

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**

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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



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Welcome

Marcos Fernández Gomez,
PMS Product Co-Owner, EMA

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Demo & Summary

Marcos Fernández Gómez,
PMS Product Co-Owner, EMA

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Background

Marcos Fernández Gomez,
PMS Product Co-Owner, EMA

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Q&A
30 mins

Moderator: Vivian Leamy, PMS
Change Management Team

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**Consuming systems
& actions**

Marcos Fernández Gomez,
PMS Product Co-Owner, EMA

7

Closing

Marcos Fernández Gómez,
PMS Product Co-Owner, EMA

4

**Source systems
& review**

Marcos Fernández Gomez,
PMS Product Co-Owner, EMA

Scope

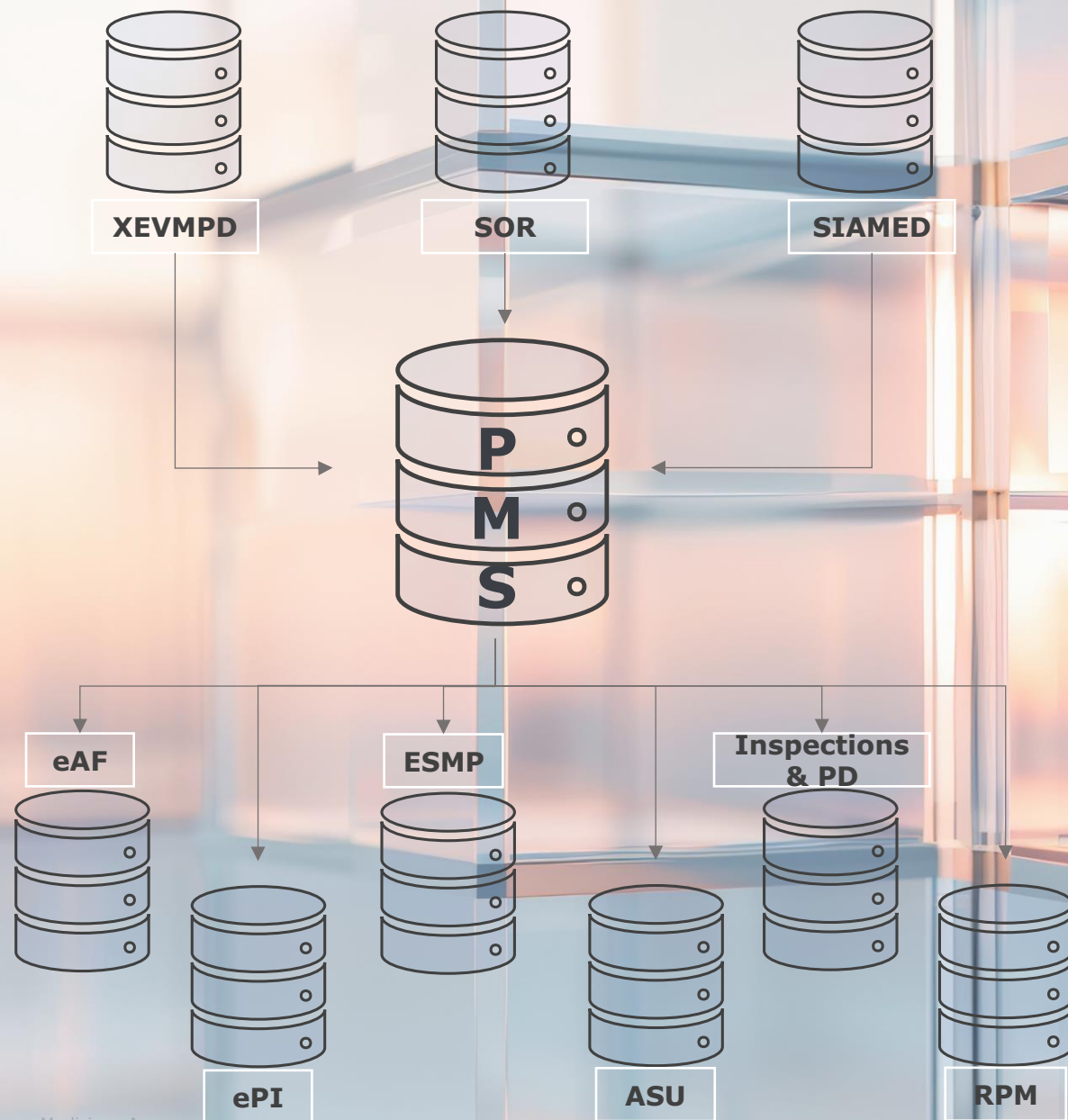
The scope of this presentation is to provide an overview of activities that MAHs should perform to be compliant with PMS and other systems.

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.

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**

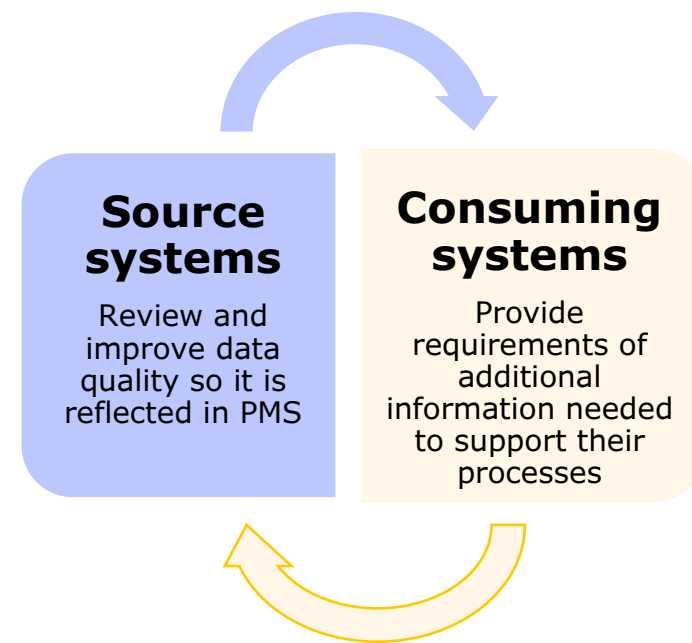
PMS provides data to different consuming systems

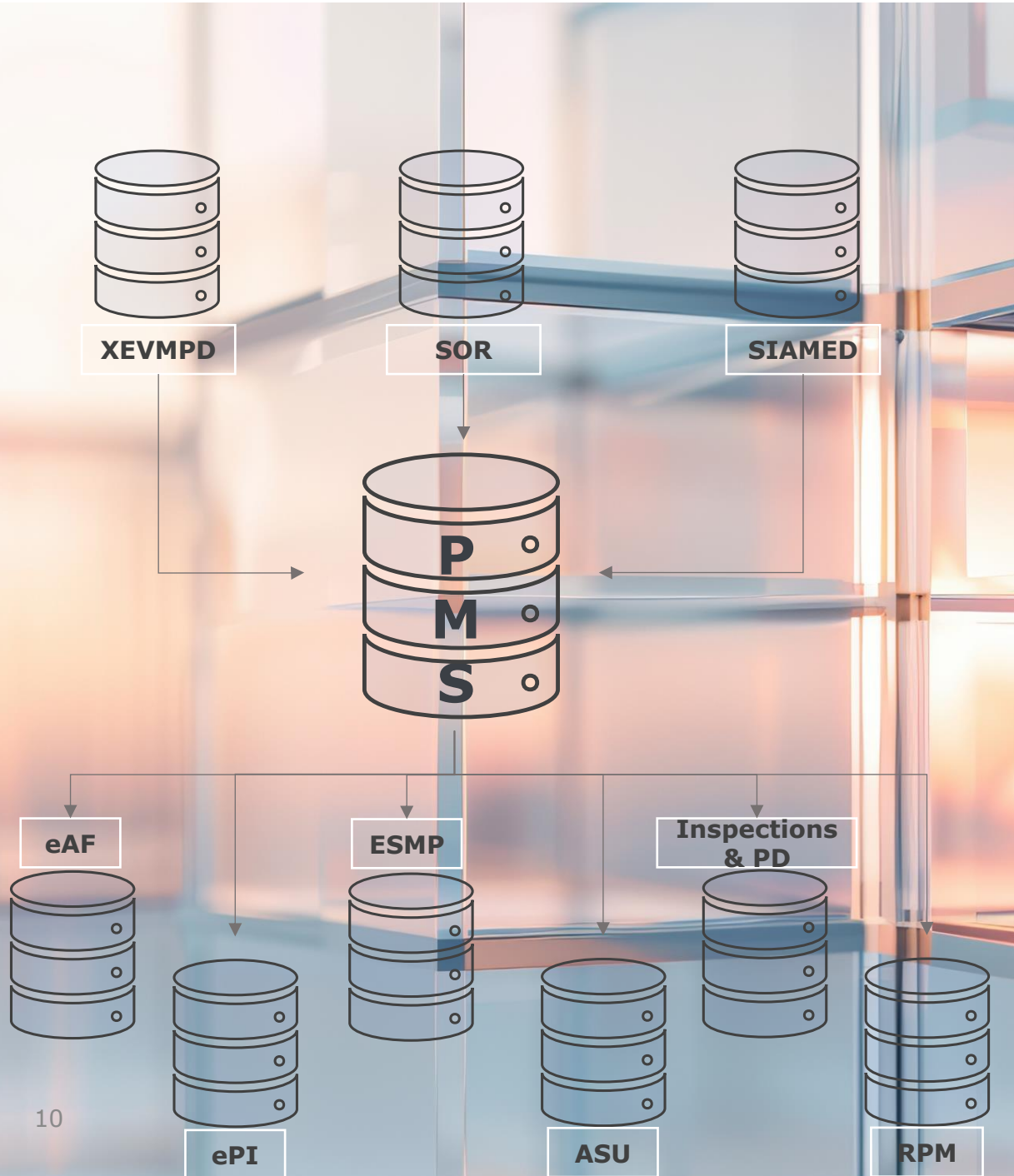
- Web-based variation eAF: products to be included in the variation form come from PMS
- ePI: in the future PMS products and the ePI will be linked
- ESMP: pre-filled templates contain PMS product data
- ASU: Antimicrobial Sales and Use Platform consumes PMS authorised products used in animals
- Inspections & 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

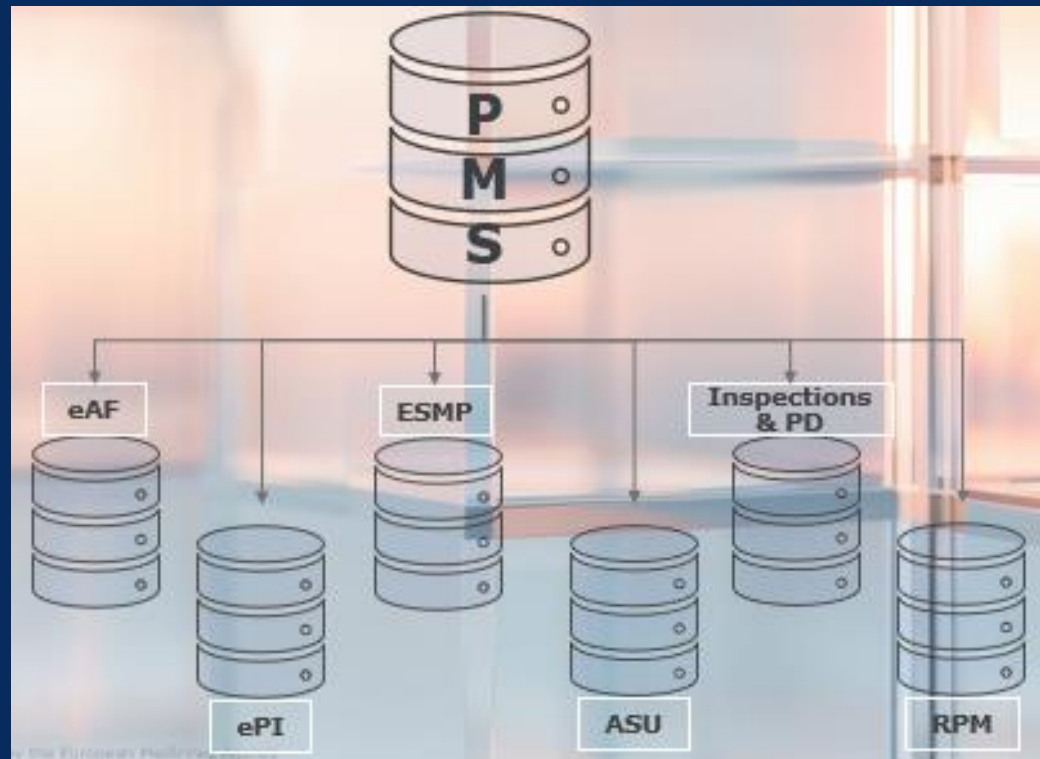
Provide requirements of additional information needed to support their processes

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

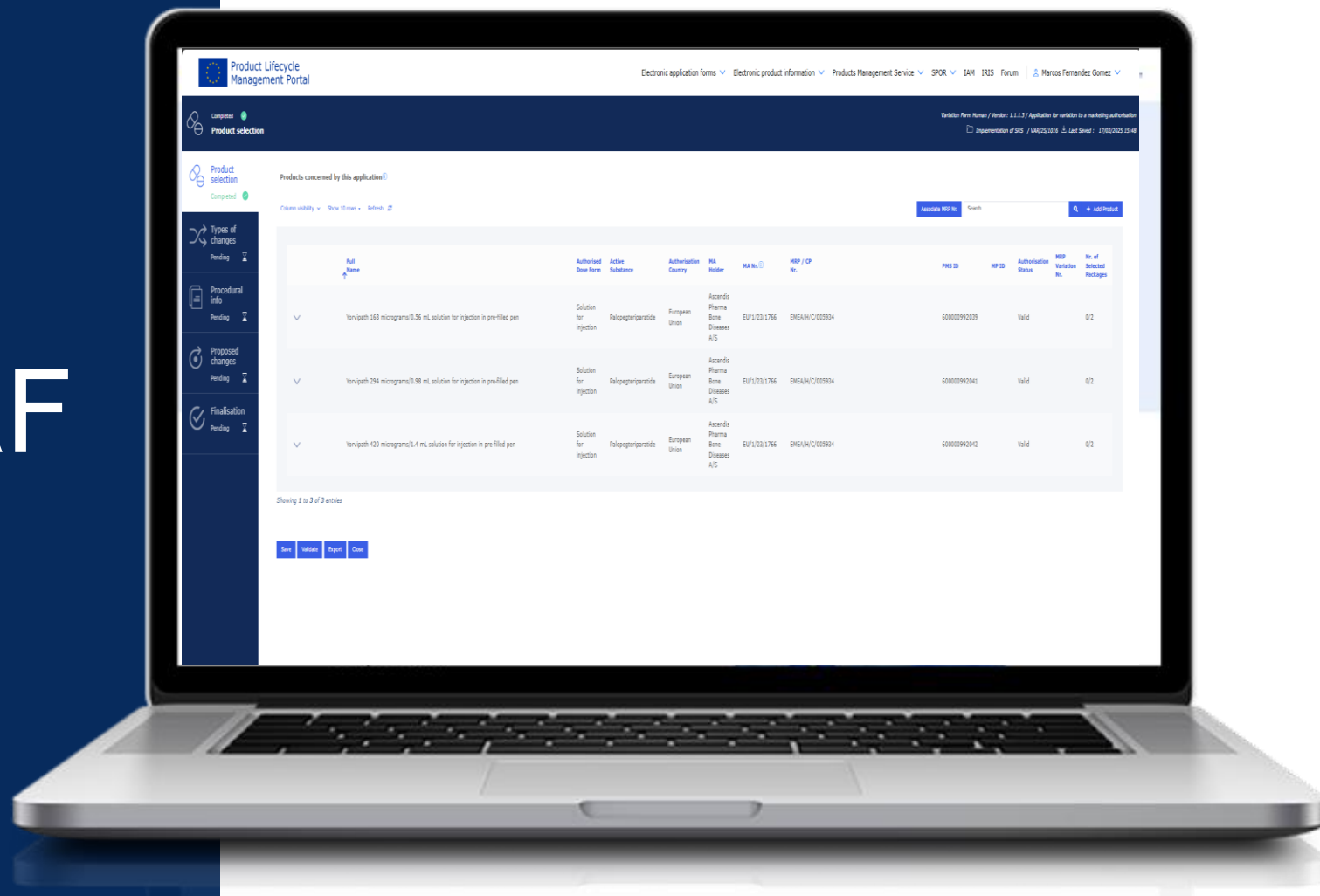
- **PLM**: accurate OMS ID to access products
- **eAF**: any product subject to be used in the web-based variation form
- **ESMP**: manufacturers and structured pack size details for ULCM
- **ASU**: pack sizes for impacted products
- **Inspections, PD & RPM**: accurate product data

Consuming systems

Additional information is required to support their processes



Web-based eAF



Web-based eAF and PMS

Completed

Product selection

Product selection

Completed

Types of changes

Completed

Procedural info

Completed

Proposed changes

Pending

Additional info

Completed

Finalisation

Completed

Variation Form Human / Version: 1.1.1.3 / Application for variation to a marketing authorisation

Braftovi - update of PI section 4.8 Elderly / VAR/25/813 Last Saved : 14/02/2025 15:25

Products concerned by this application ⓘ

Column visibility Show 10 rows Refresh

Associate MRP Nr. Search + Add Product

Full Name	Authorised Dose Form	Active Substance	Authorisation Country	MA Holder	MA Nr. ⓘ	MRP / CP Nr.	PMS ID	MP ID	Authorisation Status	MRP Variation Nr.	Nr. of Selected Packages
^ Braftovi 50 mg hard capsules	Capsule, hard	Encorafenib	European Union	Pierre Fabre Medicament	EU/1/18/1314	EMEA/H/C/004580	600000000288		Valid		2/2
Selected Packaged Medicinal Product(s)											
Search											
	Full Name	Pack Size	Package Description	MA Number	Package ID	Authorisation Status					
☒	Braftovi 50 mg hard capsules	112 capsules	Packaging: blister (PA/alu/PVC/alu/ PET/paper), Package size: 112 capsules	EU/1/18/1314/003		Valid					
☒	Braftovi 50 mg hard capsules	28 capsules	Packaging: blister (PA/alu/PVC/alu/ PET/paper), Package size: 28 capsules	EU/1/18/1314/001		Valid					

^ Braftovi 75 mg hard capsules	Capsule, hard	Encorafenib	European Union	Pierre Fabre Medicament	EU/1/18/1314	EMEA/H/C/004580	6000000003916		Valid		2/2
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Showing 1 to 2 of 2 entries

Save Validate Export Close

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.

ePI



ePI and PMS

EPI/25/84 / Draft
First-time ePI creation / Human / CAP
Name of medicinal product - **New ePI** Procedure Number - **EMA/H/C/1234**

1 Manage ePI 2 Link product 3 Finalisation

Link product

On this page, you can link ePI documents to the medicinal products in PMS they relate to. Select the document then click 'Add/Remove Link' to search and select products. Links will be added to the default language.

Add/Remove Link

Summary of Product Characteristics ^

Full Name	PMS ID
Metalyse 10,000 units powder and solvent for solution for injection	UAT600000001010

More data for linked product

MA number	Data carrier identifier system	Data carrier identifier value
EU/1/00/169/006UAT	-	-
EU/1/00/169/006UAT	-	-
EU/1/00/169/006UAT	-	-
EU/1/00/169/006UAT	GS1 Global Trade Item Number	3400956492602
EU/1/00/169/006UAT	GS1 Global Trade Item Number	4048846015297
EU/1/00/169/006UAT	GS1 Global Trade Item Number	4048846015488
EU/1/00/169/006UAT	GS1 Global Trade Item Number	4048846018335
EU/1/00/169/006UAT	GS1 Global Trade Item Number	4049001000554
EU/1/00/169/006UAT	GS1 Global Trade Item Number	4150014402508
EU/1/00/169/006UAT	GS1 Global Trade Item Number	5012816003071
EU/1/00/169/006UAT	GS1 Global Trade Item Number	5012816081604
EU/1/00/169/006UAT	GS1 Global Trade Item Number	5012816099524
EU/1/00/169/006UAT	GS1 Global Trade Item Number	7046265909194
EU/1/00/169/006UAT	GS1 Global Trade Item Number	8470009494612
EU/1/00/169/006UAT	GS1 Global Trade Item Number	8711642002506
EU/1/00/169/006UAT	GS1 Global Trade Item Number	9006968003863
EU/1/00/169/006UAT	GS1 Global Trade Item Number	9006968005089
EU/1/00/169/006UAT	-	-
EU/1/00/169/006UAT	-	-
EU/1/00/169/006UAT	-	-

Labelling
Package Leaflet

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

Home > Product(s) of my organisation(s) > Packaged Medicinal Product

Beyontra 356 mg - Film-coated tablet
PMS ID : 600001880836 | Authorisation Country : EU | MAH : ORG-100036497 | Authorisation Status : Valid |
Version Number : 2 | Last updated date : 14/02/2025

Medicinal Product > **Packaged Medicinal Product**

Download

MA number	Package size(s)	PCID	EV code	Legal status of supply	Authorisation Status
EU/1/24/1906/001	120 Tablet	—	—	Medicinal product on medical prescription for renewable or non-renewable delivery	Valid

Package description Packaging: blister (PVC/PCTFE/alu), Package size: 120 tablets

Pack Size Open all

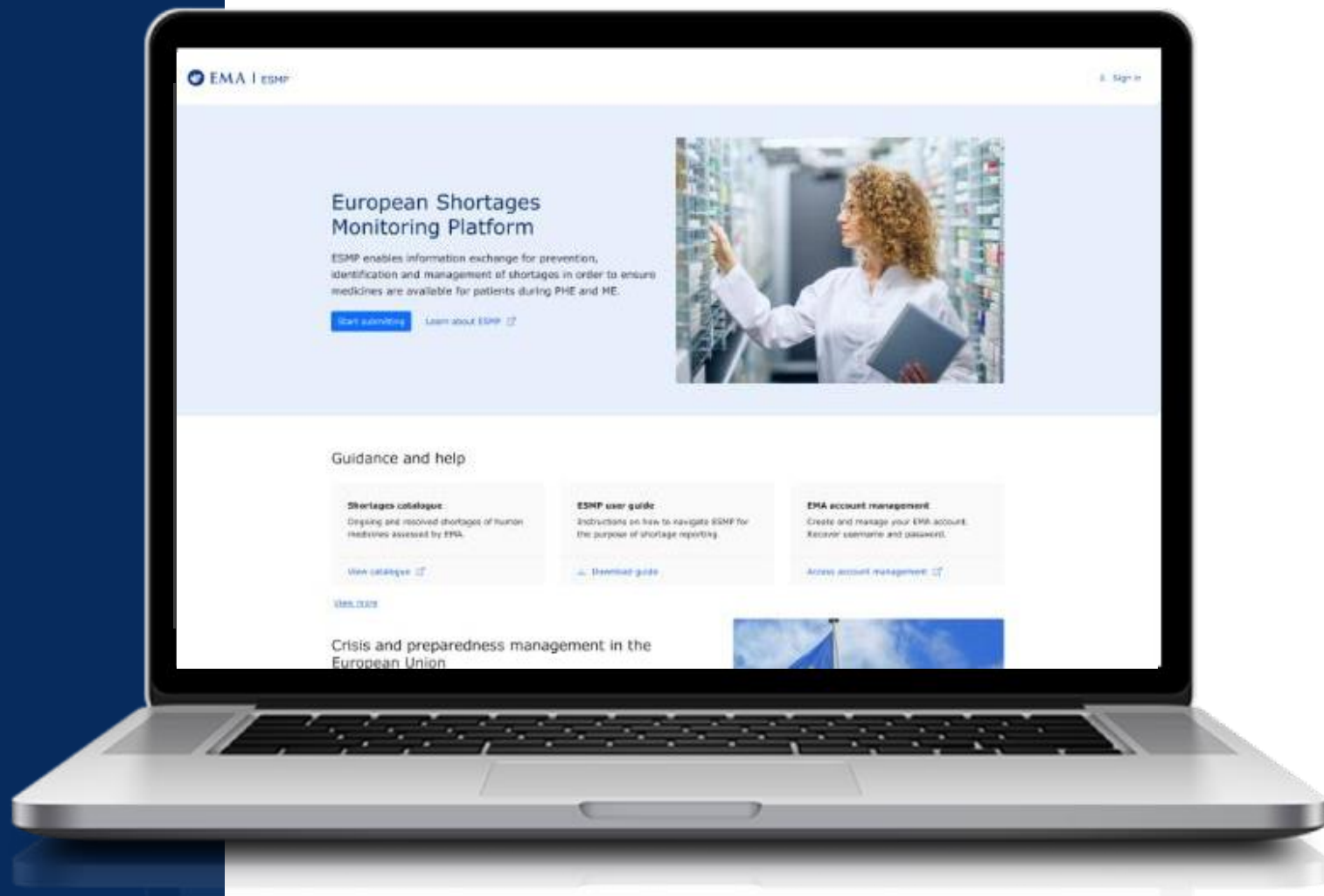
Shelf life / Storage Open

Data carrier identifier(s) Close

Identifier value	Identifier system
⚠ Data are not available in SIAMED/XEVMPD and not loaded. Users are encouraged to provide it when applicable.	

Close Refresh Export to XML

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

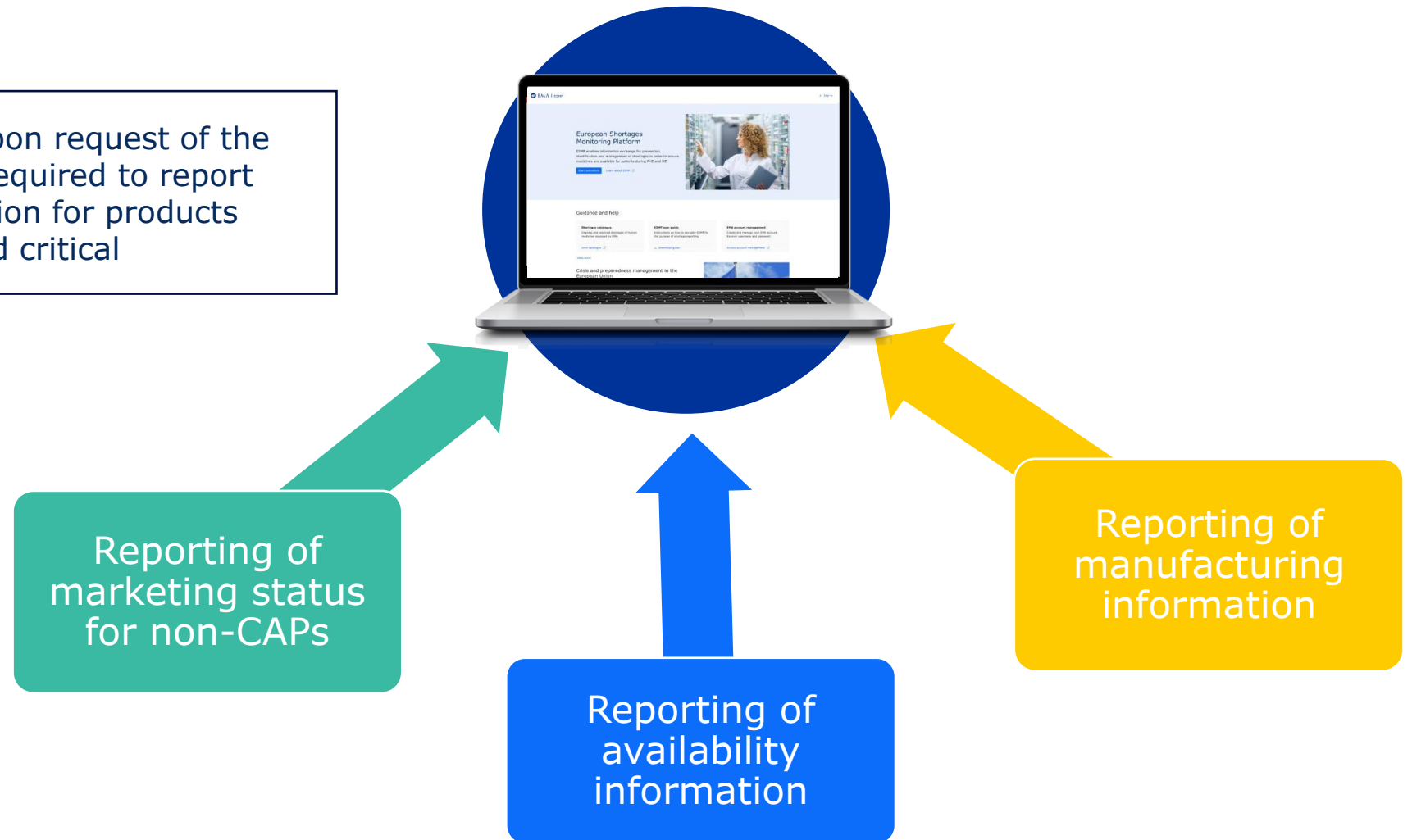
Structured pack size data together with manufacturers and MBOs can be submitted through the Product UI. EMA is working on the implementation of the bulk update functionality and the write PMS API.

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



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)

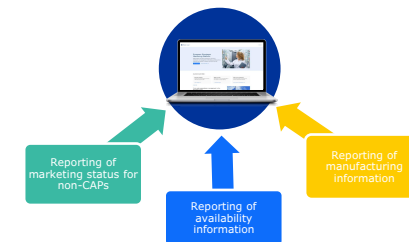
Product information (pre-populated from PMS)	PMS ID (Packaged medicinal product)
	Full product name
	Short product name
	Active substance
	Strength
	Pharmaceutical form
	Pack size
	Packaging
	PCID
Marketing status details	Country of authorisation
	Marketing status
	Date of planned permanent withdrawal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



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

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)

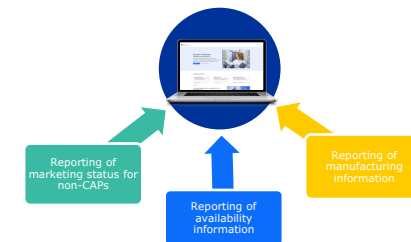
Product information (pre-populated from PMS and IRIS)	PMS ID (Packaged medicinal product)
	Full product name
	Short product name
	Active substance
	Strength
	Pharmaceutical form
	Pack size
	Packaging
	PCID
	Country of authorisation
Shortage information	Marketing status
	Shortage status
	Shortage start 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

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

ESMP and PMS

Reporting of manufacturing information



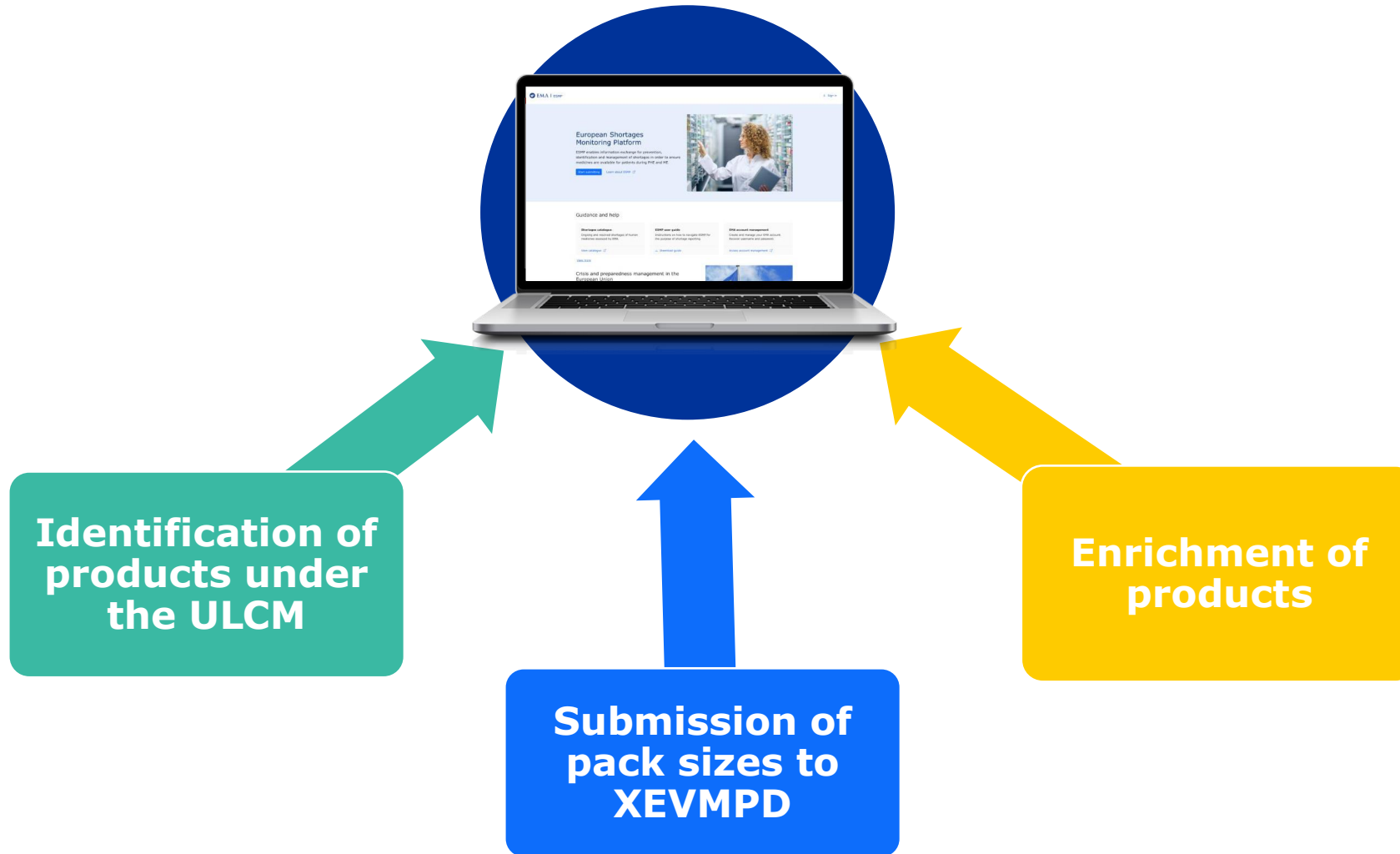
Fields consumed from PMS. This data is coming from either XEVMPD or Product UI (not to be changed in the exported templates)

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

Product information (pre-filled from PMS)	<i>PMS ID (Medicinal product)</i>
	<i>Full product name</i>
	<i>Active substance</i>
Organisation information (pre-filled from PMS and OMS)	<i>Organisation ID (Manufacturer)</i>
	<i>Manufacturer</i>
	<i>Operation type ID</i>
	<i>Operation type</i>
	<i>Location ID (Manufacturer)</i>
	<i>City</i>
	<i>Country</i>
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

Actions for MAHs in relation to ESMP



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)

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

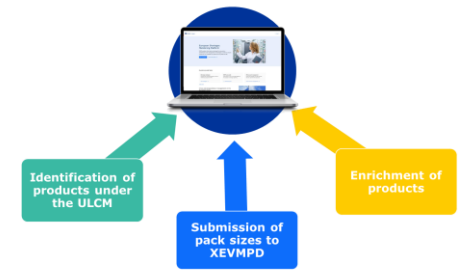
List of EV Codes linked to each product

Route of admin can be filtered

Medicinal Products						
Route of Administration	Full Name	MA Nr.	EV code	MAH/owner	Active substance(s)	
Oral use	Ibukern 600 mg suspensión oral	67.930	PRD2005892	Kern Pharma S.L.	Ibuprofen	
Simultaneous use	Ibudol 50 mg/g gel	62.054	PRD2005882	Kern Pharma S.L.	Ibuprofen	
Oral use	Rizatriptán Flas KERN	77082	PRD795359	Kern Pharma S.L.	Rizatriptan	
Intravenous	Imipenem/Cilastatina Kern Pharma 500 mg/500 mg polvo para solución para perfusión EFG	79.429	PRD3165602	Kern Pharma S.L.	Imipenem monohydrate, Cilastatin sodium	
Oral use	Zonisamida Kern Pharma 25 mg cápsulas duras EFG	80.826	PRD4095788	Kern Pharma S.L.	Zonisamide	
Oral use	Oxicodona Kern Pharma 80 mg comprimidos de liberación prolongada EFG	74696	PRD2707301	Kern Pharma S.L.	Oxycodone hydrochloride	
Oral use	Glimepirida Kern Pharma 4 mg comprimidos EFG	67.670	PRD382834	Kern Pharma S.L.	Glimepiride	
Oral use	Vesolta 6 mg/0,4 mg comprimidos de liberación modificada EFG	88218	PRD9990922	Kern Pharma S.L.	Solifenacin succinate, Tamsulosin hydrochloride	
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

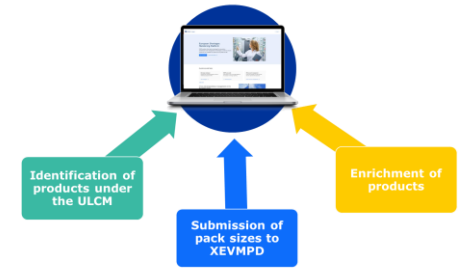


Submission of pack sizes to XEVMPD

- **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

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

Actions for MAHs in relation to ESMP

Submission of pack sizes to XEVMPD

Product Lifecycle Management Portal

Electronic application forms ▾ Electronic product information ▾ Products Management Service ▾ SPOR ▾ IAM IRIS Forum | Marcos Fernandez Gomez ▾

Home > Product(s) of my organisation(s) > Packaged Medicinal Product

Version Number : 1 | Last updated date : 08/10/2024

Medicinal Product ▾

- Marketing Authorisation Information
- Therapeutic Indications
- Manufacturers
- Ingredients
- Medical Devices
- Manufactured Items
- Packaged Medicinal Product**
- Marketing Authorisation Information
- Package Items
- Manufacturers
- Manufactured Items
- Medical Devices

Pharmaceutical Product

Workspace ▾

History

Packaged Medicinal Product

Download

MA number	Package size(s)	PCID	EV code	Legal status of supply	Authorisation Status
123456	—	—	PRD5566	—	Valid
Package description NATURALEZA DEL ENVASE JERINGAS PRECARGADAS DE CRISTAL INCOLORO (TIPO I) DE 1 ML DE CAPACIDAD CON AGUJA DE INYECCIÓN ACOPLADA, ENVASADAS EN BLISTERES, TAPONES DEL ÉMBOLO DE GOMA DE CLOROBUTILO (TIPO I), VARILLAS DE POLIESTIRENO INSERTADAS EN EL					
Language —					
Open all ▾					
Pack Size Open ▾					
Shelf life / Storage Open ▾					
Data carrier identifier(s) Open ▾					
123456	—	—	PRD7788	—	Valid
Package description NATURALEZA DEL ENVASE JERINGAS PRECARGADAS DE CRISTAL INCOLORO (TIPO I) DE 1 ML DE CAPACIDAD CON AGUJA DE INYECCIÓN ACOPLADA, ENVASADAS EN BLISTERES, TAPONES DEL ÉMBOLO DE GOMA DE CLOROBUTILO (TIPO I), VARILLAS DE POLIESTIRENO INSERTADAS EN EL					
Language —					
Open all ▾					
Pack Size Open ▾					
Shelf life / Storage Open ▾					
Data carrier identifier(s) Open ▾					

Showing 1 to 2 of 2 entries

Actions for MAHs in relation to ESMP

Submission of pack sizes to XEVMPD

Product Lifecycle Management Portal

Electronic application forms ▾ Electronic product information ▾ Products Management Service ▾ SPOR ▾ IAM IRIS Forum | Marcos Fernandez Gomez ▾

Home > Product(s) of my organisation(s) > Packaged Medicinal Product

Version Number : 3 | Last updated date : 31/01/2025

Medicinal Product ▾

- Marketing Authorisation Information
- Therapeutic Indications
- Manufacturers
- Ingredients
- Medical Devices
- Manufactured Items
- Packaged Medicinal Product**
- Marketing Authorisation Information
- Package Items
- Manufacturers
- Manufactured Items
- Medical Devices

Pharmaceutical Product

Workspace ▾

- History

Packaged Medicinal Product

Download

MA number	Package size(s)	PCID	EV code	Legal status of supply	Authorisation Status						
123456	—	—	PRD5566	—	Valid						
Package description 10 vials (5 ml) - CN: 76321 Language — Open all ▾ <table><tr><td>Pack Size</td><td>Open ▾</td></tr><tr><td>Shelf life / Storage</td><td>Open ▾</td></tr><tr><td>Data carrier identifier(s)</td><td>Open ▾</td></tr></table>						Pack Size	Open ▾	Shelf life / Storage	Open ▾	Data carrier identifier(s)	Open ▾
Pack Size	Open ▾										
Shelf life / Storage	Open ▾										
Data carrier identifier(s)	Open ▾										
123456	—	—	PRD7788	—	Valid						
Package description 10 vials (2 ml) - CN: 76321 Language — Open all ▾ <table><tr><td>Pack Size</td><td>Open ▾</td></tr><tr><td>Shelf life / Storage</td><td>Open ▾</td></tr><tr><td>Data carrier identifier(s)</td><td>Open ▾</td></tr></table>						Pack Size	Open ▾	Shelf life / Storage	Open ▾	Data carrier identifier(s)	Open ▾
Pack Size	Open ▾										
Shelf life / Storage	Open ▾										
Data carrier identifier(s)	Open ▾										

Showing 1 to 2 of 2 entries

Can you quickly identify which pack size each of the entries belong to?

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.



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 manufacturing operations

All ingredients

All packages 

All ATC codes

All Packages Report

Medicinal Product

Packages													
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	31100		68.830	PRD119	Valid		659107 - 56 Tablet - Blister / Alu - Alu
							31100		68.830	PRD119	Valid		605822 - 100 Tablet - Blister / Alu - Alu
							31754		68.830	PRD54	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 medicinal product)	Full product name	Short product name	Pack size	Packaging	PCID	Country of origin	Marketing status	Shortage status
311100	Olanzapina cinfa 10mg comprimidos EFG	Olanzapina cinfa	56 tablets	Blister		ES	Marketed	No shortage
311100	Olanzapina cinfa 10mg comprimidos EFG	Olanzapina cinfa	100 tablets	Blister		ES	Temporarily unavailable	No shortage
317540	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](#)

Home > Product(s) of my organisation(s) > Packaged Medicinal Product

Beyontra 356 mg - Film-coated tablet
PMS ID : 600001880836 | Authorisation Country : EU | MAH : ORG-100036497 | Authorisation Status : Valid |
Version Number : 2 | Last updated date : 14/02/2025

Packaged Medicinal Product

Download

MA number	Package size(s)	PCID	EV code	Legal status of supply	Authorisation Status
EU/1/24/1906/001	120 Tablet	—	—	Medicinal product on medical prescription for renewable or non-renewable delivery	Valid

Package description Packaging: blister (PVC/PCTFE/alu), Package size: 120 tablets

Language —

Pack Size

Unit of Presentation	Quantity
Tablet	120

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

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

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.

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

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/PD/0000 - Saved

Scientific Content · Parallel Distribution ▾

Applicant Submission MP # Microsoft CRM Portals Owner

General Initial Notification - Parallel Distrib... Post Initial Notice Submission Related ▾

Details of CAP

Product  PRD/0000013068

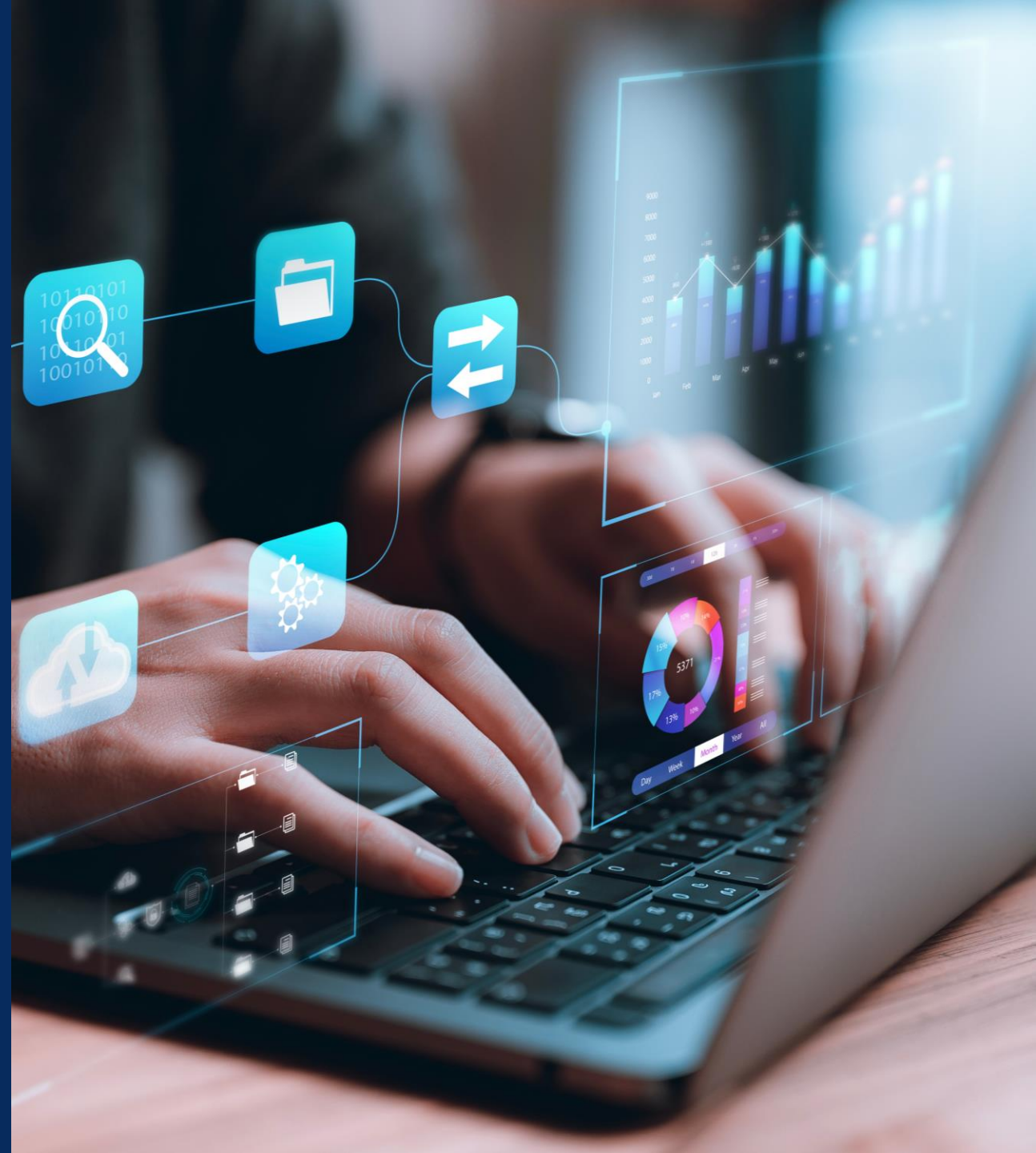
Pack Size Changed  Yes

Sourced presentations

 Add Existing Product (...)  Refresh  Flow ▾  Run Report ▾

☐	EU Number ↑ ▾	Product name ▾	Invented name ▾	Strength ▾	Pharmaceutical form ▾	Packaging ▾	Content ▾	Pack Size ▾	Authorisation status ▾	Product Number ▾
☐	EU/1/17/1231/001	Ocrevus 300 mg concentrate for solution...	Ocrevus	300 mg	Concentrate for solution for infusion	Vial	10 ml (30 mg/ml)	1 vial	Valid	PRD/0000013067

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.

The screenshot displays the EMA PMS interface for a case titled 'EMA/PSUR/0000[REDACTED]'. The interface includes a progress bar with stages: Identify, Assign, Recommendation (8 D), and Resolve. Below the progress bar, there are tabs for Case details, Application details, Products, Timetables and meetings, Industry submissions, Case resources, Outcome, Minutes, EC decision and EPAR update, and Related. The 'Products' tab is active, showing a form for 'Centrally authorised products' and a table of products.

Centrally authorised products

Form fields:

- Invented name: Renagel
- Product Type: Authorisation Medicinal Product
- EU Number: EU/1/99/123
- EMA Number: EMEA/H/C/000254
- MAH/applicant: Sanofi Winthrop Industrie

Buttons: Add packaged products (No), Add Existing Product (...), Refresh, Flow, Run Report, Excel Templates

☐	Invented name	Active substance(s)	EMA Number	EU Number	MAH/owner	SAP Customer Number (MAH/owner)	Product Number	Parent Product	Authorisation status
☐	Renagel	Sevelamer	EMEA/H/C/000254	EU/1/99/123	Sanofi Winthrop Industrie	[REDACTED]	[REDACTED]	[REDACTED]	Valid
☐	Renvela	Sevelamer carbonate	EMEA/H/C/000993	EU/1/09/521	Sanofi Winthrop Industrie	[REDACTED]	[REDACTED]	[REDACTED]	Valid
☐	Sevelamer carbonate ...	Sevelamer carbonate	EMEA/H/C/003971	EU/1/14/952	Sanofi Winthrop Industrie	[REDACTED]	[REDACTED]	[REDACTED]	Valid

Rows: 3

Nationally authorised products (NAP/DCP/MRP)

☐	Invented name	Active substance(s)	EMA Number	EU Number	MAH/owner	SAP Customer Number (MAH/owner)	Product Number	Parent Product	Authorisation status
☐	Sevelamer Ledpharm	Sevelamer carbonate	DK/H/1948/001	022733	O.S.K. Ledpharm Limited	[REDACTED]	[REDACTED]	[REDACTED]	Valid
☐	Sevelamer Sandoz	Sevelamer carbonate	DK/H/1953/001	HR-H-817320041	Sandoz d.o.o.	[REDACTED]	[REDACTED]	[REDACTED]	Valid
☐	Sevelamer Auxilia	Sevelamer carbonate	DK/H/1948/001	845914	Auxilia Pharma OÜ	[REDACTED]	[REDACTED]	[REDACTED]	Valid - Transferred marketing authoris...
☐	Sevelamer carbonat St...	Sevelamer carbonate	DK/H/2248/001	IS/1/17/067/01	STADA Arzneimittel AG	[REDACTED]	[REDACTED]	[REDACTED]	Valid

Summary

eAF

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

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.

ePI

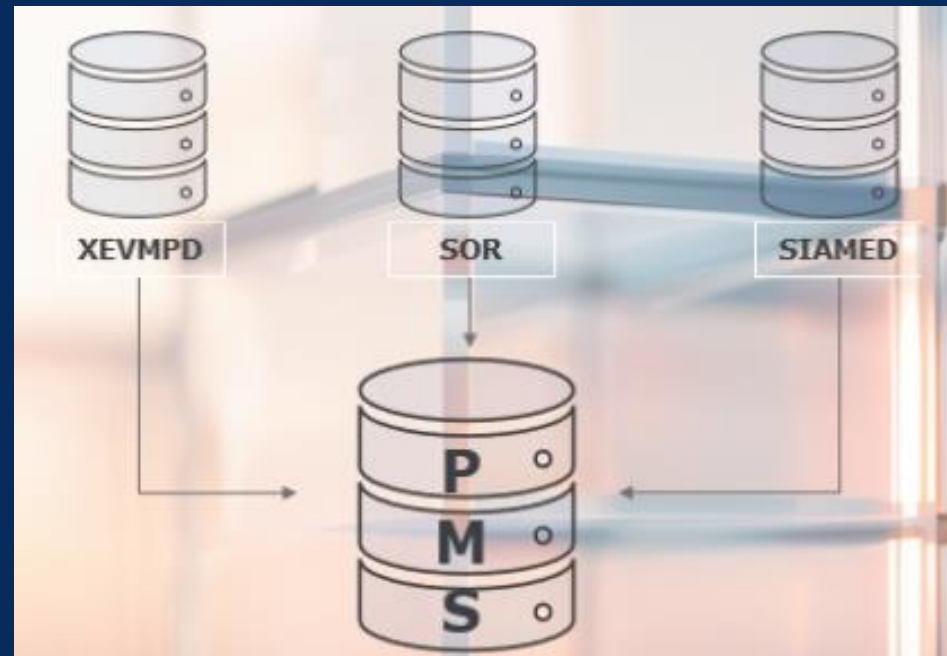
- From Q2 2025, **enrich data carrier ID** through Product UI for non-CAPs with ePIs.
- **For CAPs**, EMA will release additional information

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

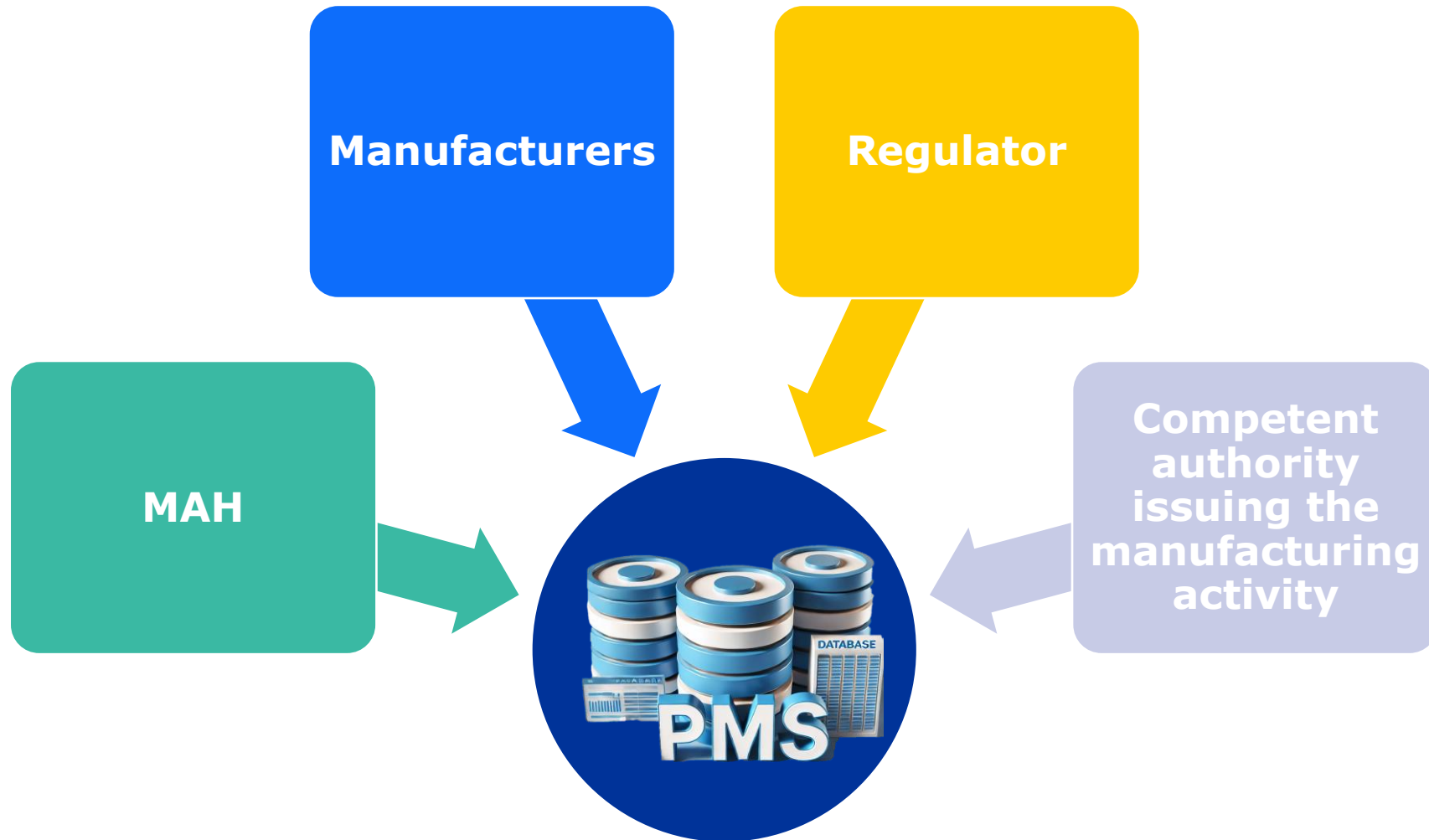


OMS

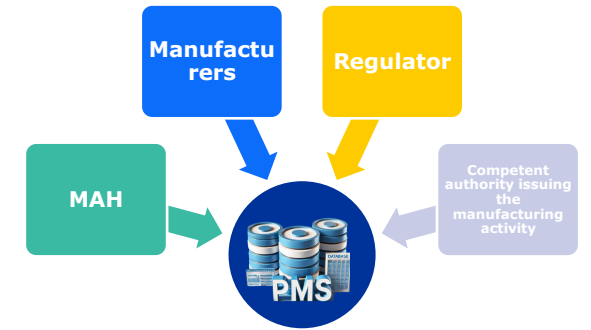
OMS data consumed by PMS



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

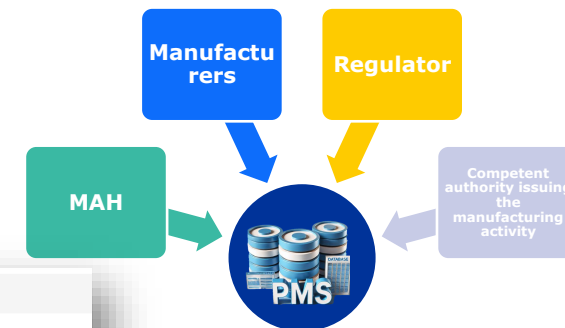
- **Make sure the manufacturer's organisation is present in OMS**
 - Otherwise, please, submit a change request to OMS to create it.

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

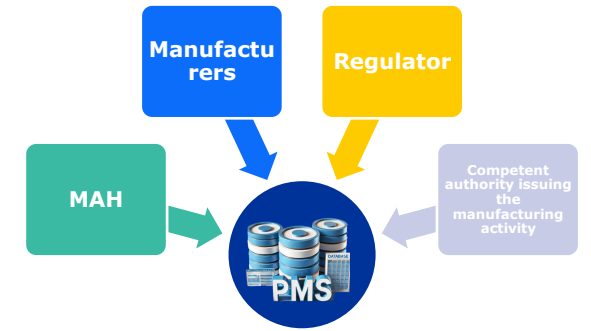
Organisation Details

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

Location Details

Location ID:	LOC-100002956
Address:	EN Calle Venus 72 Poligono Industrial Colom II Terrassa Barcelona 08228 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			ORG-100013839 and ORG-100000703 were merged	
Organisation ID	Organisation Name ▲	Country ▼	Location ID ▼	City ▼		
ORG-100000703	Alcon Healthcare S.A.	Spain	LOC-100044192	Cornella De Llobregat		

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).

In IAM, MAHs can request access to the old organisation

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

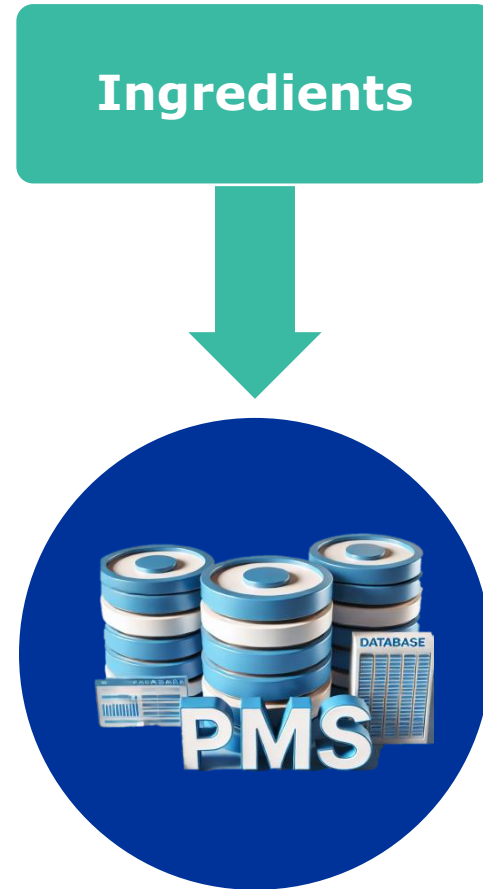
Id		Name	Country	Location
☐	ORG-100000703	Alcon Healthcare S.A.	Spain	LOC-100044192
☐	ORG-100000703	Alcon Healthcare S.A.	Spain	LOC-100009066
☐	ORG-100013839 (Historical)	Alcon Healthcare S.A.	Spain	ORG-100013839 Merged into ORG-100000703

SMS

SMS data consumed by PMS



Use of SMS data in PMS



Actions for MAHs in relation to SMS

Ingredients



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

Actions for MAHs in relation to SMS

Ingredients



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



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



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 long 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



Ingredients

In [SPOR](#), MAHs can download the list of current substances with the information on SVG flag, the replacement substance, etc.

EUROPEAN MEDICINES AGENCY
SPOR - Substances Management System

Substances Products

SPOR Home

Substances Management Services (SMS)

SMS provides a central dictionary of substance data in multiple languages. SMS supports the continuous exchange of information between the European medicines regulatory network and across the pharmaceutical industry.

External users can refer to the [SMS guidance for external users](#) for more detailed information on SMS.

SMS is currently live but not yet available in the SPOR Portal. External users can, however, access the SMS data in the following ways:

- [EUTCT](#) or [IRIS](#) to view and search substance data;

~~Export of substance data are available below:~~

- [Download SMS Export \(current\)](#)
- [Download SMS Export \(non-current\)](#)

For any change requests or general questions about substances, user shall:

- Submit substance change requests in the [EMA Service Desk](#) portal;
- Submit substance general queries in the [EMA Service Desk](#) portal (Service "SPOR", Service Offering "SMS").

Data management and data quality processes drive the SPOR data management services to ensure that the highest data quality is maintained throughout the data management processes.

Actions for MAHs in relation to SMS

Ingredients



Ingredients

#SMS_ID	Substance_N	Is_Pref	Language	Name	Substa	Status	Substa	Molecu	Molecu	Inchike	Comment	EV_Cod	SVG_Flag
100000076694	Ammonia solu	TRUE	English	EUROPEAN	Human us	Current	Specified Substance Group 1					SUB117061	1
100000078041	MAIZE STARCH	TRUE	English	EUROPEAN	Human us	Current	Mixture					SUB20356	1
100000159843	PRIMULA FLOW	TRUE	English	SPC	Human us	Current	Structurally Diverse - Herbal				Duplicate of 100000137994/SUB77	SUB170659	0
300000058425	Opadry 20O580	TRUE	English	COLORCO	Human us	Current	Specified Substance Group 1					SUB416950	1
300000058426	AUTX-703	TRUE	English	INVESTIGA	Human us	Current	Chemical					SUB416951	1
300000058451	ECI830	TRUE	English	INVESTIGA	Human us	Current	Chemical					SUB417081	1
300000058427	LY4045004	TRUE	English	INVESTIGA	Human us	Current	Chemical					SUB416952	1
300000040691	4-(2-[(2-Amino-	TRUE	English	INVESTIGA	Human us	Current	Chemical	C19H20ClN	417.91			SUB258371	1
100000089650	ANHYDROUS Ca	TRUE	English	MARTINDA	Human us	Current	Chemical				Duplicate of 100000089693/SUB13	SUB260771	0
100000085772	Carbomer 940	TRUE	English	SPC	Human us	Current	Polymer					SUB205631	1
100000088994	ARTIFICIAL ORA	TRUE	English	COMPANY	Human us	Current	Specified Substance Group 1				Duplicate of 100000076148/SUB16	SUB235361	0
100000133013	Hydroxyethylce	TRUE	English	USP	Human us	Current	Polymer					SUB494451	1
100000134903	DIISOPROPYL A	TRUE	English	SPC	Human us	Current	Chemical				Duplicate of 100000088709/SUB23	SUB688591	0
100000076353	Ethanol (96 per	TRUE	English	EUROPEAN	Human us	Current	Specified Substance Group 1					SUB119461	1

Actions for MAHs in relation to SMS

Ingredients



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



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

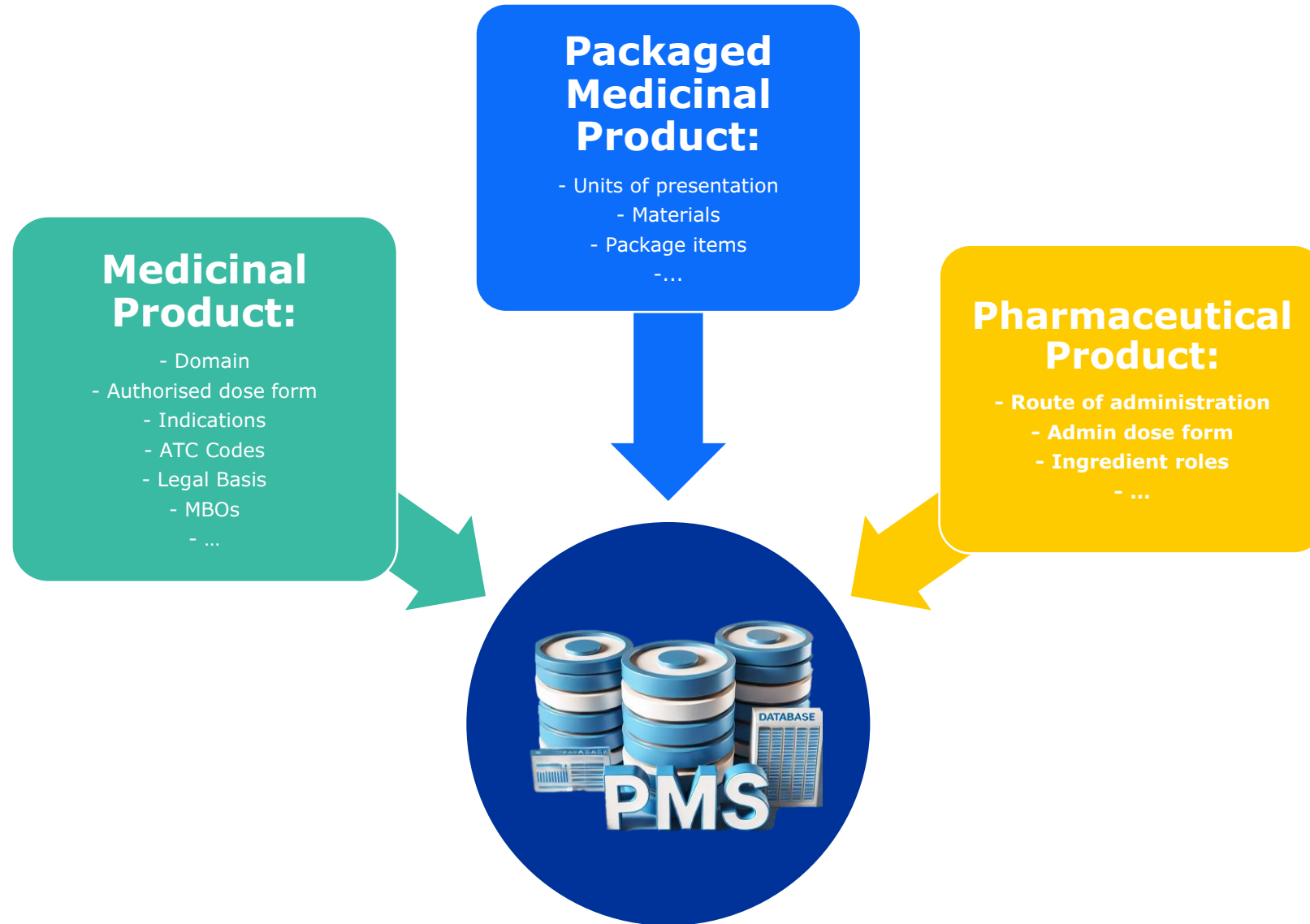
As the specific replacement substance is unclear, EMA will only validate the product and composition if the corresponding reference source of information (SmPC/M3) is provided AND accurately reflects it.

RMS

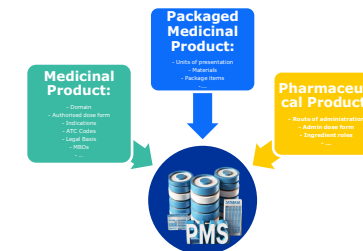
RMS data consumed by PMS



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
------------	----------	---------------	--------------

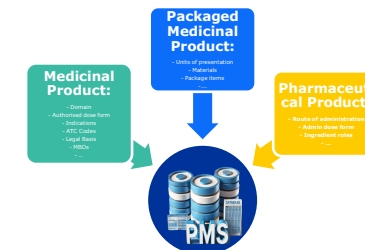
[SPOR Home](#) [Lists](#) [Documents](#)

[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:

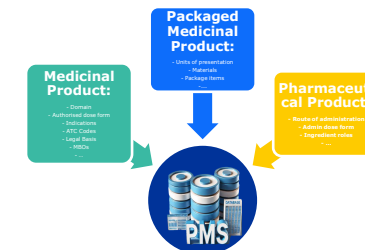
• EMA has released a mapping document for Authorised Dose Forms

- 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	Depends by the product: multiple solutions available	Select the correct pharmaceutical dose form.
CUTANEOUS SPRAY	Pharmaceutical Dose Form	200000016453	Cutaneous spray	NON_CURRENT	Depends by the product: multiple	Depends by the product: multiple solutions available	Select the correct pharmaceutical dose form.
EAR DROPS	Pharmaceutical Dose Form	200000016455	Ear drops	NON_CURRENT	Depends by the product: multiple	Depends by the product: multiple solutions available	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 for
ΠΟΣΙΜΟ ΔΙΑΛΥΜΑ	Pharmaceutical Dose Form	100000073846	Oral solution	CURRENT	PHF00169MIG	Oral solution	Review mapping. Term not to be used for
ΕΠΙΚΑΛΥΜΜΕΝΟ ΔΙΣΚΙΟ	Pharmaceutical Dose Form	100000073839	Inhalation powder	CURRENT	PHF00110MIG	Inhalation powder	Review mapping. Term not to be used for
ΓΑΣΤΡΟΑΝΤΙΣΤΗΝΟ ΔΙΣΚΙΟ	Pharmaceutical Dose Form	100000073667	Gastro-resistant tablet	CURRENT	PHF00094MIG	Gastro-resistant tablet	Review mapping. Term not to be used for

Actions for MAHs in relation to RMS

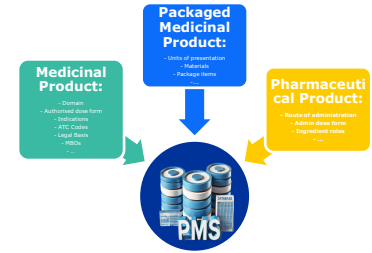


Medicinal Product:

- **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.

XEVMPT ATC Code	XEVMPT Proposed Replacement ATC Code	XEVMPT Proposed Replacement ATC Code Description	RMS List ID	RMS List Name	RMS Term ID	RMS Term Name	RMS Status	XEVMPT 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 antilululents	200000016508	National Classification list	200000016819	A02D	CURRENT	Outdated ATC code. A current ATC code should be added
A02DA	A02AF	antacids with antilululents	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	Sabalıs 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

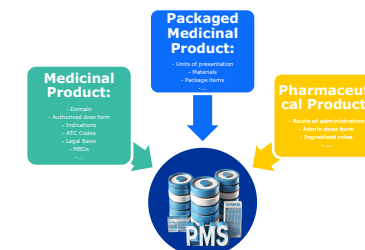


Packaged Medicinal Product

- **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 without	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 without	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 without	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 without	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 without	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 without	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 without	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 without	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 without	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 without	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.

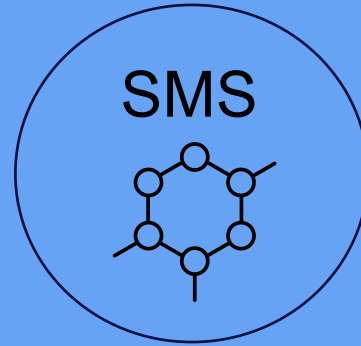
Subdermal use is a legacy term. Subcutaneous use is the current term.

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

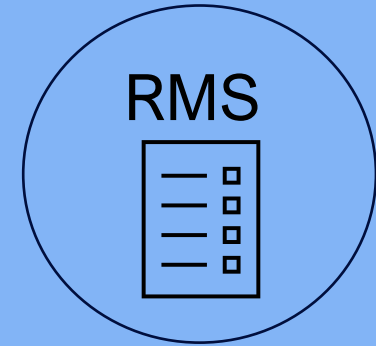
Summary



- 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

Using XEVPMD queries for the review

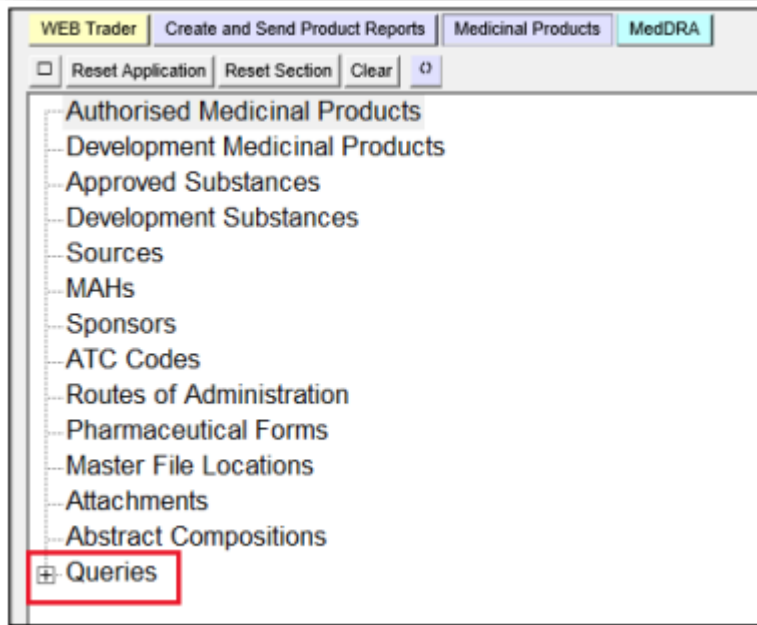
The following tips are just suggestions on how MAHs can review their data.
Other strategies might be followed.



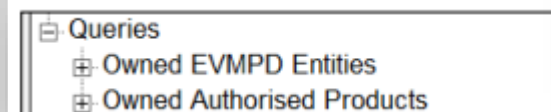
Using XEVPMD queries for the review

- MAHs can use the [advanced queries from XEVPMD](#) 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

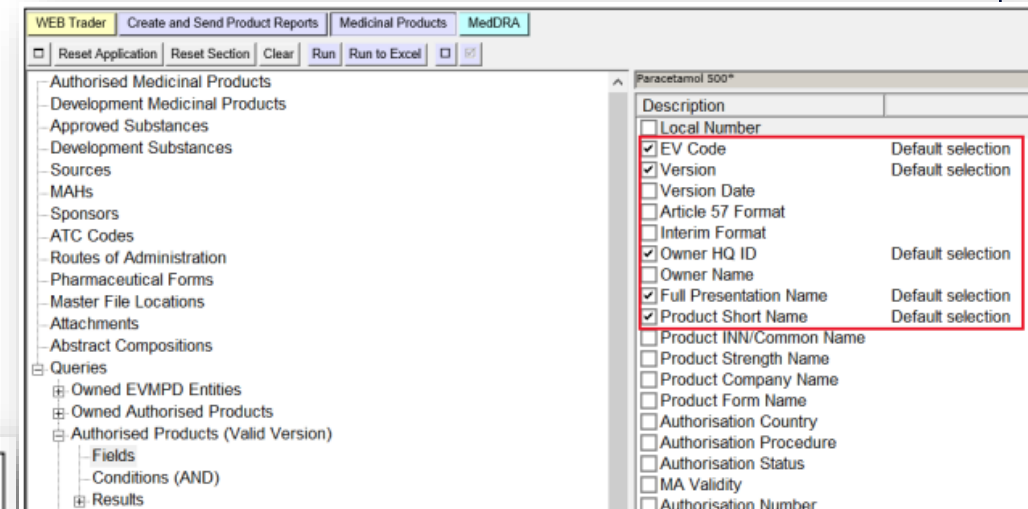
1. Select the queries section in XEVPMD



2. Select Owned Authorised Products

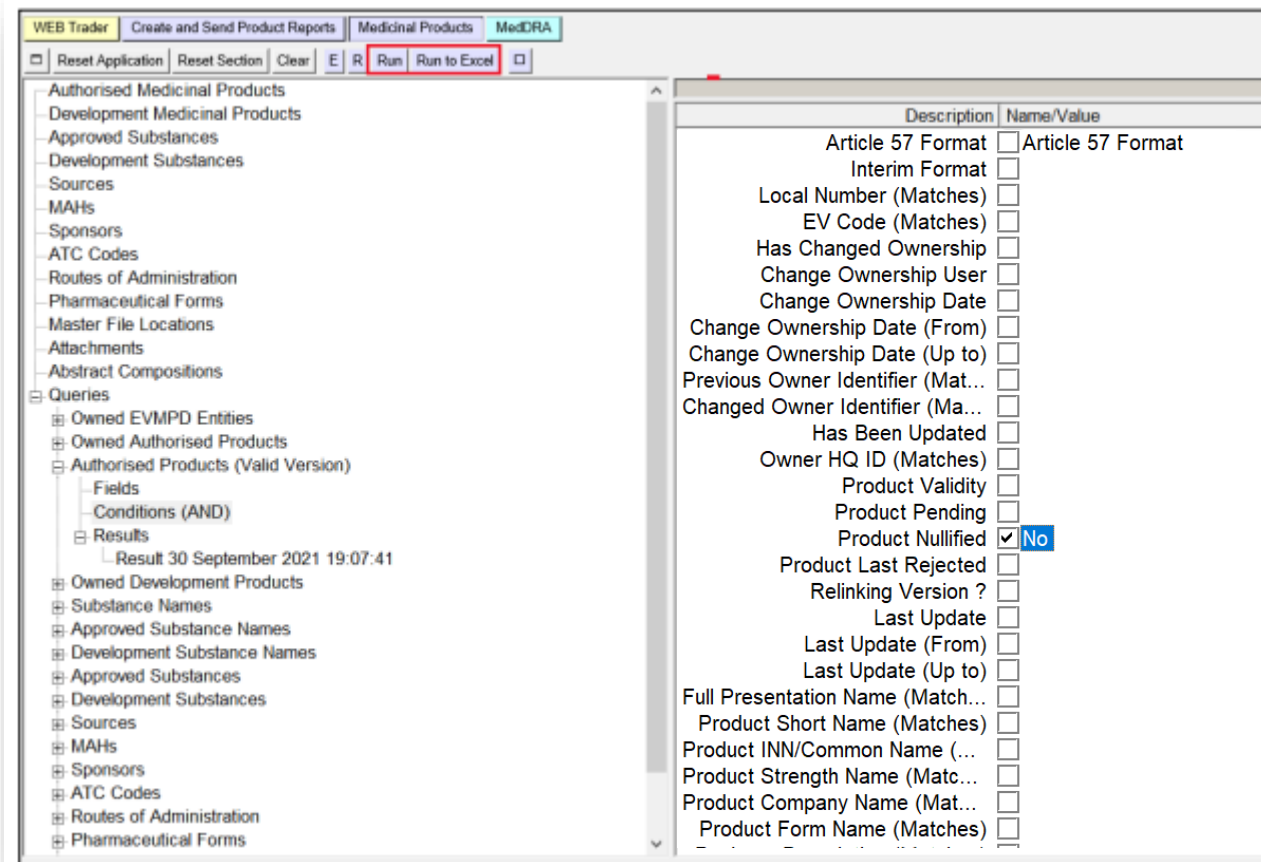


3. Select the different fields you want to export such as EV Code, Product Validity, Full presentation name, Route of administration, Pharmaceutical form, authorisation status, etc



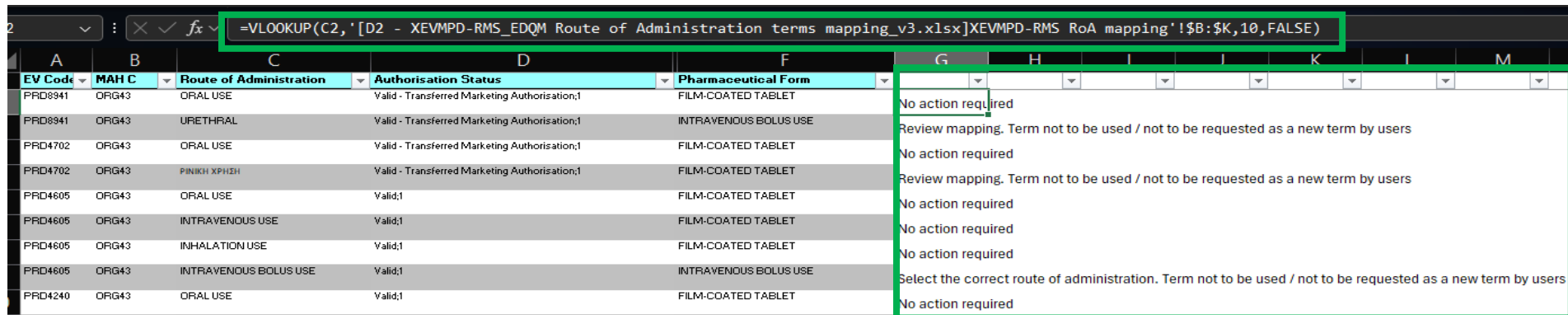
Using XEVPMD queries for the review

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 XEVMPD 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.



The screenshot shows an Excel spreadsheet with a VLOOKUP formula in the formula bar and a data table below it. The formula bar contains the formula: `=VLOOKUP(C2,'[D2 - XEVMPD-RMS_EDQM Route of Administration terms mapping_v3.xlsx]XEVMPD-RMS RoA mapping'!$B:$K,10,FALSE)`. The data table has columns A through M. Columns A, B, C, D, and F are highlighted in light blue. Column A is 'EV Code', B is 'MAH C', C is 'Route of Administration', D is 'Authorisation Status', and F is 'Pharmaceutical Form'. Column G is a dropdown menu with a list of actions. The actions listed are: 'No action required', 'Review mapping. Term not to be used / not to be requested as a new term by users', and 'Select the correct route of administration. Term not to be requested as a new term by users'.

A	B	C	D	F	G	H	I	J	K	L	M
EV Code	MAH C	Route of Administration	Authorisation Status	Pharmaceutical Form							
PRD8941	ORG43	ORAL USE	Valid - Transferred Marketing Authorisation;1	FILM-COATED TABLET	No action required						
PRD8941	ORG43	URETHRAL	Valid - Transferred Marketing Authorisation;1	INTRAVENOUS BOLUS USE	Review mapping. Term not to be used / not to be requested as a new term by users						
PRD4702	ORG43	ORAL USE	Valid - Transferred Marketing Authorisation;1	FILM-COATED TABLET	No action required						
PRD4702	ORG43	PINKISH XPHEN	Valid - Transferred Marketing Authorisation;1	FILM-COATED TABLET	Review mapping. Term not to be used / not to be requested as a new term by users						
PRD4605	ORG43	ORAL USE	Valid;1	FILM-COATED TABLET	No action required						
PRD4605	ORG43	INTRAVENOUS USE	Valid;1	FILM-COATED TABLET	No action required						
PRD4605	ORG43	INHALATION USE	Valid;1	FILM-COATED TABLET	No action required						
PRD4605	ORG43	INTRAVENOUS BOLUS USE	Valid;1	INTRAVENOUS BOLUS USE	No action required						
PRD4240	ORG43	ORAL USE	Valid;1	FILM-COATED TABLET	Select the correct route of administration. Term not to be used / not to be requested as a new term by users						
					No action required						

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

The screenshot shows the 'Eudavigilance xEVMPD Export Manager' interface. At the top left is the European Medicines Agency logo. The title 'Eudavigilance xEVMPD Export Manager' is centered. Below the title, there's a 'Filters' section with a text box and a 'Click the name to display / hide the filter Data and Actions. The Filter Name is highlighted if the filter is valued. The Active Filters section will display the Valued Filters and allow to disable them.' instruction. To the right of the filters is the user information: 'fernandezgom (EVHUMANWT - Eudavigilance Web Trader) Human Production V. 7.42.2.0'. Below the filters, there are several filter categories: 'QPPV', 'Master File Location', 'Owner Organisation', 'Authorisation Country Code', 'Authorisation Procedure', 'Authorisation Status', and 'Any Name'. Each category has a dropdown menu and 'Refresh' and 'Clear' buttons. The 'Authorisation Procedure' dropdown is open, showing options like 'EU authorisation procedures - Centralised Procedure', 'EU authorisation procedures - Mutual Recognition Procedure', 'EU authorisation procedures - Decentralised Procedure', 'EU authorisation procedures - National Procedure', and 'Non EU authorisation procedure'. The 'Authorisation Status' dropdown is also open, showing options like 'Valid', 'Valid - Renewed/Varied Marketing Authorisation', 'Valid - Transferred Marketing Authorisation', 'Valid - Suspended', and 'Valid - Pending national phase'. At the bottom, there's an 'Active Filters' section with a 'Click on the Name of the Filter to disable/enable it' instruction. Below this, there's a table with columns 'MAH / Sponsor', 'Authorisation Procedure', and 'Authorisation Status'. The table has a 'Title' input field, checkboxes for 'xEVMPD' and 'Excel', and a 'Count' of 81. There are also 'Request' and 'Refresh List' buttons.

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SCIENCE. MEDICINES. HEALTH.

Eudavigilance xEVMPD Export Manager

Click the name to display / hide the filter Data and Actions. The Filter Name is highlighted if the filter is valued. The Active Filters section will display the Valued Filters and allow to disable them.

fernandezgom (EVHUMANWT - Eudavigilance Web Trader)
Human Production V. 7.42.2.0

Order: ☐ Code ☐ Text ^

QPPV

Master File Location

Owner Organisation

Authorisation Country Code

Authorisation Procedure

EU authorisation procedures - Centralised Procedure
EU authorisation procedures - Mutual Recognition Procedure
EU authorisation procedures - Decentralised Procedure
EU authorisation procedures - National Procedure
Non EU authorisation procedure

Authorisation Procedures of Products. Lookup automatically executed. Multiple selection list.

Refresh Clear

Authorisation Status

Valid
Valid - Renewed/Varied Marketing Authorisation
Valid - Transferred Marketing Authorisation
Valid - Suspended
Valid - Pending national phase

Authorisation Statuses of Products. Lookup automatically executed. Multiple selection list.

Refresh Clear

Any Name

Active Filters

Click on the Name of the Filter to disable/enable it

MAH / Sponsor

Authorisation Procedure

Authorisation Status

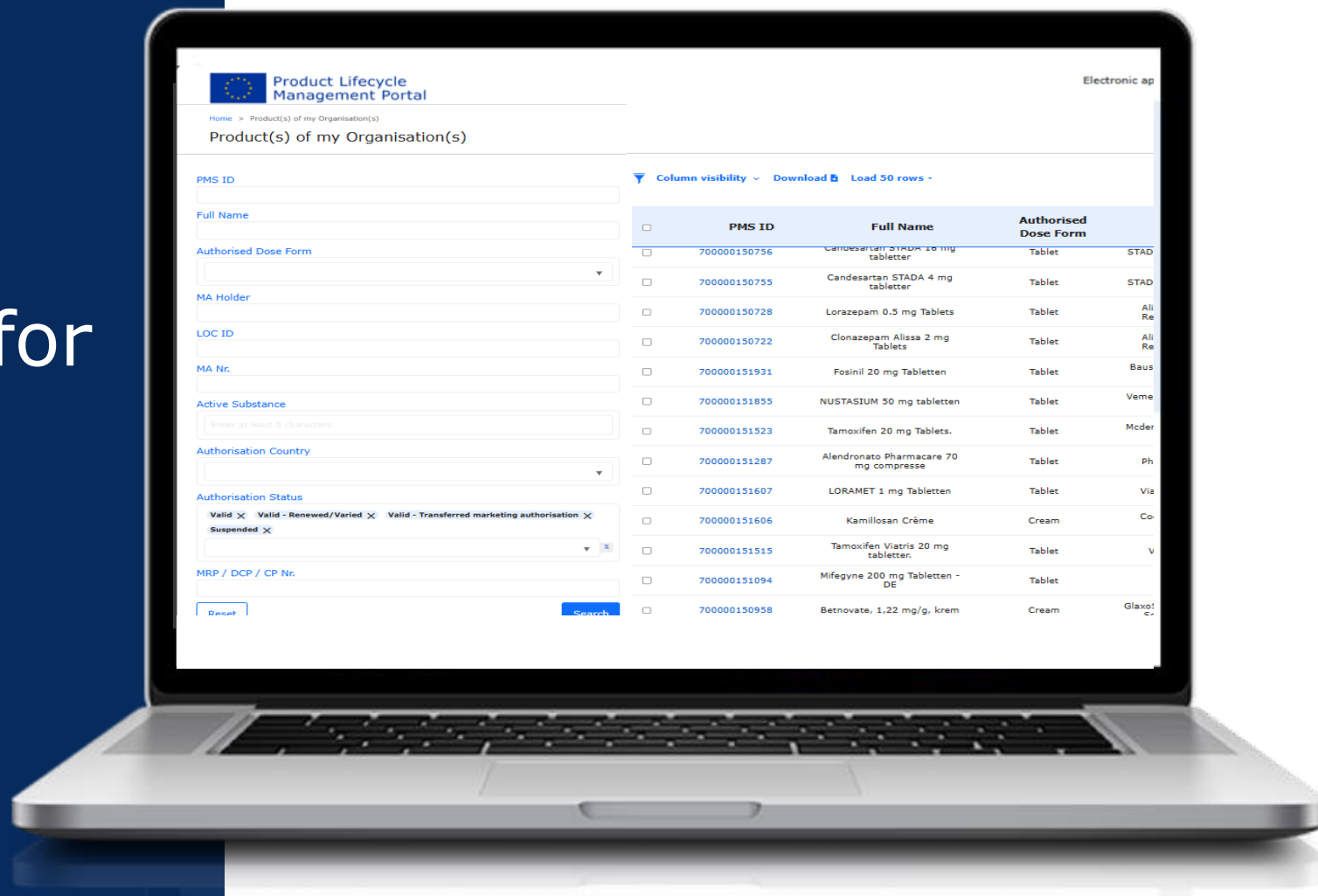
Title:

☐ xEVMPD ☐ (Decoded)
☒ Excel ☒ (Decoded)

Count 81

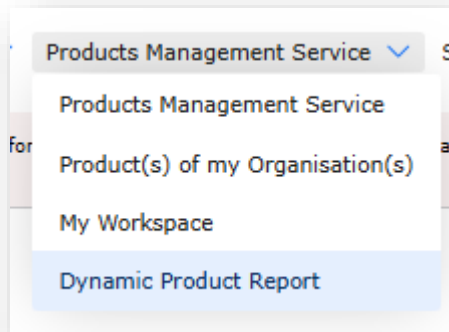
Request Refresh List

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.
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.

Manufacturer												
Operations												
PMS ID	Full Name	Manufacturer	Organisation Id	Location Id	Address	Operation Type	Start date	End date	Effective date	Confidentiality Indicator	Manufacturing Authorisation Reference Number	Medicines Regulatory Agency
600000000006	Idefixir 11 mg powder for concentrate for solution for infusion						14/12/2021			Confidential		European Medicines Agency
							25/08/2020			Confidential		European Medicines Agency
							25/08/2020			Confidential		European Medicines Agency
							25/08/2020			Confidential		European Medicines Agency

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

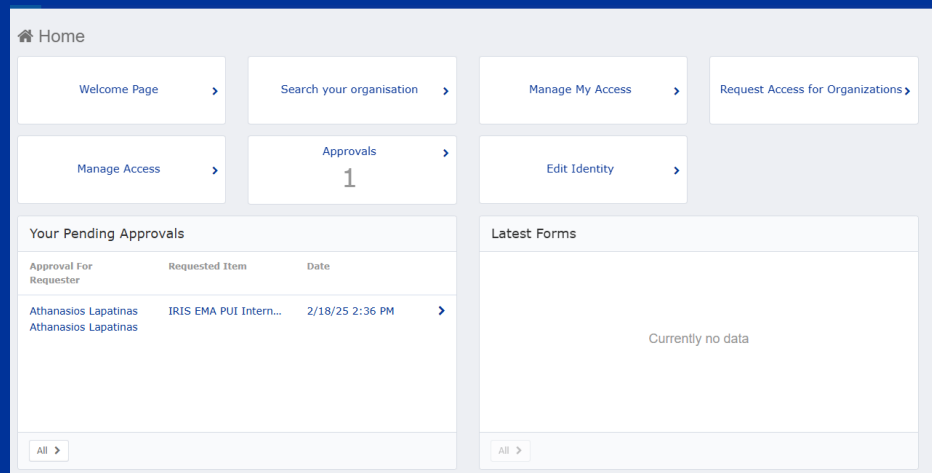
- Use [advanced queries](#) from XEVMPD to export EV Codes' data
- Check if any of the route of administrations or dose forms used by MAH **should be replaced**
- Use [XEVMPD export tool](#) to review substances with SVG =0 (not mandatory for the moment) and ATC Codes

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**

Proposed process to start the PMS journey

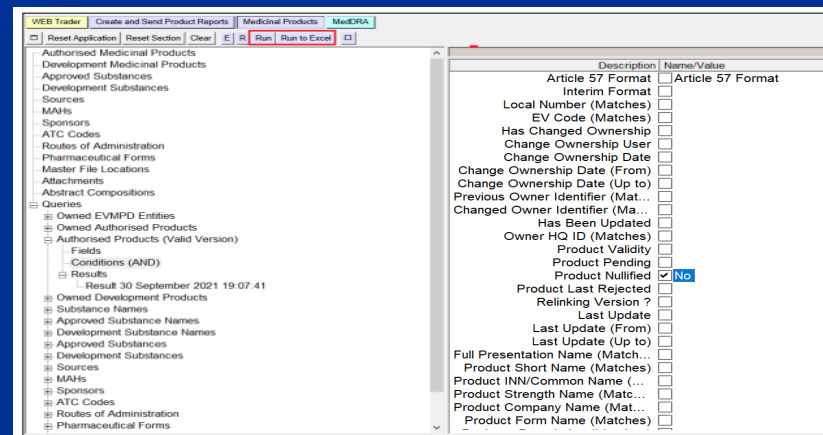
Request access to Product UI



Remember
that access
can be
requested to
historical
organisations

Request access to Product UI

Export EV Codes' data from XEVMPD
advanced queries

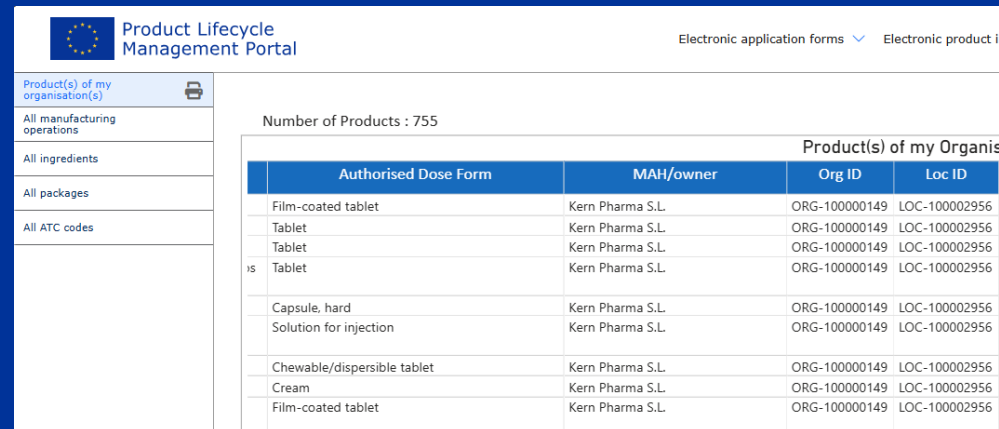


Check the ORG
EV Code for
your records
and the
mappings in
OMS

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



The screenshot displays the 'Product Lifecycle Management Portal' interface. On the left, there is a sidebar with navigation links: 'Product(s) of my organisation(s)', 'All manufacturing operations', 'All ingredients', 'All packages', and 'All ATC codes'. The main content area shows a table titled 'Product(s) of my Organisation' with the following columns: 'Authorised Dose Form', 'MAH/owner', 'Org ID', and 'Loc ID'. The table lists several products, all owned by 'Kern Pharma S.L.', with 'Org ID' 'ORG-100000149' and 'Loc ID' 'LOC-100002956'. The products include 'Film-coated tablet', 'Tablet', 'Capsule, hard', 'Solution for injection', 'Chewable/dispersible tablet', 'Cream', and 'Film-coated tablet'.

Product(s) of my Organisation			
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	200000016508
A02AF		antacids with antilululents	200000016508	National Classification list	200000016508
A02AF		antacids with antilululents	200000016508	National Classification list	200000016508
A02AH		Antacids with sodium bicarbonate	200000016508	National Classification list	200000016508
C03AA02		Losartan	200000016508	National Classification list	200000016508
C03EB		other cardiac preparations	200000016508	National Classification list	200000016508
G04C02		Sabalb serrulatae fructus	200000016508	National Classification list	200000016508
M01AB05		ketorolac	200000016508	National Classification list	200000016508
N07BC02		methadone	200000016508	National Classification list	200000017000
N02BE51		paracetamol combinations excl. psycholeptics	200000016508	National Classification list	200000017000
A06A001		Thiostic acid	200000016508	National Classification list	200000017000
S01EE01		latanoprost	200000016508	National Classification list	200000017000
V03AF03		calcium folinate	200000016508	National Classification list	200000017000
N07BB04		naltrexone	200000016508	National Classification list	200000017000
H05ED02		paricalcitol	100000035333	Anatomical Therapeutic Chemical classification system - Human	100000034400
J05AP54		elbasvir and grazoprevir	100000035333	Anatomical Therapeutic Chemical classification system - Human	2000000032
L01DA03		glasdegib	100000035333	Anatomical Therapeutic Chemical classification system - Human	2000000103
L01EX02		larotrectinib	100000035333	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

Product Lifecycle Management Portal

Electronic application forms Electronic product information

Product(s) of my organisation(s)

All manufacturing operations

All ingredients

All packages

All ATC codes

All Packages Report

Medicinal Product

Packages								
PMS ID	Full Name	Authorisation Country	Authorisation Status	MA Holder	Org ID	Loc ID	Package ID	PCID
600001435681	Ibukern 600 mg suspensión oral	Kingdom of Spain	Valid	Kern Pharma S.L.	ORG-100000149	LOC-100002956	31360349	
600001435724	Ibudol 50 mg/g gel	Kingdom of Spain	Valid - Transferred marketing authorisation	Kern Pharma S.L.	ORG-100000149	LOC-100002956	31349504	
600001436207	Rizatriptán Flax KERN PHARMA 10 mg comprimidos bucodispersables EFG	Kingdom of Spain	Valid	Kern Pharma S.L.	ORG-100000149	LOC-100002956	31691567	

Try to identify duplicates looking for duplicates in the product name

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

Product Lifecycle Management Portal

Electronic application forms Electronic product information

Product(s) of my organisation(s)

All manufacturing operations

All ingredients

All packages

All ATC codes

ATC Code

All

Manufacturing Operation

Medicinal Products

PMS ID	ATC Code	Route of Administration	Full Name	MA Nr.	
600001435681	M01AE01	Oral use	Ibukern 600 mg suspensión oral	67.930	PRD2
600001435724	M02AA13	Cutaneous use	Ibudol 50 mg/g gel	62.054	PRD2
600001436207	N02CC04	Oral use	Rizatriptán Flas KERN PHARMA 10 mg comprimidos bucodispersables EFG	77082	PRD7
600001437366	J01DH51	Intravenous use	Imipenem/Cilastatina Kern Pharma 500 mg/500 mg polvo para solución para perfusión EFG	79.429	PRD3

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



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SCIENCE MEDICINES HEALTH

Thank you

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