EMA
EUROPEAN MEDICINES AGENCY

Unlocking Integration – MAH & Software Developers to explore PMS API Machine-to-Machine Connection

14 March 2025

10:00 – 12:00 CET

Presented by Veronica Lipucci Di Paola and Marcos Fernández Gómez, *PMS Product Owners*

Andrei Idu, *SPOR platform architect*

Rik Smithies, *FHIR Specialist*

Luis Gouveia, Marco Oliveira, *Web & Azure Cloud Experts*

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#PMSAPI

- 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
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Aim of this webinar

Today's webinar aims at **exploring** Product Management Service (PMS) **Application Programming Interface (API) Machine-to-Machine Connection to write in PMS** for Marketing Authorisation Holders (MAH) and Software Developers.

DEEPEN YOUR KNOWLEDGE ABOUT THE PMS API WRITE

Gain information and step-by-step guidance on accessing, navigating, and utilizing API, including where to find the right resources.

PRESENT THE CALL FOR INTEREST ON PMS API UAT

Explain the User Acceptance Testing scope, structure, timeframe and deadline for nominations to participate.

COLLECT FEEDBACK & CLARIFY QUESTIONS

Collect information on the level of stakeholders' readiness to machine-to-machine PMS API integration and address any questions to ensure you are fully prepared its use.

Agenda

1	**Welcome** *5 min*	**Veronica Lipucci Di Paola**, PMS Product Co-Owner, EMA	5	**Details of the call for interest and UAT** *5 min*	**Veronica Lipucci Di Paola**, PMS Product Co-Owner, EMA
2	**PMS intro and roadmap** *20 min*	**Veronica Lipucci Di Paola**, PMS Product Co-Owner, EMA	6	**EU Survey** *5 min*	**Moderator: Greta Salerno,** PMS Change Management Team
3	**Focus on PMS API** *20 min*	**Andrei Idu**, SPOR platform architect, EMA	7	**Q&A** *30 min*	**Moderator: Greta Salerno,** PMS Change Management Team
4	**PMS API Integration knowledge sharing** *30 min*	**Rik Smithies**, FHIR Specialist **Luis Gouveia**, **Marco Oliveira** Web & Azure Cloud Experts	8	**Closing** *5 min*	**Veronica Lipucci Di Paola**, PMS Product Co-Owner, EMA

PMS introduction and roadmap

Product Management Service (PMS) Vision

To make available, for human and machine interaction, **structured, standardised and consistent authorised product data** from across the European Medicines Regulatory Network.

PMS data to be used by regulators and industry in **regulatory and non-regulatory procedures** as well for the general benefit of European citizens.

Transform our stakeholders experience during the interaction with the regulatory Network by providing **an integrated customer and data digital journey through medicines regulatory processes, to the benefit of public human health in EU.**

Key changes

Enriched data set in ISO IDMP-compliant structure

Integrated data journey through regulatory procedures

Trustworthy and quality data in one single source

Quality product data built into all new digital tools

Product Lifecycle of an authorised medicinal product

- **SPOR Master Data Management (S**ubstances, **P**roduct, **O**rganisations, **R**eferentials)
- **PMS: Product Management Services**

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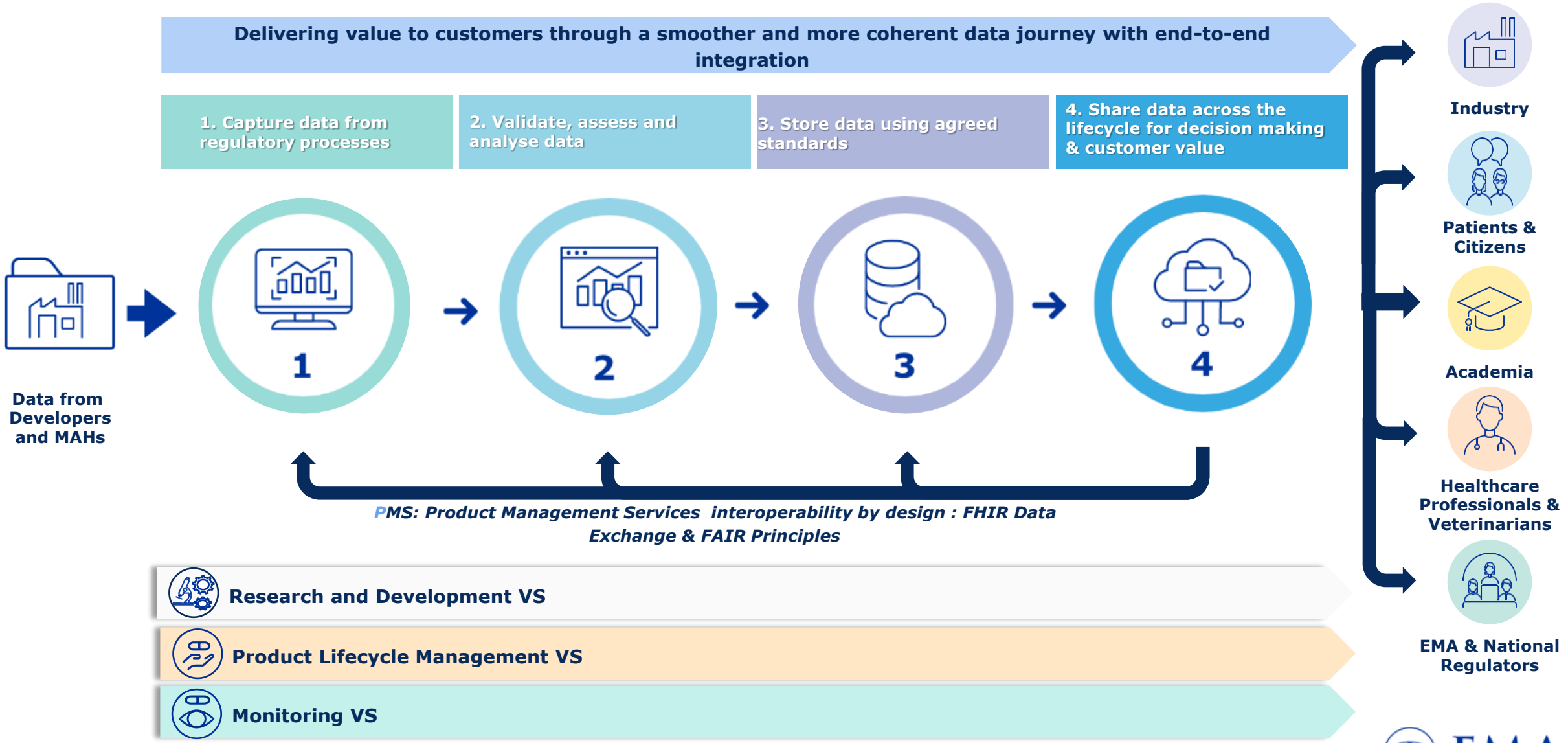
End-to-end product data integration



PMS Use Cases & EU Systems

Product Lifecycle Management VS Products

ePI

Up-to-date and easily accessible, authorised electronic product information in all available EU languages for all EU citizens

RPM

End-to-end Regulatory Procedure Management for CAP products for increase of efficiency, transparency and collaboration

eAF

Web-based, user-friendly forms, for H & V medicinal product applications enabling data integration

Product UI

Customer facing interface to access, review, update and enrich product data

PMS

Single source of truth for trustworthy , enriched, validated , **authorised medicinal product data**

Monitoring VS Products

ESMP

Prevention and management of human medicines shortages, ensuring availability of medicines during public health emergencies or major events

ASU

European surveillance for sales and use data of antimicrobials in animals to detect patterns and help develop measures against antimicrobial resistance

EV Human

<u>In transition to Value Stream</u>
Manage and analyzing information on suspected adverse reactions to medicines which have been authorised or are being studied in clinical trials in the EEA

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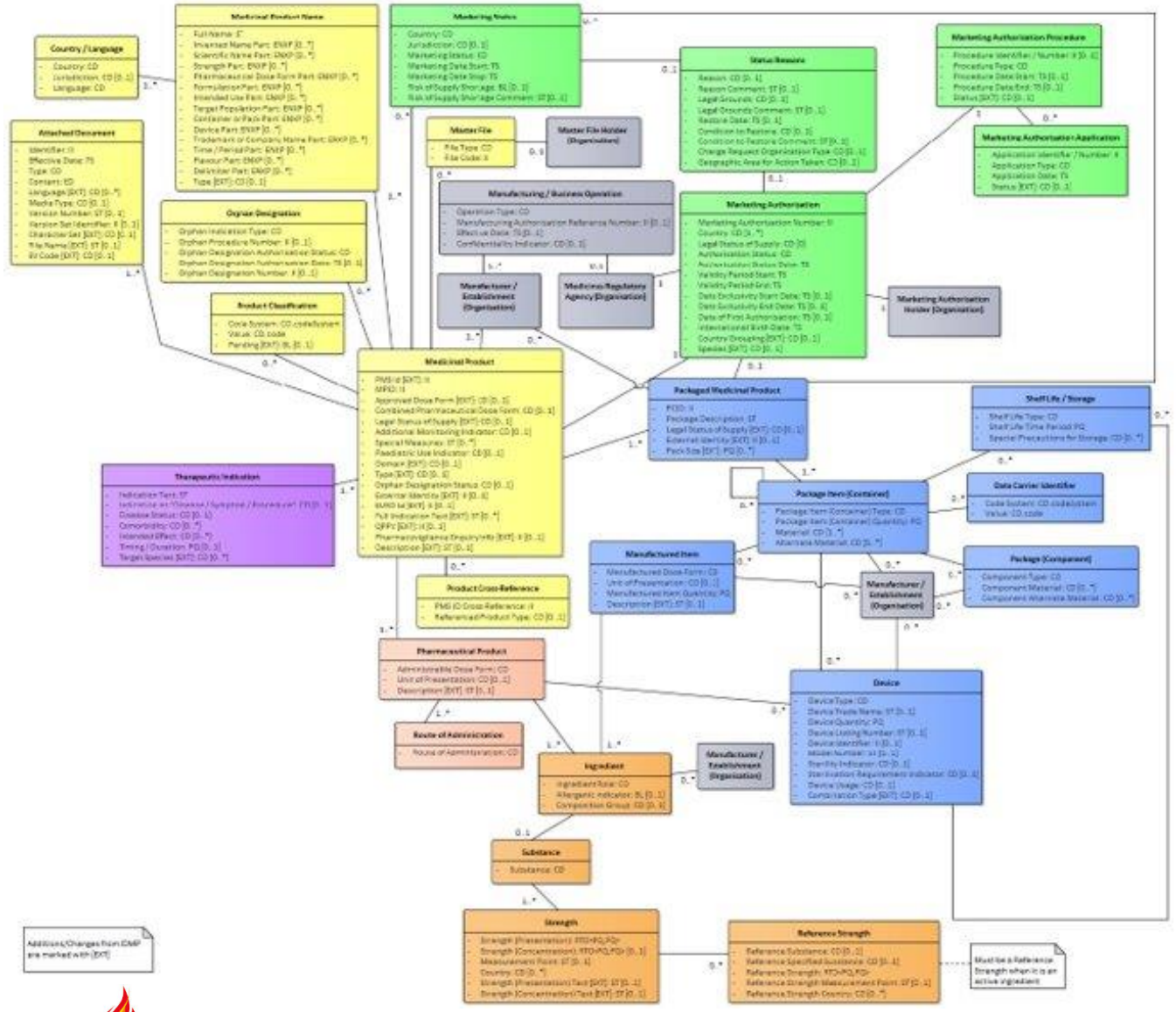
PMS Data model



- The **PMS data model** includes **180+ fields**, most of which are repeatable.
- **Chapter 2** of the **EU Implementation Guideline (EU IG)** provides a **business-focused** overview, covering:
  - The data model, business rules, and technical conformance
  - Repeatability, RMS lists, and field-specific guidelines
- **Chapter 6** of the **EU IG** serves as a **technical guide**, detailing how to connect to, use, and query the **PMS API**
- **PMS data model** aligns with **ISO IDMP** for **Authorised Medicinal Products**, though only a **subset of ISO IDMP fields** is implemented.

Colour legend

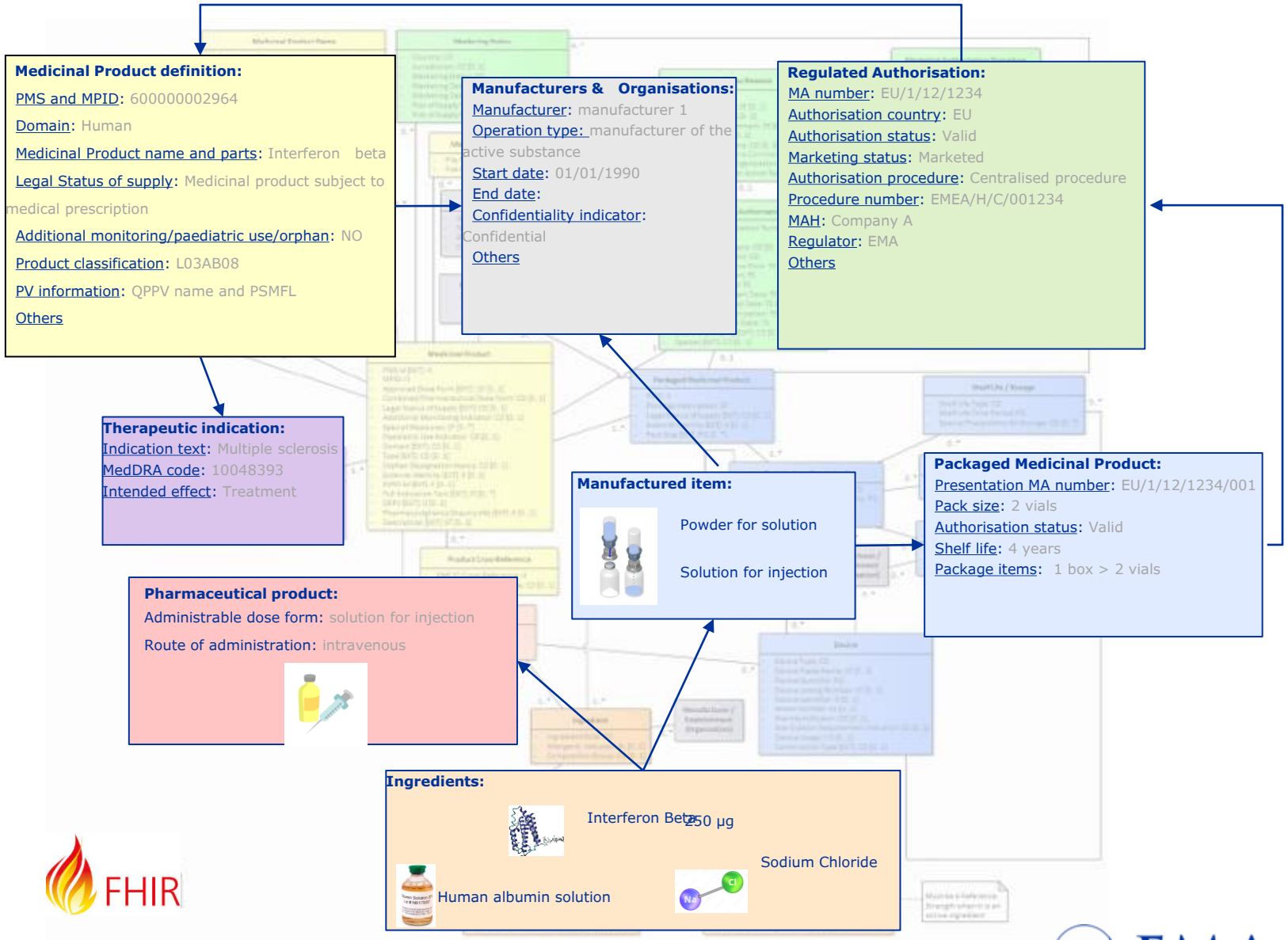
- Medicinal Product definition
- Regulated Authorisation (Marketing Authorisation)
- Manufacturer / Organization definition
- Therapeutic indication
- Packaged Medicinal Product Definition
- Pharmaceutical Product
- Ingredient

FHIR Slido #PMSAPI

EMA

PMS Data model

- **Chapter 2:** full list of data elements from the PMS data model
- **Chapter 6:** API technical specifications; Introduction - Zip folder
- **Chapter 8:** specific and detailed examples of real medicinal products



Simplified representations of the PMS data model

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How to access PMS standardised data

PMS standardised data

3th July 2024: API view-only for registered MAHs

18th September 2024: API view-only for registered H&V NCAs

17th December 2024: API view-only for registered all NCAs (H-only included)

Releases pending to be delivered:
1. PMS API write MVP
2. PMS Public API

31st May 2024: PUI view-only

31st January 2025: PUI MVP edit for registered MAHs

Access to PMS API –PMS Admin & API role overview

Admin roles

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

Industry roles

User	Role names	PMS Access Level (*EU IG Ch.5)*
Industry user(s)	PMS Industry API User	Level 2a (active)

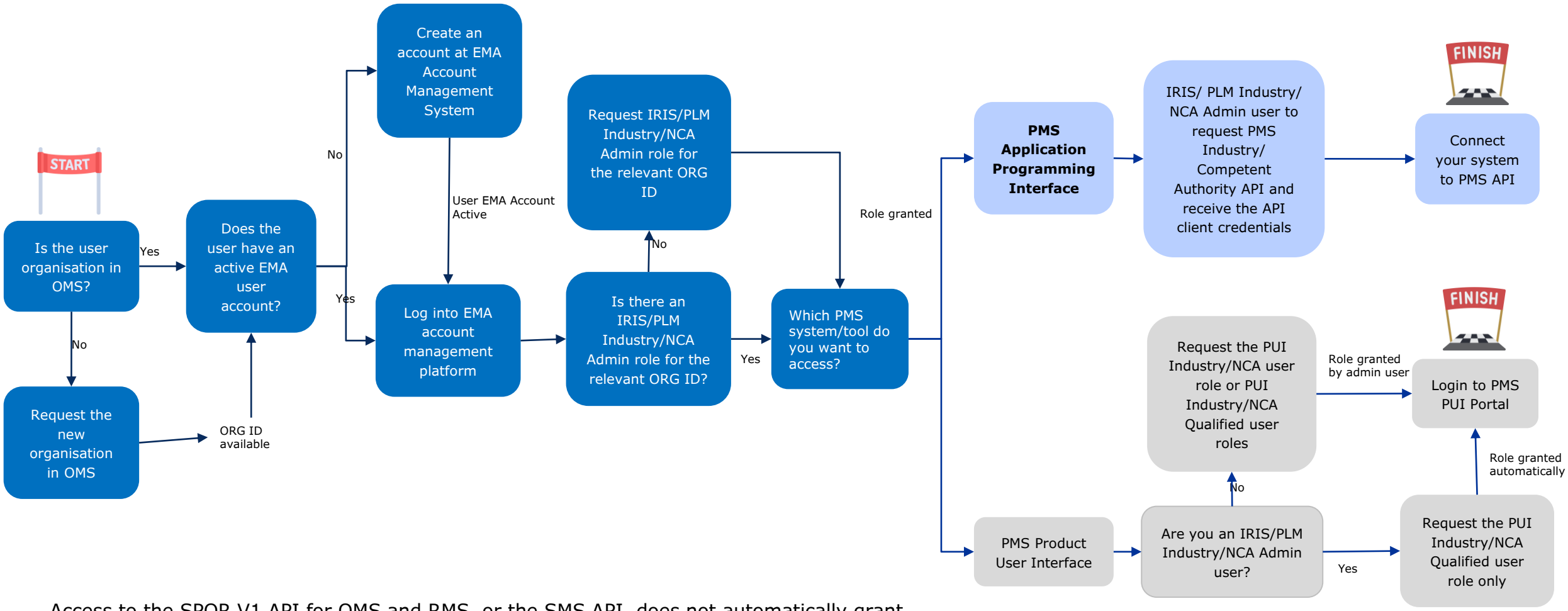
Regulator roles

User	Role names	PMS Access Level (*EU IG Ch.5)*
NCA user(s)	API Competent Authority User	Level 3 (active)

Key role characteristics and recommendations

IRIS/PLM NCA Admin	API Competent Authority User
• **No direct READ 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 Competent Authority Admin 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 PMS API**

PMS User Registration process



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.

Access to PMS – EU IG Chapter 5 & Annex A

Access Levels:

- **Level 1 – General Public** (Not available yet)→ Limited access to PMS data
- **Level 2 – Marketing Authorisation Holders (MAHs) & Service Providers***
  - 2a: Full access to owned PMS data (Applicable to API & PUI)
  - 2b: Partial access to owned PMS data (Applicable to PUI only)
- **Level 3 – Health Authorities & Service Providers**→ Full access to PMS data*

Service Providers (Vendors & Software Developers):

✓ Can only access **PMS API Level 2a/3** on behalf of a client (for security reasons)

✓ PMS API Level 2a/3 requires sharing of **registered MAH/NCA secret credentials**

✓ Secret credentials are granted only to registered **PLM/IRIS Industry/NCA admin users** at **ORG-ID level (Ref. EU IG Chapter 1)**

✓ In the future, the release of the **PMS Public API** will provide public access to a limited product dataset **without requiring appropriate registration**

***** Access is linked to the organisation (ORG-ID) they are registered with

How to access PMS API WRITE in future?

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

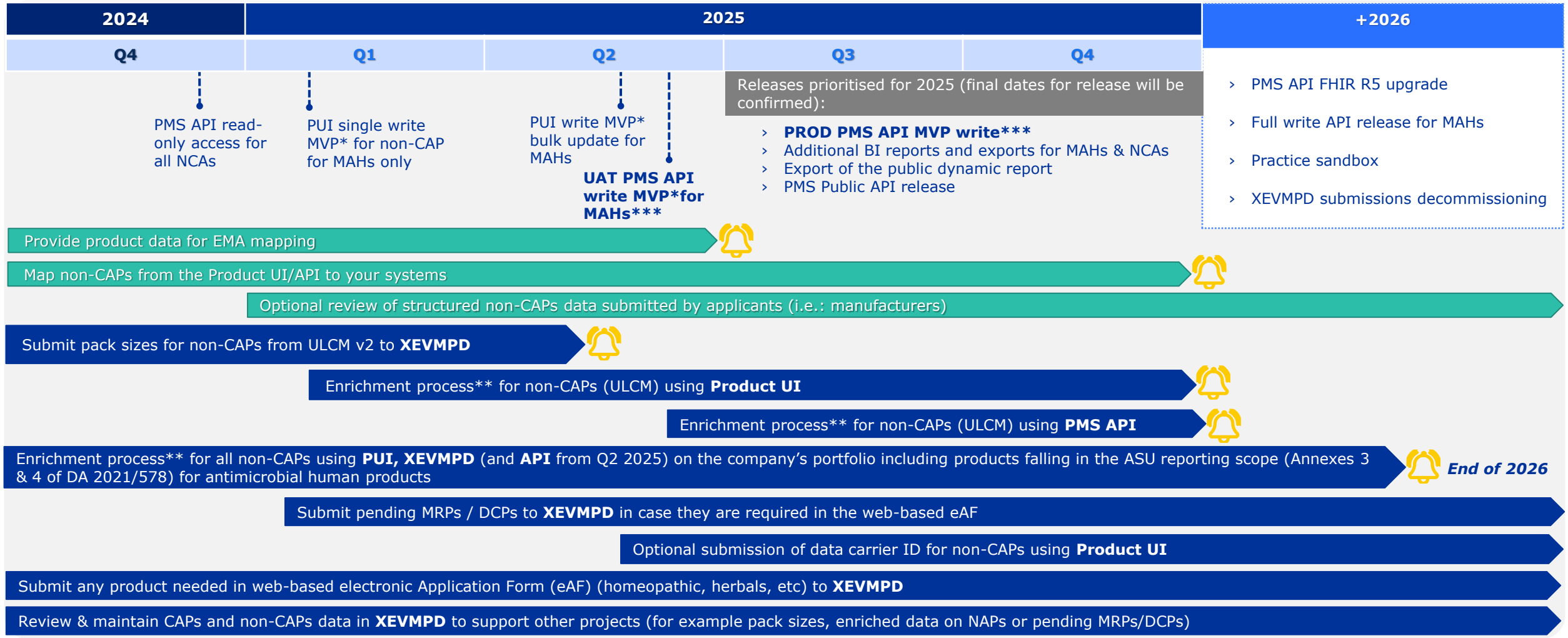
- ✓ WRITE privileges will be added to your existing user role
- ✓ No further actions on the EMA Account management portal are required
- ✓ Your PMS API role name will remain unchanged
- ✓ You will have full **read and write** MVP access to all PMS data for your affiliated ORG ID

If you do NOT have access to PMS API 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

Product Management Service roadmap



* MVP: limited to structured pack size data, manufacturers and MBOs
**only for structured pack size data, manufacturers and MBOs
*** Subject to Industry user's readiness

Legend

NCA action | MAH action | Milestone | Deadline

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

What MAHs need to do in PMS to support use cases

Summary of MAH's Actions in PMS

Access

Request access to the PMS API and ensure RIM systems are ready for MAHs to access product data via PMS API.

Data Submission

Ensure the medicinal product data in the MAH's RIM system is accurate, up-to-date, and ready for submission. Submit packaged products in XEVMPD and limited non-CAP product data impacted by the ULCM list to the PMS API via a machine-to-machine connection.

Updates & Maintenance

Regularly update product data to ensure compliance with ongoing regulatory changes and legal requirements.

Collaboration

Work closely with software developers/vendors to ensure a seamless machine-to-machine connection between the MAH's RIM system and the PMS API for accurate data submission.

Why MAHs need to consider PMS API & its benefits

Key Benefits of PMS API

Efficiency: Automates and simplifies the process of data submission and updates.

Handling Large Volumes against deadlines:

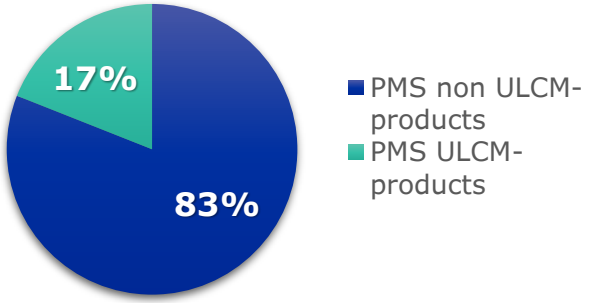
- 17% of products by end 2025 equal to ~ 83.671 products
- 83% of products by end 2026 equal to ~ 422.103 products
- MAHs with big portfolio may prefer using PMS API rather than PUI to submit products data

Real-Time Updates: Instantaneous data exchange for MAH users and data access for Competent Authorities.

Reduced Errors: Automation minimizes human error and ensures compliance.

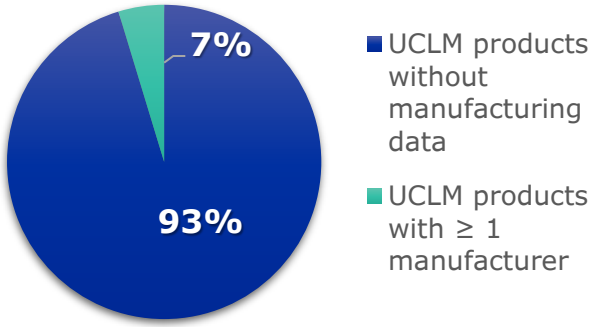
Data Transparency: Better data tracking and reporting capabilities.

Overview of PMS products



Calculation is based on ULCM v2

UCLM-products: status of manufacturers data in PUI



Calculation is based on ULCM v2 and as of 7th March 2025

Future use of PMS Data & Opportunities for Software Developers/Vendors

How PMS Data will be used in the Future?

- Future transition from paper-based submissions to electronic data submissions (replacing XEVMPD submissions), driving the shift towards full **digitalisation**. Discussions are ongoing.
- **PMS Integration into EU Regulatory Processes**: All pharmaceutical companies will be required to integrate PMS data, enabling the exchange of structured data and its reuse throughout the product lifecycle.
- **PMS Public API**: **PMS Public API**: Enhances transparency by providing general public access, without appropriate authorisation.
- **PMS in European Health Data Space (EHDS)**: PMS structured data to potentially support EHDS in the context of ePrescription and eDispensasion
- **PMS Link to ePI**: Direct connection to electronic Patient Information (ePI) systems.

Focus on PMS Application Programming Interface (API): Full READ vs WRITE MVP*

*MVP: minimum viable product

Overview of PMS API

PMS API Read	PMS API Write (MVP)
FHIR v 4.4.0 (R5 preview 2)	FHIR R5 major
Search, Get Product data by ID	Get product data by ID Update products with specific data elements
OAuth2 Client Credentials flow	OAuth2 Client Credentials flow
Same set of credentials	

*MVP: minimum viable product

PMS API READ timelines

```
<?xml version="1.0" encoding="utf-8"?>
<Bundle xmlns="http://hl7.org/fhir">
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        <versionId value="13" />
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                    <Provenance>
                        <target>
                            <reference value="#" />
                        </target>
                        <occurredDateTime value="2025-02-11T13:33:04
```

READ access timelines in 2024:

1. *3rd July*: read access to all industry users
2. *18th September*: read access to all H&V NCA users
3. *17th December*: read access to all NCAs, including H-only Competent authorities
4. 2025-2026 (tbc):
   - PMS Public API read release
   - PMS API FHIR R5 upgrade

PMS API READ data access

```
<?xml version="1.0" encoding="utf-8"?>
<Bundle xmlns="http://hl7.org/fhir">
    <id value="600001856403" />
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        <versionId value="13" />
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                        </target>
                        <occurredDateTime value="2025-02-11T13:33:04
```
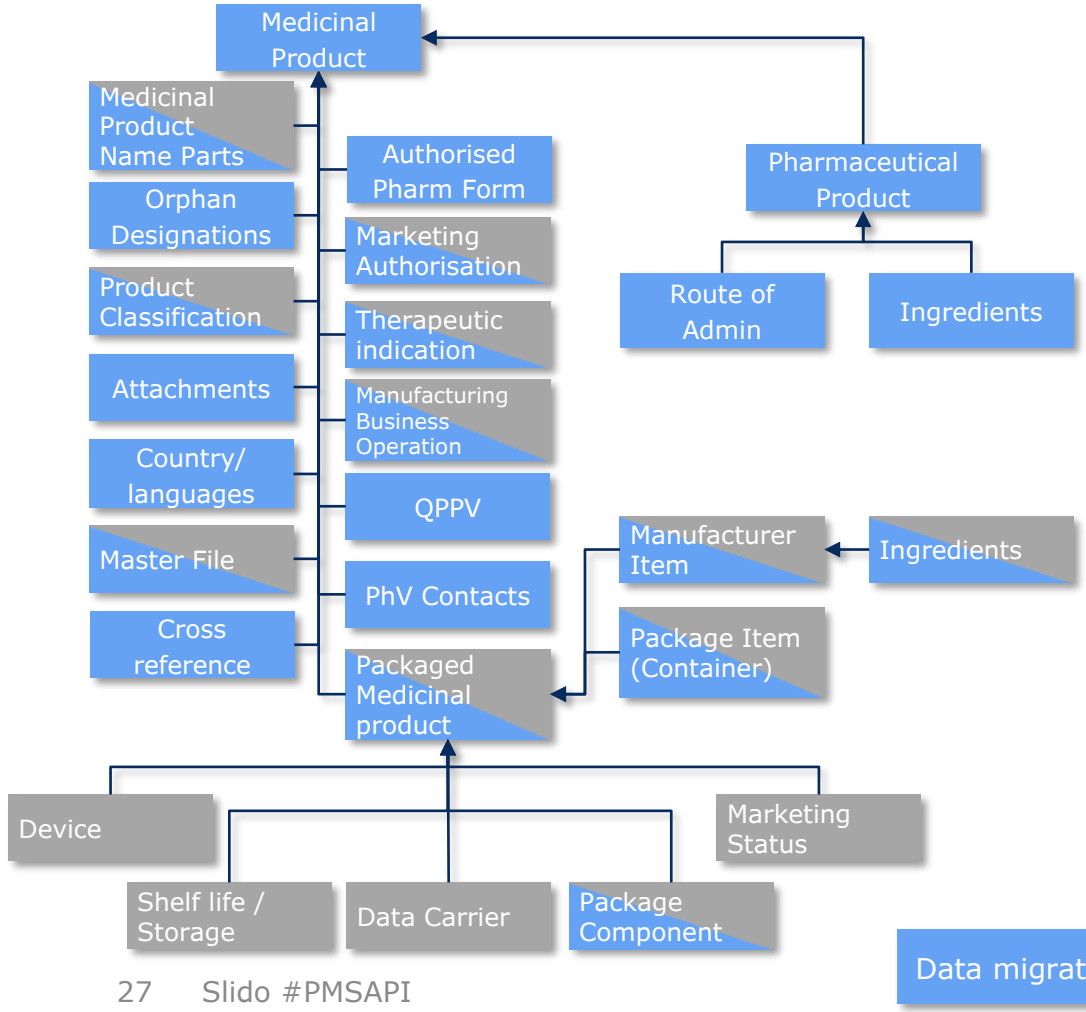

- PMS API contains authorised **CAPs and non-CAPs data**
- The **PMS** data model is completed with a combination of the available data from both **SIAMED II (EMA database)** and **XEVMPD**.
- Authorised products data are loaded in PMS API as per migration rules outlined in **EU IG Chapter 7**
- Given the high volume of new data elements in PMS vs the existing number of XEVMPD/SIAMED attributes, ~ **80 fields are empty** & will have to be **enriched by MAH**, as applicable.

PMS API READ data access



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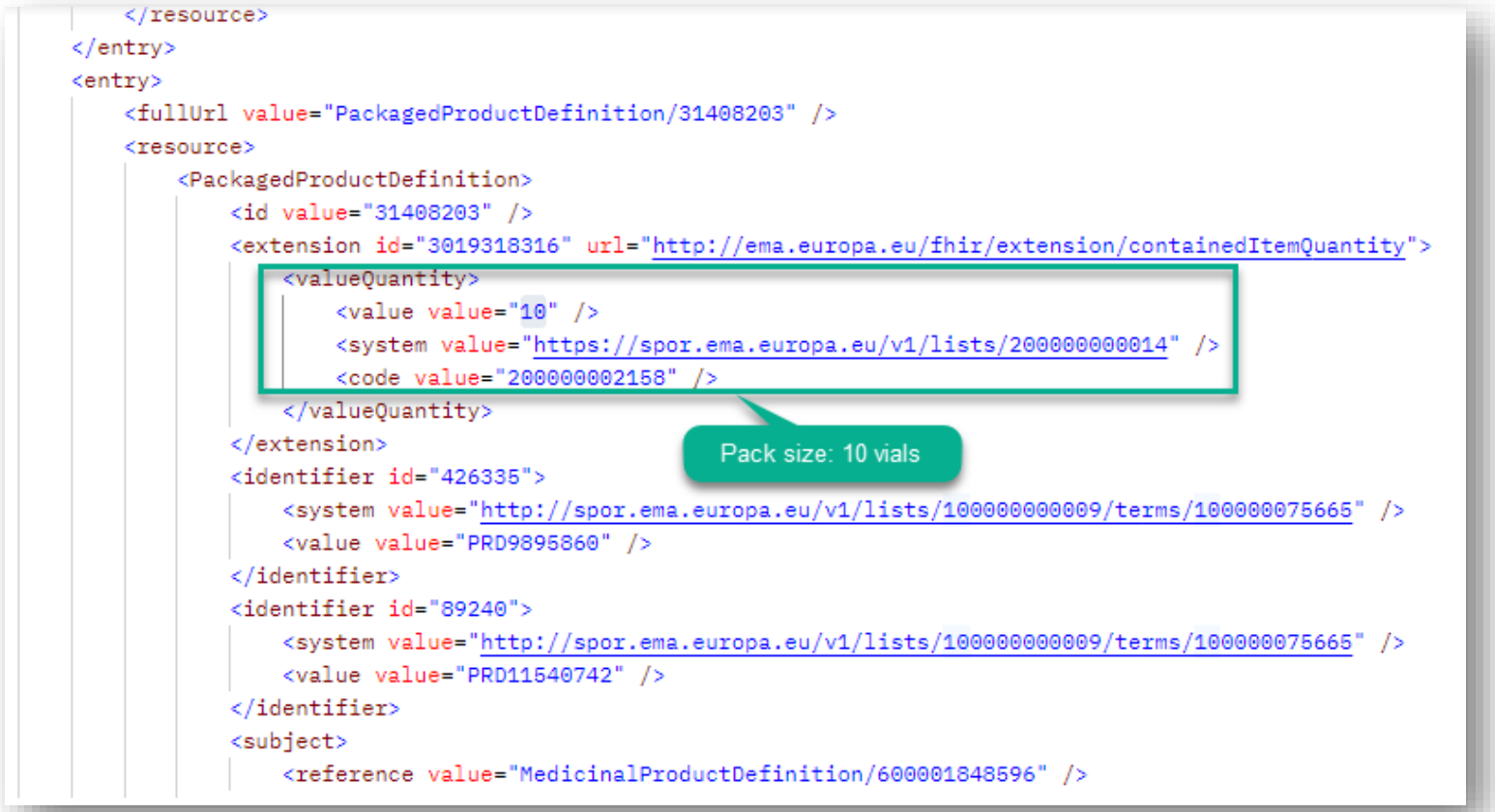
- Authorised products data are loaded in PMS API as per migration rules outlined in **EU IG Chapter 7**
- Given the high volume of new data elements in PMS vs the existing number of XEVMPD/SIAMED attributes, ~ **80 fields are empty** & will have to be **enriched by MAH**, as applicable.

PMS API READ data access

- **Access is based on the user's ORG-ID.**
  - **Level 2a (Industry)**: Access product data linked to the organisation (ORG-ID) they are registered with.
  - **Level 3 (Competent Authorities)**: Access all authorised products available in PMS.
- **Registered PMS API users can**:
  - Search for Product data using the FHIR standard search capabilities
  - Retrieve all data elements related to each Product (Ref. PMS API read training)
- **If you do not have access to PMS API READ yet:**
  - Request the PMS API access
  - Refer to slides 15 and 16 of this presentation
  - Follow the instructions reported in the EU IG Chapter 1

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

PMS API WRITE MVP*

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READ access timelines in 2025 & beyond:

1. Q2 (TBC): UAT PMS API write MVP for MAHs*
2. Q3 (TBC): WRITE MVP access to all non-Centrally Authorised Products MAHs (industry users)*
3. + 2026 (TBC):
   - Full write API release for MAHs
   - Practice sandbox TBC in 2026

* Subject to Industry user's readiness

*MVP: minimum viable product

What PMS API write is?

- Capability to update data fields on existing PMS products which are held by the specific Organisation. Fields:
  - Manufacturing Business Operations
  - Pack sizes
- Implements FHIR R5 Major version
- Currently as MVP under *alpha* version, full version released together with FHIR R5 upgrade of PMS API
- The process of updating data is asynchronous
  1. Initiate an update Operation via a POST to the PMS API
  2. Poll for the Operation outcome via the PMS API until a success (or error) status is retrieved
- Validation according to the published Write API EU IG Chapter 2

*MVP: minimum viable product

PMS API WRITE MVP*

The PMS API WRITE feature will enable **non-CAP MAHs** to submit a structured, IDMP-compatible dataset of their owned medicinal products **from MAHs' RIM** systems to the **PMS API**. Scope: Support data submission for non-CAPs **affected by the ULCM list**.


```
    </resource>
</entry>
<entry>
    <fullUrl value="PackagedProductDefinition/31408203" />
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            <subject>
                <reference value="MedicinalProductDefinition/600001848596" />
```

Pack size data:

- Quantity: **10**
- Unit of presentation: RMS ID 200000002158 = **Vial**

Data are expressed with a numeric value and unit.

The units are specified as a Term ID listed in RMS Units of Presentation list as applicable.

*Abbreviations:

- MVP: minimum viable product
- non-CAP: non-Centrally Authorised Products
- MAH: Marketing Authorization Holders
- RIM: Regulatory Information Management
- IDMP: Identification of Medicinal products
- ULCM: Union List of Critical Medciines

PMS API WRITE MVP*

The PMS API WRITE feature will enable **non-CAP MAHs** to submit a structured, IDMP-compatible dataset of their owned medicinal products **from MAHs' RIM** systems to the **PMS API**. Scope: Support data submission for non-CAPs **affected by the ULCM list**.

Manufacturer data:

- Manufacturer (OMS)
- Business operation (Manufacturing Activity RMS list)
- Operation start date (Date)
- Operation end date (Date)
- Confidentiality indicator (Data Classification RMS list)
- Authorisation reference number (Reference number)
- Effective date (Date)
- Medicines Regulatory Agency (OMS)

*Abbreviations:
- MVP: minimum viable product
- non-CAP: non-Centrally Authorised Products
- MAH: Marketing Authorization Holders
- RIM: Regulatory Information Management
- IDMP: Identification of Medicinal products

How to use PMS API WRITE?

PMS API Implementation guide:

- Published on 21st January 2025 on EMA PMS webpage
- Subject to further updates by end Q1 2025

Content

- FHIR profile and extensions
- Value sets and Code Systems
- Conformance resources
- Technical artifacts

Documentation

- European Medicines Agency Write PMS API implementation Guide
- European Medicines Agency Write PMS API implementation Guide (zip)

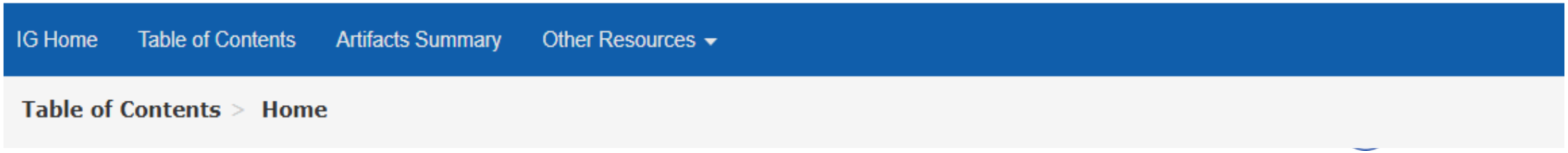
Write MVP PMS API Integration knowledge sharing

This session addresses the major feedback received on the January 2025 EMA Write PMS API Guide, aiming to provide clearer user insights.

What is a FHIR Implementation Guide?

- The html document sent for review is a FHIR Implementation Guide (IG)
- An 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)

EMA Write PMS API Implementation Guide - Enrichments



What is a FHIR Implementation Guide?

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

What is a FHIR Implementation Guide?

No limit to what you can put in an IG, but the main focus is:

- Overview of the API
- Profiles of FHIR resources
- Extensions
- Value Sets and Code Systems (FHIR versions of parts of RMS)
- *Example XML*

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

We will be adding *XML examples* into the IG shortly

What is a FHIR Implementation Guide?

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

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

IG Feedback – 1

Have a "Getting started with PMS" guide

We intend to add a better overview to the IG

The general sequences, and parts of the API to use, with diagrams

However the IG is not the place to cover the basics of FHIR REST and Postman etc.

FHIR is an "off the shelf" standard

So there are lots of learning materials available, online, for free

(As well as "paid for" classroom training)

IG Feedback – 2

Where is there information about FHIR?

We use FHIR so that anyone can learn it without needing to depend on any particular team

A hands on guide: http://www.nprogram.co.uk/FHIR-Hands-On-Guide.pdf

Video FHIR tutorial: https://www.youtube.com/watch?v=YbQcJj1GqH0

FHIR Training courses: https://www.hl7.org.uk/training-online-courses/

While not specific to PMS, the fundamentals taught in these all apply to these APIs

IG Feedback – 3

How to do FHIR development?

There is free/open-source code that implements FHIR in Java, C#, Python, and JavaScript
(as well as R, Ruby, Pascal, Swift, PHP, Dart, Clojure and Kotlin)

See:
https://confluence.hl7.org/spaces/FHIR/pages/35718838/Open+Source+Implementations

IG Feedback – 4

What FHIR version is being used?

This PMS Write API uses FHIR 5.0.0 (also known as FHIR R5)

The PMS Read API uses FHIR 4.4.0 (FHIR R5 draft) - and this is what is documented in “Chapter 2”.

4.4.0 is *not FHIR R4*, despite the “4” digit.

Over 90% of 4.4.0 is the same in 5.0.0 (in PMS data)*

A mapping will be distributed (however the Write API does automatic mapping).

eAF and ePI are already on FHIR R5

* based on an example that uses each resource once. 33 differences in 505 lines of XML

IG Feedback – 5

Summary of the Write API

Read PMS data (R5 format): GET /**$everything**

- Data retrieved is a "searchset" Bundle - all editable resources

Write PMS data (R5 format): POST /**$merge**

- Data sent is a "transaction" Bundle – all edited resources
  - Also needs a "request" adding to each resource in Bundle, to say:
    - PUT = edit, POST = create new, DELETE = delete
  - Response is a "transaction-response" Bundle

IG Feedback – 6

Read single resource vs $everything

This API only supports getting the entire set of resources at once

- using $everything, with a MedicinalProductDefinition.id

This works the same as PMS read API

- and as documented in the SPOR API v2

GET of single resources is *not* supported in the Write API

- this is a pending correction to the Write API IG

IG Feedback – 7

Why are we using $merge?

(And not for instance just “PUT”?)

FHIR REST normally just overwrites all data, and we are not doing that

This API only supports updating a subset of PMS (by design)

It looks at updates to that specific subset and merges only those into PMS

For data integrity reasons we ignore changes to any other fields

So this is a merge, not a full update, hence we have a special “operation” for it

IG Feedback – 8

What is $merge?

- $merge acts like a FHIR transaction (https://hl7.org/fhir/http.html#transaction)
  - Multiple resources at once
  - *But*, unlike normal FHIR transactions, it only changes the specific fields
- $merge accepts a transaction Bundle (*not* a single domain resource)
- $merge is new, and not part of the SPOR API v2, and is entirely documented as part of the Write API
- No other type of update is supported (no other parts of SPOR API v2)

IG Feedback – 9

What data is sent to $merge?

- All the data in each resource should be sent, whether or not it is being updated
- Resources that are not being updated can be omitted
- If data is omitted that is mandatory in PMS, the update will be rejected, even if those items are not being changed
- Rationale - standard FHIR behaviour is for all data to be sent, even if it not being updated, and it means "make the data like this"
- We adhere to that, even though some data is in effect being ignored (for now)
- This means that the current partial write API and the eventual full(-er) write API behave the same. No surprises later.

IG Feedback – 10

What is the return data from $merge?

- $merge does a FHIR transaction
- The eventual response is a FHIR "transaction-response" Bundle
- It is a set of resources in a Bundle, mirroring what was sent
  - each with an http status code (e.g. 200 OK or 201 Created) and a location for where each new resource was put (the id)

IG Feedback – 11

What is the return data from $merge?

- $merge also uses the FHIR standard *asynchronous pattern.* This is documented in the SPOR API V2 and https://hl7.org/fhir/async.html
- Clients need to be ready for a 200 OK ***or*** a 202 Accepted code and a content-location header.
  - 200 – data is in the body
  - 202 – data will be available at the content-location, eventually – via polling

IG Feedback – 12

Will there be a synchronous option?

As with any of the SPOR APIs the output of the API may be synchronous or asynchronous. It cannot be guaranteed to be synchronous (so “no”).

Clients need to be able to deal with “202 Accepted” and treat it as an asynchronous response. However, if a 200 (or 201) is received then they already have the data (synchronously) and there is no need to poll.

How often to poll?

Recommended polling frequency is not yet published (and will not be in the IG, as with other non-functional requirements).
But the FHIR standard API covers automatic polling management (“Retry-After” header and potentially “429 Too Many Requests”).
With a correct implementation by the client, this will be transparent in use.

IG Feedback – 13

Relationship between the Write API and SPOR API v2

This API is distinct from the SPOR API v2.

$merge was not part of the original SPOR v2 API definition. It is new.

$everything (the way that the Write API provides Read capability) is consistent with SPOR API v2 and with PMS.

Most of the other endpoints in SPOR API v2 are not provided in this API

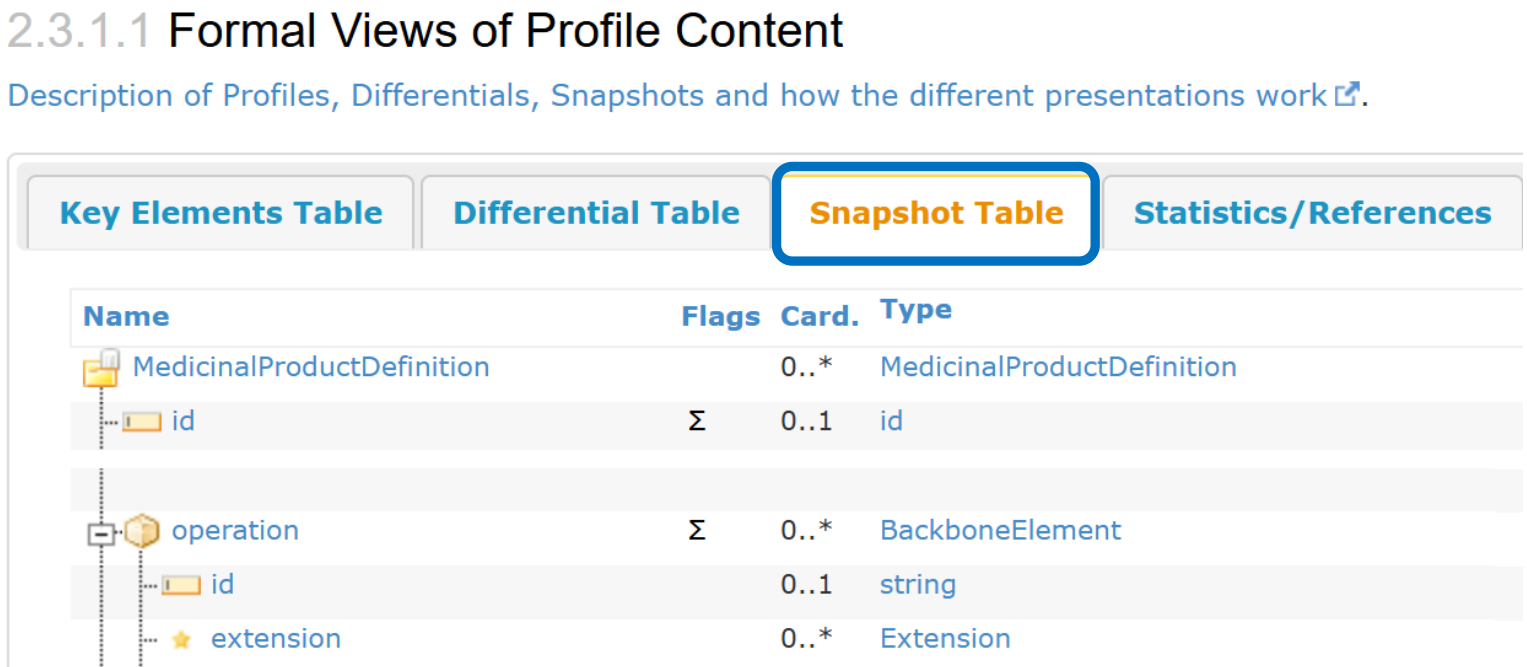
This API does not affect or replace anything in the PMS (Read) API. This is all additional to that.

IG Feedback, specifics – 1

Missing "operation" attribute

All elements are shown on the *Snapshot* tab.

The Key Elements Table tab is a summary and does not show every element (by design). It shows mandatory elements from FHIR and from the profile. Operation is not mandatory in either.



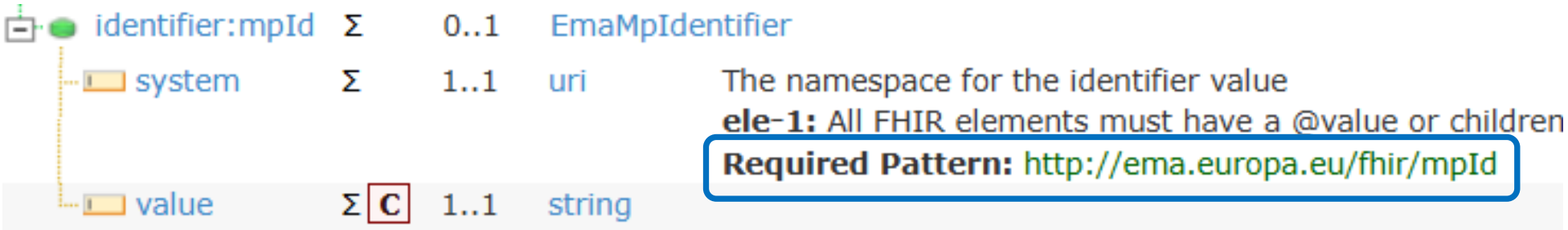
IG Feedback, specifics - 2

The URLs don't work

FHIR uses URLs for the unique *names* of things (e.g. types of identifiers)

These are *not* web addresses and are *not* expected to actually resolve to a page. These are not broken. The IG will show what these are.

```
<MedicinalProductDefinition>
   <identifier>
      <system value="http://ema.europa.eu/fhir/mpId"/>
      <value value="600000704559"/>
```



IG Feedback, specifics – 3

What are "slices"?

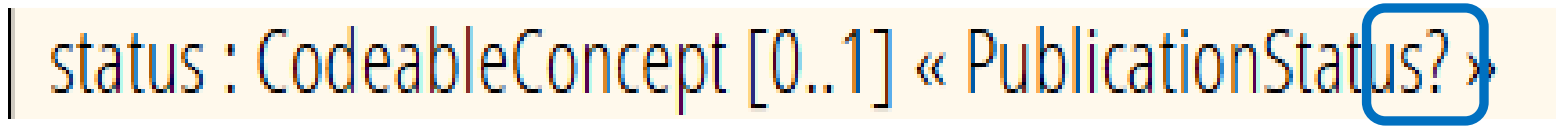
- Slices are a part of profile. They have little significance other than a convenience for documentation.
- https://hl7.org/fhir/profiling.html#slicing
- Two slices on a part of a model (e.g. an identifier), is just a way to specify two different variants of identifier and to be able to document each one separately (in 2 parts, or "slices")
- They have names just so we can tell them apart
  - "identifier:mpid" is some information about how identifiers which are mpids must be.
  - ":mpid" is a "slice name"

IG Feedback, specifics – 4

The names of codes have ? or ?? after them. Does this mean they are not finished?

No, this is not related to whether things are finished.

FHIR uses a shorthand notation on UML diagrams to save space.



Hover over it to see what it means (or switch to the “Structure” tab)

? Means it is a “Preferred” list. It means you are intended use these codes but are not forced to.

! Means a “Required” list – a mandatory set, you cannot use other codes

See https://hl7.org/fhir/terminologies.html#strength to see them all

Handover to the next speaker

Luís Gouveia,
Web & Azure Cloud Expert

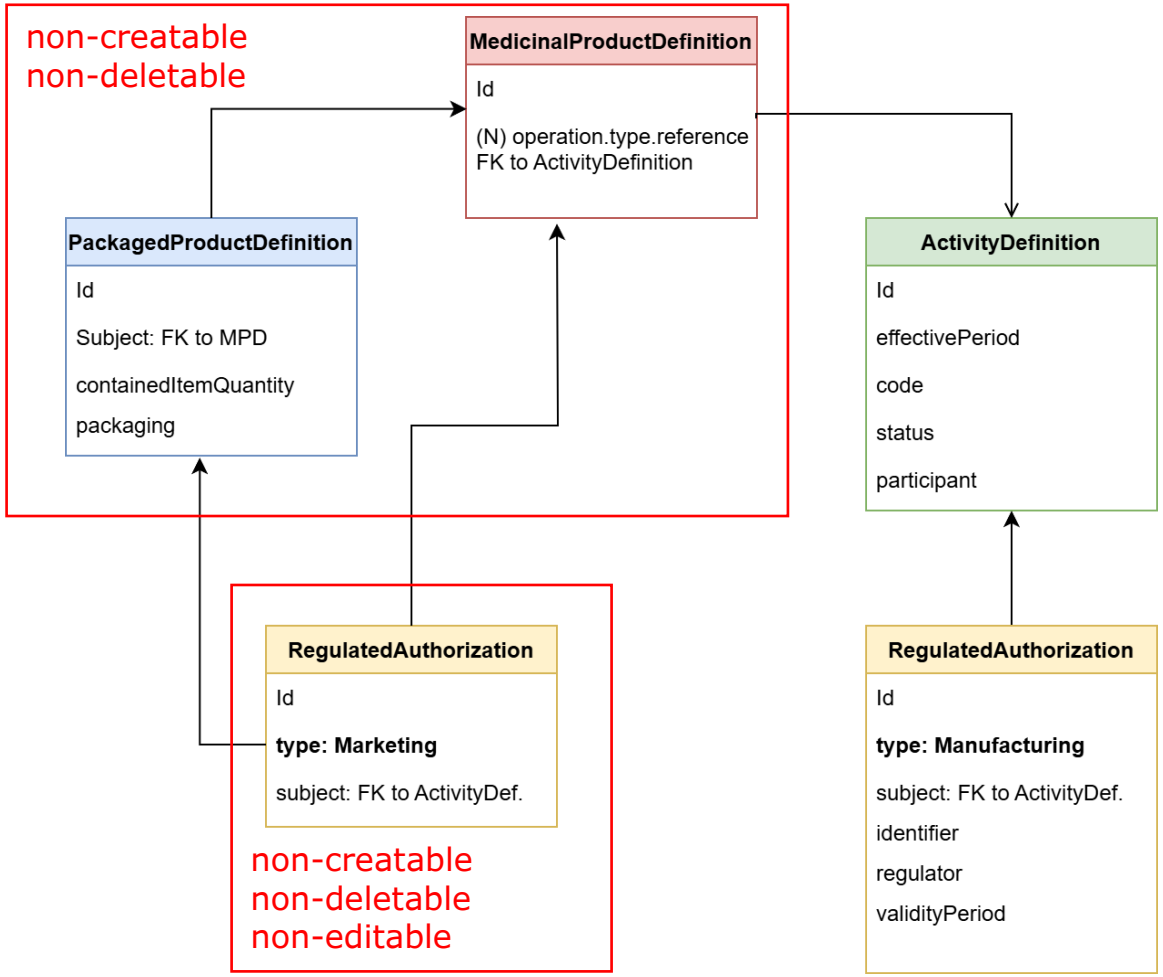
Write API – Operations

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



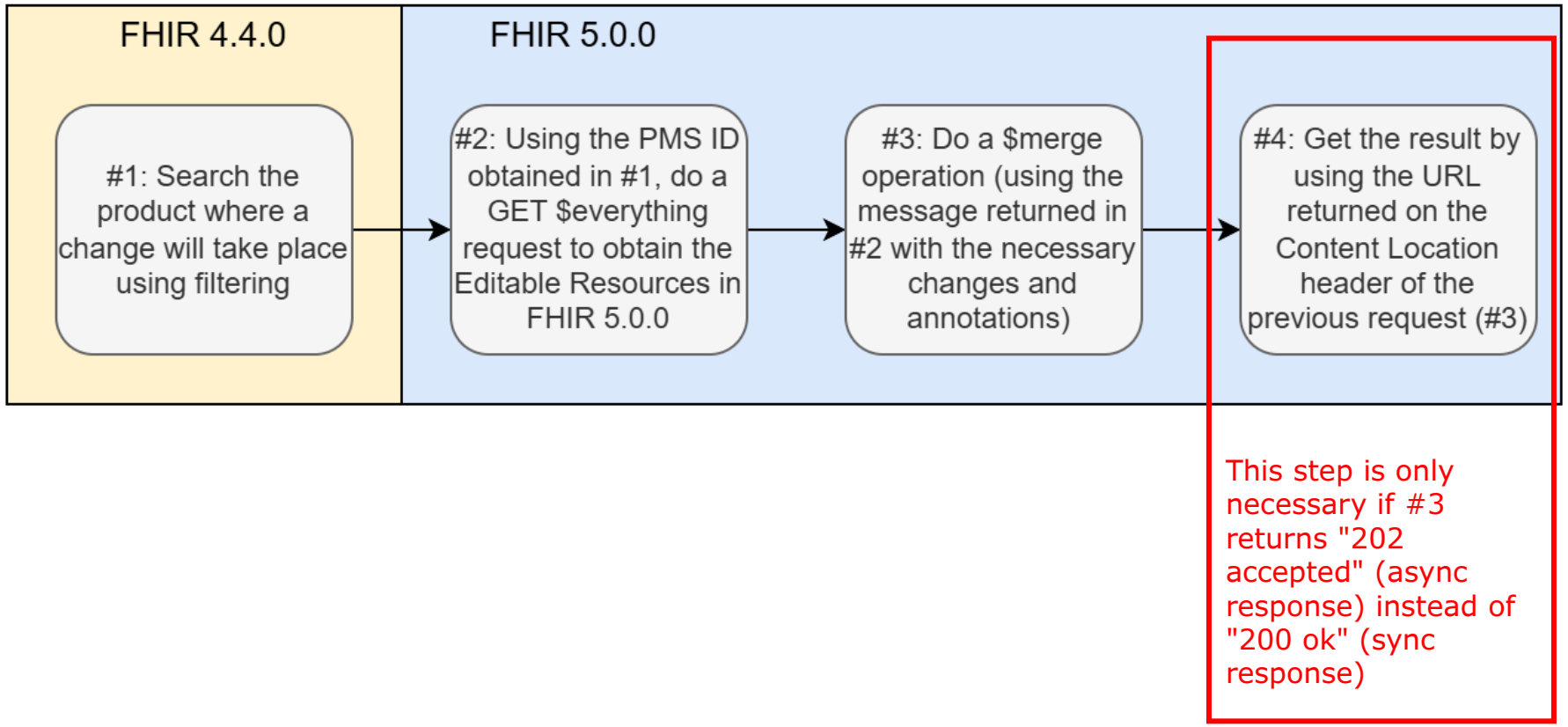
Write API – Editable Properties

Resource	Attribute	Description
MedicinalProductDefinition	*operation.type*	[Manufacturer] - Manufacturing Activity (e.g., Manufacturer of medical device - 100000160480). See SPOR list 100000160406.
	operation.confidentialityIndicator	[Manufacturer] - Data Classification (e.g., Public - 200000004985). See SPOR list 200000004983.
	operation.type.reference	[Manufacturer] - Reference to the ActivityDefinition resource.
PackagedProductDefinition	*containedItemQuantity*	[Package] - The package size.
	packaging.identifier	[Package] - The package identifier.
ActivityDefinition (Manufacturer Specific)	*effectivePeriod*	[Manufacturer] - The effective period (yyyy-MM-dd).
	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).

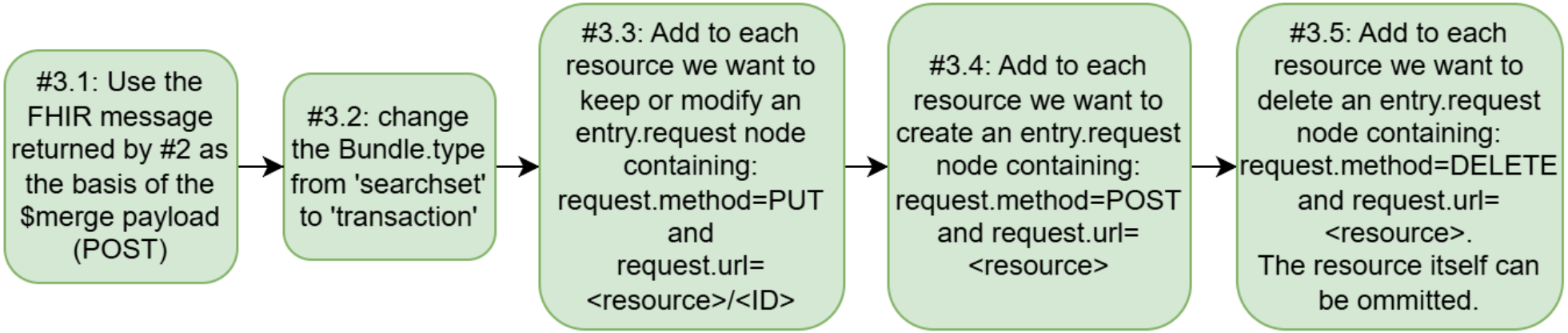
Write API – Editable Properties

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 (220000000099 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

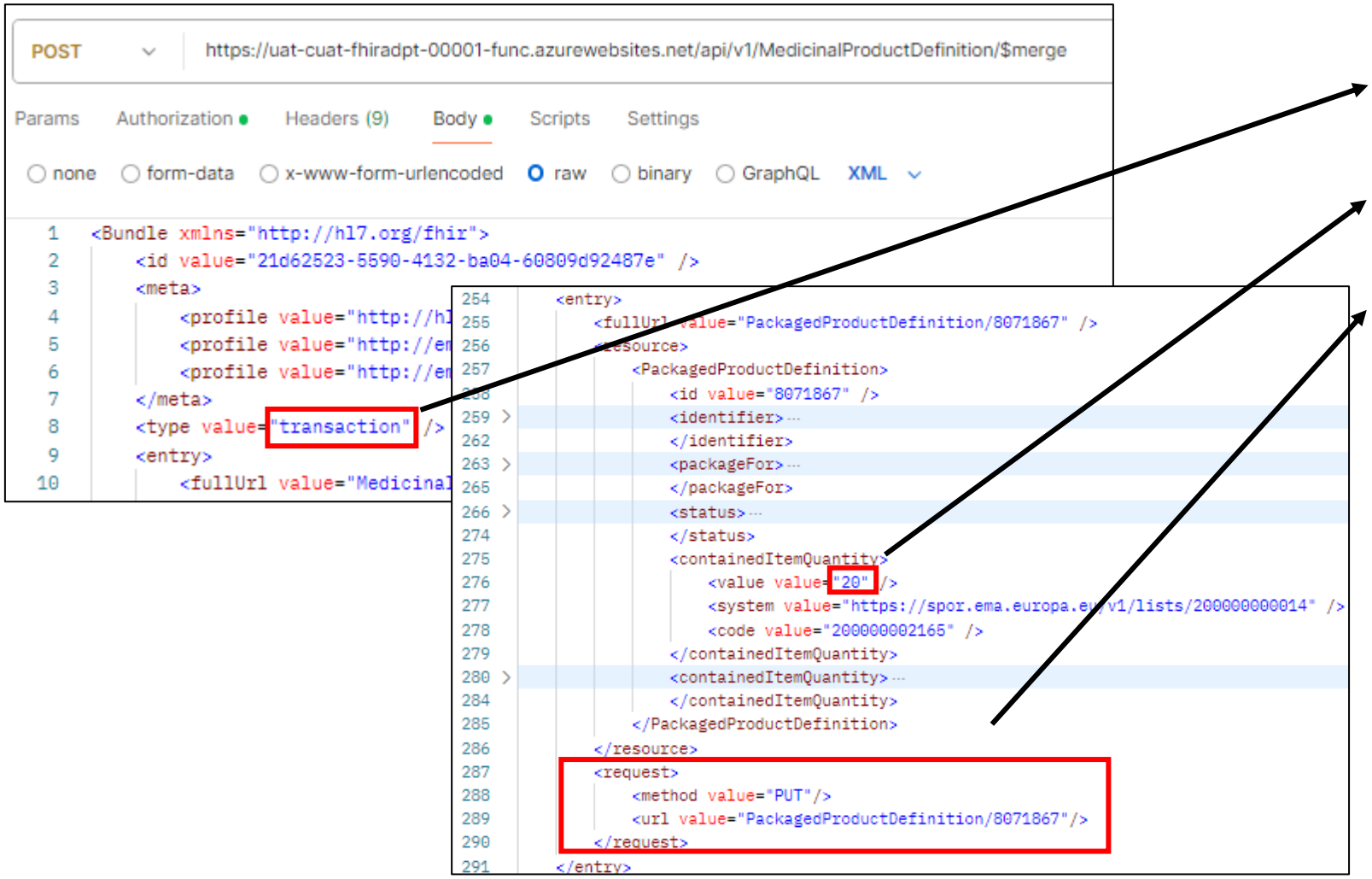
Body Cookies Headers (6) Test Results 200 OK 191 ms 27.46 KB

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>
```

Write API Examples – #2: Merge – request

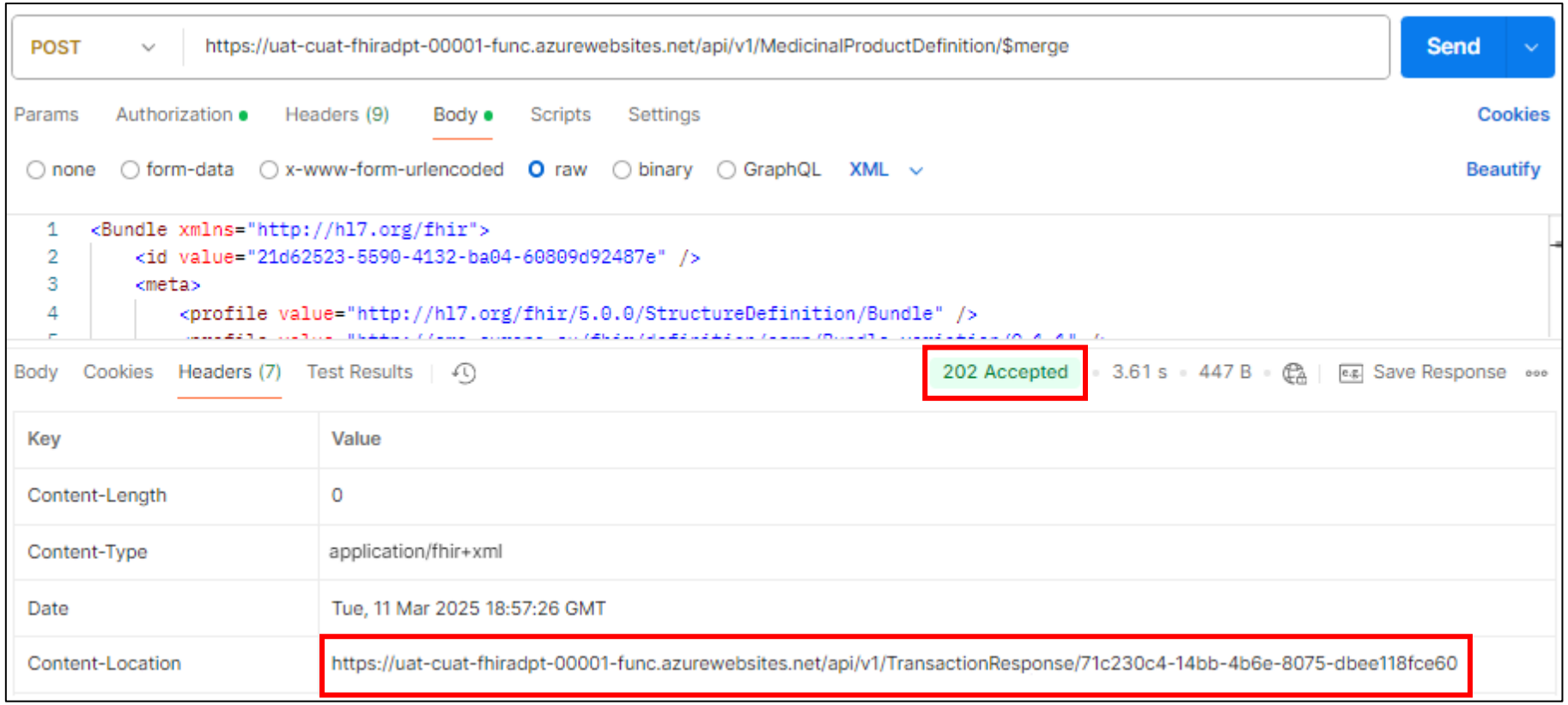


#1 – The bundle.type was modified from 'searchset' to 'transaction'

#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

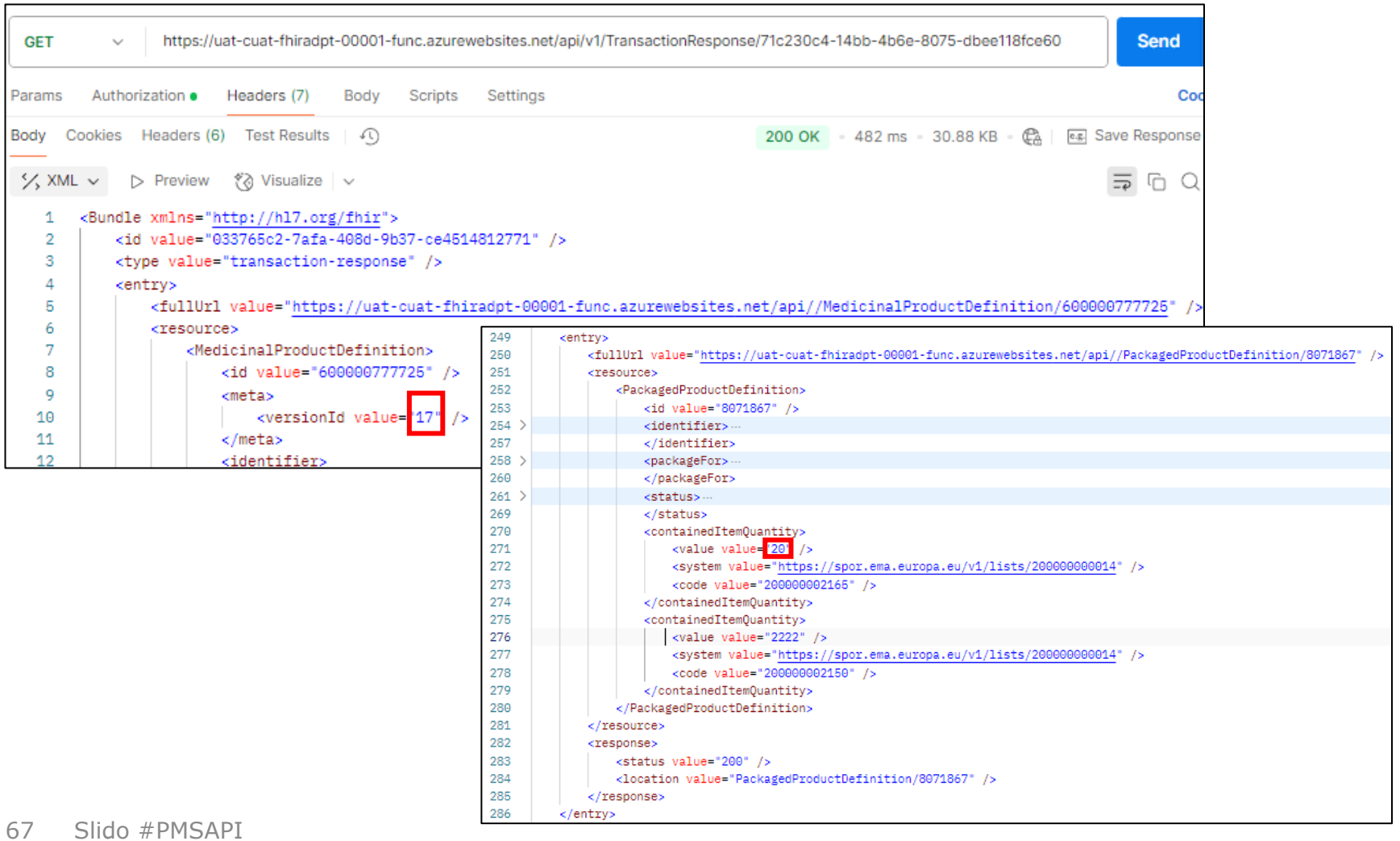
Write API Examples – #2: Merge - response



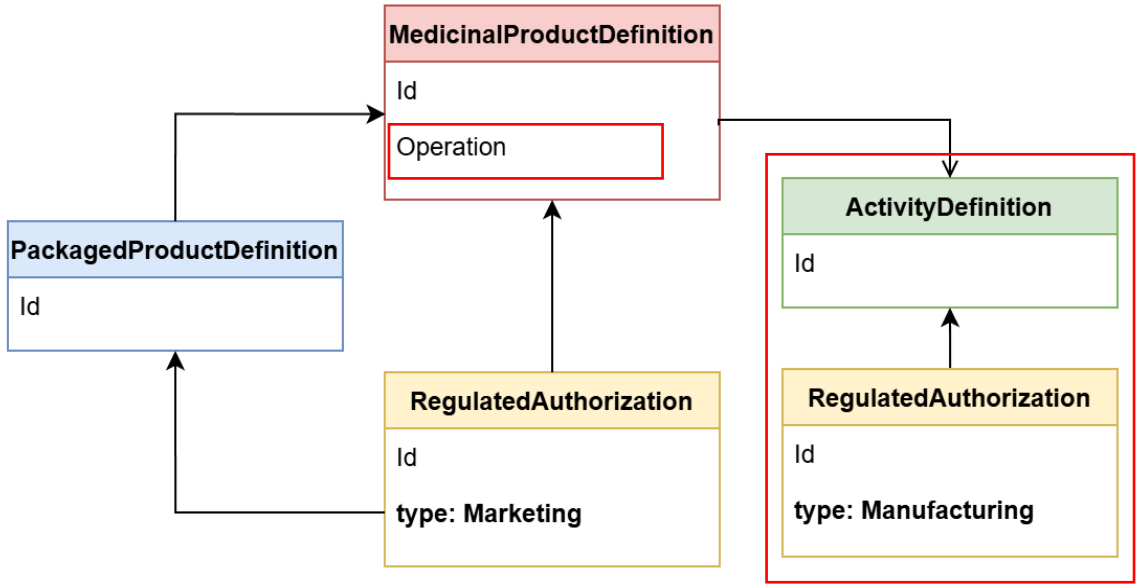
In this example, the response was asynchronous (HTTP 202 – Accepted), and a 3rd request (Content-Location URL) will have to be executed to fetch the result.

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).

Write API Examples – #3: Get Merge Result



Write API Examples – Add/Del Manufacturer



Add manufacturer:

- 1. Add ActivityDefinition
- 2. Add Manufacturing Regulated Authorization
- 3. Add MedicinalProductDefinition.operation node

Delete a manufacturer:

- 1. Remove ActivityDefinition
- 2. Remove Mananufacturing Regulated Authorization
- 3. Remove MedicinalProductDefinition.operation node

Call for Interest on PMS API User Acceptance Testing

UAT on write PMS API

Scope:

Verify whether registered Marketing Authorization Holders (MAHs) can successfully submit a limited product dataset from their RIM systems to the PMS API via their machine-to-machine connection

Date of UAT:

Ideally from Q2 2025, depending on the tester's readiness

How is it structured?

- *1st round*: test the PMS API write access and functionalities and identify any bug;
- *2nd round*: confirm whether the fixes implemented by EMA have addressed the previously identified issue(s).
- Circulated among the Industry Trade Organisations (TOs) on 6th March 2025

Deadline for nomination:

8th April 2025 EOB

Nominations of UAT testers

Up to 5 representatives/Industry TO. Upon justification, additional representatives to meet the Diverse Software Representation can be proposed.

To ensure fair representation of **all MAHs using different software providers, each nominee may be associated with a different software development** company.

Ideally the following entities should be represented in the testing activities:

- **Software Development Companies Associated with a Marketing Authorisation Holder (MAH)**
- **Marketing Authorisation Holders (MAHs) with In-House Software Development**
- **Independent Software Development Companies**

Essential Technical Expertise

- Experience in **REST API development and integration**
- Proficiency in **JSON/XML data handling and processing**
- Knowledge of **FHIR standards** or a strong willingness to learn
- Understanding and implementation of **API security best practices**

Industry Trade Organisations informed

EFPIA	**EUCOPE**	**Vaccines Europe**	**AESGP**
Medicines For Europe	**EuropaBio**	**Europharm SMC**	**IPFA**
PPTA	**MPP**	**PHUSE**	

Interested parties can contact their relevant Industry Trade Organisation

EU Survey

Level of stakeholders' readiness to machine-to-machine PMS API integration

Q&A

with PMS PI experts

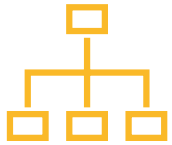
30’

- **Join Slido.com** using this code **#PMSAPI** 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

Next steps

Upcoming events and useful resources

Upcoming events

Q&A clinics on PMS UI and API

From March to June 2025

- **25 March 2025** (11:00 – 12:00 CET): Event page
- **29 April 2025** (11:00 – 12:00 CET): Event page
- **19 May 2025** (15:00 – 16:00 CET): Event page
- **17 June 2025** (11:00 – 12:00 CET): Event page

Public system demo

26 March 2025

Live broadcast on EMA's website event page

SPOR & XEVMPD status update webinars

Live broadcast on event page

- **9 April 2025** (10:00 – 12:30 CET): Event page
- **9 July 2025** (10:00 – 12:30 CET): Event page
- **8 October 2025** (10:00 – 12:30 CET): Event page

PMS Info-Day

21 May 2025 (9:00 – 17:30 CET)

Live broadcast on event page

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

Subscribe to quarterly PLM Insights newsletter

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SCIENCE MEDICINES HEALTH

Thank you

ema.europa.eu;
PMS Web Page

European Medicines Agency

PLM.ValueStream@ema.Europa.eu

Send a question via our website