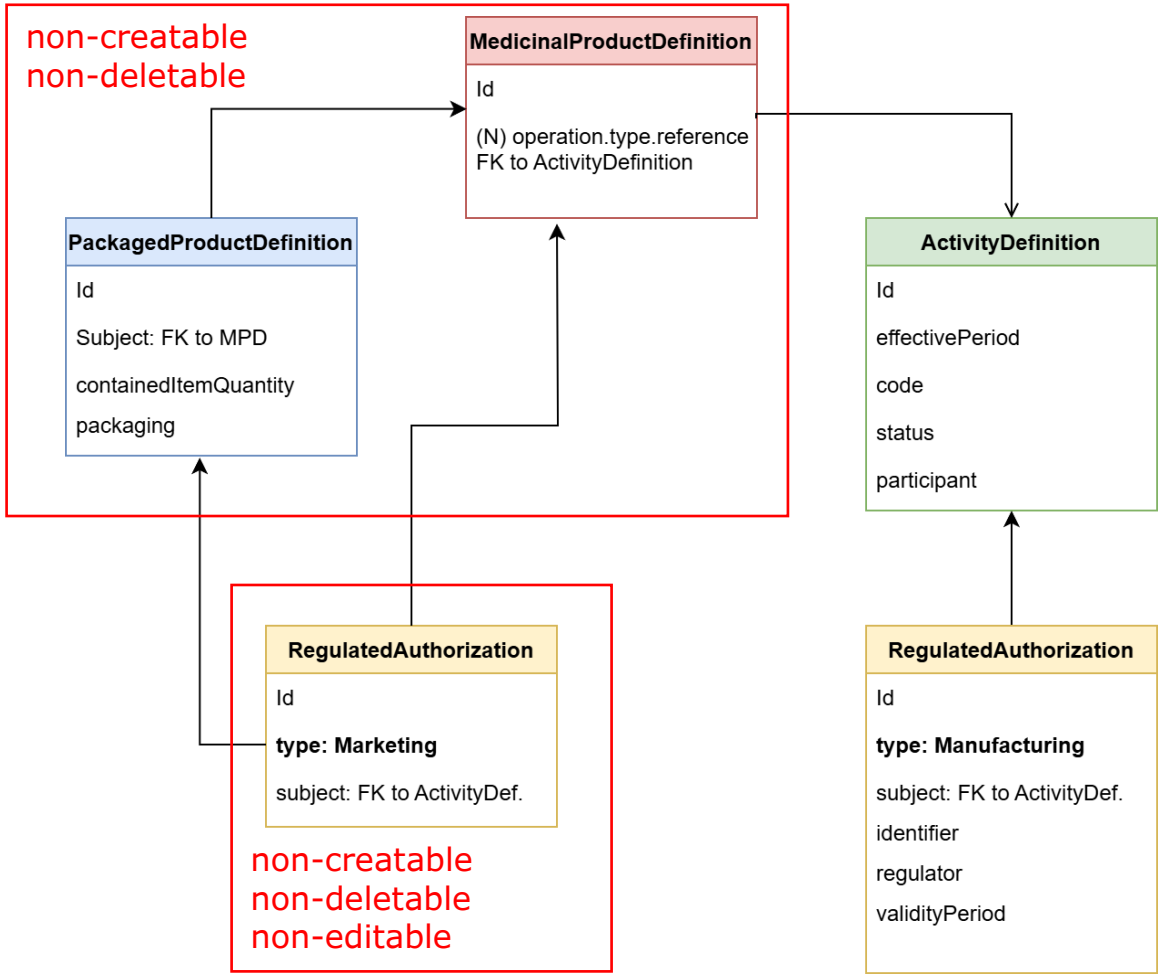
Write API – Operations

Available Operations:

- **Get Bundle**: (GET) /MedicinalProductDefinition/$everything
  - Get the Bundle containing the MedicinalProductDefinition and related PackagedProductDefinition, ActivityDefinition and RegulatedAuthorization resources

- **Merge**: (POST) /$merge
  - The body contains the Bundle with the changes (for the editable properties)
  - Asynchronous return

Write API – Resources



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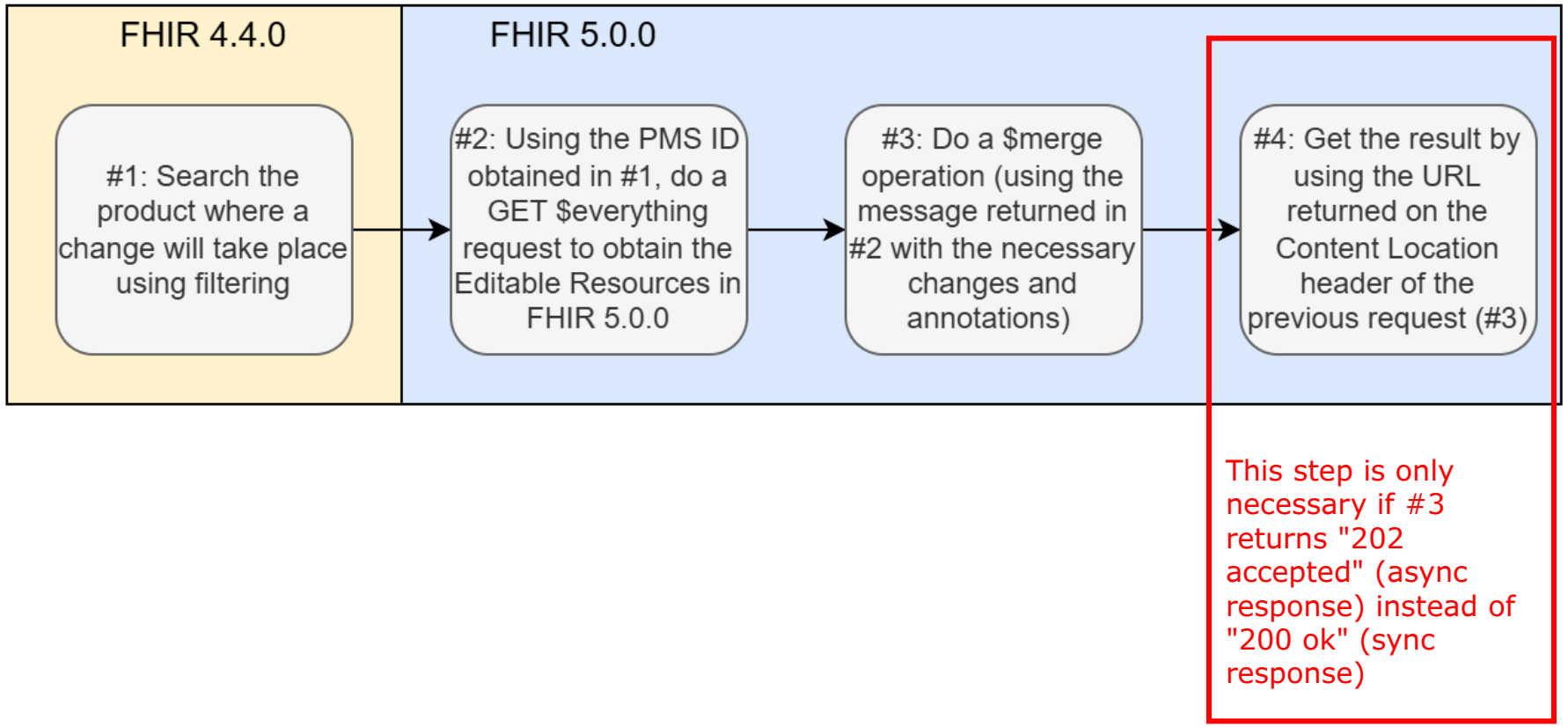
Write API – Editable Properties

Resource	Attribute	Description
MedicinalProductDefinition	*operation.confidentialityIndicator*	[Manufacturer] - Data Classification (e.g., Public - 200000004985). See SPOR list 200000004983.
	operation.type.reference	[Manufacturer] - Reference to the ActivityDefinition resource.
	containedItemQuantity	[Package] - The package size.
PackagedProductDefinition	*packaging.identifier*	[Package] - The Data Carrier Identifier.
	effectivePeriod	[Manufacturer] - The effective period (yyyy-MM-dd).
ActivityDefinition (Manufacturer Specific)	*code*	[Manufacturer] - Manufacturing Activity (e.g., Manufacturer of Active Substance - 100000160467). See SPOR list 100000160406.
	status	[Manufacturer] - Status (e.g., active).
	participant	[Manufacturer] - The Participant (e.g., Euroapi Italy S.r.l. - LOC-100061735).

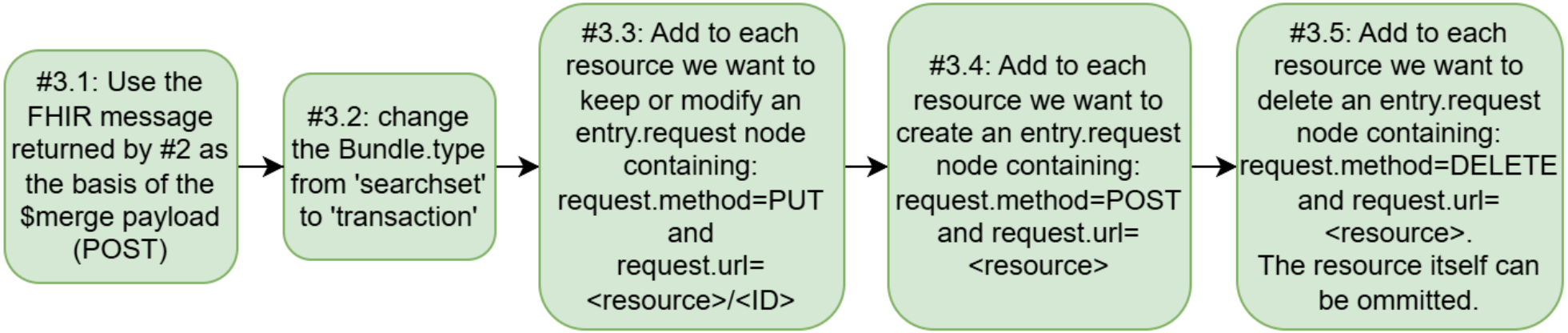
Write API – Editable Properties

Resource	Attribute	Description
RegulatedAuthorization (Only Manufacturer R.A. is Editable)	*validityPeriod*	[Manufacturer] - The validity period (yyyy-MM-dd).
	identifier	[Manufacturer] - Manufacturing Authorization Reference Number (e.g., EU/1/00/142).
		[Marketing] (READ ONLY) - Marketing Authorization Reference Number (e.g., PA 1077/044/015).
	type	[Manufacturer] - Regulatory Entitlement Type (200000051585 for manufacturing). See SPOR list 220000000060.
		[Marketing] (READ ONLY) - R.A. type (220000000061 for marketing). See SPOR list 220000000060.
	regulator	[Manufacturer] - Medicines Regulatory Agency Organisation (e.g., LOC-100020260).
	subject	[Manufacturer] - Corresponding ActivityDefinition.
		[Marketing] (READ ONLY) - Corresponding MedicinalProductDefinition/PackagedProductDefinition.

Write API – User Journey Diagram



Write API – User Journey Diagram - $merge



Write API – Errors & Warnings

- **The following $merge requests will fail, returning an error:**
  - A request where MedicinalProductDefinition.meta.versionId differs from the one in PMS
  - A Creation/Deletion of a MedicinalProductDefinition, PackagedProductDefinition or Marketing RegulatedAuthorization
  - A request containing duplicated manufacturers for the same operation
  - A request where one or more operations don't have a manufacturer
  - A request where one or more manufacturers do not have at least a manufacturer operation

- **The following $merge request will return a warning (but the data will still be persisted on PMS):**
  - A request where one or more PackagedProductDefinition do not have at least one package size

- **The following operation will be ignored:**
  - Attempting to modify non-editable resource nodes will result in that node change being ignored – example: changing the MedicinalProductDefinition.domain

Write API Examples – #1: Get Bundle

GET https://uat-cuat-fhiradpt-00001-func.azurewebsites.net/api/v1/MedicinalProductDefinition/600000777725/$everything

Params Authorization Headers (7) Body Scripts Settings

Body Cookies Headers (6) Test Results 200 OK 191 ms 27.46 KB

XML Preview Visualize

```
<Bundle xmlns="http://hl7.org/fhir">
    <id value="d48f891e-2ea0-4724-9dc4-ad5b8d542d13" />
    <meta>
        <profile value="http://hl7.org/fhir/5.0.0/StructureDefinition/Bundle" />
        <profile value="http://ema.europa.eu/fhir/definition/esmp/Bundle-variation/0.1.1" />
        <profile value="http://ema.europa.eu/fhir/definition/fhir-adapter/1.0.0.5" />
    </meta>
    <type value="searchset" />
    <entry>
        <fullUrl value="MedicinalProductDefinition/600000777725" />
        <resource>
            <MedicinalProductDefinition>
                <id value="600000777725" />
                <meta>
                    <versionId value="16" />
                </meta>
                <identifier>
```

```
<entry>
    <fullUrl value="PackagedProductDefinition/8071867" />
    <resource>
        <PackagedProductDefinition>
            <id value="8071867" />
            <identifier>···
            </identifier>
            <packageFor>
                <reference value="MedicinalProductDefinition/600000777725" />
            </packageFor>
            <status>···
            </status>
            <containedItemQuantity>
                <value value="10" />
                <system value="https://spor.ema.europa.eu/v1/lists/200000000014" />
                <code value="200000002165" />
            </containedItemQuantity>
```

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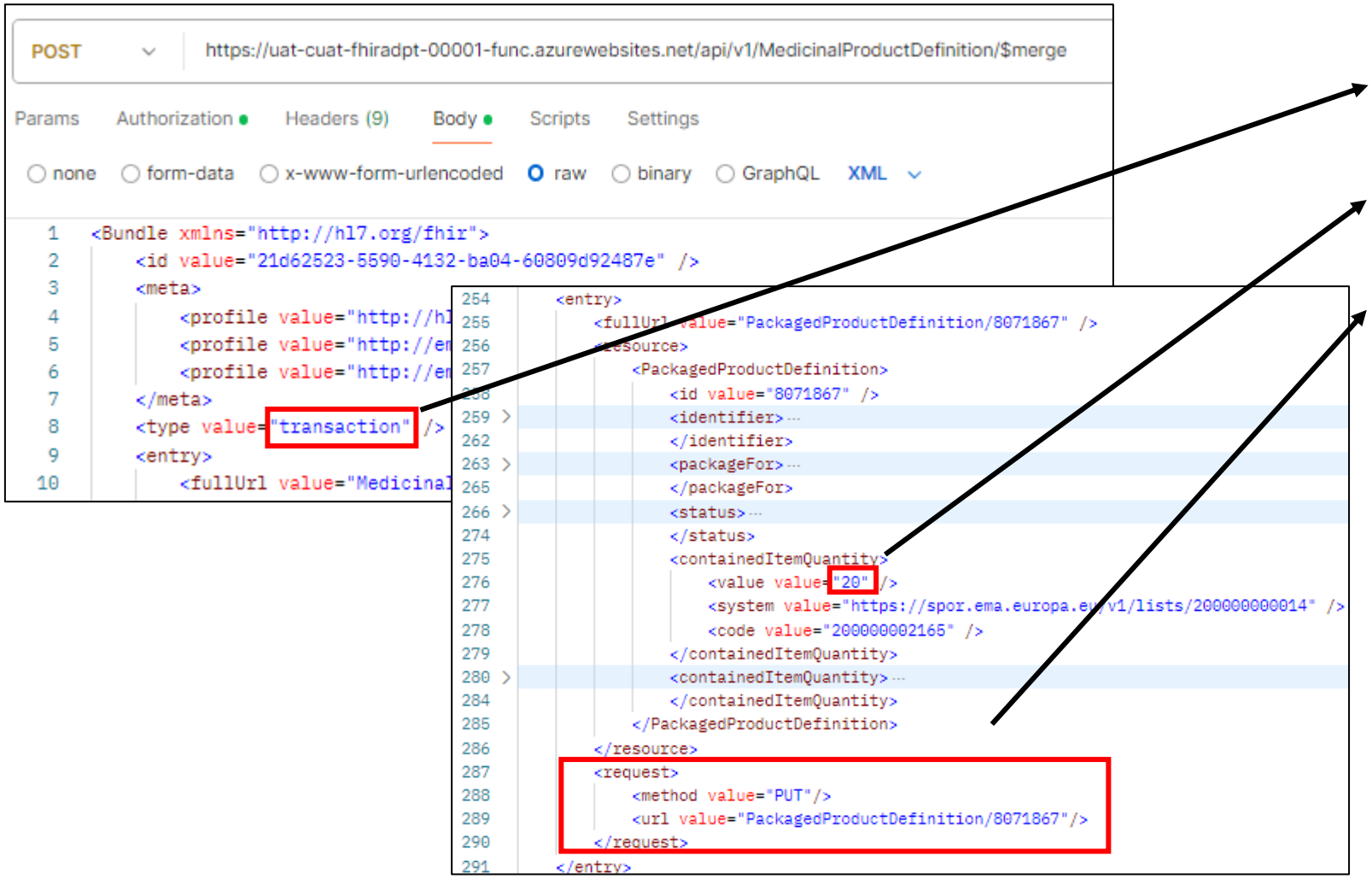
Write API Examples – #2: Merge – request



#1 – The bundle.type was modified from 'searchset' to 'transaction'

#2 – The packsize is modified from 10 to 20

#3 – The <entry> gets a new 'request' node (line 287) where request.method=PUT (update) and request.url is PackagedProductDefinition/ 8071867

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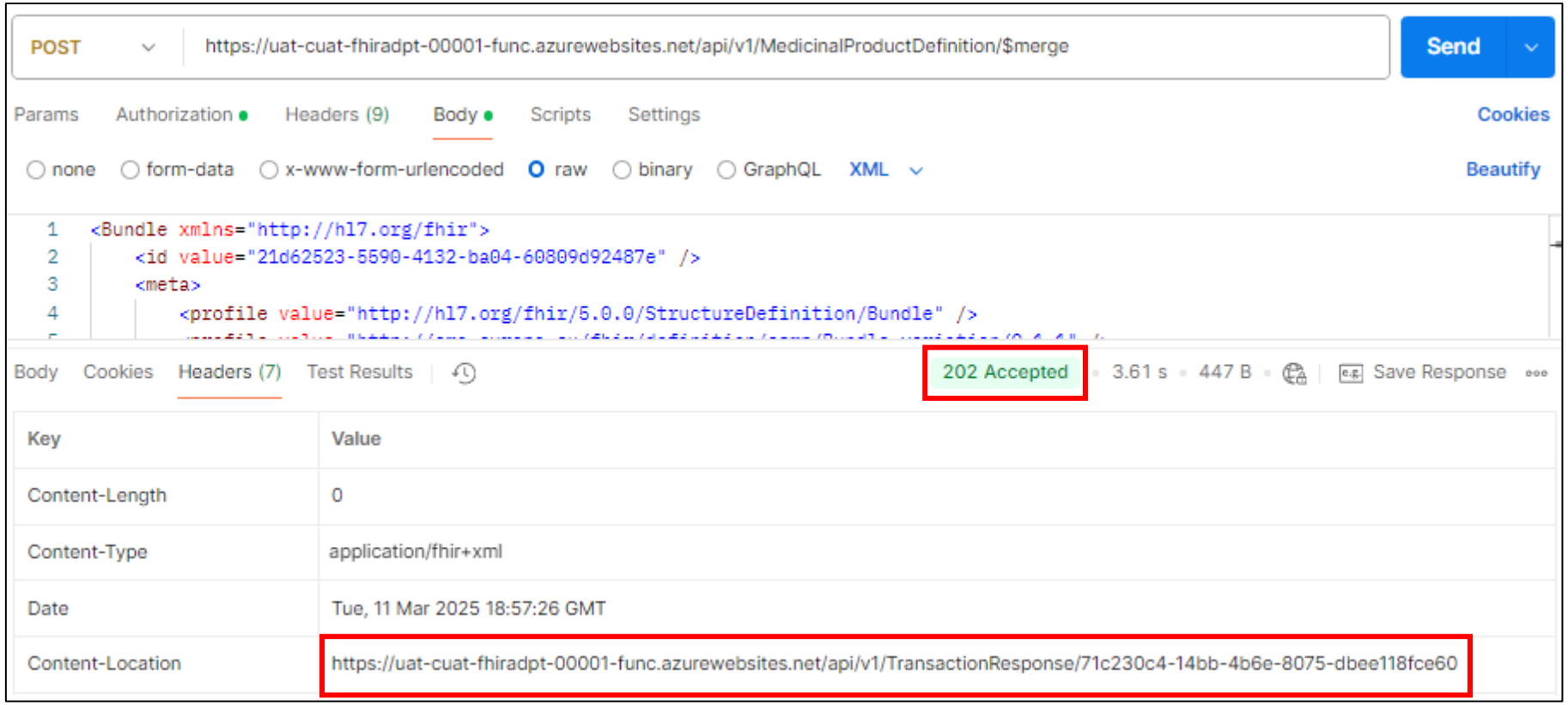
Write API Examples – #2: Merge - response



In this example, the response was asynchronous (HTTP 202 – Accepted), and a 3rd request (Content-Location URL) will have to be executed to fetch the result.

It could have been synchronous (HTTP 200 – OK) and those cases the returning bundle (after the change) can be immediately found in the response body (there's no need to execute the extra request presented in the next slide).

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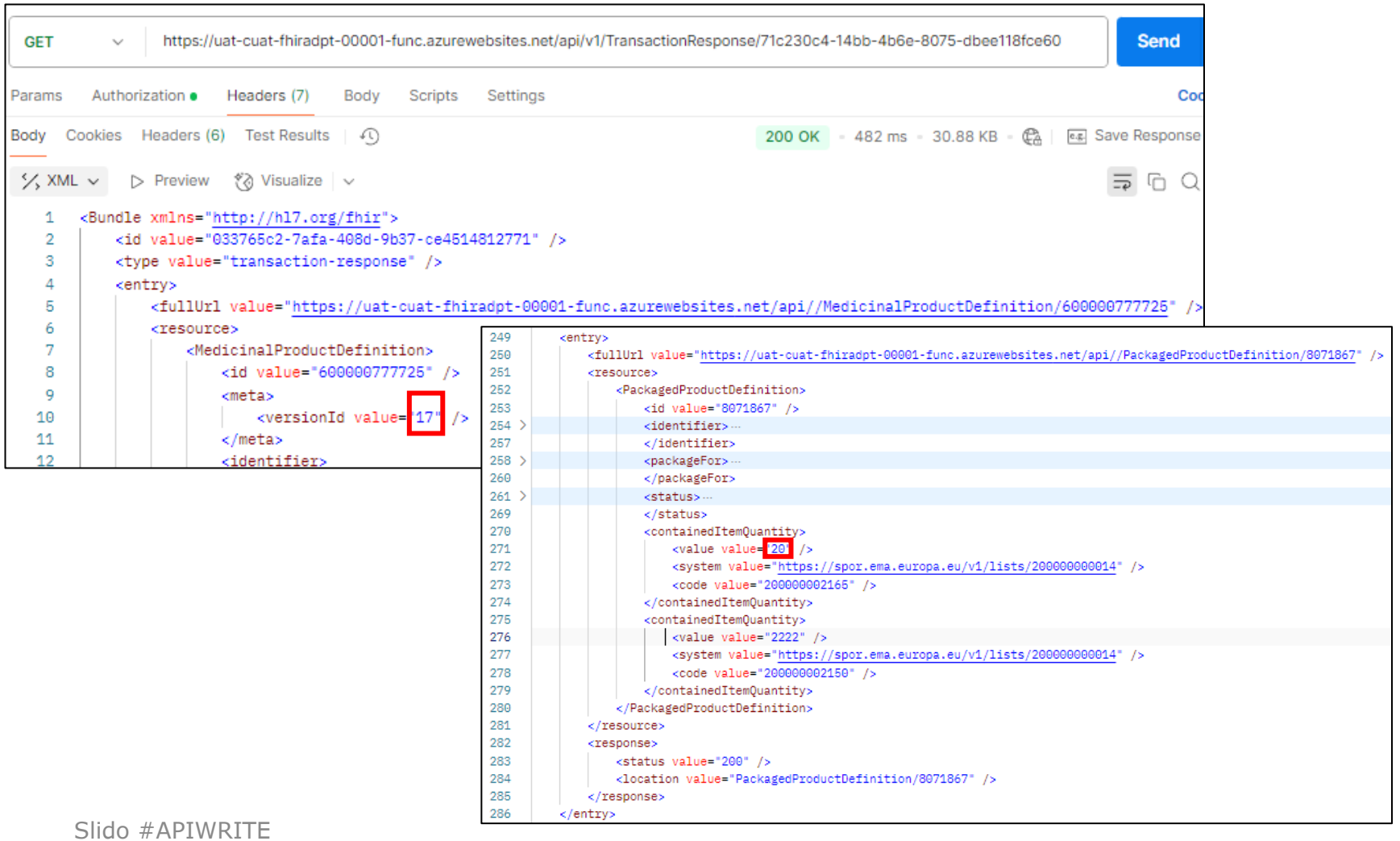
Write API Examples – #3: Get Merge Result



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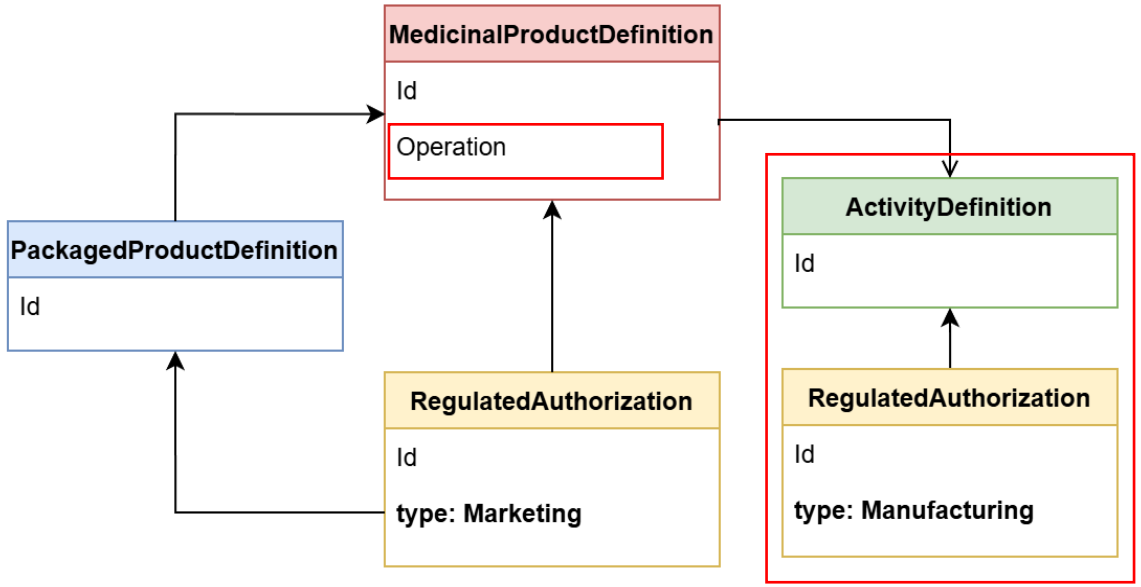
Write API Examples – Add/Del Manufacturer



Add a manufacturer:

- 1. ADD ActivityDefinition
- 2. ADD Manufacturing Regulated Authorization (optional)
- 3. ADD MedicinalProductDefinition.operation node

Delete a manufacturer:

- 1. RM ActivityDefinition
- 2. RM Mananufacturing Regulated Authorization (optional)
- 3. RM MedicinalProductDefinition.operation node

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Live demonstration!

Write PMS API

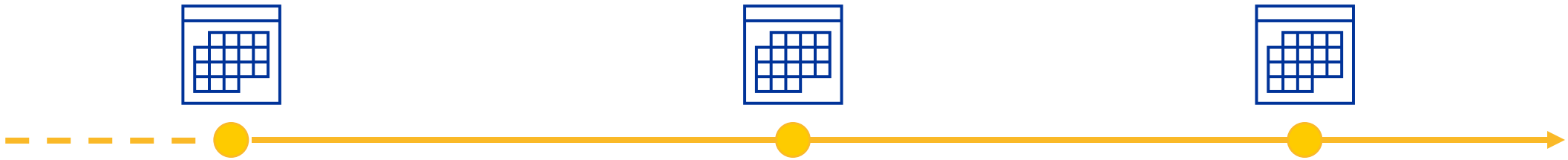
Data displayed during the demo are not real

Q&A

30’

- **Join Slido.com** using this code **#APIWRITE** or scanning the QR code
- Ask your questions or vote the ones you would like to be answered
- We will read out **selected questions** that will be answered verbally

Upcoming Q&A Clinics



Q&A Clinics on SOR

- **10 November 2025** (11:00 – 12:00 CET): Register here
- **15 December 2025** (11:00 – 12:00 CET): Register here

The SOR team is available to answer questions regarding the SMS, RMS and OMS.

Q&A Clinics on PMS

- **18 November 2025** (11:00 – 12:00 CET): Register here
- **18 December 2025** (11:00 – 12:00 CET): Register here

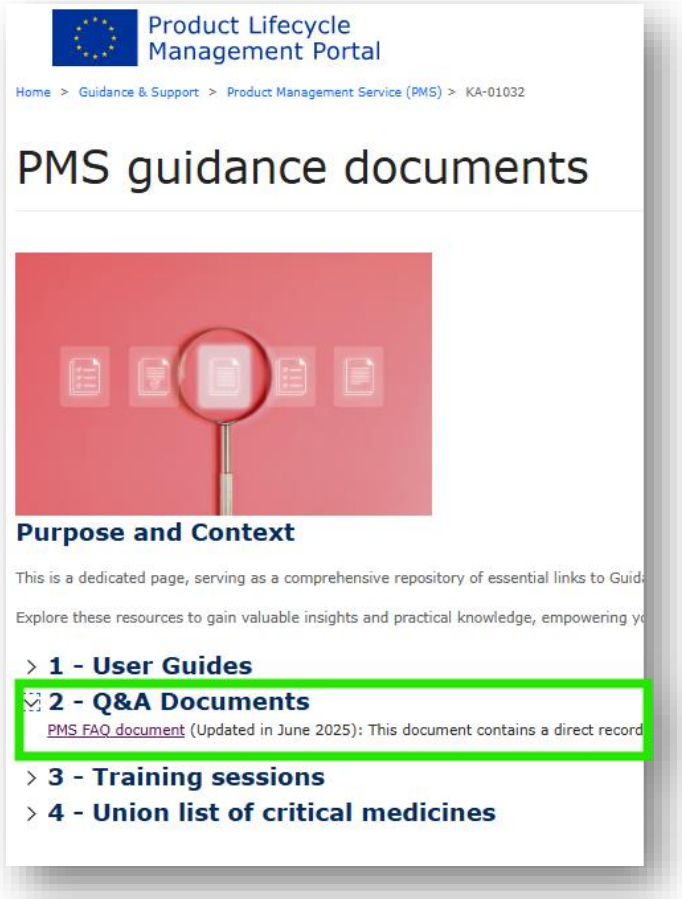
The PMS team is available to answer questions regarding the PMS PUI and API.

Q&A Clinics on XEVMPD

- **18 November 2025** (14:00 – 15:00 CET): Register here
- **18 December 2025** (14:00 – 15:00 CET): Register here

The XEVMPD team is available to answer questions regarding the XEVMPD service.

Stay updated with the PMS Q&A!



- Stay informed on the known issues and their resolution by checking the PMS Q&A document
- Please, **do not** submit a ticket to SNOW if your product is impacted by a known issue. Those issues affect multiple products and will be prioritised and solved when capacity permits.

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PMS Progresses | How to stay informed

PMS News page

Check:
- News
- Events announcements
- Downtime comms

Check regularly

PLM Newsletter

- See planned PMS engagement activities for upcoming quarter
- **Subscribe** here

Receive via email quarterly after subscription

PMS webinars

- **Q&A Clinics** to answer users' questions
- **Targeted training sessions** on PMS systems' use

Check EMA's Website Events Pages (when also targeting Industry), EU-NTC (for Network only)

PMS FAQ Document + PLM Portal Forum

- Check FAQs on PMS (Document)
- Ask questions (Forum)

Check regularly

Quarterly System Demos

- See the latest developments
- Give your feedback on features and priorities
- **Next system demo:** 26 Mar 2025

Announced via EMA's Website Events Pages - broadcast live

PMS Web Page

Find:
- PMS overview
- EU Implementation Guide

Check for general info on PMS

Next issue mid-October

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