EMA
EUROPEAN MEDICINES AGENCY

# PMS Project Made Easy: Summary of activities and practical tips for SMEs

Presented by Marcos Fernandez Gomez
(PMS Co-Product Owner)

24 February 2025, 14:00 – 16:00 (CET)

# Housekeeping

*Please note that **this session is being recorded** and **will be made available** through **EMA corporate website** and **YouTube channel***

*Participants can ask questions or give their input via the audience interaction tool **Slido**.*

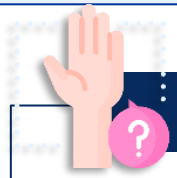
*Interaction via Slido is voluntary, and you may opt to remain anonymous. If you chose to use Slido, **you consent to the processing of your personal data** as explained in the EMA Data Privacy Statement for Slido.*

# Housekeeping notes – Q&A

- 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 **verbally address 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.

# Agenda

| | | |
|---|---|---|
| 1 | **Welcome** | **Marcos Fernández Gomez**, PMS Product Co-Owner, EMA |
| 2 | **Background** | **Marcos Fernández Gomez**, PMS Product Co-Owner, EMA |
| 3 | **Consuming systems & actions** | **Marcos Fernández Gomez**, PMS Product Co-Owner, EMA |
| 4 | **Source systems & review** | **Marcos Fernández Gomez**, PMS Product Co-Owner, EMA |
| 5 | **Demo & Summary** | **Marcos Fernández Gómez**, PMS Product Co-Owner, EMA |
| 6 | **Q&A** **30 mins** | **Moderator: Vivian Leamy**, PMS Change Management Team |
| 7 | **Closing** | **Marcos Fernández Gómez**, PMS Product Co-Owner, EMA |

# Scope

**The scope of this presentation is to provide an overview of activities that MAHs should perform to be compliant with PMS and other systems.**

**Links to additional information and deeper explanations can be found in each slide.**

**During the demo, EMA will suggest how MAHs can review their PMS migrated data and make sure the XEVMPD data is accurate. MAHs might follow other processes for the same purpose.**

**It is important that MAHs review the documentation provided to understand all the processes and requirements and to review known issues and the expected time of resolution.**

EMA
EUROPEAN MEDICINES AGENCY

# Background


## PMS is consuming data from XEVMPD, SIAMED & SOR

- XEVMPD: CAP and non-CAP products managed by MAHs through Art. 57
- SIAMED: EMA's database containing CAP data
- SOR: master data services for substances, organisations and referentials

Please, review EU IG Chapters 7 and 9 to understand how these sources feed PMS.

Data in PMS can be accessed through the **Product UI** or through the **PMS API**

## PMS provides data to different consuming systems

- Web-based variation eAF: products to be included in the variation form come from PMS
- ePI: in the future PMS products and the ePI will be linked
- ESMP: pre-filled templates contain PMS product data
- ASU: Antimicrobial Sales and Use Platform consumes PMS authorised products used in animals
- Inspections & parallel distribution: CAPs and their manufacturers are consumed from PMS
- RPM: The EMA Regulatory Procedure Management System consumes CAPs' data from PMS

# Background

**PMS is the source of product information for different systems, therefore it should contain harmonised product data.**

- Sources shall be reviewed to make sure data quality in PMS is the desired one.
- Additional data is required by PMS consuming systems. Submission of this data has to be done through different platforms
  - Product UI/PMS API
  - XEVMPD


**Source systems**

Review and improve data quality so it is reflected in PMS

**Consuming systems**

Provide requirements of additional information needed to support their processes


## Source systems

Review and improve data quality so it is reflected in PMS

- Review of data in XEVMPD
- Review mappings to SOR to enable continuous synchronization of products
- Review CAP data from SIAMED

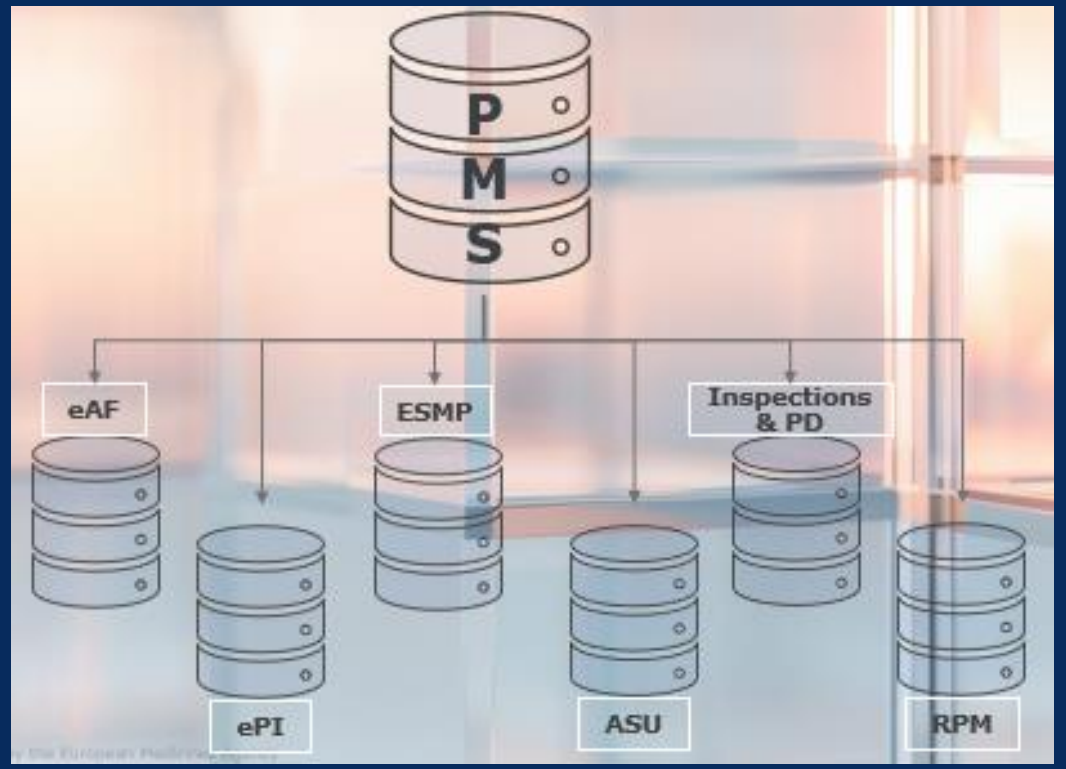
## Consuming systems

Provide requirements of additional information needed to support their processes

- **PLM**: accurante OMS ID to access products
- **eAF**: any product subject to be used in the web-based variation form
- **ESMP**: manufacturers and structured pack size details for ULCM
- **ASU**: pack sizes for impacted products
- **Inspections, PD & RPM**: accurate product data

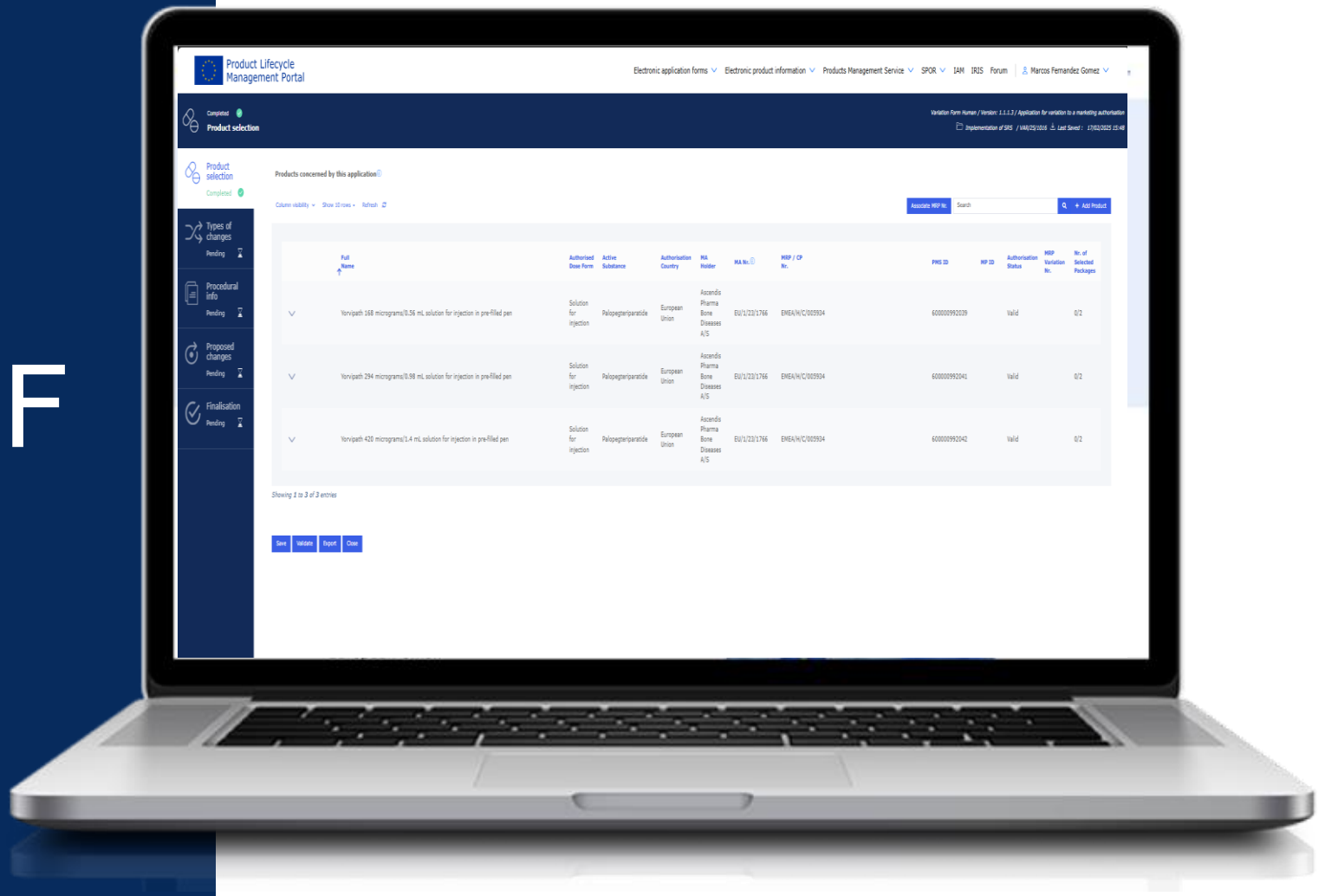
# Consuming systems

Additional information is required to support their processes

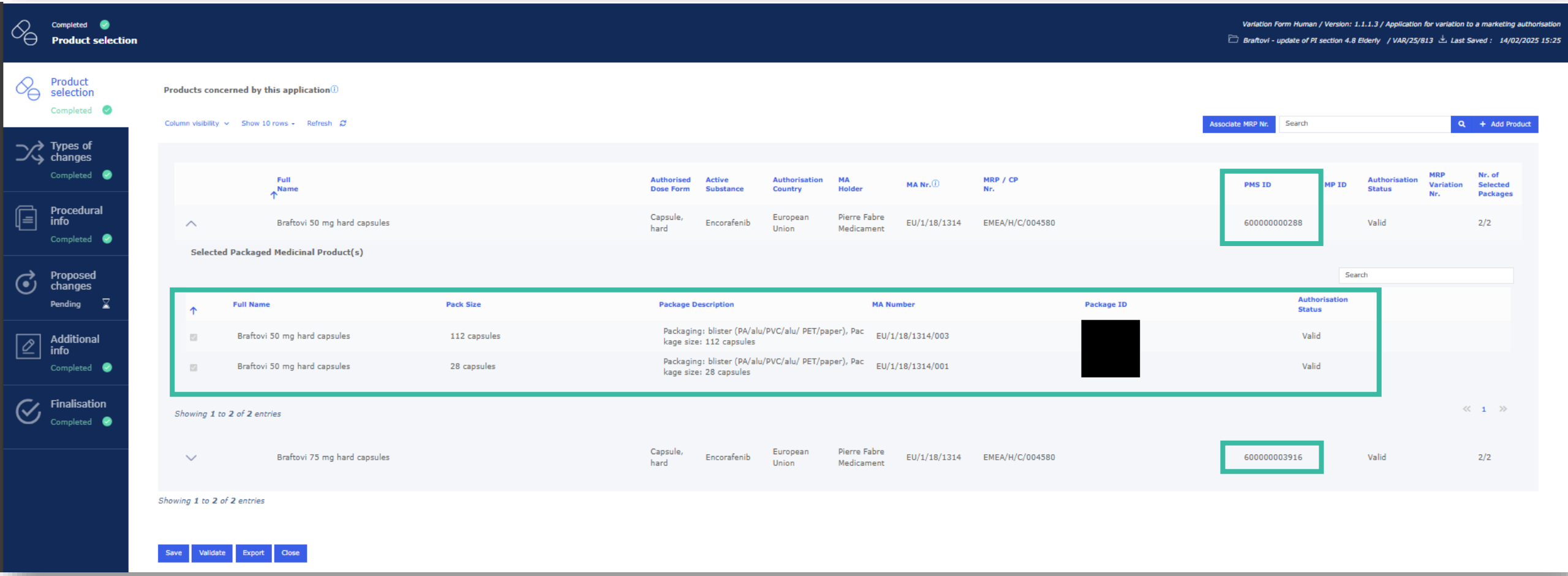


EMA
EUROPEAN MEDICINES AGENCY

# Web-based eAF



# Web-based eAF and PMS



# Web-based eAF and PMS

The web-based variation form is consuming products from PMS
Therefore, products subject to be used in the eAF shall be captured in PMS

Authorised products falling under the **scope of Art. 57** are already present in PMS and therefore in eAF

Authorised or registered products falling **out of scope of Art. 57** can be submitted on a voluntary basis to XEVMPD (e.g. herbals or homeopathics)

For MRPs/DCPs, as soon as the medicinal product is authorised by the RMS, the submission of a variation might be needed. XEVMPD now allows the submission of the products in the CMSs where the **authorization is still pending** (under evaluation) so the products can be selected in the web-based eAF. Submission should be performed for new products, not for updates.

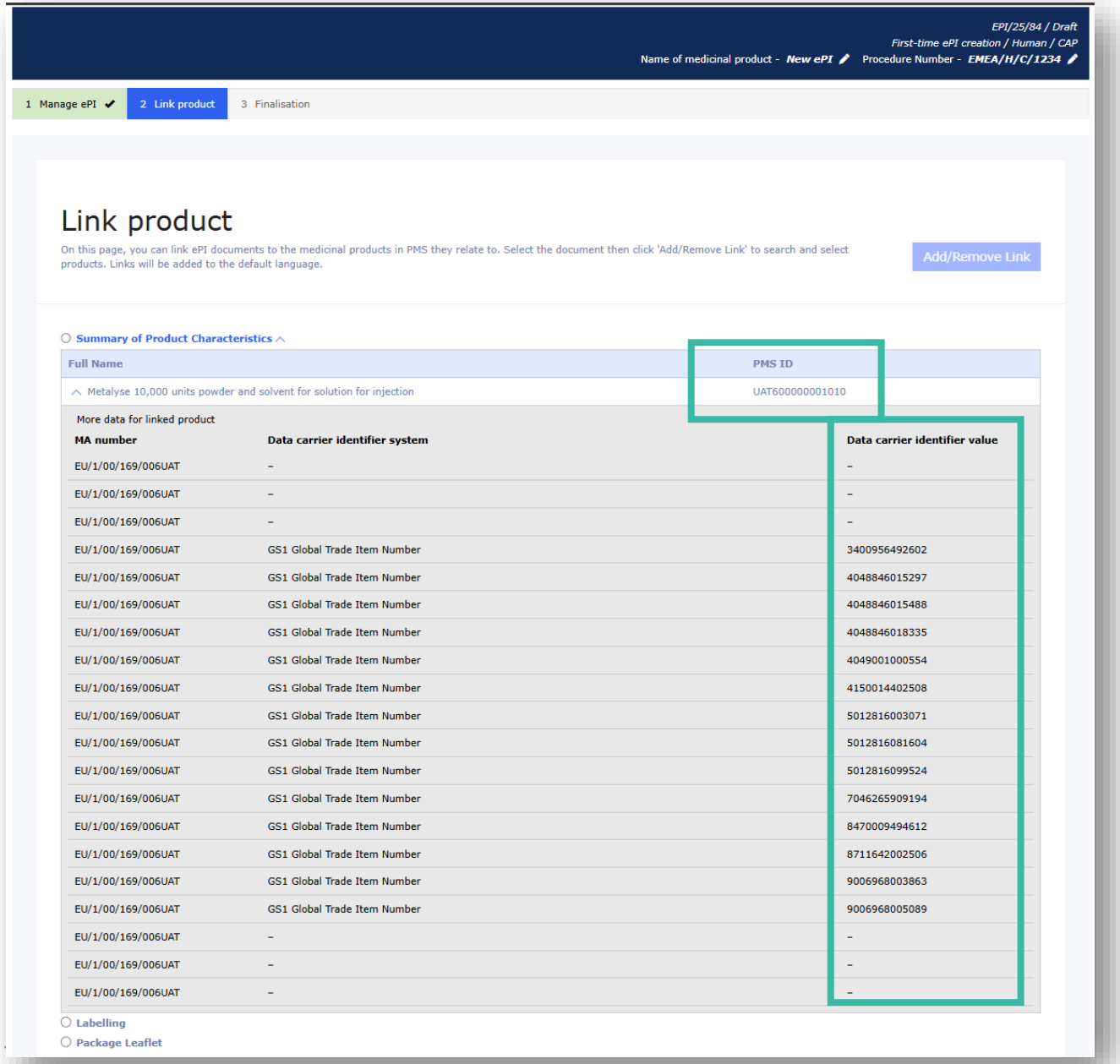


Please, review Chapter 3.II of XEVMPD for additional information

EMA
EUROPEAN MEDICINES AGENCY

# ePI

# ePI and PMS

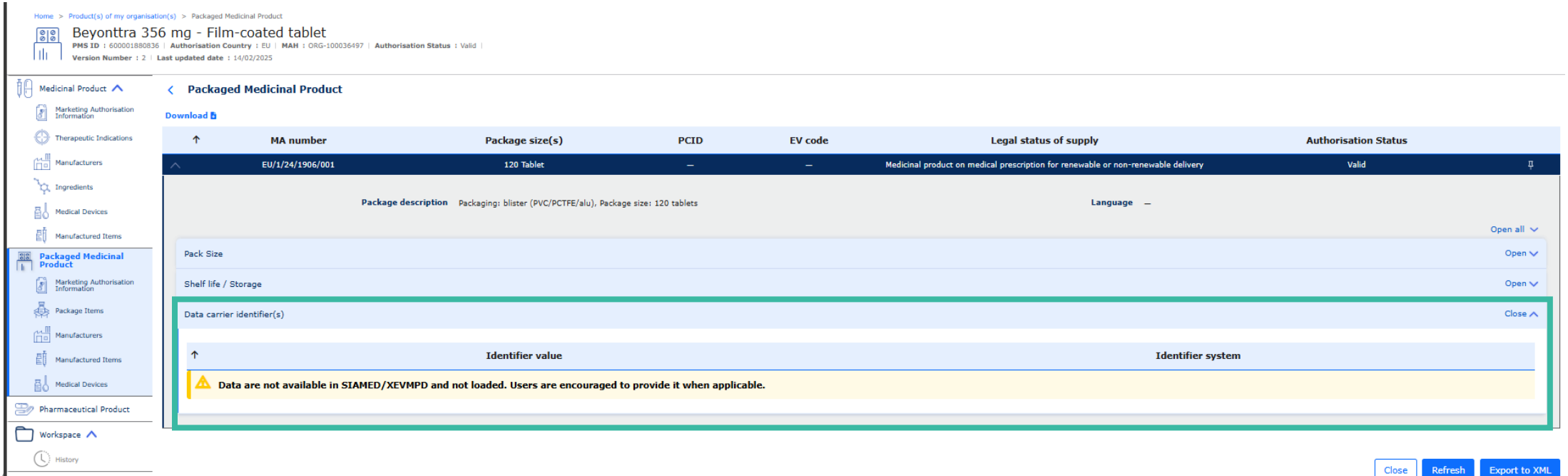



ePI will allow linking the PMS ID of a product to an ePI.

ePI will consume the data carrier IDs from PMS.

# Actions for MAHs in relation to ePI

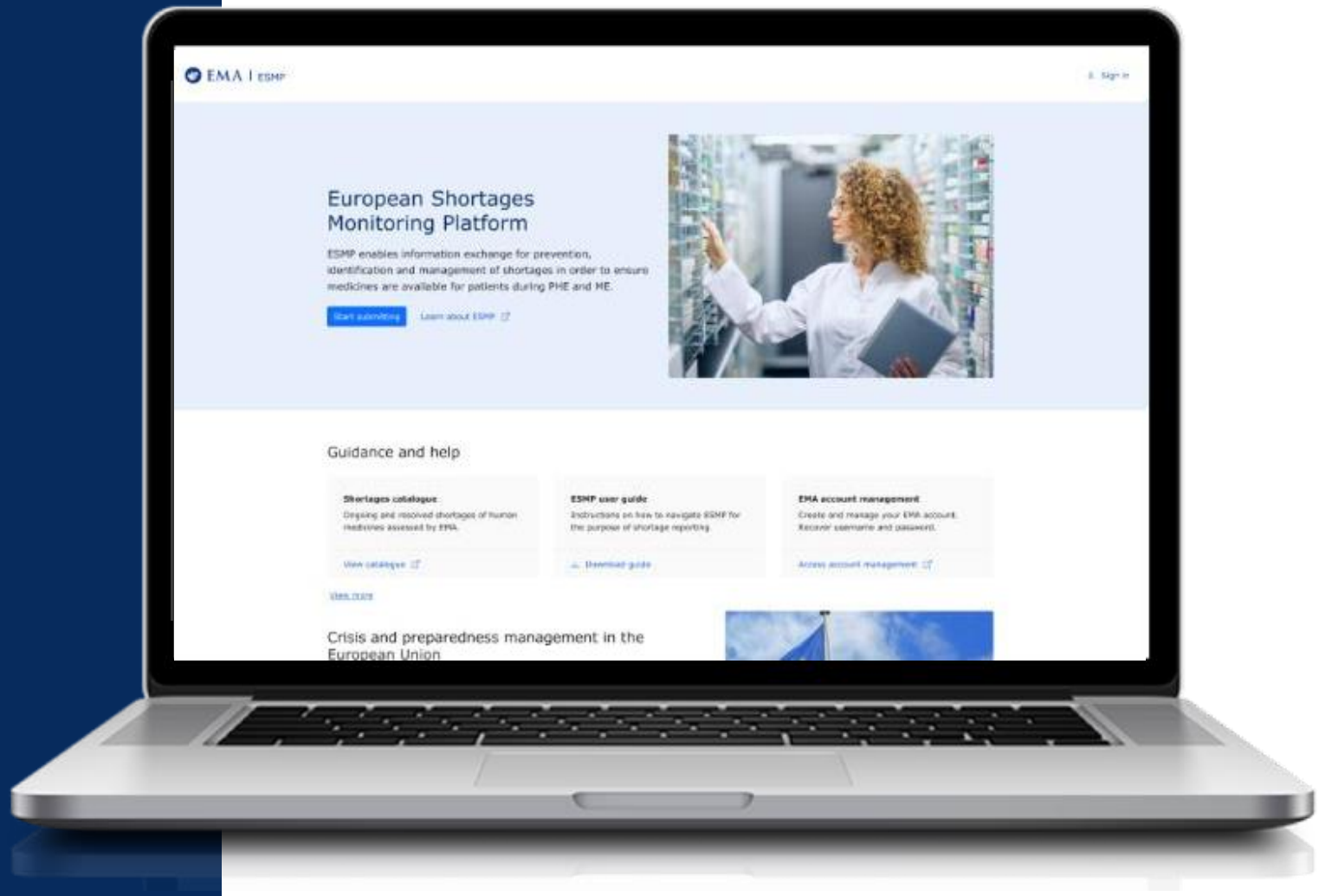
- **Enrichment of the Data Carrier ID**
  - From Q2 2025 through the Product UI for non-CAPs. For CAPs a Service Now process will be implemented
  - Enrich each packaged medicinal product with the relevant data carrier ID
  - Recommended submission for products with an ePI and optional for the rest




Additional information: [EU IG Chapter 3]

EMA
EUROPEAN MEDICINES AGENCY

# ESMP



# ESMP and PMS

ESMP requires information of pack sizes, structured pack size data, manufacturers and MBOs for the products that are considered critical

If authorised pack sizes are not yet submitted to XEVMPD, they should be submitted

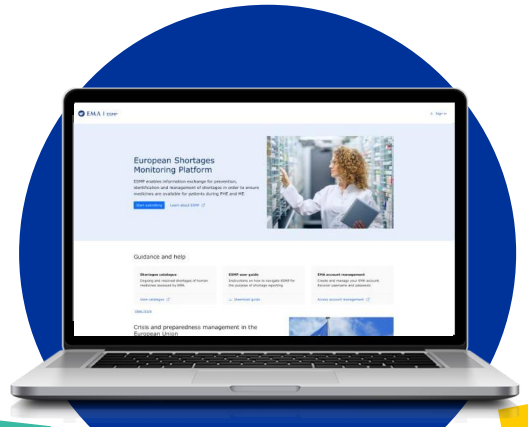
Structured pack size data together with manufacturers and MBOs can be submitted through the Product UI. EMA is working on the implementation of the bulk update functionality and the write PMS API.

New version of the ULCM is available.

Dynamic “All ATC codes” reports in the Product UI can be used to identify products in PMS under the ULCM.

# ESMP and PMS

During a crisis or upon request of the MSSG, MAHs are required to report different information for products considered critical




Reporting of marketing status for non-CAPs

Reporting of availability information

Reporting of manufacturing information



Source: Introductory webinar on the European Shortages Monitoring Platform (ESMP)

# ESMP and PMS


## Reporting of marketing status for non-CAPs under ULCM

Fields consumed from PMS. This data is coming from either XEVMPD or Product UI (not to be changed in the exported templates)

| | |
|---|---|
| **Product information** (pre-populated from PMS) | *PMS ID (Packaged medicinal product)* |
| | *Full product name* |
| | *Short product name* |
| | *Active substance* |
| | *Strength* |
| | *Pharmaceutical form* |
| | *Pack size* |
| | *Packaging* |
| | *PCID* |
| | *Country of authorisation* |
| **Marketing status details** | Marketing status |
| | Date of planned permanent withdrawal |
| | Planned withdrawal comment |

This reporting is performed at pack size level.
Therefore, **pack sizes should have been submitted to XEVMPD.**



Source: Introductory webinar on the European Shortages Monitoring Platform (ESMP)

# ESMP and PMS


## Reporting of availability information

Fields consumed from PMS. This data is coming from either XEVMPD or Product UI (not to be changed in the exported templates)

This reporting is performed at pack size level. Therefore, **pack sizes should have been submitted to XEVMPD. Package size should have been enriched.**

| | |
|---|---|
| **Product information** *(pre-populated from PMS and IRIS)* | *PMS ID (Packaged medicinal product)* |
| | *Full product name* |
| | *Short product name* |
| | *Active substance* |
| | *Strength* |
| | *Pharmaceutical form* |
| | *Pack size* |
| | *Packaging* |
| | *PCID* |
| | *Country of authorisation* |
| | *Marketing status* |
| **Shortage information** | Shortage status |
| | Shortage start date or expected start date |
| | Shortage end date or expected end date |
| | Point in supply chain at which disruption occurs |
| | Root cause of the shortage |
| | Countries in which manufacturing issues occur |
| | Countries in which increased demand occurs |
| | Countries in which distribution issues occur |
| | Additional information on the root cause of the shortage |
| **Prevention and mitigation plans** | Shortage prevention and mitigation plans |
| | Shortage prevention and mitigation plans – ongoing and planned steps |
| **Impact assessment** | Affected population estimate |
| | Market share |
| | Shortage impact risk assessment |
| | Shortage impact risk assessment – additional information |
| **Potential alternatives therapies** | Alternatives available (yes/no) |
| | Alternative therapies |
| **Additional information** | Rapid alert reference number |
| | Other authorities notified (e.g., other NCAs, EMA), including reference to Quality Defect report |
| | Reference to related pending regulatory action |
| | Required NCA actions, if any |



Source: European Shortages Monitoring Platform (ESMP) training on routine shortage reporting for marketing authorisation holders (MAHs) of centrally authorised products (CAPs)

# ESMP and PMS

## Reporting of manufacturing information


Fields consumed from PMS. This data is coming from either XEVMPD or Product UI (not to be changed in the exported templates)

This reporting is performed at product level. **Manufacturers and MBOs should have been enriched.**

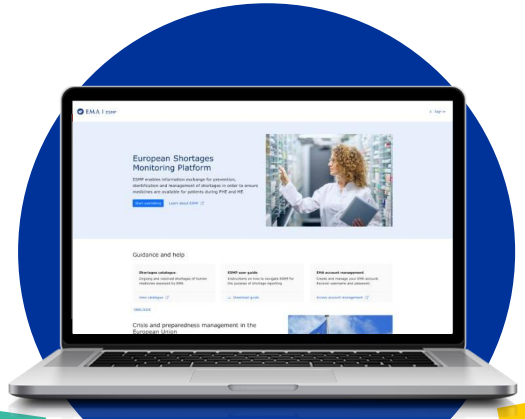
| | |
|---|---|
| **Product information** *(pre-filled from PMS)* | *PMS ID (Medicinal product)* |
| | *Full product name* |
| | *Active substance* |
| **Organisation information** *(pre-filled from PMS and OMS.* | *Organisation ID (Manufacturer)* |
| | *Manufacturer* |
| | *Operation type ID* |
| | *Operation type* |
| | *Location ID (Manufacturer)* |
| | *City* |
| | *Country* |
| **Manufacturing details** | Manufacturing site status (active/backup) |
| | Is the site a contract manufacturer? (yes/no) |
| **Alternative sites** | Alternative site Location ID |
| | Alternative site Country |

| | |
|---|---|
| | Unit of measurement (kg/units) |
| **Production plan** *(for API and FDF)* | Global monthly production plan - month 1 |
| | Global monthly production plan – month 2 |
| | Global monthly production plan – month 3 |
| | Global monthly production plan – month 4 |
| | Global monthly production plan – month 5 |
| | Global monthly production plan – month 6 |
| | Additional information on the production plan |
| **Production capacity** *(for API and FDF)* | Average global monthly production output of previous year |
| | Peak global monthly production output of previous year |



Source: Introductory webinar on the European Shortages Monitoring Platform (ESMP)

# Actions for MAHs in relation to ESMP

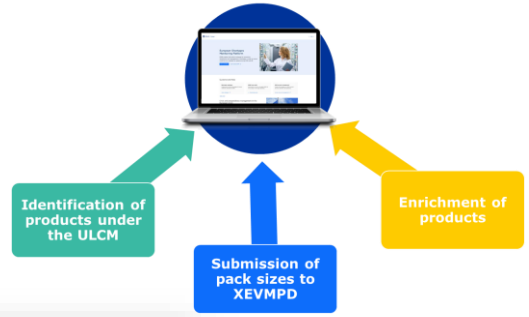



**Identification of products under the ULCM**

**Submission of pack sizes to XEVMPD**

**Enrichment of products**

# Actions for MAHs in relation to ESMP




**Identification of products under the ULCM**

Product Lifecycle Management Portal

Electronic application forms | Electronic product information | Products Management Service | SPOR | IAM | IRIS | Forum | Marcos Fe

Product(s) of my organisation(s)

All packages

All ATC codes

Multiple ATC Code selection

ATC Code

All

Search

A10BD07
A10BD08
A10BG03
A10BH01
A10BH02
A10BX02

Manufacturing Operation

Possibility to see also list of manufacturers and MBOs

List of EV Codes linked to each product

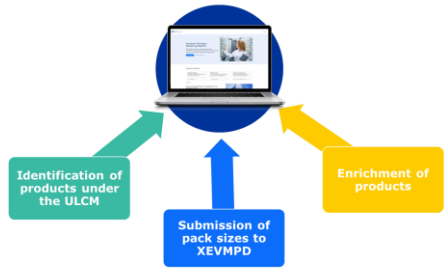
Route of admin can be filtered

Medicinal Products

| | | Route of Administration | Full Name | MA Nr. | EV code | MAH/owner | Active substance(s) |
|---|---|---|---|---|---|---|---|
| | | ral use | Ibukern 600 mg suspensión oral | 67.930 | PRD2005892 | Kern Pharma S.L. | Ibuprofen |
| | | taneous use | Ibudol 50 mg/g gel | 62.054 | PRD2005882 | Kern Pharma S.L. | Ibuprofen |
| | | ral use | Rizatriptán Flas KERN 10 mg comprimidos ersables EFG | 77082 | PRD795359 | Kern Pharma S.L. | Rizatriptan |
| 600001437366 | J01DH51 | Intravenou | n/Cilastatina Kern Pharma 500 mg/500 mg polvo para solución para perfusión EFG | 79.429 | PRD3165602 | Kern Pharma S.L. | Imipenem monohydrate, Cilastatin sodium |
| 600001437657 | N03AX15 | Oral use | Zonisamida Kern Pharma 25 mg cápsulas duras EFG | 80.826 | PRD4095788 | Kern Pharma S.L. | Zonisamide |
| 600001437866 | N02AA05 | Oral use | Oxicodona Kern Pharma 80 mg comprimidos de liberación prolongada EFG | 74696 | PRD2707301 | Kern Pharma S.L. | Oxycodone hydrochloride |
| 600001437928 | A10BB12 | Oral use | Glimepirida Kern Pharma 4 mg comprimidos EFG | 67.670 | PRD382834 | Kern Pharma S.L. | Glimepiride |
| 600001438255 | G04CA53 | Oral use | Vesolta 6 mg/0,4 mg comprimidos de liberación modificada EFG | 88218 | PRD9990922 | Kern Pharma S.L. | Solifenacin succinate, Tamsulosin hydrochloride |
| 600001438616 | H02AB07 | Oral use | Prednisona KERN PHARMA 5 | 70.106 | PRD373641 | Kern Pharma S.L. | Prednisone |

MAHs can use the dynamic "All ATC codes" reports in the product UI to filter by ATC codes and access their specific list of critical products

# Actions for MAHs in relation to ESMP



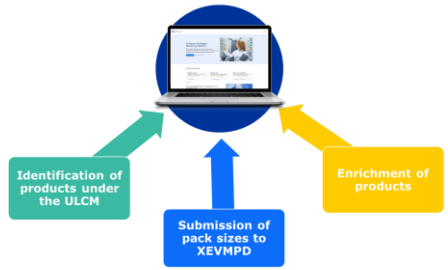

## Submission of pack sizes to XEVMPD

- **CAPs:**
  - No action needed as all pack sizes shall be submitted to XEVMPD
- **Non-CAPs under ULCM:**
  - By 31st of Jan 2025, all marketed pack sizes for products with MA number at product level should have been submitted to XEVMPD. MAHs should maintain this data as part of the lifecycle of the product.
  - For new products authorised under the ULCM, submit pack sizes to XEVMPD not later than 15 days after approval.
  - All authorised pack sizes shall be submitted for products with MA number at pack size level
- **Rest of non-CAPs:**
  - All authorised pack sizes shall be submitted for products with MA number at pack size level
  - For rest of products, submit all pack sizes by end of 2026 – good practice to submit all pack sizes for all new authorised products



Additional information: Detailed guidance on the electronic submission of information on medicinal products for human use by marketing authorisation holders to the European Medicines Agency in accordance with Article 57(2) of Regulation (EC) No. 726/2004

# Actions for MAHs in relation to ESMP




**Submission of pack sizes to XEVMPD**

- **Package description in XEVMPD**
  - This field should be used to identify pack sizes. Very important when the MA number is granted at medicinal product level
  - This field will be shown in the Product UI and its information shall allow the user to identify each pack size
  - Recommended information to be included in the package description:
    - National identifier (review PMS Q&A document for additional information on the national IDs per country).
      EMA is not providing the national IDs. These are provided by the NCAs.
    - Package size (18 tablets, 3 vials, etc) and material
    - In case of different pack sizes with the same package size but different amount of content, please, submit the content as: Content: 25 ml

      Example: 763947 – 3 vials – Content: 25 ml

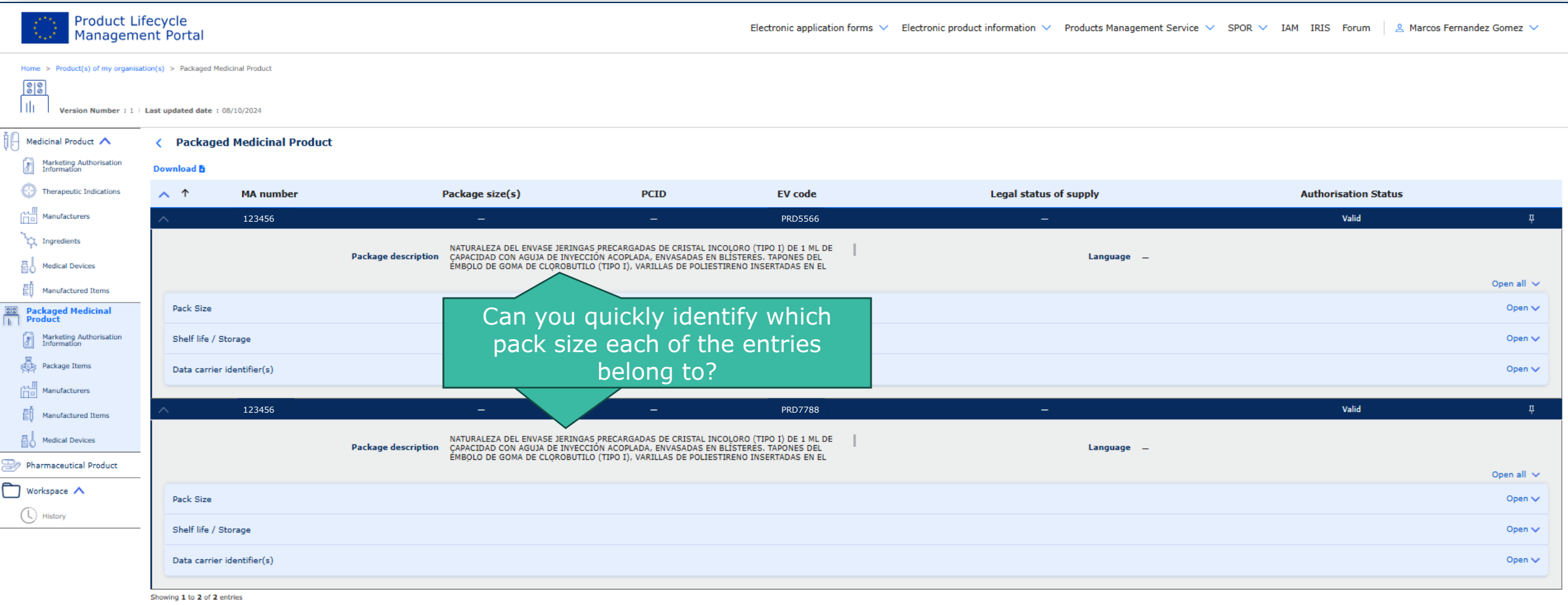
      Example: 763950 – 3 vials – Content: 100 ml

      Example: 92846 – 28 tablets – Blister Alu/Alu

Additional information: Detailed guidance on the electronic submission of information on medicinal products for human use by marketing authorisation holders to the European Medicines Agency in accordance with Article 57(2) of Regulation (EC) No. 726/2004

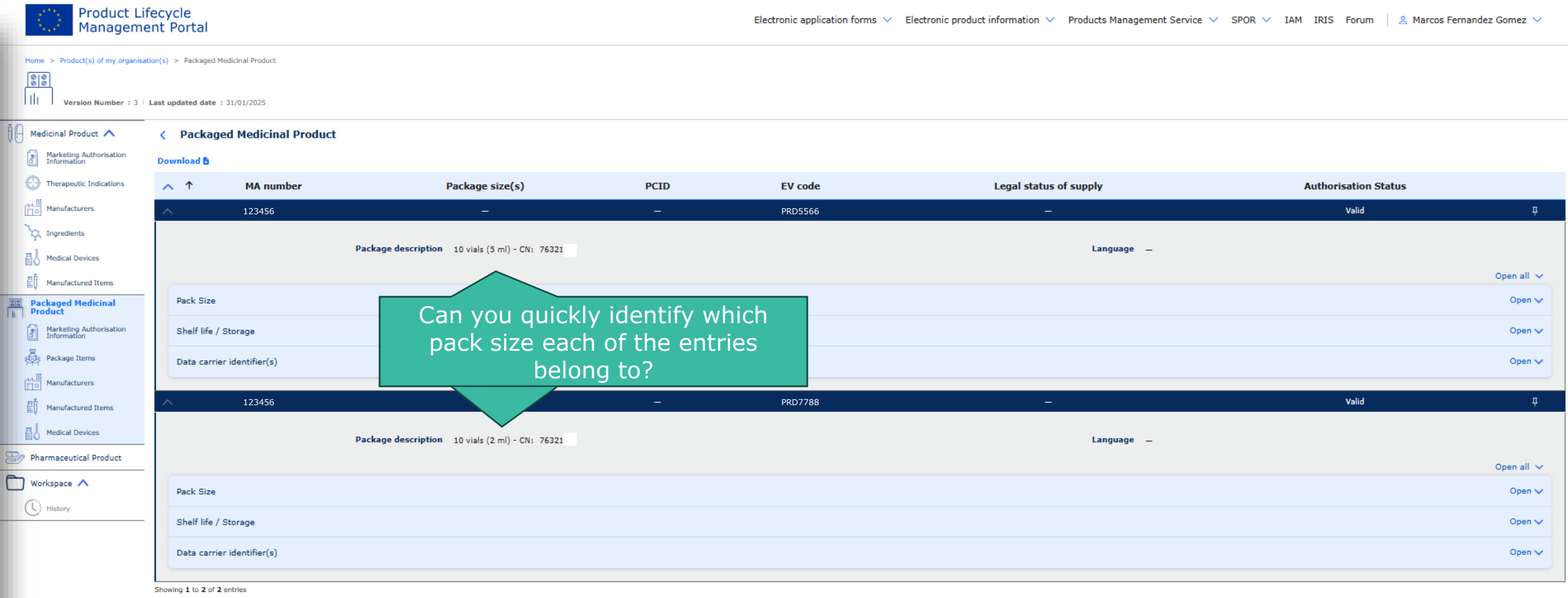
# Actions for MAHs in relation to ESMP

**Submission of pack sizes to XEVMPD**



# Actions for MAHs in relation to ESMP

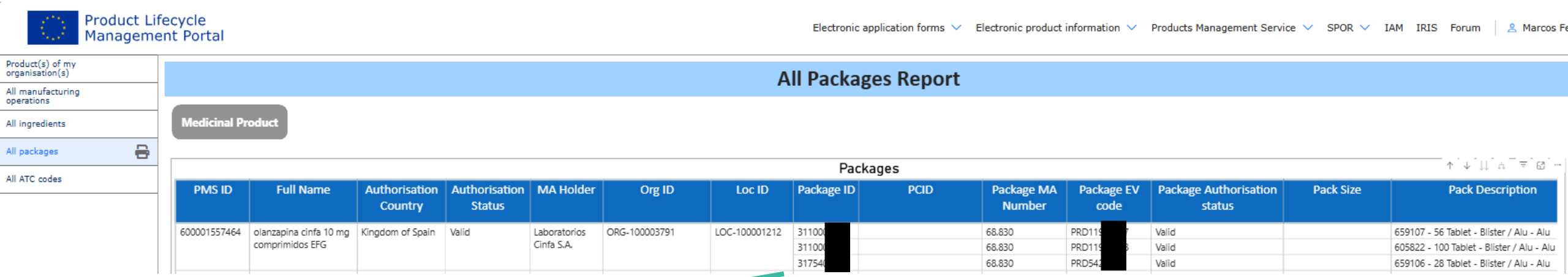
**Submission of pack sizes to XEVMPD**



# Actions for MAHs in relation to ESMP

## Submission of pack sizes to XEVMPD

*All packages* dynamic report can be used to see all pack sizes submitted, Package PMS ID, package description, etc.




| PMS ID | Full Name | Authorisation Country | Authorisation Status | MA Holder | Org ID | Loc ID | Package ID | PCID | Package MA Number | Package EV code | Package Authorisation status | Pack Size | Pack Description |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 600001557464 | olanzapina cinfa 10 mg comprimidos EFG | Kingdom of Spain | Valid | Laboratorios Cinfa S.A. | ORG-100003791 | LOC-100001212 | 311000[redacted] | | 68.830 | PRD119[redacted] | Valid | | 659107 - 56 Tablet - Blister / Alu - Alu |
| | | | | | | | 311000[redacted] | | 68.830 | PRD119[redacted] | Valid | | 605822 - 100 Tablet - Blister / Alu - Alu |
| | | | | | | | 317540[redacted] | | 68.830 | PRD542[redacted] | Valid | | 659106 - 28 Tablet - Blister / Alu - Alu |

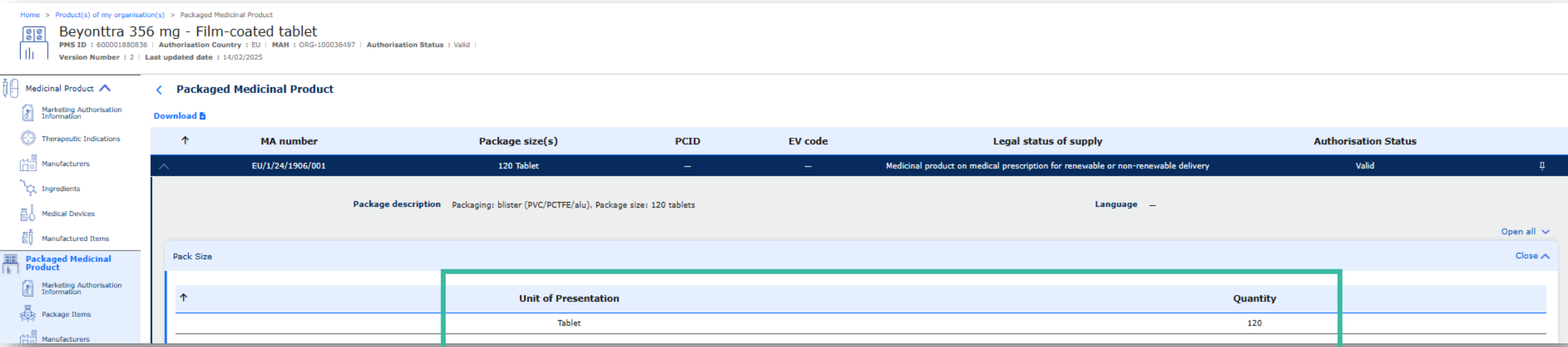
This information can be used to map your pack sizes as this information is reflected on the pre-filled templates from ESMP.

| PMS ID (Packaged me | Full product name | Short product name | Pack size | Packaging | PCID | Country of | Marketing status | Shortage s | Shorta |
|---|---|---|---|---|---|---|---|---|---|
| 311100[redacted] | Olanzapina cinfa 10mg comprimidos EFG | Olanzapina cinfa | 56 tablets | Blister | | ES | Marketed | No shortage | |
| 311100[redacted] | Olanzapina cinfa 10mg comprimidos EFG | Olanzapina cinfa | 100 tablets | Blister | | ES | Temporarily unavailable | No shortage | |
| 317540[redacted] | Olanzapina cinfa 10mg comprimidos EFG | Olanzapina cinfa | 28 tablets | Blister | | ES | Marketed | No shortage | |

# Actions for MAHs in relation to ESMP

**Enrichment of products**

- **Structured pack size data**
  - The quantity and units of presentation shall be submitted for non-CAPs under the ULCM
  - Product UI should be used for the enrichment process – please review **Product data submission in PMS PUI**




Additional information: Submission of Manufacturers, Manufacturing Business Operations (MBOs) and structured pack size data to Product Management Service (PMS) | European Medicines Agency (EMA)

# Actions for MAHs in relation to ESMP

**Enrichment of products**

- **Manufacturers and MBOs**
  - Review manufacturers and MBOs already present for CAPs in the Product UI / PMS API
  - Manufacturers and MBOs should be submitted for non-CAPs under the ULCM by December 2025
  - Product UI should be used for the enrichment process – please review **Product data submission in PMS PUI**

- **Manufacturers and MBOs**
  - Only authorised manufacturers are needed during the first enrichment. Deleted manufacturers shall not be provided.
  - During maintenance of the enriched data, if a manufacturer or MBO is deleted, please, update the 'End date'.
  - Maintenance of the enriched data is required: updates of submitted information should be performed through the Product UI.
  - EU IG Chapter 3 has been updated with the list of MBOs to be enriched in PMS



Additional information: Submission of Manufacturers, Manufacturing Business Operations (MBOs) and structured pack size data to Product Management Service (PMS) | European Medicines Agency (EMA)

| Manufacturing business operation | RMS short name | RMS ID |
|---|---|---|
| **Authorised manufacturer responsible for batch release** | | |
| Manufacturer responsible for batch certification | Batch certification | 100000160407 |
| **Batch control Testing arrangements** | | |
| Quality control testing of medicinal product | Quality control testing of medicinal product | 100000160408 |
| Microbiological testing: sterility | Quality Control Testing – Medicinal product – Microbiological – sterility | 100000160409 |
| Microbiological testing: non-sterility | Quality Control Testing – Medicinal product – Microbiological – non-sterility | 100000160410 |
| Chemical/Physical testing | Quality Control Testing – Medicinal product – Chemical/Physical | 100000160411 |
| Biological testing | Quality Control Testing – Medicinal product – Biological | 100000160412 |
| **Manufacturer(s) of the medicinal product** | | |
| Manufacturing of solvent / diluent | Manufacturing of solvent/diluent | 100000160415 |
| Physical Importation | Physical Importation | 100000160465 |
| Primary packaging | Primary packaging | 100000160463 |
| Processing of non-sterile medicinal product | Processing of non-sterile medicinal product | 100000163618 |
| Processing of sterile medicinal product – aseptically prepared | Processing of sterile medicinal product – aseptically prepared | 100000163709 |
| Processing of sterile medicinal product – terminally sterilised | Processing of sterile medicinal product – terminally sterilised | 100000163737 |
| Processing operations for the medicinal product | Processing operations for the medicinal product | 100000160413 |
| Quality control testing of medicinal product | Quality control testing of medicinal product | 100000160408 |
| Microbiological testing: sterility | Quality Control Testing – Medicinal product – Microbiological – sterility | 100000160409 |
| Microbiological testing: non-sterility | Quality Control Testing – Medicinal product – Microbiological – non-sterility | 100000160410 |
| Chemical/Physical testing | Quality Control Testing – Medicinal product – Chemical/Physical | 100000160411 |
| Biological testing | Quality Control Testing – Medicinal product – Biological | 100000160412 |
| Secondary packaging | Secondary packaging | 100000160464 |
| Sterilisation | Sterilisation | 100000160456 |
| Filtration | Sterilisation – Filtration | 100000160457 |
| Dry heat | Sterilisation – Dry heat | 100000160458 |
| Moist heat | Sterilisation – Moist heat | 100000160459 |
| Chemical | Sterilisation – Chemical | 100000160460 |
| Gamma irradiation | Sterilisation – Gamma irradiation | 100000160461 |
| Electron beam | Sterilisation – Electron beam | 100000160462 |
| Storage and/or distribution of medicinal product | Storage and/or distribution of medicinal product | 100000160466 |
| **Manufacturer(s) of the active substance(s)** | | |
| Active substance intermediate physical processing | Active substance intermediate physical processing | 100000163715 |
| Active substance physical processing | Active substance physical processing | 100000163846 |
| Extraction of active substance from natural sources | Extraction of active substance from natural sources | 100000163844 |
| Manufacturing of active substance | Manufacturing of active substance | 100000160467 |
| Manufacturing of active substance by chemical synthesis | Manufacturing of active substance by chemical synthesis | 100000163843 |
| Manufacturing of active substance intermediate | Manufacturing of active substance intermediate | 100000160453 |
| Manufacturing of active substance intermediate by chemical synthesis | Manufacturing of active substance intermediate by chemical synthesis | 100000163713 |
| Manufacturing of active substance intermediate using biological processes | Manufacturing of active substance intermediate using biological processes | 100000163714 |
| Manufacturing of active substance using biological processes | Manufacturing of active substance using biological processes | 100000163845 |
| Packaging of active substance | Packaging of active substance | 100000160454 |
| Preparation of Working Cell Bank | Preparation of Working Cell Bank | 100000160476 |
| Primary Packaging of active substance | Primary Packaging of active substance | 100000163716 |
| Quality control testing of active substance | Quality Control Testing of active substance | 100000160448 |
| Microbiological testing: sterility | Quality Control Testing – Active substance – Microbiological – sterility | 100000160449 |
| Microbiological testing: non-sterility | Quality Control Testing – Active substance – Microbiological – non-sterility | 100000160450 |
| Chemical/Physical testing | Quality Control Testing – Active substance – Chemical/Physical | 100000160451 |
| Biological testing | Quality Control Testing – Active substance – Biological | 100000160452 |
| Secondary Packaging of active substance | Secondary Packaging of active substance | 100000163717 |
| Storage and/or distribution of active substance | Storage and/or distribution of active substance | 100000160455 |
| Storage of Master Cell Bank and/or Working Cell Bank | Storage of Master Cell Bank and/or Working Cell Bank | 100000160477 |

- These MBOs are the same as the ones to be provided in the eAF for Initial MAA.
- No MBOs related to excipients apply
- Not all these MBOs apply to all products
- If there are additional MBOs in the dossier that do not appear in this list, there is no need to submit them to PMS

EMA
EUROPEAN MEDICINES AGENCY

# ASU

# ASU and PMS

A **reference European surveillance system** for EU/EEA member states to **submit data on sales and use of antimicrobials in animals**, enabling data intelligence to detect patterns and help develop **measures against antimicrobial resistance**, thus contributing towards the One Health goal of safeguarding animal and public health.

Availability of good-quality PMS data will enable the **collection of data on use of antimicrobial human medicinal products in animals via the ASU Platform** and their analyses in the ASU Power BI application.

MAHs will have to submit pack sizes for antimicrobial human products falling in the ASU reporting scope (Annexes 3 & 4 of DA 2021/578) to XEVMPD by the end of 2026.

NCAs will be in charge of reporting the rest of the data needed by ASU



Additional information: PMS Info Day 2024

EMA
EUROPEAN MEDICINES AGENCY

# Inspections & Parallel distribution

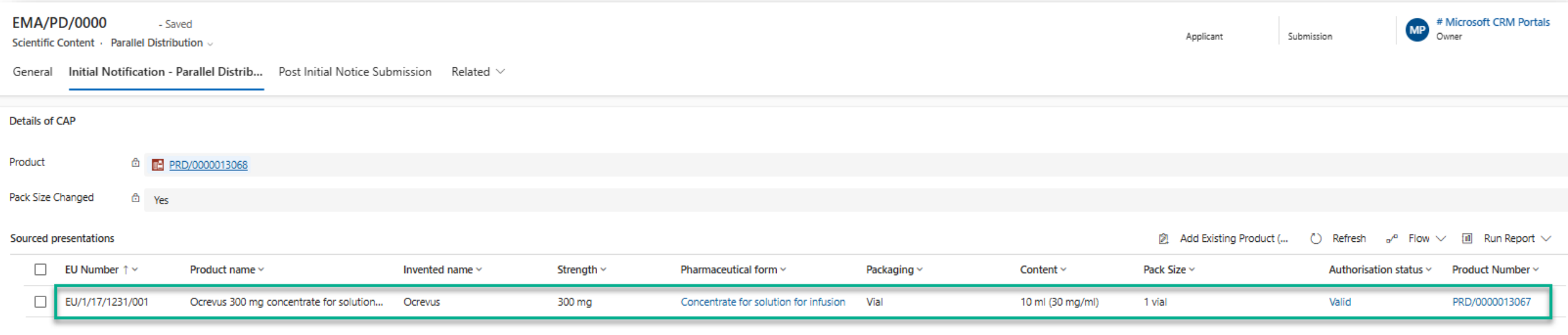
# Inspections & PD and PMS

The Inspections team rely on the manufacturers and MBOs that have been migrated from SIAMED to PMS.

Use the *All Manufacturers* dynamic report in the product UI to **review the data migrated from SIAMED**.

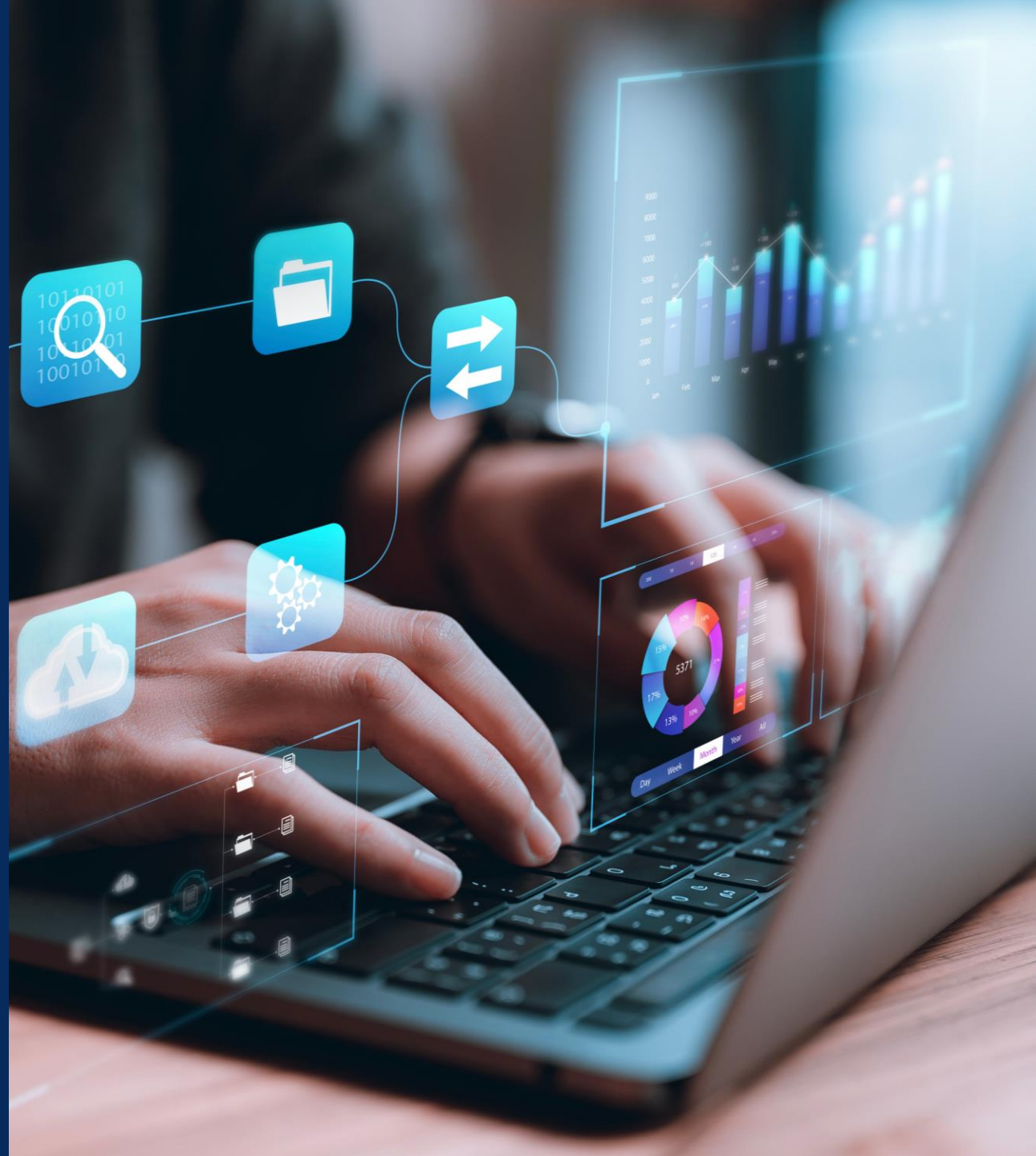
MAHs can also use these reports or the view pages of the Product UI to make sure changes are correctly implemented by EMA after variations affecting manufacturers and MBO data are approved.

The Parallel Distribution team also consumes PMS Data on CAPs to track the parallel distribution case form.



EMA
EUROPEAN MEDICINES AGENCY

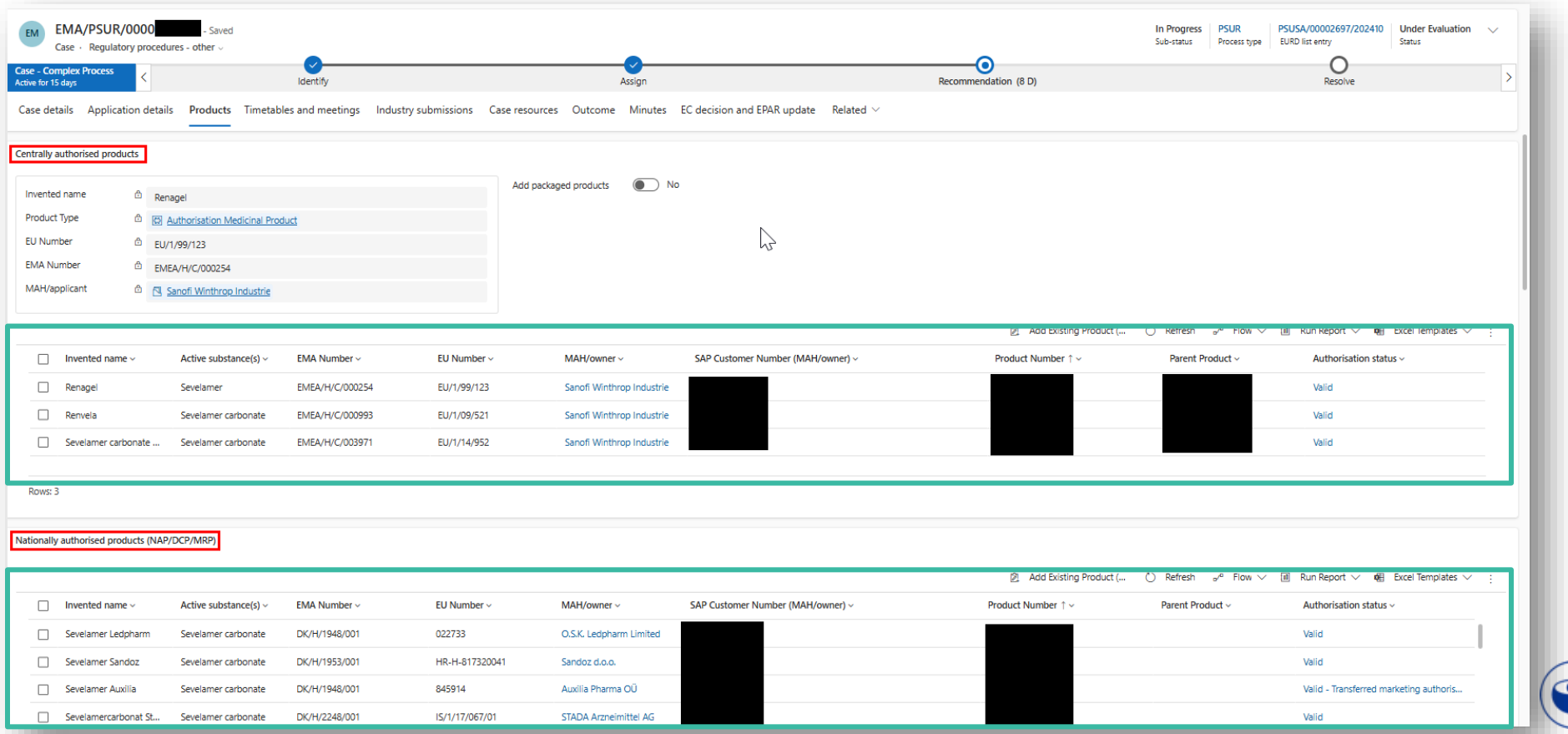
# RPM



# RPM and PMS

The Regulatory Procedure Management at EMA is also relying on PMS data for different procedures.

MAHs shall **keep product data up to date in XEVMPD** to make sure accurate information is captured in PMS.



# Summary

## eAF

- Submit and maintain in XEVMPD products that are needed in the web-based eAF (e.g: **herbal, homeopathics, pending MRPs/DCPs**)

## ePI

- From Q2 2025, **enrich data carrier ID** through Product UI for non-CAPs with ePIs.
- **For CAPs**, EMA will release additional information

## ESMP

- Use the **ATC Code dynamic report** to know which products are under the ULCM
- Submit **all pack sizes** to XEVMPD for these products
- Enrich **manufacturers, MBOs and structured pack size** data for these products
- Review **EU IG Chapter 3** for additional information
- **Bulk update** functionality available in Q2
- **Write PMS API** available after UAT is performed (Q2-Q3 2025)

## ASU

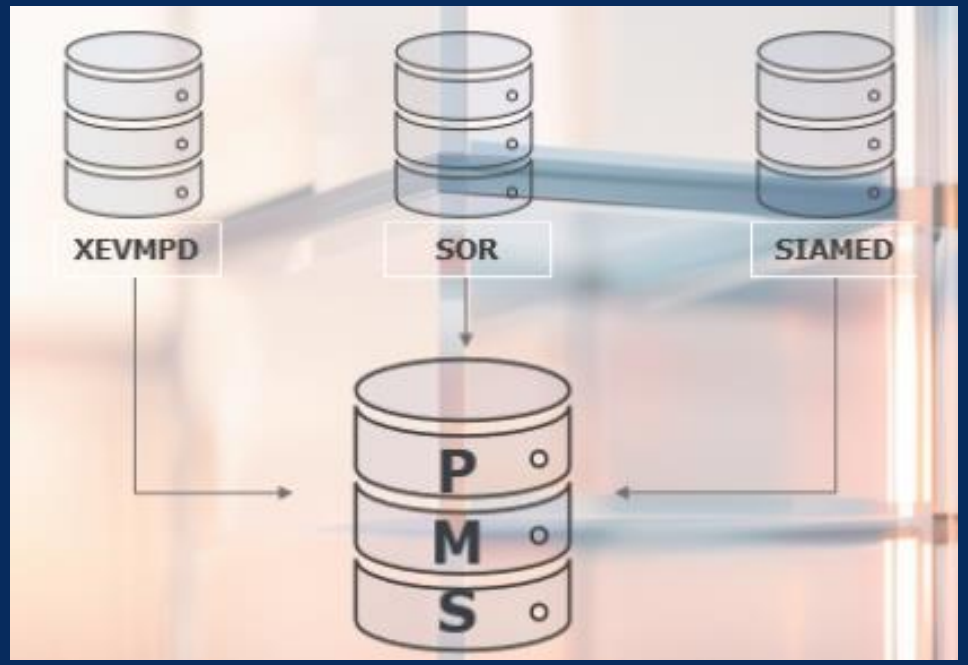
- Submit **pack sizes for antimicrobial human products falling in the ASU reporting scope** (Annexes 3 & 4 of DA 2021/578) to XEVMPD by the end of 2026.

## RPM, Inspections & PD

- **Review manufacturers and MBOs for CAPs** through the Product UI or PMS API
- **Keep data in XEVMPD up to date**

# Source systems

Review and improve data quality so it is reflected in PMS

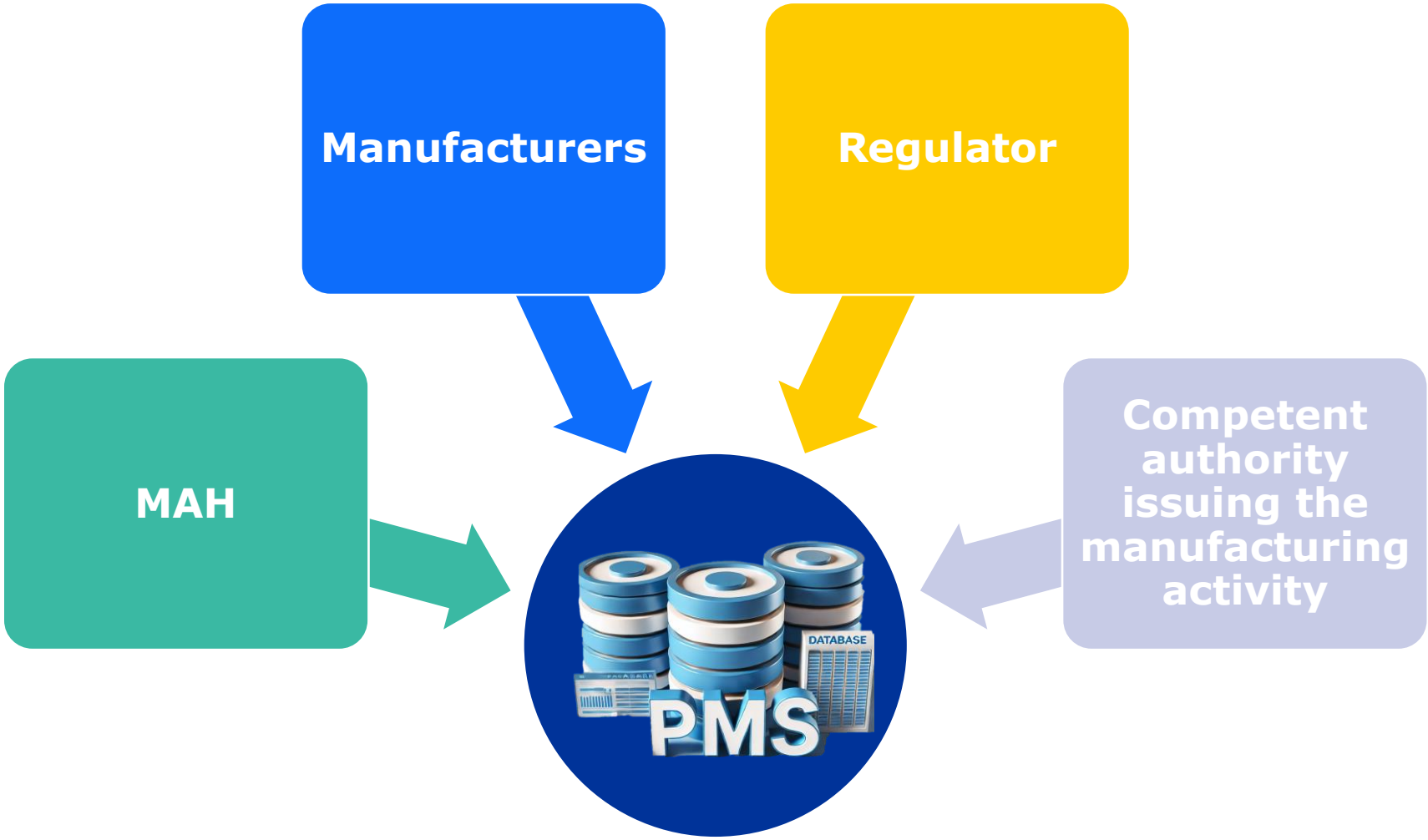


EMA
EUROPEAN MEDICINES AGENCY

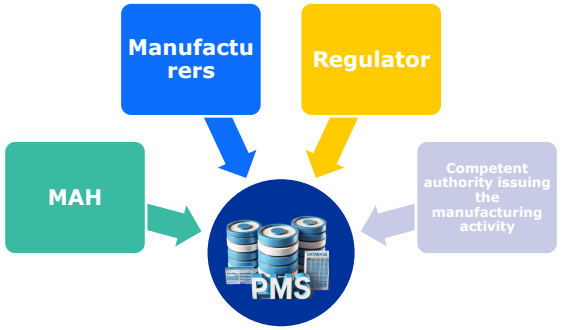
# OMS

OMS data consumed by PMS

# Use of OMS data in PMS



# Actions for MAHs in relation to OMS




## MAH

- **Make sure the ORG EV Code from XEVMPD is mapped to the correct LOC ID in OMS**
  - Products linked to inactive organisations in OMS might not be shown in the Product UI

## Manufacturers

- **Make sure the manufacturer's organisation is present in OMS**
  - Otherwise, please, submit a change request to OMS to create it.

## Regulator

Competent authority issuing the manufacturing activity

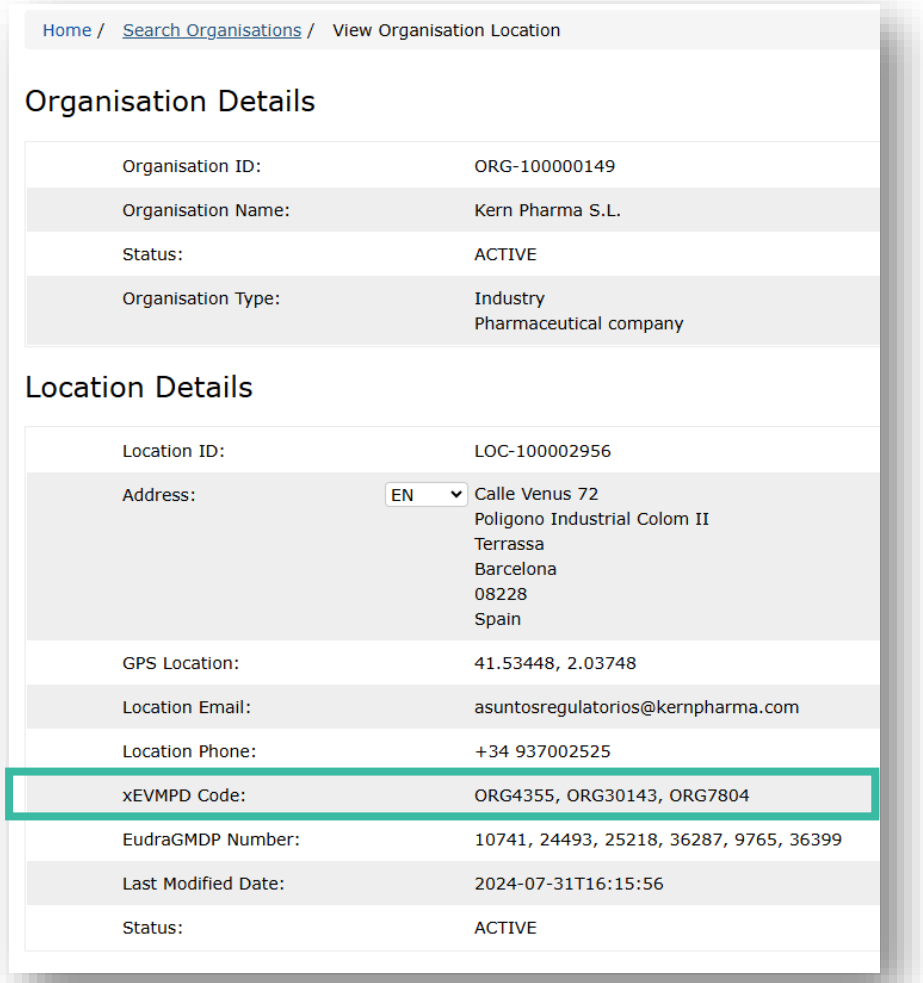
- **No action is needed**
  - Known issue: for some countries, the link to the regulator's LOC ID is missing in PMS. EMA is working to solve the issue. This bug has no impact on any process.

# Actions for MAHs in relation to OMS


**MAH**

- **Make sure the ORG EV Code from XEVMPD is mapped to the correct LOC ID in OMS**
- If this mapping is not correct, users will not have access to their products in PLM Portal

Changes to the name in OMS are not reflected in the product UI. EMA is working to solve this issue.



Home / Search Organisations / View Organisation Location

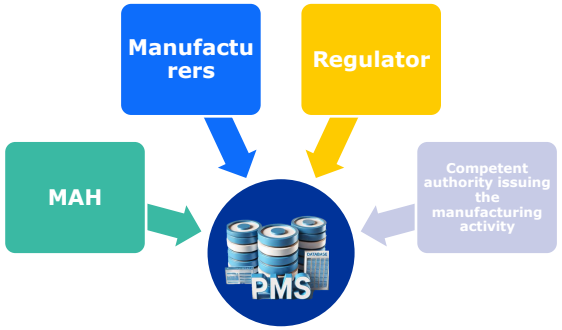
## Organisation Details

| | |
|---|---|
| Organisation ID: | ORG-100000149 |
| Organisation Name: | Kern Pharma S.L. |
| Status: | ACTIVE |
| Organisation Type: | Industry<br>Pharmaceutical company |

## Location Details

| | | |
|---|---|---|
| Location ID: | | LOC-100002956 |
| Address: | EN | Calle Venus 72<br>Poligono Industrial Colom II<br>Terrassa<br>Barcelona<br>08228<br>Spain |
| GPS Location: | | 41.53448, 2.03748 |
| Location Email: | | asuntosregulatorios@kernpharma.com |
| Location Phone: | | +34 937002525 |
| xEVMPD Code: | | ORG4355, ORG30143, ORG7804 |
| EudraGMDP Number: | | 10741, 24493, 25218, 36287, 9765, 36399 |
| Last Modified Date: | | 2024-07-31T16:15:56 |
| Status: | | ACTIVE |

# Actions for MAHs in relation to OMS




**MAH**

- **For merged organisations, if products are linked to the old ORG ID, applicants can request access to that ORG ID in IAM**

# Actions for MAHs in relation to OMS

| Organisation ID | ORG-100013839 |
|---|---|

| Organisation ID | Organisation Name ▲ | Country | Location ID | City |
|---|---|---|---|---|
| ORG-100000703 | Alcon Healthcare S.A. | Spain | LOC-100044192 | Cornella De Llobregat |

ORG-100013839 and ORG-100000703 were merged

Product(s) of my Organisation(s)

| PMS ID | Full Name | Authorised Dose Form | MAH/owner | Org ID | Loc ID |
|---|---|---|---|---|---|
| 600001489940 | COLIROFTA TROPICAMIDA 10 mg/ml colirio en solución | Eye drops, solution | Alcon Healthcare S.A. | ORG-100013839 | LOC-100044192 |
| 600001509392 | ®COLIROFTA FLUOTEST | Eye drops, solution | Alcon Healthcare S.A. | ORG-100013839 | LOC-100044192 |

Products are linked to the correct LOC ID (LOC-100044192) but old ORG ID (ORG-100013839).

| | Id | Name | Country | Location |
|---|---|---|---|---|
| ☐ | ORG-100000703 | Alcon Healthcare S.A. | Spain | LOC-100044192 |
| ☐ | ORG-100000703 | Alcon Healthcare S.A. | Spain | LOC-100009066 |
| ☐ | ORG-100013839 (Historical) | Alcon Healthcare S.A. | Spain | ORG-100013839 Merged into ORG-100000703 |

In IAM, MAHs can request access to the old organisation

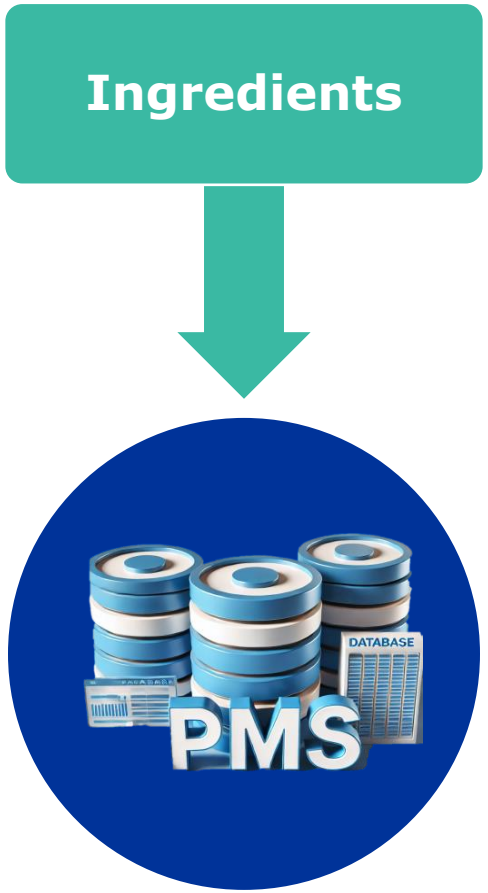
https://register.ema.europa.eu/identityiq/help/requestaccess.html#mergedOrganisation

EMA
EUROPEAN MEDICINES AGENCY

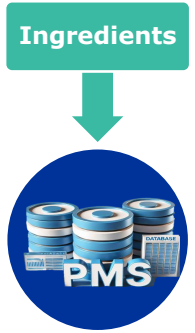
# SMS

## SMS data consumed by PMS

# Use of SMS data in PMS



# Actions for MAHs in relation to SMS




## Ingredients

- **Make sure the composition is consistent across all EV Codes belonging to the same medicinal product.**
  - The active substance and strength are grouping elements. Differences in substance codes and/or strength in any particular ingredient in XEVMPD will lead to the generation of duplicate products in PMS.

1. THE NAME OF THE MEDICINAL PRODUCT

Aciclovir 25 mg/ml, concentrate for solution for infusion.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains aciclovir sodium equivalent to 25 mg aciclovir.
Each 10 ml vial of concentrate contains aciclovir sodium equivalent to 250 mg aciclovir.
Each vial of 20 ml of concentrate contains aciclovir sodium equivalent to 500 mg of aciclovir.
Each vial of 40 ml of concentrate contains aciclovir sodium equivalent to 1 g of aciclovir.

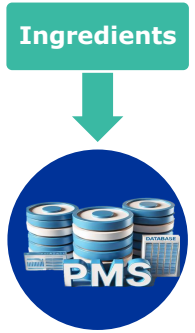
Strength should be submitted to XEVMPD for all pack sizes as:

Aciclovir – 25mg/ml



Additional information: EU IG Chapter 7 & EU IG Chapter 9

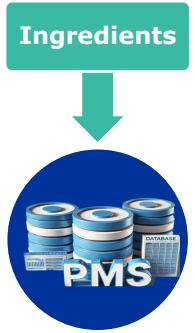
# Actions for MAHs in relation to SMS




**Ingredients**

- **Make sure the composition in XEVMPD is the same for all the EV Codes belonging to the same medicinal product.**
  - The active substance and strength are grouping elements. Differences in these two elements, will allocate the EV codes in different medicinal products in PMS.
  - If all EV Codes belonging to a product are migrated correctly i.e. did not generate duplicate products, you can assume the composition is the same for all of them. If not, review and compare the composition in XEVMPD (among other grouping fields that differ based on the authorization country – review EU IG Chapter 7).

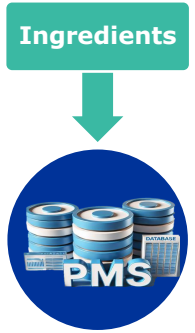
# Actions for MAHs in relation to SMS




**Ingredients**

- **EMA announced that composition can be provided to XEVMPD as stated in M3 (3.2.P.1) or as stated in the SmPC**
  - Applicants can update the XEVMPD composition to reflect the information captured in M3 (3.2.P.1 should be provided as attachment)
  - Full composition as in M3 or as in SmPC: It is not allowed to mix the information from both documents.
  - Applicants can, **optionally**, update composition as per M3. When applicants update the composition of one EV code, it should be done consistently for every EV code of that product.
  - Additional information can be found in Chapter 3.II of XEVMPD

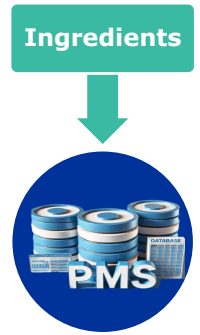
# Actions for MAHs in relation to SMS




**Ingredients**

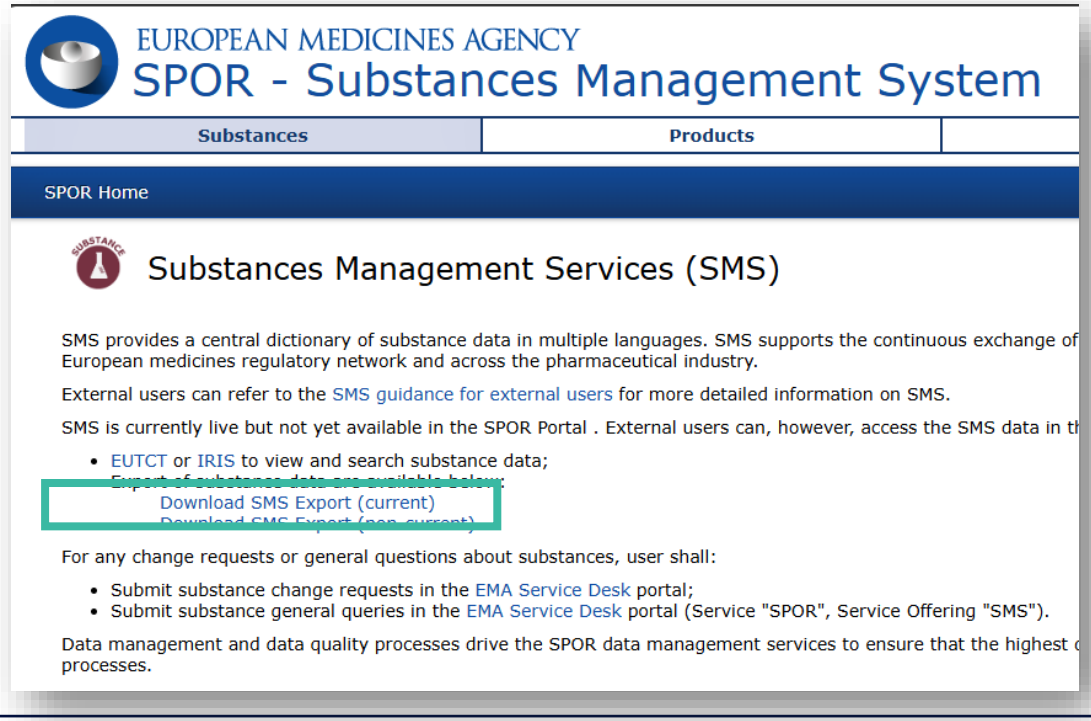
- **EMA announced that substances with SVG = 0 should not be used**
  - Updating the composition in XEVMPD to change these substances **IS NOT** mandatory for the moment.
  - MAHs can, if they want, replace substances with SVG = 0 as log as previous rules are adhered to i.e. the composition is in line with SmPC/M3
  - Suggestion: for new products (inserts), start using as much as possible, SVG = 1 substances.

# Actions for MAHs in relation to SMS




## Ingredients

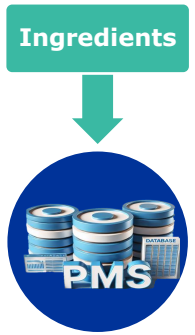
In SPOR, MAHs can download the list of current substances whit the information on SVG flag, the replacement substance, etc.






This excel file can be found in the SPOR webpage (SMS section)

# Actions for MAHs in relation to SMS



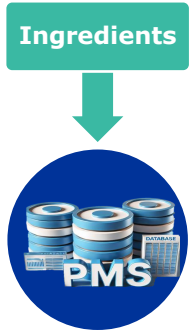

**Ingredients**

| #SMS_ID | Substance_N | Is_Prefe | Langua | Name_ | Substar | Status | Substar | Molecu | Molecu | Inchike | Comment | EV_Cod | SVG_Flag |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 100000076694 | Ammonia solu | TRUE | English | EUROPEAI | Human us | Current | Specified Substance Group 1 | | | | | SUB11706 | 1 |
| 100000078041 | MAIZE STARCH | TRUE | English | EUROPEAI | Human us | Current | Mixture | | | | | SUB20356 | 1 |
| 100000159843 | PRIMULA FLOW | TRUE | English | SPC | Human us | Current | Structurally Diverse - Herbal | | | | Duplicate of 100000137994/SUB77 | SUB17065 | 0 |
| 300000058425 | Opadry 20O580 | TRUE | English | COLORCO | Human us | Current | Specified Substance Group 1 | | | | | SUB41695 | 1 |
| 300000058426 | AUTX-703 | TRUE | English | INVESTIGA | Human us | Current | Chemical | | | | | SUB41695 | 1 |
| 300000058451 | ECI830 | TRUE | English | INVESTIGA | Human us | Current | Chemical | | | | | SUB41708 | 1 |
| 300000058427 | LY4045004 | TRUE | English | INVESTIGA | Human us | Current | Chemical | | | | | SUB41695 | 1 |
| 300000040691 | 4-(2-{[2-Amino- | TRUE | English | INVESTIGA | Human us | Current | Chemical | C19H20Cl | 417.91 | | | SUB25837 | 1 |
| 100000089650 | ANHYDROUS CA | TRUE | English | MARTINDA | Human us | Current | Chemical | | | | Duplicate of 100000089693/SUB13 | SUB26077 | 0 |
| 100000085772 | Carbomer 940 | TRUE | English | SPC | Human us | Current | Polymer | | | | | SUB20563 | 1 |
| 100000088994 | ARTIFICIAL ORA | TRUE | English | COMPANY | Human us | Current | Specified Substance Group 1 | | | | Duplicate of 100000076148/SUB16 | SUB23536 | 0 |
| 100000133013 | Hydroxyethylce | TRUE | English | USP | Human us | Current | Polymer | | | | | SUB49445 | 1 |
| 100000134903 | DIISOPROPYL A | TRUE | English | SPC | Human us | Current | Chemical | | | | Duplicate of 100000088709/SUB23 | SUB68859 | 0 |
| 100000076353 | Ethanol (96 per | TRUE | English | EUROPEAI | Human us | Current | Specified Substance Group 1 | | | | | SUB11946 | 1 |



This excel file can be found in the SPOR webpage (SMS section)

# Actions for MAHs in relation to SMS




## Ingredients

**SVG = 0 and a unique replacement.**

| #SMS_ID | Substance_Name | Comment |
|---|---|---|
| 100000092285 | MAIZE STARCH PREGELATINISED AND PHOSPHATED | Duplicate of 100000078041/SUB20356 |
| 100000172962 | MAIZE STARCH PREGELATINISED, LOW MOISTURE | Duplicate of 100000078041/SUB20356 |
| 100000134332 | PARTIALLY PREGELATINIZED MAIZE STARCH | Duplicate of 100000078041/SUB20356 |
| 100000129277 | PREGELATINIZED CORN STARCH GLUTEN FREE | Duplicate of 100000078041/SUB20356 |
| 100000134697 | STARCH MAIZE PREGELATINISED MODIFIED | Duplicate of 100000078041/SUB20356 |

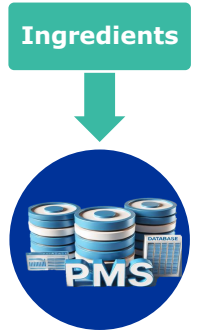
| #SMS_ID | Substance_Name |
|---|---|
| 100000078041 | MAIZE STARCH PREGELATINISED |

MAHs can submit the SVG = 1 substance indicated in SMS even if it does not appear in the SmPC/M3. No update to the SmPC or M3 is required.

As the replacement substance is very clear, EMA will validate the composition /product, even if the corresponding reference source of information (SmPC/M3) does not completely reflect it.

MAHs can change from MAIZE STARCH PREGELATINISED AND PHOSPHATED to MAIZE STARCH PREGELATINISED

# Actions for MAHs in relation to SMS




## Ingredients

**SVG = 0 and unspecified replacement.**

| #SMS_ID | Substance_Name | Comment |
|---|---|---|
| 100000086041 | Sodium starch glycolate | Unspecified |

| #SMS_ID | Substance_Name | Status | EV_Code | SVG_Flag |
|---|---|---|---|---|
| 100000079341 | Sodium starch glycolate (type B) | Current | SUB12307MIG | 1 |
| 100000079557 | Sodium starch glycolate (type A) | Current | SUB12311MIG | 1 |
| 100000079577 | Sodium starch glycolate (type C) | Current | SUB12312MIG | 1 |

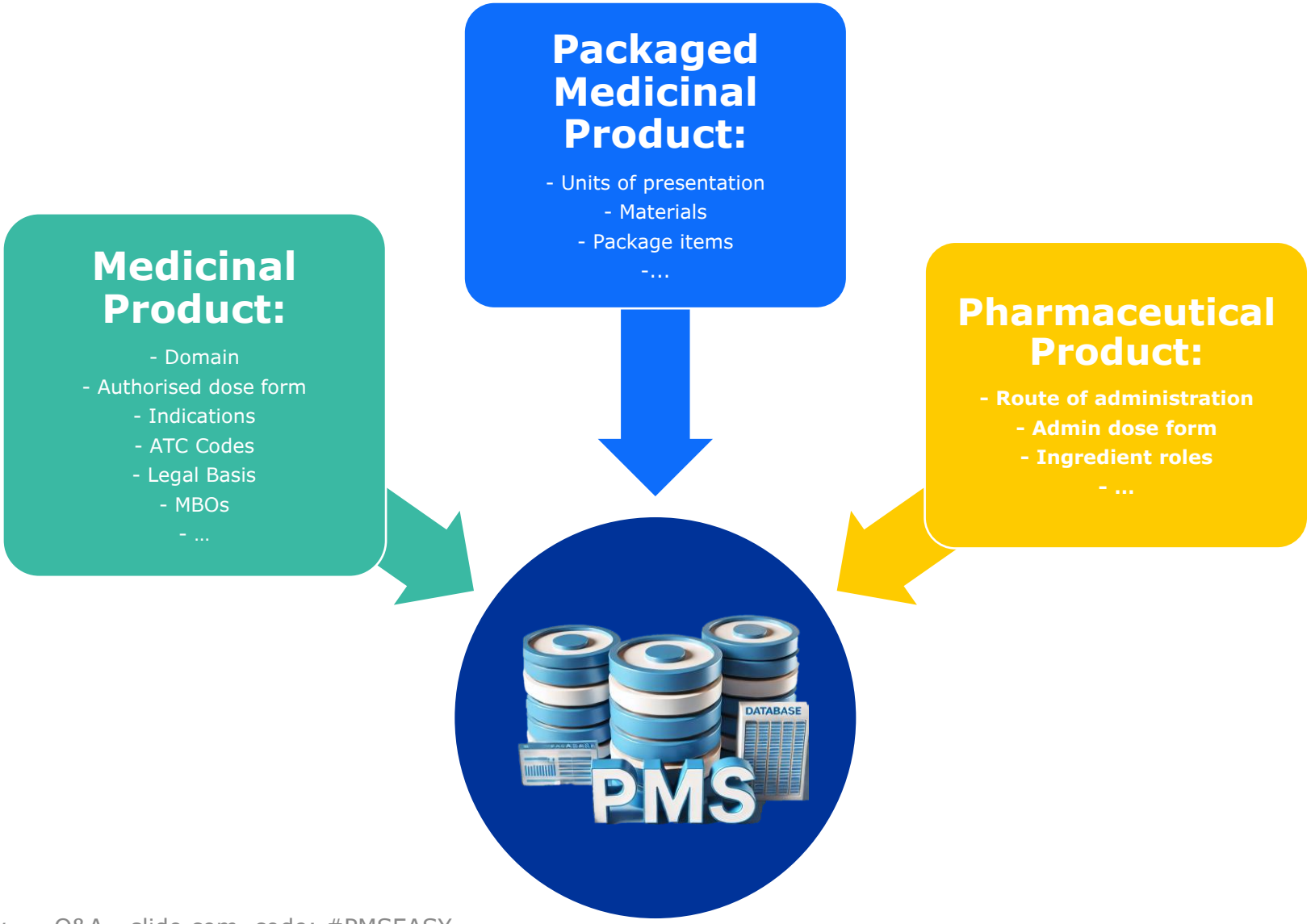
As the specific replacement substance is unclear, EMA will only validate the product and composition if the corresponding reference source of information (SmPC/M3) is provided AND accurately reflects it.

EMA
EUROPEAN MEDICINES AGENCY

# RMS

RMS data consumed by PMS

# Use of RMS data in PMS



# Actions for MAHs in relation to RMS


**Medicinal Product:**

In the documents section of RMS, MAHs can download the mapping excels with different actions for MAHs in relation to: Authorised dose form, Route of Administration and ATC Codes.

EUROPEAN MEDICINES AGENCY
SPOR - Referentials Management System

Substances | Products | Organisations | Referentials

SPOR Home | Lists | Documents

Home / View Documents

General | Technical

| Document Name ▲ | Document Description |
|---|---|
| A - About RMS | General - Legal disclaimer, copyright and other policies of using referential data. |
| D1 - XEVMPD-RMS_EDQM Pharmaceutical Dose Form terms mapping v2 | Data mapping - Quick instructions and overview explaining how the EV codes of the Pharmaceutical Dose Form and other lists haven been mapped against the applicable RMS ID/Terms |
| D2 - XEVMPD-RMS_EDQM Route of Administration terms mapping v3 | Data mapping - Quick instructions and overview explaining how the EV codes of the Route of Administration list haven been mapped against the applicable RMS ID/Terms |
| D3 - XEVMPD-RMS_WHO-National ATC codes mapping v2 | Data mapping - Quick instructions and overview explaining how the EV codes of the ATC lists haven been mapped against the applicable RMS ID/Terms |
| D4 - XEVMPD-RMS Change Requests process | Manual - How to identifying the correct path to submit a Change Request (CR) in RMS portal as result of the XEVMPD-RMS data mapping exercise performed by the MAHs of authorised medicinal products. |

# Actions for MAHs in relation to RMS


**Medicinal Product:**

- **EMA has released a mapping document for Authorised Dose Forms**
  - Filter by XEVMPD Action for Users:
    - *Select the correct pharmaceutical dose form* → Review the authorised dose form and administrable dose form and change it by a standard term
    - *Review mapping* → EMA performed a mapping to an RMS term. Check if this is correct, if not, notify RMS team.

| XEVMPD Pharmaceutical Form Name | RMS List | RMS Term ID | RMS Term Name | RMS Status | XEVMPD Proposed Replacement EV Code | XEVMPD Proposed Replacement Pharmaceutical Form Name | XEVMPD Action for Users |
|---|---|---|---|---|---|---|---|
| CAPSULE | Pharmaceutical Dose Form | 200000016452 | Capsule | NON_CURRENT | Depends by the product: multiple s | Depends by the product: multiple solutions availa | Select the correct pharmaceutical dose form. |
| CUTANEOUS SPRAY | Pharmaceutical Dose Form | 200000016453 | Cutaneous spray | NON_CURRENT | Depends by the product: multiple s | Depends by the product: multiple solutions availa | Select the correct pharmaceutical dose form. |
| EAR DROPS | Pharmaceutical Dose Form | 200000016455 | Ear drops | NON_CURRENT | Depends by the product: multiple s | Depends by the product: multiple solutions availa | Select the correct pharmaceutical dose form. |
| DISPERSION | Pharmaceutical Dose Form | 100000073922 | Dispersion | NON_CURRENT | To be added | To be added | Select the correct pharmaceutical dose form. |
| LIQUID | Pharmaceutical Dose Form | 200000016468 | Liquid | NON_CURRENT | To be added | To be added | Select the correct pharmaceutical dose form. |
| OPHTHALMIC SOLUTION | Pharmaceutical Dose Form | 200000016475 | Ophthalmic solution | NON_CURRENT | To be added | To be added | Select the correct pharmaceutical dose form. |

| XEVMPD Pharmaceutical Form Name | RMS List | RMS Term ID | RMS Term Name | RMS Status | XEVMPD Proposed Replacement EV Code | XEVMPD Proposed Replacement Pharmaceutical Form Name | XEVMPD Action for Users |
|---|---|---|---|---|---|---|---|
| ΕΝΕΣΙΜΟ ΔΙΑΛΥΜΑ | Pharmaceutical Dose Form | 100000073863 | Solution for injection | CURRENT | PHF00231MIG | Solution for injection | Review mapping. Term not to be used f |
| ΠΟΣΙΜΟ ΔΙΑΛΥΜΑ | Pharmaceutical Dose Form | 100000073646 | Oral solution | CURRENT | PHF00169MIG | Oral solution | Review mapping. Term not to be used f |
| ΕΠΙΚΑΛΥΜΜΕΝΟ ΔΙΣΚΙΟ | Pharmaceutical Dose Form | 100000073839 | Inhalation powder | CURRENT | PHF00110MIG | Inhalation powder | Review mapping. Term not to be used f |
| ΓΑΣΤΡΟΑΝΘΕΚΤΙΚΟ ΔΙΣΚΙΟ | Pharmaceutical Dose Form | 100000073667 | Gastro-resistant tablet | CURRENT | PHF00094MIG | Gastro-resistant tablet | Review mapping. Term not to be used f |

# Actions for MAHs in relation to RMS


**Medicinal Product:**

- **EMA has released a mapping document for ATC Codes**
  - Filter by XEVMPD Action for Users:
    - *Outdated ATC code. A current ATC code should be added* → Review the ATC Code and replace by a current one. Check the XEVMPD proposed replacement.

| XEVMPD ATC Code | XEVMPD Proposed Replacement ATC Code | XEVMPD Proposed Replacement ATC Code Description | RMS List ID | RMS List Name | RMS Term ID | RMS Term Name | RMS Status | XEVMPD Action for Users |
|---|---|---|---|---|---|---|---|---|
| A02AD10 | A02AD01 | Ordinary salt combinations | 200000016508 | National Classification list | 200000016816 | A02AD10 | CURRENT | Outdated ATC code. A current ATC code should be added |
| A02D | A02AF | antacids with antiflatulents | 200000016508 | National Classification list | 200000016819 | A02D | CURRENT | Outdated ATC code. A current ATC code should be added |
| A02DA | A02AF | antacids with antiflatulents | 200000016508 | National Classification list | 200000016820 | A02DA | CURRENT | Outdated ATC code. A current ATC code should be added |
| A02EA | A02AH | Antacids with sodium bicarbonate | 200000016508 | National Classification list | 200000016821 | A02EA | CURRENT | Outdated ATC code. A current ATC code should be added |
| B04A | C10AA02 | Lovastatin | 200000016508 | National Classification list | 200000016876 | B04A | CURRENT | Outdated ATC code. A current ATC code should be added |
| C01EP01 | C01EB | other cardiac preparations | 200000016508 | National Classification list | 200000016887 | C01EP01 | CURRENT | Outdated ATC code. A current ATC code should be added |
| G04CP06 | G04CX02 | Sabalis serrulatae fructus | 200000016508 | National Classification list | 200000016964 | G04CP06 | CURRENT | Outdated ATC code. A current ATC code should be added |
| M01AX03 | M01AB15 | ketorolac | 200000016508 | National Classification list | 200000016979 | M01AX03 | CURRENT | Outdated ATC code. A current ATC code should be added |
| N02AC02 | N07BC02 | methadone | 200000016508 | National Classification list | 200000017003 | N02AC02 | CURRENT | Outdated ATC code. A current ATC code should be added |
| N02BE91 | N02BE51 | paracetamol, combinations excl. psycholeptics | 200000016508 | National Classification list | 200000017007 | N02BE91 | CURRENT | Outdated ATC code. A current ATC code should be added |
| N07XB01 | A16AX01 | Thioctic acid | 200000016508 | National Classification list | 200000017038 | N07XB01 | CURRENT | Outdated ATC code. A current ATC code should be added |
| S01EX03 | S01EE01 | latanoprost | 200000016508 | National Classification list | 200000017086 | S01EX03 | CURRENT | Outdated ATC code. A current ATC code should be added |
| V03AB28 | V03AF03 | calcium folinate | 200000016508 | National Classification list | 200000017091 | V03AB28 | CURRENT | Outdated ATC code. A current ATC code should be added |
| V03AB30 | N07BB04 | naltrexone | 200000016508 | National Classification list | 200000017092 | V03AB30 | CURRENT | Outdated ATC code. A current ATC code should be added |
| A11CC07 | H05BX02 | paricalcitol | 100000093533 | Anatomical Therapeutic Chemical classification system - Human | 100000094102 | paricalcitol | NON_CURRENT | Outdated ATC code. A current ATC code should be added |
| J05AX68 | J05AP54 | elbasvir and grazoprevir | 100000093533 | Anatomical Therapeutic Chemical classification system - Human | 200000003283 | elbasvir and grazoprevir | NON_CURRENT | Outdated ATC code. A current ATC code should be added |
| L01XX63 | L01XJ03 | glasdegib | 100000093533 | Anatomical Therapeutic Chemical classification system - Human | 200000010392 | glasdegib | NON_CURRENT | Outdated ATC code. A current ATC code should be added |
| L01XE53 | L01EX12 | larotrectinib | 100000093533 | Anatomical Therapeutic Chemical classification system - Human | 200000010402 | larotrectinib | NON_CURRENT | Outdated ATC code. A current ATC code should be added |

# Actions for MAHs in relation to RMS


**Packaged Medicinal Product**

- **No immediate actions for MAHs**
  - No RMS terms are used for the moment in the packaged medicinal product. EV Codes, MA numbers and package description is consumed from XEVMPD and not linked to any RMS term.
  - Enrichment of structured pack size data is performed through the Product UI (direct link to RMS terms)
  - Additional information can be found in EU IG Chapter 3.
  - Materials and package items will be discussed in due course (granularity, new terms, etc). Please, do not submit change requests for additional terms in RMS for these lists until additional information is provided.

# Actions for MAHs in relation to RMS


**Pharmaceutical Product**

- **EMA has released a mapping document for route of administrations with actions for MAHs**
  - Filter by XEVMPD Action for Users:
    - *Select the correct route of administration* → Review the authorised dose form and administrable dose form and change it by a standard term. Check the *Case* column for more information

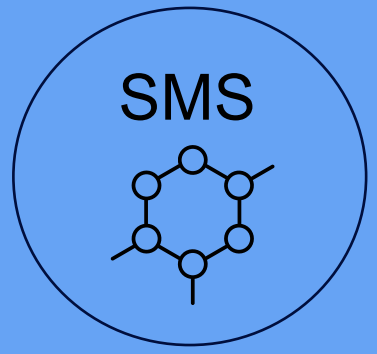
| XEVMPD EV Code | XEVMPD Administration Route Name | XEVMPD Type | XEVMPD Status | RMS Term ID | RMS Term Name | RMS Status | XEVMPD Proposed | XEVMPD Proposed | Case | XEVMPD Action for Users |
|---|---|---|---|---|---|---|---|---|---|---|
| ADR428 | PARENTERAL USE | Proposed | Not nullified | 100000075266 | Parenteral use | NON_CURRENT | Mapping is not possible without user i | Mapping is not possible witho | Legacy term | Select the correct route of administration. |
| ADR618 | PARENTERAL USE | Proposed | Not nullified | 100000075266 | Parenteral use | NON_CURRENT | Mapping is not possible without user i | Mapping is not possible witho | Legacy term | Select the correct route of administration. |
| ADR112 | PERCUTANEOUS USE | Standard | Not nullified | 100000075254 | Percutaneous use | NON_CURRENT | Mapping is not possible without user i | Mapping is not possible witho | Legacy term | Select the correct route of administration. |
| ADR00055MIG | RESPIRATORY USE | Standard | Not nullified | 100000075265 | Respiratory use | NON_CURRENT | Mapping is not possible without user i | Mapping is not possible witho | Legacy term | Select the correct route of administration. |
| ADR115 | SOFT TISSUE USE | Standard | Not nullified | 100000075253 | Soft tissue use | NON_CURRENT | Mapping is not possible without user i | Mapping is not possible witho | Legacy term | Select the correct route of administration. |
| ADR00059MIG | SUBDERMAL USE | Standard | Not nullified | 100000075263 | Subdermal use | NON_CURRENT | Mapping is not possible without user i | Mapping is not possible witho | Legacy term | Select the correct route of administration. |
| ADR00061MIG | TOPICAL USE | Standard | Not nullified | 100000075262 | Topical use | NON_CURRENT | Mapping is not possible without user i | Mapping is not possible witho | Legacy term | Select the correct route of administration. |
| ADR00064MIG | TRANSPLACENTAL USE | Standard | Not nullified | 100000111217 | Transplacental use | NON_CURRENT | Mapping is not possible without user i | Mapping is not possible witho | Legacy term | Select the correct route of administration. |
| ADR00065MIG | UNKNOWN USE | Standard | Not nullified | 100000075261 | Unknown use | NON_CURRENT | Mapping is not possible without user i | Mapping is not possible witho | Legacy term | Select the correct route of administration. |
| ADR800 | USE IN BODY CAVITIES | Proposed | Not nullified | 200000042479 | Use in body cavities | NON_CURRENT | Mapping is not possible without user i | Mapping is not possible witho | Legacy term | Select the correct route of administration. |
| ADR660 | CONCENTRATE FOR SOLUTION FOR INFUSION | Proposed | Not nullified | 200000017723 | Concentrate for solution for infusio | NON_CURRENT | Not a RoA | Not a RoA | Incorrect RoA term used | Select the correct route of administration. |
| ADR309 | INFUSION | Standard | Not nullified | 200000016449 | Infusion | NON_CURRENT | Not a RoA | Not a RoA | Incorrect RoA term used | Select the correct route of administration. |
| ADR231 | INJECTION | Proposed | Not nullified | 200000016447 | Injection | NON_CURRENT | Not a RoA | Not a RoA | Incorrect RoA term used | Select the correct route of administration. |
| ADR335 | INJECTION | Standard | Not nullified | 200000016447 | Injection | NON_CURRENT | Not a RoA | Not a RoA | Incorrect RoA term used | Select the correct route of administration. |
| ADR747 | SOLUTION FOR INFUSION | Proposed | Not nullified | 200000016448 | Solution for infusion | NON_CURRENT | Not a RoA | Not a RoA | Incorrect RoA term used | Select the correct route of administration. |
| ADR185 | SOLUTION FOR INJECTION | Proposed | Not nullified | 200000017724 | Solution for injection | NON_CURRENT | Not a RoA | Not a RoA | Incorrect RoA term used | Select the correct route of administration. |
| ADR240 | SOLUTION FOR INJECTION | Proposed | Not nullified | 200000017724 | Solution for injection | NON_CURRENT | Not a RoA | Not a RoA | Incorrect RoA term used | Select the correct route of administration. |

Subdermal use is a legacy term. Subcutaneous use is the current term.

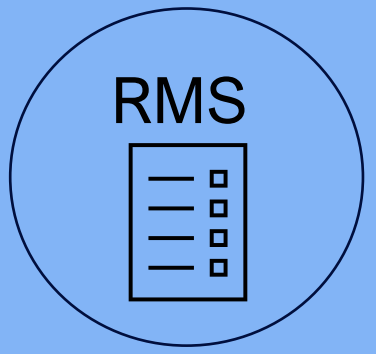
Solution for infusion is not a route of administration – select a correct RoA.

# Summary


- Make sure the **mapping** between the **ORG EV Code** and the **LOC ID** is correct
- Products linked to inactive organisations might appear in the Product UI
- If needed, MAHs can request access to historical organisations in OMS
- Make sure your **manufacturers** are included **in OMS**




- Make sure that EV Codes belonging to the same product have the same active substance(s) and strength.
- Composition can be submitted as in **M3 or SmPC** (MAHs decides)
- Substances with **SVG = 0** should be avoided (replacement is not yet mandatory). Good practice to submit newly authorised products following this recommendation.




- **Review the mapping excels** available in RMS.
- Use the advance queries from XEVMPD to check if any change is required on the route of administration or authorised dose form.
- **Terms for materials or package items** shall not be requested. EMA will review the data needed in these fields and communicate in due course.

# Review of migrated data

# Being ready for PMS compliance

EMA
EUROPEAN MEDICINES AGENCY

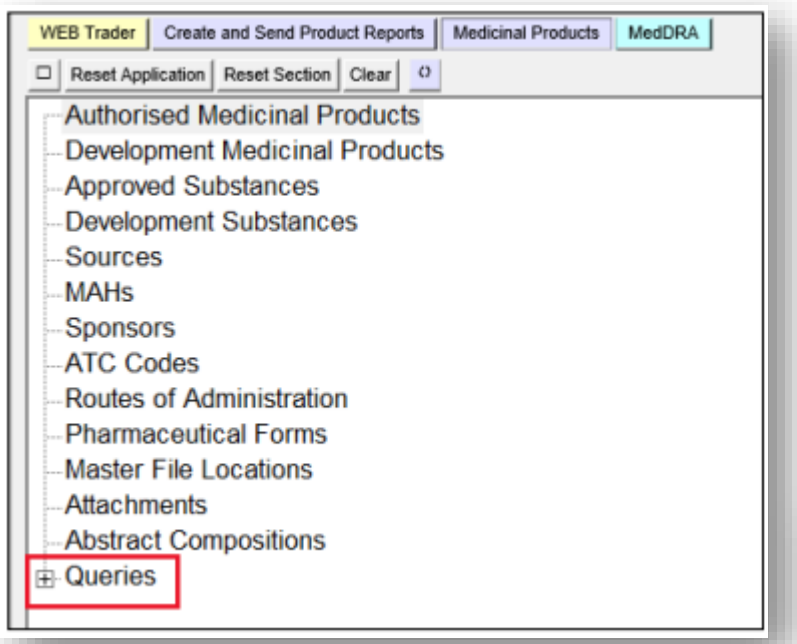
# Using XEVPMD queries for the review

The following tips are just suggestions on how MAHs can review their data. Other strategies might be followed.

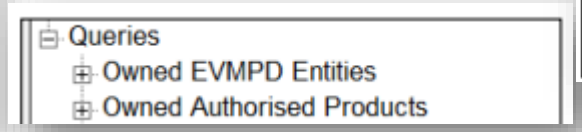
# Using XEVPMD queries for the review

- MAHs can use the advanced queries from XEVMPD to export EV Codes' data and review if any action is needed
- By comparing data from the advanced queries with data from RMS data mappings excels, MAH's actions can be identified

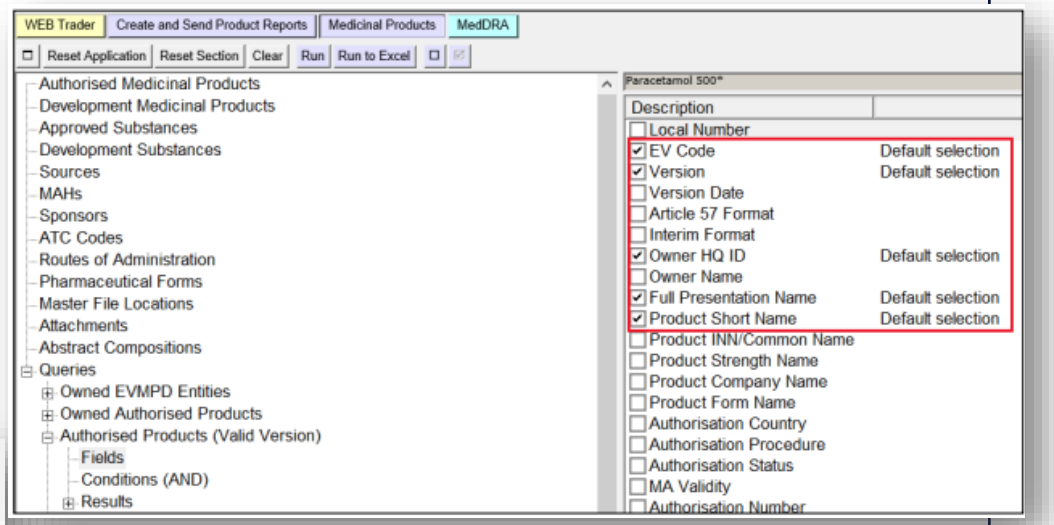
1. Select the queries section in XEVMPD




2. Select Owned Authorised Products



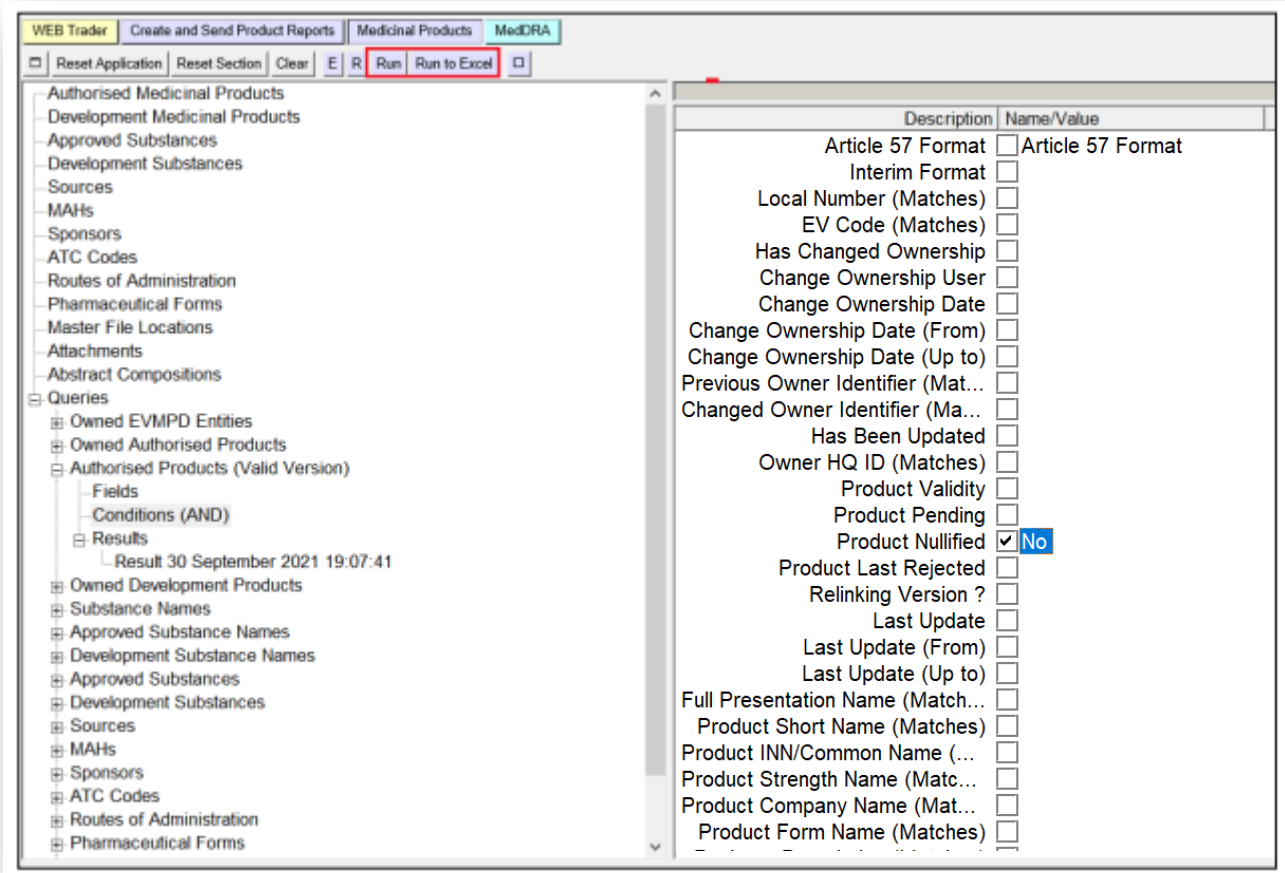

3. Select the different fields you want to export such as EV Code, Product Validity, Full presentation name, Route of administration, Pharmaceutical form, authorisation status, etc



# Using XEVPMD queries for the review

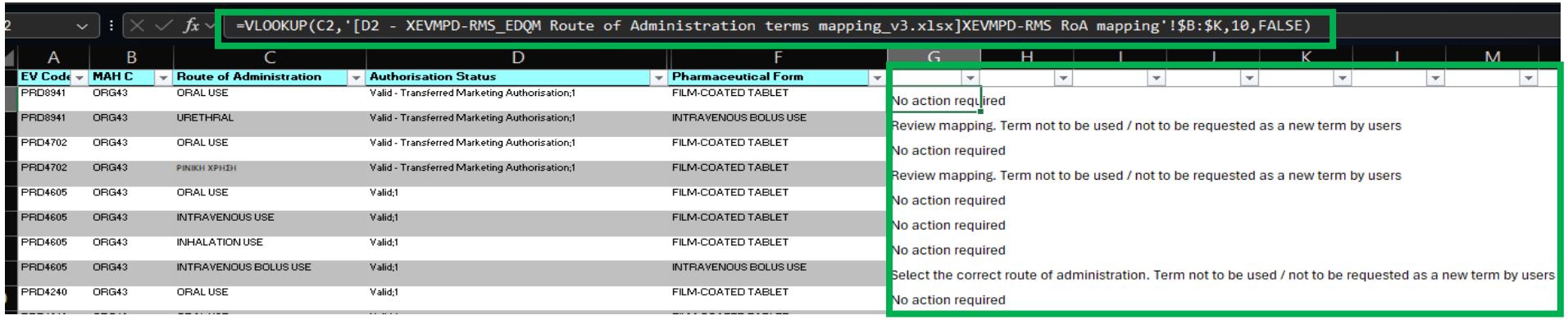
4. In the conditions, filter out the nullified products (Product nullified = NO)

5. Export to Excel and **save it as Excel** (otherwise it will be saved as Web page)



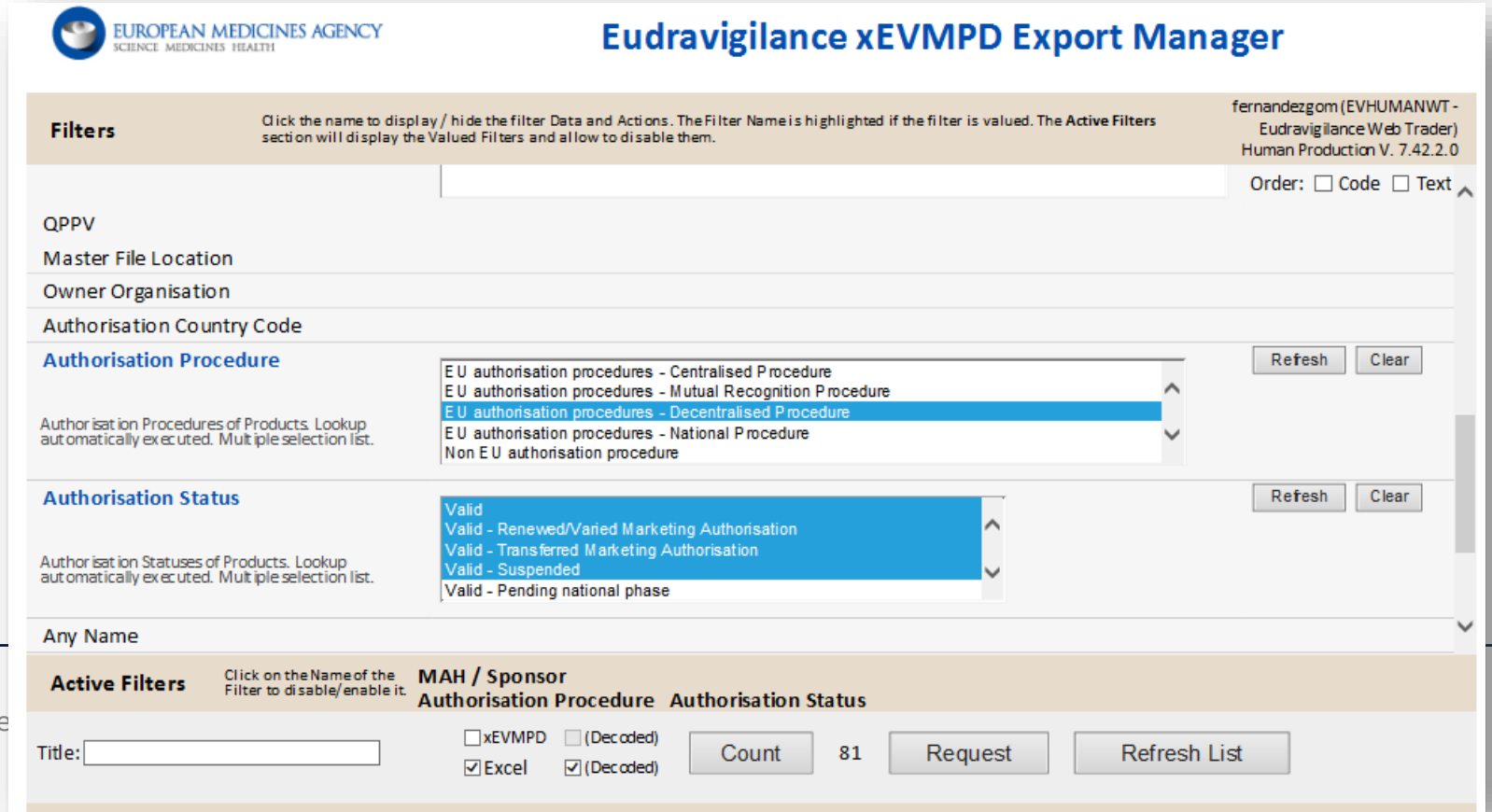
# Using XEVPMD queries for the review

- Users can **compare the Exports** from the advanced queries and the RMS mapping excels to check which EV Codes have any MAH action to be performed.
- Please, review the **Product Validity** field to check if there are Valid EV Codes not validated by XEVMPD. You can open a ticket for the XEVMPD team requesting the validation.
- This query can also be used to **check the MAH Code** linked to each EV Code and review the OMS mapping
- Review the recording of the webinar to see a live demo.



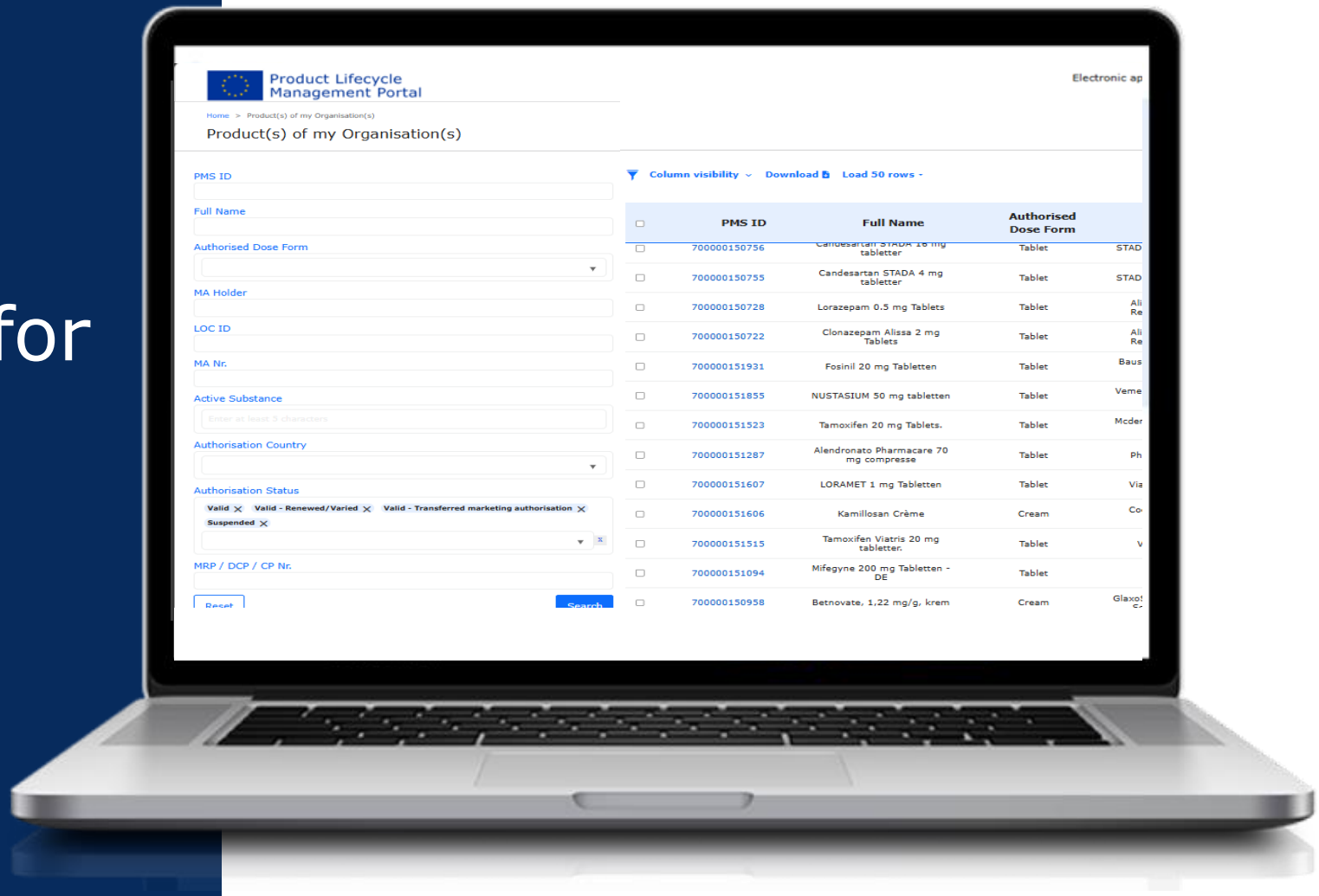
# Using XEVPMD export tool for the review

- MAHs can use the export tool from XEVMPD to export additional EV Codes' data that can be used to identify changes needed on substances for example
- **Comparing data** from export with data from the **SMS** excel, MAH's actions can be identified
- Comparing this data, also actions on **ATC codes** can be identified
- Note: these exports are quite heavy, suggestion to perform the review in groups



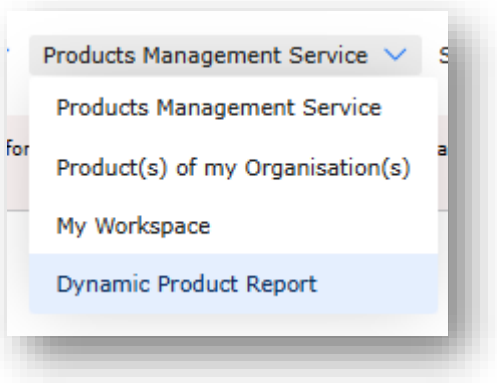
EMA
EUROPEAN MEDICINES AGENCY

# Using the Product UI for the review



# Using Product UI for the review

- Dynamic reports from the Product UI can be used to compare data with XEVMPD exports, review CAP data, identify critical medicines or review mapping actions for MAHs linked to RMS.





| | |
|---|---|
| Products of my organisation | Review LOC ID and ORG ID correctly mapped between XEVMPD and OMS |
| All manufacturing operations | Review CAP manufacturers and MBOs and enriched non-CAPs |
| All ingredients | Review migrated ingredients.<br>Can be used to identify SVG = 0 substances |
| All packages | Review if all EV Codes have been migrated from XEVMPD. EV Codes correctly assigned to each product |
| All ATC Codes | Identify critical products and outdated or missing ATC Codes |

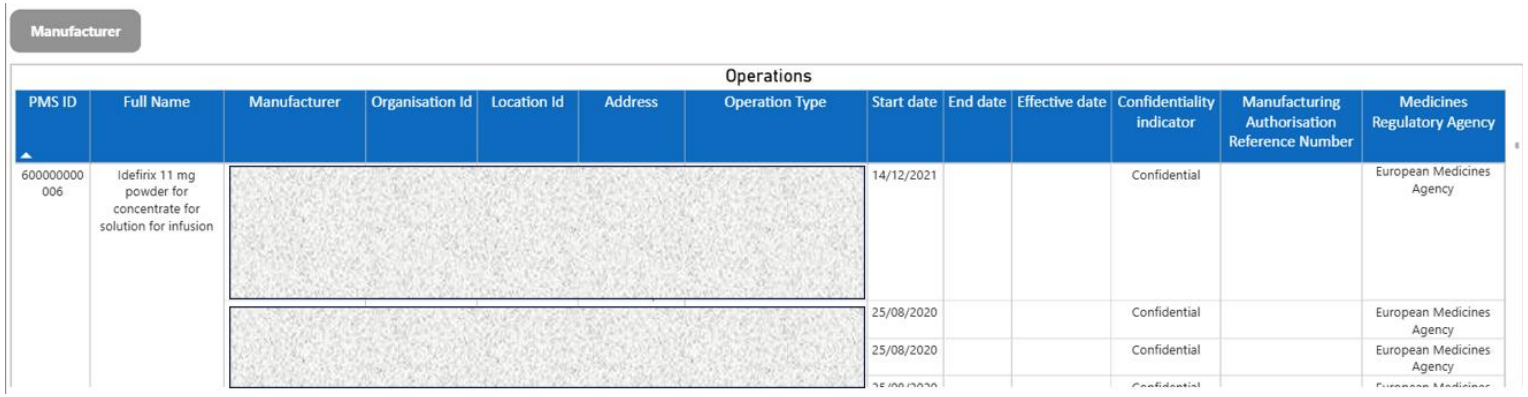
# Using Product UI for the review

- Use the ***All packages*** Dynamic Report to check if all EV codes from XEVMPD have been migrated and available in the Product UI
- Compare all packages EV Codes export and advanced query from XEVMPD to check missing EV Codes

- Steps:
  - 1) From the advanced query of XEVMPD, remove products with Authorisation status *Not valid – transferred* (these products were not migrated to PMS)
  - 2) From the advanced query of XEVMPD, remove the products with Authorisation status *Valid – transferred* in PMS. For the moment, the product UI is showing the Previous EV Code. Therefore, we will not be able to match these products. (EMA is working on this issue)
  - 3) Compare the data in the advanced query from XEVMPD with the data in the all packages dynamic report (using Excel formulas (VLOOK UP)– review the demo performed during the webinar)
  - 4) Review the missing products (not matched) and with the known issues in the PMS Q&A document, check if they are not migrated due to a known issue (missing mapping with the authorised dose form, inactive MAH). Otherwise, open a ticket providing the missing EV Codes.

# Using Product UI for the review

- Use the ***All manufacturing operations*** Dynamic Report to check manufacturers and MBOs migrated from SIAMED. If any discrepancy is found, you can raise a ticket providing all the information so the correction can be performed.
- It can also be used to review the data provided for non-CAPs as part of the enrichment process
- Notes:
  - Please, review EU IG Chapter 3 for additional information on which manufacturers and MBOs should be submitted to PMS.



# Using Product UI for the review

- Use the ***All ATC** codes* Dynamic Report to identify the Medicinal products in scope of the ULCM
- Filter by  the ATC Codes from the ULCM and RoA can also be filtered afterwards. That would be the list of products MAHs need to enrich with manufacturers, MBOs and structured pack size data
- This report can be used to identify products with missing ATC codes as well

- Notes:
  - Not valid products (withdrawn, not renewed, etc) are out of scope of the ULCM – you can remove them from the export
  - Use version 2 of the ULCM for this exercise
  - You can use the formula  =IF(ISNUMBER(SEARCH(C2, I2)), “YES", "NO") to compare the route of administration where C2 contains the route of admin from the PUI and I2 contains the route of admin from the ULCM excel.
  - For products with multiple RoA we recommend a manual check
  - Remember to keep always up to date the ATC codes in XEVMPD

# Using Product UI for the review

- Rest of the data of the Product UI pages, can be done product by product until we have other reports for data such as:
  - Indications
  - Legal basis
  - Additional monitoring
  - Paediatric use
  - etc.
- Verification of this data can be done at a later stage when reports are available

# Summary

# Use XEVMPD to review improvements in data

- Use **advanced queries** from XEVMPD to export EV Codes' data
- Check if any of the route of administrations or dose forms used by MAH **should be replaced**
- Use **XEVMPD export tool** to review substances with SVG =0 (not mandatory for the moment) and ATC Codes

# Use Dynamic reports in UI to review migrated data in PMS

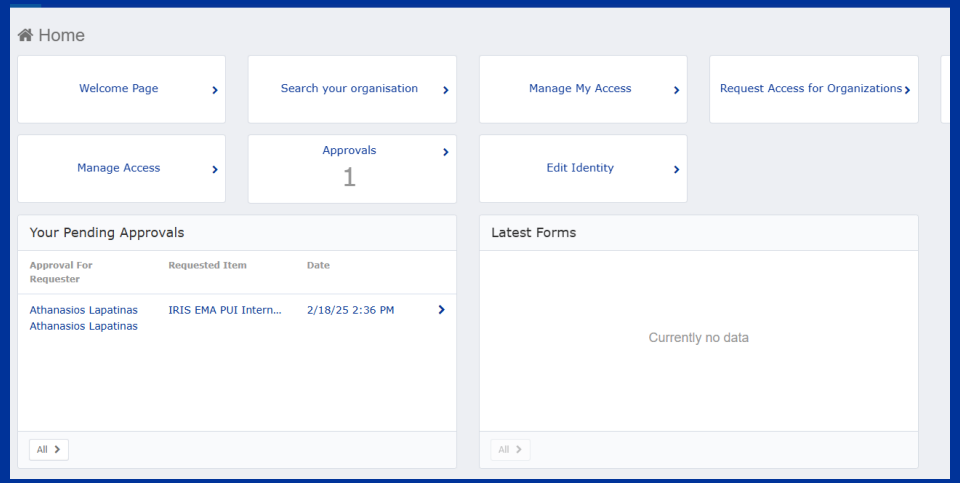
- Use Dynamic reports in the Product UI together with the exports from XEVMPD to **make sure all EV Codes have been migrated**
- Remember that EV Codes with auth status '*Valid – transferred*' are showing for the moment the previous - EV Code
- Use dynamic reports to **review manufacturers' data for CAPs**
- Use ATC Codes dynamic report to **identify products belonging to the ULCM**

Product UI navigation guide

EMA
EUROPEAN MEDICINES AGENCY

# Proposed process to start the PMS journey

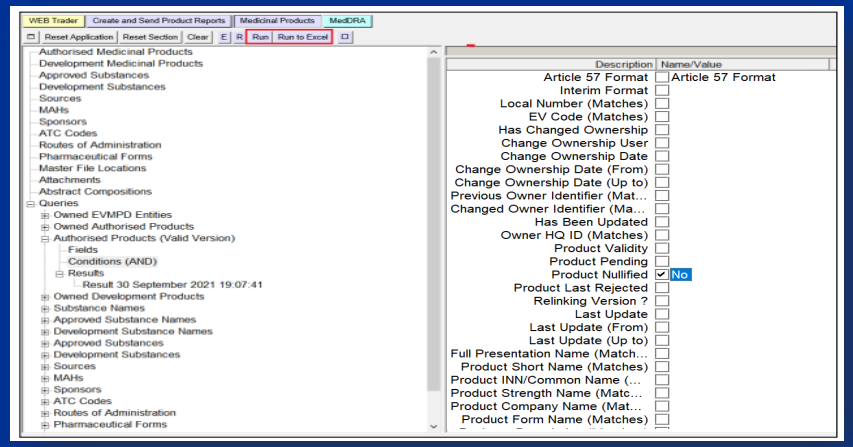
# Request access to Product UI




Remember that access can be requested to historical organisations

# Request access to Product UI

## Export EV Codes' data from XEVMPD advanced queries

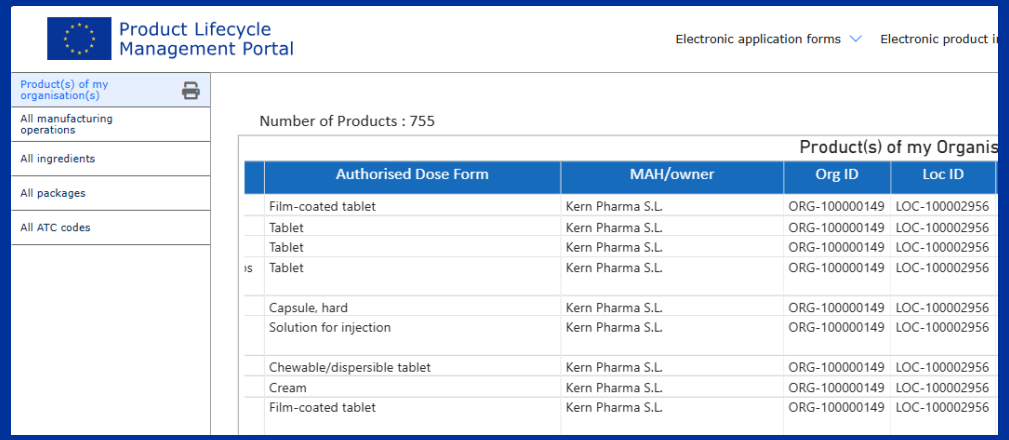



Check the ORG EV Code for your records and the mappings in OMS

Request access to Product UI

Export EV Codes' data from XEVMPD advanced queries

Use the dynamic reports to make sure correct LOC ID and ORG ID are used in PMS




| Authorised Dose Form | MAH/owner | Org ID | Loc ID |
|---|---|---|---|
| Film-coated tablet | Kern Pharma S.L. | ORG-100000149 | LOC-100002956 |
| Tablet | Kern Pharma S.L. | ORG-100000149 | LOC-100002956 |
| Tablet | Kern Pharma S.L. | ORG-100000149 | LOC-100002956 |
| Tablet | Kern Pharma S.L. | ORG-100000149 | LOC-100002956 |
| Capsule, hard | Kern Pharma S.L. | ORG-100000149 | LOC-100002956 |
| Solution for injection | Kern Pharma S.L. | ORG-100000149 | LOC-100002956 |
| Chewable/dispersible tablet | Kern Pharma S.L. | ORG-100000149 | LOC-100002956 |
| Cream | Kern Pharma S.L. | ORG-100000149 | LOC-100002956 |
| Film-coated tablet | Kern Pharma S.L. | ORG-100000149 | LOC-100002956 |

Request access to Product UI

Export EV Codes' data from XEVMPD advanced queries

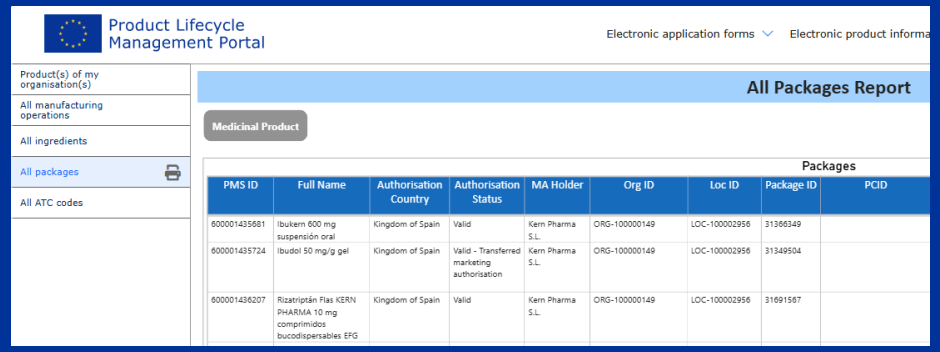
Use the dynamic reports to make sure correct LOC ID and ORG ID are used in PMS

Review RMS/SMS mappings and perform necessary changes in XEVMPD

| Code | XEVMPD Proposed Replacement ATC Code | XEVMPD Proposed Replacement ATC Code Description | RMS List ID | RMS List Name | RMS Ter |
|---|---|---|---|---|---|
| | A02AD01 | Ordinary salt combinations | 200000016508 | National Classification list | 2000000163 |
| | A02AF | antacids with antiflatulents | 200000016508 | National Classification list | 2000000163 |
| | A02AF | antacids with antiflatulents | 200000016508 | National Classification list | 2000000163 |
| | A02AH | Antacids with sodium bicarbonate | 200000016508 | National Classification list | 2000000163 |
| | C10AA02 | Lovastatin | 200000016508 | National Classification list | 2000000163 |
| | C01EB | other cardiac preparations | 200000016508 | National Classification list | 2000000163 |
| | G04CX02 | Sabalis serrulatae fructus | 200000016508 | National Classification list | 2000000163 |
| | M01AB15 | ketorolac | 200000016508 | National Classification list | 2000000163 |
| | N07BC02 | methadone | 200000016508 | National Classification list | 2000000170 |
| | N02BE51 | paracetamol, combinations excl. psycholeptics | 200000016508 | National Classification list | 2000000170 |
| | A16AX01 | Thioctic acid | 200000016508 | National Classification list | 2000000170 |
| | S01EE01 | latanoprost | 200000016508 | National Classification list | 2000000170 |
| | V03AF03 | calcium folinate | 200000016508 | National Classification list | 2000000170 |
| | N07BB04 | naltrexone | 200000016508 | National Classification list | 2000000170 |
| | H05BX02 | paricalcitol | 100000093533 | Anatomical Therapeutic Chemical classification system - Human | 1000000941 |
| | J05AP54 | elbasvir and grazoprevir | 100000093533 | Anatomical Therapeutic Chemical classification system - Human | 2000000032 |
| | L01XJ03 | glasdegib | 100000093533 | Anatomical Therapeutic Chemical classification system - Human | 2000000103 |
| | L01EX12 | larotrectinib | 100000093533 | Anatomical Therapeutic Chemical classification system - Human | 2000000104 |

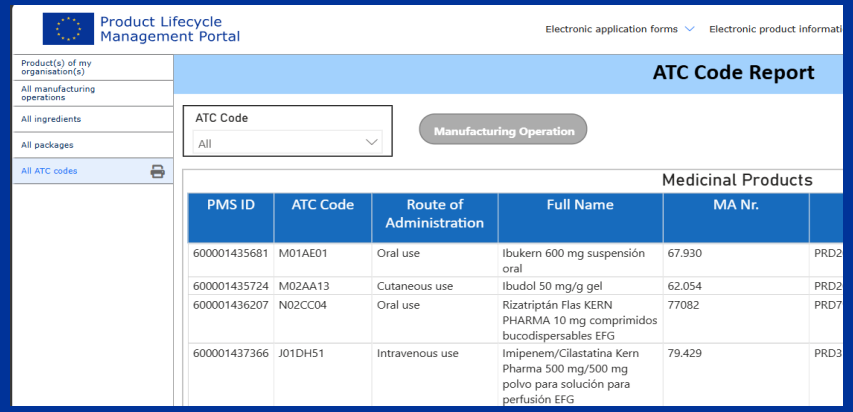
SMS changes are not mandatory

# Make sure all packs are migrated using the combination of XEVMPD exports and dynamic reports




Try to identify duplicates looking for duplicates in the product name

# Review if any product of the portfolio is considered a critical medicine.



Submit all marketed pack sizes if applicable

Start collecting data for these products and review manufacturers for CAPs

For the review, focus first on critical medicines or products that MAH will use in the web-based variation form

Keep track of new EV Codes submitted and make sure they are allocated in the correct PMS medicinal product

Enrichment of critical products can be started or wait for Bulk Update functionality in Q2

Always review the documentation to understand changes, bug resolutions, business rules, etc

# Useful documentation

## EU Implementation guideline

Access to PMS data (UI & API)
Data model
Enrichment process
View PMS API specifications
Examples

## PMS Q&A document

Frequently asked questions
Known issues and expected timelines for resolution

## Chapter 3.II of XEVMPD

Provides information on how to submit data to XEVMPD

## Navigation guide of Product UI

Explains how to navigate and use the Product UI (view and write)

## Write PMS API implementation guide

Technical guidance to implement the write PMS API

## Other webinars

List of past webinars related to PMS

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# Thank you

PLM.ValueStream@ema.europa.eu

Follow us