



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Pack Size Submissions: from XEVMPD to PMS

11 July 2024, 10:00 – 11:30 Central European Summer Time (CEST)

Presented by Marcos Fernandez Gomez on 11th July 2024

An agency of the European Union





1

Welcome

5 min

Marcos Fernández Gomez,
PMS Product Co-Owner, EMA

2

Background

10 min

Marcos Fernández Gomez,
PMS Product Co-Owner, EMA

3

Submission of pack size information through XEVMPD

40 min

Marcos Fernández Gomez,
PMS Product Co-Owner, EMA

4

Next steps

5 min

Marcos Fernández Gómez,
PMS Product Co-Owner, EMA

5

Q&A

25 min

Moderator: Caterina Scarpati,
PMS Change Management Team

6

Closing

5 min

Veronica Lipucci Di Paola,
PMS Product Co-Owner, EMA
Marcos Fernández Gómez,
PMS Product Co-Owner, EMA



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



At certain points throughout the session, participants will be able to ask questions or give their input via the audience interaction tool **Slido**.

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- **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 (unanswered) top voted questions** at the end in the live Q&A session.



Unanswered questions

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



Background

ESMP as a consumer of PMS data



The EMA's role in **crisis preparedness and management** in reference to availability of medicinal products has increased significantly following the outbreak of the Covid-19 pandemic. **Regulation 2022/123** formalises the structures and processes established during the pandemic.



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Vision

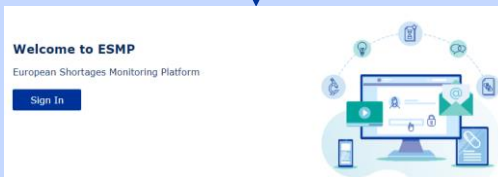
ESMP will enable **information exchange** for better **prevention, identification** and **management of shortages**, and communication between the EMA, National Competent Authorities and Industry stakeholders to **ensure medicines availability** for patients during Public Health Emergencies and Major Events.

Member State data systems

NCAs report critical national shortages and provide data on demand for medicinal products in crisis and in preparedness situations

Industry data systems

MAHs perform routine shortage reporting and provide data on supply of medicinal products in crisis and in preparedness situations

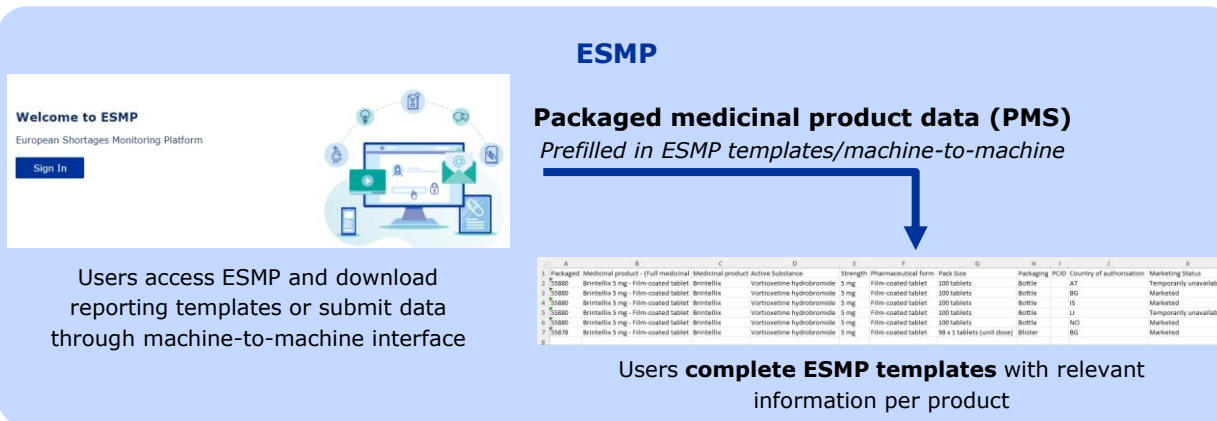


Users access ESMP and download reporting templates or submit data through machine-to-machine interface

ESMP

Packaged medicinal product data (PMS)
Prefilled in ESMP templates/machine-to-machine

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ESMP consumes data from PMS.

More specifically, ESMP requires Medicinal Products and Packaged Medicinal Products from PMS

ESMP pre-filled templates will show PMS data.

Product (package ID and name)

Active substance, strength and dose form

**Structured pack size data
(quantity and units of presentation)**

Product Information									
Packaged medicinal product ID (PMS ID)	Medicinal product (Full medicinal product name)	Medicinal product (Invented name)	Active Substance	Strength	Pharmaceutical form	Pack Size	Packaging	PCID	Country of authorisation
P1.1	P1.2	P1.3	P1.4	P1.5	P1.6	P1.7	P1.8	P1.9	P1.10
Mandatory	Optional	Optional	Optional	Optional	Optional	Optional	Optional	Optional	Mandatory
76708	Xeljanz 5 mg - Film-coated tablet	Xeljanz	tofacitinib	5 mg	Film-coated tablet	60 tablets	Bottle		BE
76706	Xeljanz 10 mg - Film-coated tablet	Xeljanz	tofacitinib	10 mg	Film-coated tablet	180 tablets	Blister		NL
76707	Xeljanz 11 mg - Tablet, prolonged-release	Xeljanz	tofacitinib	11 mg	Prolonged-release tablet	112 tablets	Blister		AT
76709	Xeljanz 1 mg/ml - Oral solution	Xeljanz	tofacitinib	1 mg/ml	Oral solution	1 bottle + 1 syringe	Bottle		DE



For more information on ESMP, please consult the "ESMP Essentials and Industry Reporting Requirements" webinar materials [here](#)



How is pack size information included in PMS?

From SIAMED and XEVMPD to PMS

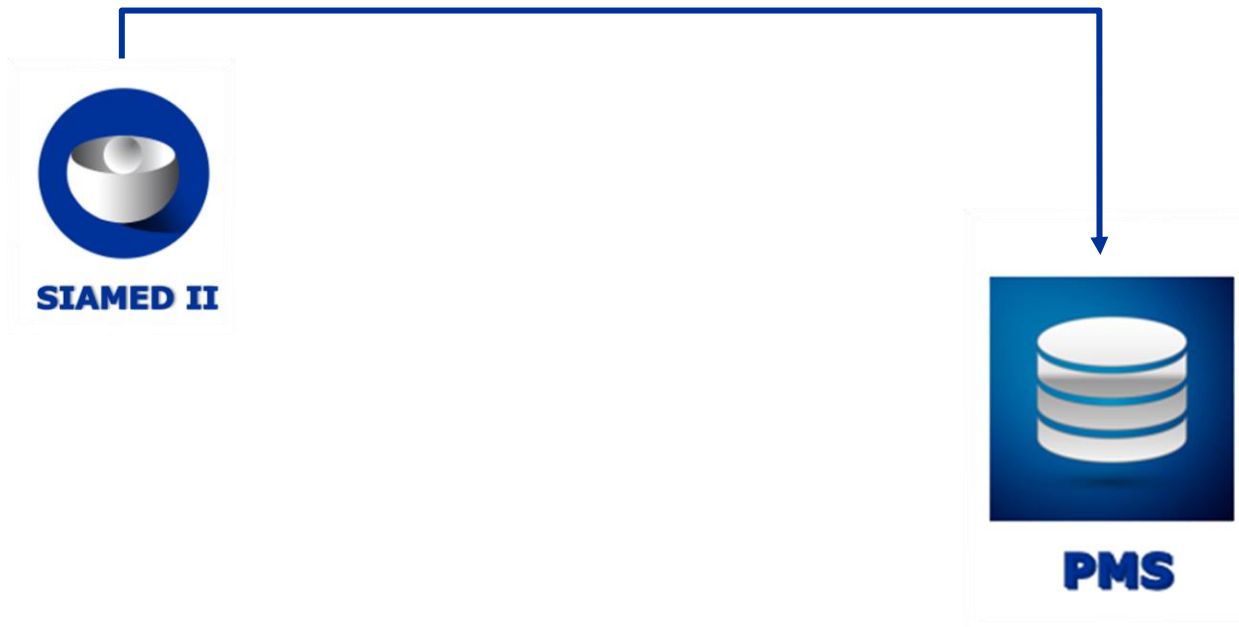




SIAMED II is the internal EMA database and contains all centrally authorised medicinal products in the EU.

In SIAMED II, a “product” is an umbrella term which can contain several IDMP medicinal products, and each medicinal product can contain multiple presentations.

Selected product		Product number	EMEA/H/C/002157
Umbrella product		Product (Invented) name	Skilarence
Product	Product relationships	Form/Strength/Presentation	Manufacturers
120 mg - Gastro-resistant tablet		Medicinal products	Packaged medicinal products
30 mg - Gastro-resistant tablet			
Medicinal products		EU number	
		EU/1/17/1201/002	
		EU/1/17/1201/003	
		EU/1/17/1201/004	
		EU/1/17/1201/005	
		EU/1/17/1201/006	
		EU/1/17/1201/007	



Skilarence 30 mg gastro-resistant tablets

PMS ID: 600000002964 | Authorisation Country: EU | MAH: ORG-100000571 | Authorisation Status: Valid
Version Number: 3 | Last updated date: 20/06/2024

Medicinal Product

Marketing Authorisation Information

Therapeutic Indications

Manufacturers

Ingredients

Medical Devices

Manufactured Items

⏏

⏏

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⏏

Packaged Medicinal Product

Download

	MA number	Package size(s)	PCID	EV code	Legal status of supply
⏏	EU/1/17/1201/001	42 tablets	—	PRD5131781	Medicinal product subject to medical prescription
⏏	EU/1/17/1201/013	70 tablets	—	PRD7628868	Medicinal product subject to medical prescription
⏏	EU/1/17/1201/014	210 tablets	—	PRD7628869	Medicinal product subject to medical prescription

Showing 1 to 3 of 3 entries

Close

Refresh

Export to XML

Full presentation name **Pack size MA number** **Package description** **EV Code** **Structured pack size data**

Skilarence 30 mg gastro-resistant tablets

PMS ID: 600000002964 | Authorisation Country: EU | MAH: ORIG-100000571 | Authorisation status: Valid
Version Number: 3 | Last updated date: 20/06/2024

Medical Product > **Packaged Medicinal Product**

Download

MA number	Package size(s)	PCID	EV code	Legal status of supply
EU/1/17/1201/001	42 tablets	—	PRD5131781	Medicinal product subject to medical prescription

Package description Packaging: blister (PVC/PVDC-alu), Package size: 42 tablets

Language —

Pack Size

Unit of Presentation	Quantity
Tablet	42

Shelf life / Storage Open

Data carrier identifier(s) Open

EU/1/17/1201/013	70 tablets	—	PRD7628868	Medicinal product subject to medical prescription
EU/1/17/1201/014	210 tablets	—	PRD7628869	Medicinal product subject to medical prescription

Showing 1 to 3 of 3 entries

In PMS:

- All pack sizes are migrated from SIAMED

MA number
EU/1/17/1201/001
EU/1/17/1201/013
EU/1/17/1201/014

and there is a relationship with XEVMPD

EV code
PRD5131781
PRD7628868
PRD7628869

- Package description is a concatenation of different fields in SIAMED (packaging + package size + content)

Package description Packaging: blister (PVC/PVDC-alu), Package size: 42 tablets

- Structured pack size data comes from SIAMED

Unit of Presentation	Quantity
Tablet	42



Skilarence 30 mg gastro-resistant tablets

PMS ID: 600000002964 | Authorisation Country: EU | MAH: ORG-10000571 | Authorisation Status: Valid
Version Number: 3 | Last updated date: 20/06/2024

Medical Product

Marking Authorisation Information

Therapeutic Indications

Manufacturers

Ingredients

Medical Devices

Manufactured Items

Packaged Medicinal Product

Marking Authorisation Information

Package Items

Manufacturers

< Packaged Medicinal Product

Download

MA number	Package size(s)	PCID	EV code	Legal status of supply
EU/1/17/1201/001	42 tablets	—	PRD5131781	Medicinal product subject to medical prescription

Package description Packaging: blister (PVC/PVDC-alu), Package size: 42 tablets

Language —

Pack Size

Unit of Presentation	Quantity
Tablet	42

 **Ogluo 1 mg solution for injection in pre-filled syringe.**

PMS ID: 60000993436 | Authorisation Country: EU | MAH: ORG-100037904 | Authorisation Status: Valid - Transferred marketing authorisation
Version Number: 6 | Last updated date: 27/06/2024

 Medicinal Product  **< Packaged Medicinal Product**

 Download

 	MA number	Package size(s)	PCID	EV code	Legal status of supply
	EU/1/20/1523/003	1 pre-filled syringe	—	PRD9373846	Medicinal product subject to medical prescription
	EU/1/20/1523/004	2 pre-filled syringes	—	PRD9373843	Medicinal product subject to medical prescription

Showing 1 to 2 of 2 entries

- All pack sizes are migrated from SIAMED and there is a relationship with XEVMPD

Ogluo 1 mg solution for injection in pre-filled syringe.

PMS ID: 60000993436 | Authorisation Country: EU | MAH: ORG-100037904 | Authorisation Status: Valid - Transferred marketing authorisation
Version Number: 6 | Last updated date: 27/06/2024

- 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

Download

MA number	Package size(s)	PCID	EV code	Legal status of supply
EU/1/20/1523/003	1 pre-filled syringe	—	PRD9373846	Medicinal product subject to medical prescription

Package description Packaging: pre-filled syringe (COP), Package size: 1 pre-filled syringe, Content: 0.1 ml | **Language** —

Pack Size

Unit of Presentation	Quantity
Syringe	1

Shelf life / Storage

Data carrier identifier(s)

Structured pack size data comes from SIAMED

EU/1/20/1523/004	2 pre-filled syringes	—	PRD9373843	Medicinal product subject to medical prescription
------------------	-----------------------	---	------------	---

Package description Packaging: pre-filled syringe (COP), Package size: 2 pre-filled syringes, Content: 0.1 ml | **Language** —

Pack Size

Unit of Presentation	Quantity
Syringe	2

Continue business as usual:

- Submit and maintain authorised medicinal products to XEVMPD

4 records per presentation

- 1 record for EU
- 3 records for IS, LI, NO (EEA countries)

- *Package description is still optional.*
This information will be taken from SIAMED

Make sure **match and merge** is performed in PMS and the **EV code is present** in the product UI or the PMS API

→ *Currently there is a bug and some products don't have the EV code. PMS team is working on this.*



XEVMPD is a database maintained by marketing authorization holders and contains central and national medicinal products authorised in the EU and EEA.

This database is maintained following the Art. 57 legal obligation and medicinal products can be submitted following different strategies and business rules explained in Chapter 3.II: XEVPRM User Guidance



Authorisation Country	Substance names	Pharmaceutical Form	Full Presentation Name	Authorisation Number
Romania	CROSPVIDONE, LACTOSE MONOHYDRATE, MAGNESIUM STEARATE, SILICA, CO	TABLET	Flamexin, 20 mg, comprimate	7146/2006/03
Romania	CROSPVIDONE, LACTOSE MONOHYDRATE, MAGNESIUM STEARATE, SILICA, CO	TABLET	Flamexin, 20 mg, comprimate	7146/2006/01
Romania	CROSPVIDONE, LACTOSE MONOHYDRATE, MAGNESIUM STEARATE, SILICA, CO	TABLET	Flamexin, 20 mg, comprimate	7146/2006/02

Authorisation Country	Substance names	Pharmaceutical Form	Full Presentation Name	Authorisation Number
Spain	HYDROGENATED VEGETABLE OIL, HYDROXYPROPYL DISTARCHPHOSPHAT PROLONGED-RELEASE TABLET		DOLPAR 300 mg comprimidos de liberación prolongada	67.587
Spain	HYDROGENATED VEGETABLE OIL, HYDROXYPROPYL DISTARCHPHOSPHAT PROLONGED-RELEASE TABLET		DOLPAR 100 mg comprimidos de liberación prolongada	67.585
Spain	HYDROGENATED VEGETABLE OIL, HYDROXYPROPYL DISTARCHPHOSPHAT PROLONGED-RELEASE TABLET		DOLPAR 200 mg comprimidos de liberación prolongada	67.586





*Marketing Authorisation number is provided at **pack size level***

*Marketing Authorisation number is provided at **medicinal product level***



*Marketing Authorisation number is provided at **pack size level***

Countries
such as
HU, LI, IT,
RO or SI

Repaglinide Aurobindo 2 mg compresse

041739210 "2mg compresse" 1 compressa in blister pa/al/pvc-al
041739222 "2mg compresse" 28 compresse in blister pa/al/pvc-al
041739234 "2mg compresse" 30 compresse in blister pa/al/pvc-al
041739246 "2mg compresse" 90 compresse in blister pa/al/pvc-al
041739259 "2mg compresse" 100 compresse in blister pa/al/pvc-al
041739261 "2mg compresse" 180 compresse in blister pa/al/pvc-al
041739273 "2mg compresse" 270 compresse in blister pa/al/pvc-al

*Marketing Authorisation number is provided at **medicinal product level***



*Marketing Authorisation number is provided at **pack size level***

Countries
such as
HU, LI, IT,
RO or SI

Repaglinide Aurobindo 2 mg compresse

041739210 "2mg compresse" 1 compressa in blister pa/al/pvc-al
041739222 "2mg compresse" 28 compresse in blister pa/al/pvc-al
041739234 "2mg compresse" 30 compresse in blister pa/al/pvc-al
041739246 "2mg compresse" 90 compresse in blister pa/al/pvc-al
041739259 "2mg compresse" 100 compresse in blister pa/al/pvc-al
041739261 "2mg compresse" 180 compresse in blister pa/al/pvc-al
041739273 "2mg compresse" 270 compresse in blister pa/al/pvc-al

*Marketing Authorisation number is provided at **medicinal product level***

Countries
such as
DE, ES, AT
or PO

6.5. Naturaleza y contenido del envase

Comprimidos recubiertos con película

Blisteres de aluminio (PA/Al/PVC/Al) en un estuche que contiene 14, 28 u 84 comprimidos recubiertos con película.

Puede que solamente estén comercializados algunos tamaños de envases.

*Marketing Authorisation number is provided at **pack size level***

Repaglinide Aurobindo 2 mg compresse

PMS ID: 600001128171 | Authorisation Country: IT | MAH: ORG-100000589 | Authorisation Status: Valid
Version Number: — | Last updated date: —

Medicinal Product > **Packaged Medicinal Product**

Download

	MA number	Package size(s)	PCID	EV code	Legal status of supply
▼ ↑	041739196	—	—	—	—
▼	041739208	—	—	—	—
▼	041739210	—	—	—	—
▼	041739222	—	—	—	—
▼	041739234	—	—	—	—
▼	041739246	—	—	—	—
▼	041739259	—	—	—	—
▼	041739261	—	—	—	—
▼	041739273	—	—	—	—
▼	041739309	—	—	—	—

Showing 1 to 10 of 10 entries

Navigation: < Previous 1 Next >

Buttons: Close Refresh Export to XML

Different **MA number**
per pack size

The **structured pack size data** is missing
as this information is not in XEVMPD

The **EV Codes** will appear in the
production environment.

Repaglinide Aurobindo 2 mg compresse

PMS ID: 600001128171 | Authorisation Country: IT | MAH: ORG-100000589 | Authorisation Status: Valid
Version Number: — | Last updated date: —

- 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

Packaged Medicinal Product

Download

MA number	Package size(s)	PCID	EV code	Legal status of supply
041739196	—	—	—	—
Package description LE COMPRESSE DI REPAGLINIDE AUROBINDO SONO DISPONIBILI IN FLACONE HDPE Language				
Pack Size Unit of Presentation Quantity ⚠ Data are not available in SIAMCD/XEVMPD and not loaded. Users are encouraged to provide it when applicable. Shelf life / Storage Data carrier identifier(s)				

Package description as in XEVMPD

The **structured pack size data** is missing as this information is not in XEVMPD

Do I need to update my XEVMPD records if they don't have a package description?

NO. It is not needed as the MA number at package level should be enough to identify the pack size and the structured pack size data will be provided in due course. It is a good practice though to provide this information for completeness.



Marketing Authorisation number is provided at **pack size level**

Continue business as usual:

- › Submit and maintain authorised medicinal products to XEVMPD
 - 1 record per authorised pack size
- › Package description is still optional but highly recommended as it appears in PMS (Product UI or PMS API)

Make sure **pack sizes under the same medicinal product are correctly migrated** in PMS.

→ if not, raise a ticket in Service Now.



*Marketing Authorisation number is provided at **pack size level***

Countries
such as
HU, LI, IT,
RO or SI

Pioglitazone Zentiva 15 mg compresse

14 compresse in blister OPA/AL/PVC/AL AIC n. 040694010
28 compresse in blister OPA/AL/PVC/AL AIC n. 040694022
30 compresse in blister OPA/AL/PVC/AL AIC n. 040694034
50 compresse in blister OPA/AL/PVC/AL AIC n. 040694046
56 compresse in blister OPA/AL/PVC/AL AIC n. 040694059
60 compresse in blister OPA/AL/PVC/AL AIC n. 040694061
84 compresse in blister OPA/AL/PVC/AL AIC n. 040694073
90 compresse in blister OPA/AL/PVC/AL AIC n. 040694085
98 compresse in blister OPA/AL/PVC/AL AIC n. 040694097
100 compresse in blister OPA/AL/PVC/AL AIC n. 040694109
112 compresse in blister OPA/AL/PVC/AL AIC n. 040694111
120 compresse in blister OPA/AL/PVC/AL AIC n. 040694123
196 compresse in blister OPA/AL/PVC/AL AIC n. 040694135

*Marketing Authorisation number is provided at **medicinal product level***

Countries
such as
DE, ES, AT
or PO

6.5. Naturaleza y contenido del envase

Comprimidos recubiertos con película

Blisteres de aluminio (PA/Al/PVC/Al) en un estuche que contiene 14, 28 u 84 comprimidos recubiertos con película.

Puede que solamente estén comercializados algunos tamaños de envases.

*Marketing Authorisation number is provided at **medicinal product level***

Each MAH can decide the strategy on how to submit these medicinal products to XEVMPD

XEVMPD supports two strategies:

One XEVMPD record per pack size

One XEVMPD record for all pack sizes

- For non-centrally authorised products, one authorisation number can be applicable to several pack sizes. The MAH may wish to make either:
 - one XEVMPD product entity with a brief description of all pack sizes (separated by a comma) in the "Package description" field (AP.13.7) – see EXAMPLE 2; or

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
EMA/135580/2012

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- multiple XEVMPD product entities each referencing an individual pack size in the "Package description" field (AP.13.7) – see EXAMPLE 3.

[Chapter 3.II XEVPRM user guidance of the Detailed guidance on the electronic submission of information on medicinal products for human use by marketing authorisation holders to the EMA \(europa.eu\)](#)

Applicant's requirements for non-CAPs

Marketing Authorisation number is provided at **medicinal product level**

One XEVMPD record per pack size

DOXICLAT 100 mg comprimidos recubiertos con película

PMS ID: 600001126970 | Authorisation Country: ES | MAH: ORG-100003995 | Authorisation Status: Valid
Version Number: -- | Last updated date: --

Medicinal Product < **Packaged Medicinal Product**

Download

▼ ↑	MA number	Package size(s)	PCID	EV code	Legal status of supply
▼	50,404	—	—	—	—
▼	50,404	—	—	—	—
▼	50,404	—	—	—	—

Showing 1 to 3 of 3 entries

Close Refresh Export to XML

Same **MA number** as it is the same for all pack sizes

The **structured pack size data** is missing as this information is not in XEVMPD

DOXICLAT 100 mg comprimidos recubiertos con película

PMS ID: 600001126970 | Authorisation Country: ES | MAH: ORG-100003995 | Authorisation Status: Valid
Version Number: — | Last updated date: —

- 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

Packaged Medicinal Product

Download

MA number	Package size(s)	PCID	EV code	Legal status of supply
50.404	—	—	—	—
Package description 500 TABLETS IN BLISTER PACKS (PVC/ALUMINIUM) Language — Pack Size Open Shelf life / Storage Open Data carrier identifier(s) Open				
50.404	—	—	—	—
Package description 42 TABLETS IN BLISTER PACKS (PVC/ALUMINIUM) Language — Pack Size Open Shelf life / Storage Open Data carrier identifier(s) Open				
50.404	—	—	—	—
Package description 14 TABLETS IN BLISTER PACKS (PVC/ALUMINIUM) Language — Pack Size Open Shelf life / Storage Open Data carrier identifier(s) Open				

The **package description** allows the identification of each pack size and it's mandatory in XEVMPD when following this approach.



Marketing Authorisation number is provided at **medicinal product level**
One XEVMPD record per pack size

If your organisation has followed this approach:

- **Continue business as usual:**
 - ✓ You can continue submitting data to XEVMPD following the same approach followed so far.
 - ✓ **TIP:** in the package description you can include some meaningful information such as national codes, GTINs or any other value that helps you/NCAs identify the concrete pack size based on the pack description. We will release a document with national information on national codes to be used.

For example: 694057 – 14 TABLETS IN BLISTER ALU/ALU

694058 – 42 TABLETS IN BLISTER ALU/ALU



Don't copy/paste the SmPC info. Include meaningful information in the package description.

TIPS

Marketing Authorisation number is provided at **medicinal product level**

Each MAH can decide the strategy on how to submit these medicinal products to XEVMPD

XEVMPD supports two strategies:

One XEVMPD record per pack size

One XEVMPD record for all pack sizes

- For non-centrally authorised products, one authorisation number can be applicable to several pack sizes. The MAH may wish to make either:
 - one XEVMPD product entity with a brief description of all pack sizes (separated by a comma) in the "Package description" field (AP.13.7) – see EXAMPLE 2; or

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
EMA/135580/2012

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- multiple XEVMPD product entities each referencing an individual pack size in the "Package description" field (AP.13.7) – see EXAMPLE 3.

[Chapter 3.II XEVPRM user guidance of the Detailed guidance on the electronic submission of information on medicinal products for human use by marketing authorisation holders to the EMA \(europa.eu\)](#)

Marketing Authorisation number is provided at **medicinal product level**

One XEVMPD record for all pack sizes

Tadalafil Qualigen 20 mg comprimidos recubiertos con película EFG

PMS ID: 600001125492 | Authorisation Country: ES | MAH: ORG-100000374 | Authorisation Status: Valid
Version Number: — | Last updated date: —

Medicinal Product **< Packaged Medicinal Product**

[Download](#)

↑	MA number	Package size(s)	PCID	EV code	Legal status of supply
▼	82003	—	—	—	—

Close Refresh Export to XML

**Only one pack size with multiple pack sizes
in the package description**

Marketing Authorisation number is provided at **medicinal product level**

One XEVMPD record for all pack sizes

Tadalafil Qualigen 20 mg comprimidos recubiertos con película EFG

PMS ID: 600001125492 | Authorisation Country: ES | MAH: ORG-100000374 | Authorisation Status: Valid
Version Number: — | Last updated date: —

Medicinal Product **< Packaged Medicinal Product**

Download

MA number	Package size(s)	PCID	EV code	Legal status of supply
82003	—	—	—	—

Package description: BLÍSTER DE ALUMINIO/PVC/PVDC EN ENVASES CON 4, 8 COMPRIMIDOS

Language: —

Pack Size

Shelf life / Storage

Only one pack size with multiple pack sizes in the package description



Marketing Authorisation number is provided at **medicinal product level**
One XEVMPD record per pack size

If your organisation has followed this approach:

- **You need to start submitting separate EV codes per pack size for products on the Union List of Critical Medicines.**
 - Process:
 1. Update the current EV Code to include in the package description the lowest pack size
 2. Insert new entries in XEVMPD for each additional pack size
 3. Use the package description to differentiate them
 - **TIP:** In the package description you can include some meaningful information such as national codes, GTINs or any other value that helps you/NCAs identify the concrete pack size based on the pack description. No need to use national language.

1 Identify the EV code to be updated

WEB Trader | Create and Send Product Reports | Medicinal Products | MedDRA | For the UK, as from 1.1.2021, EU Law

☐ Reset Application | ☐ Reset Section | ☐ Clear | ☐ XML | ☐ RTF | ☐ Update | ☐ Other Operations

☐ Authorised Medicinal Products

- ☒ Authorised - PRD847688 - 11/11 Valid - Rivastigmina Kern Pharma 4,6 mg/24 h parches transdérmicos EFG
- Development Medicinal Products
- Approved Substances
- Development Substances
- Sources
- MAHs
- Sponsors

Description	Name/Value
EV Code	PRD847688
Version	2/2 Valid
Type	Authorised
Version Status	Accepted
Version Validity	Valid
Version Description	Current Valid Version

Package Description | MATERIAL DE ACONDICIONA...

Value X

MATERIAL DE ACONDICIONAMIENTO PRIMARIO
CADA PARCHES ESTÁ INDIVIDUALMENTE ENVASADO EN SOBRES SELLADOS POR CALOR FABRICADOS CON PAPEL/POLIETILENO TEREFALATO (PET) / ALUMINIO /
POLIACRILONITRILLO (PAN)
MATERIAL DE ACONDICIONAMIENTO SECUNDARIO
LOS SOBRES SE ACONDICIONAN EN UNA CAJA DE CARTÓN.
RIVASTIGMINA KERN PHARMA 4,6 MG/24 H SE ENCUENTRA DISPONIBLE EN ENVASES QUE CONTIENEN 30 O 60 SOBRES.
RIVASTIGMINA KERN PHARMA 9,5 MG/24 H SE ENCUENTRA DISPONIBLE EN ENVASES QUE CONTIENEN 60 SOBRES.

2a Click on 'Update'. This will trigger the update of this EV code.

WEB Trader | Create and Send Product Reports | Medicinal Products | MedDRA

Reset Application | Reset Section | Clear | XML | RT | **Update** | Other Operations

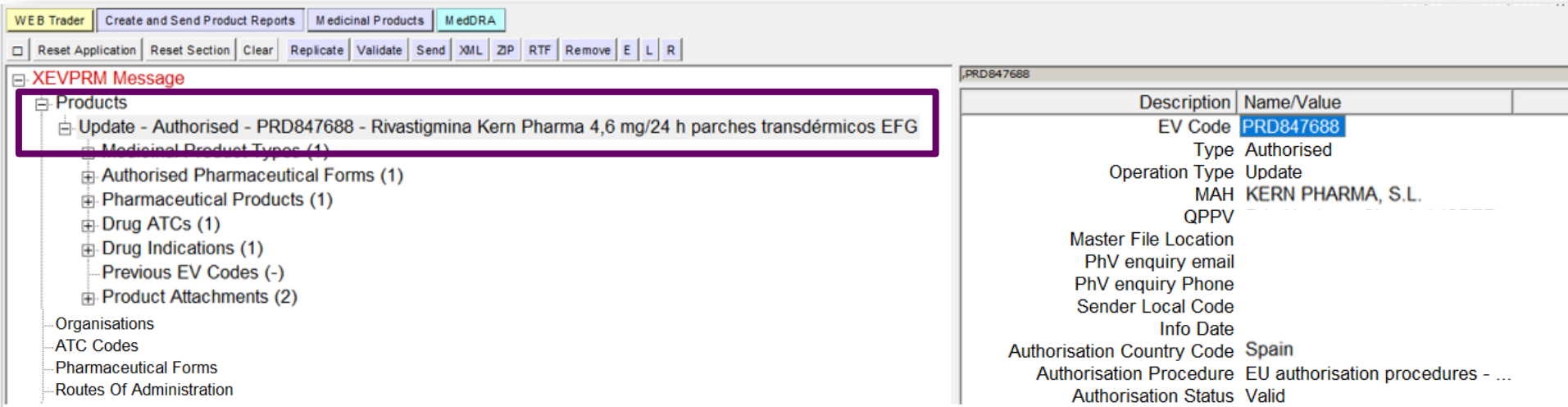
Authorized Medicinal Products

- Authorized - PRD847688 - 11/11 Valid - Rivastigmina Kern Pharma 4,6 mg/24 h parches transdérmicos EFG
- Development Medicinal Products
- Approved Substances
- Development Substances
- Sources
- MAHs
- Sponsors

PRD847688

Description	Name/Value
EV Code	PRD847688
Version	2/2 Valid
Type	Authorised
Version Status	Accepted
Version Validity	Valid
Version Description	Current Valid Version

2b The product is now moved in the 'Create and Send Product Reports' section and ready for update



WEB Trader | Create and Send Product Reports | Medicinal Products | MedDRA

Reset Application | Reset Section | Clear | Replicate | Validate | Send | XML | ZIP | RTF | Remove | E | L | R

XEVPRM Message

- Products
 - Update - Authorised - PRD847688 - Rivastigmina Kern Pharma 4,6 mg/24 h parches transdérmicos EFG
 - Medicinal Product Types (1)
 - Authorised Pharmaceutical Forms (1)
 - Pharmaceutical Products (1)
 - Drug ATCs (1)
 - Drug Indications (1)
 - Previous EV Codes (-)
 - Product Attachments (2)
- Organisations
- ATC Codes
- Pharmaceutical Forms
- Routes Of Administration

PRD847688

Description	Name/Value
EV Code	PRD847688
Type	Authorised
Operation Type	Update
MAH	KERN PHARMA, S.L.
QPPV	
Master File Location	
PhV enquiry email	
PhV enquiry Phone	
Sender Local Code	
Info Date	
Authorisation Country Code	Spain
Authorisation Procedure	EU authorisation procedures - ...
Authorisation Status	Valid

3a Identify the lowest pack size

WEB Trader Create and Send Product Reports Medicinal Products MedDRA

Reset Application Reset Section Clear Replicate Validate Send XML ZIP RTF Remove E L R

XEVPRM Message

- Products
 - Update - Authorised - PRD847688 - Rivastigmina Kern Pharma 4,6 mg/24 h parches transdérmicos EFG
 - Medicinal Product Types (1)
 - Authorised Pharmaceutical Forms (1)
 - Pharmaceutical Products (1)
 - Drug ATCs (1)
 - Drug Indications (1)
 - Previous EV Codes (-)
 - Product Attachments (2)
- Organisations
- ATC Codes
- Pharmaceutical Forms
- Routes Of Administration
- Attachments
- Master File Locations

PRD847688

Description	Name/Value
PhV enquiry email	n...
PhV enquiry Phone	
Sender Local Code	
Info Date	
Authorisation Country Code	Spain
Authorisation Procedure	EU authorisation procedures - ...
Authorisation Status	Valid
Authorisation Number	77.244
Authorisation/Renewal Date	07/03/2013
MRP/DCP/EMA Number	
EU Number	
Legal Basis	Generic application (Article 10(...
Orphan Drug	No
Additional Monitoring	
Invalidated Date	
Full Presentation Name	Rivastigmina Kern Pharma 4,6 ...
Product Short Name	
Product INN/Common Name	Rivastigmina
Product Company Name	Kern Pharma
Product Strength Name	4,6 MG/24 H
Product Form Name	PARCHES TRANSDÉRMICOS

Package Description MATERIAL DE ACONDICIONA...

Value X

MATERIAL DE ACONDICIONAMIENTO PRIMARIO
CADA PARCHES ESTÁ INDIVIDUALMENTE ENVASADO EN SOBRES SELLADOS POR CALOR FABRICADOS CON PAPEL/POLIETILENO TEREFALATO (PET) / ALUMINIO / POLIACRILONITRILLO (PAN).
MATERIAL DE ACONDICIONAMIENTO SECUNDARIO
LOS SOBRES SE ACONDICIONAN EN UNA CAJA DE CARTÓN.
RIVASTIGMINA KERN PHARMA 4,6 MG/24 H SE ENCUENTRA DISPONIBLE EN ENVASES QUE CONTIENEN 30 O 60 SOBRES.
RIVASTIGMINA KERN PHARMA 9,5 MG/24 H SE ENCUENTRA DISPONIBLE EN ENVASES QUE CONTIENEN 60 SOBRES.

This package description is useless:

- Too much information that is not used.
- Information from other medicinal products (4,6mg/24h and 9,5 mg/24h).

3b Change the package description to the lowest pack size

In the package description, I am including the national code for this pack size + the pack size + material

Product Form Name	PARCHES TRANSDÉRMICOS
Package Description	697191 - 30 parches - Papel/P...
Value ✓ ✗	
697191 - 30 parches - Papel/PET/A/PAN	

With this step, the new package description is assigned to the current record.

The additional pack sizes should be created now.

4 Go back to the 'Medicinal Products' section and, in 'Other Operations' select 'Reinsert'

This will trigger the generation of a product insert with the same information available in this EV code

WEB Trader

Create and Send Product Report

Medicinal Products

MedDRA

Reset Application

Reset Section

Clear

XML

RTF

Update

Other Operations

Choose one of the available Commands

Press A - Z to find initial letter

Press Enter to select, Escape to clear

Nullify

Reinsert

Authorised Medicinal Products

Authorised - PRD847688 - 11/11 Valid - Rivastigmine

Status: Valid - Assessed - 2020/04/21 10.14.00.51

Operation: Validity - Validate Version By Msg - Update

MAH: ORG4355 - KERN PHARMA, S.L.

MFL: MF

QPPV: F

Medicinal Product Types (1)

Authorised Pharmaceutical Forms (1)

Pharmaceutical Products (1)

Drug ATCs (1)

Drug Indications (1)

Previous EV Codes (-)

Product Attachments (2)

Legacy Products (-)

Previous Authorised Products (...)

New Authorised Products (...)

Development Products (...)

Suppliment Products (...)

Archives transdérmicos EFG

73266000

PRD847688

Description	Name/Value
EV Code	PRD847688
Version	11/11 Valid
Type	Authorised
Is EMA Owned	No
Is Legacy	No
Is Linked	No
Version Status	Accepted
Version Validity	Valid
Version Description	Current Valid Version
Product Validity	Valid
Product Pending	Assessed
Product Nullified	No
Pending vs Valid	No Pending Version
Current vs Previous	Double Click to Compare
Version Date	21/04/2020 10:13:58
Version by	EVHUMANWT
New Version ?	No
New Version by	

- 5a** The XEVPRM now references two AMP records:
- Update of an existing AMP: to update the record with multiple pack sizes to reference only one pack size
 - Insert of a new AMP: to create a new record to reference only one pack size

WEB Trader | Create and Send Product Reports | Medicinal Products | MedDRA

Reset Application | Reset Section | Clear | Validate | Send | XML | ZIP | RTF | E | L | R | □

XEVPRM Message

Products

- Update - Authorised - PRD847688 - Rivastigmina Kern Pharma 4,6 mg/24 h parches transdérmicos EFG
 - Medicinal Product Types (1)
 - Authorised Pharmaceutical Forms (1)
 - Pharmaceutical Products (1)
 - Drug ATCs (1)
 - Drug Indications (1)
 - Previous EV Codes (-)
 - Product Attachments (2)
- Insert - Authorised - Rivastigmina Kern Pharma 4,6 mg/24 h parches transdérmicos EFG
 - Medicinal Product Types (1)
 - Authorised Pharmaceutical Forms (1)
 - Pharmaceutical Products (1)
 - Drug ATCs (1)
 - Drug Indications (1)
 - Previous EV Codes (-)
 - Product Attachments (2)

PRD847688

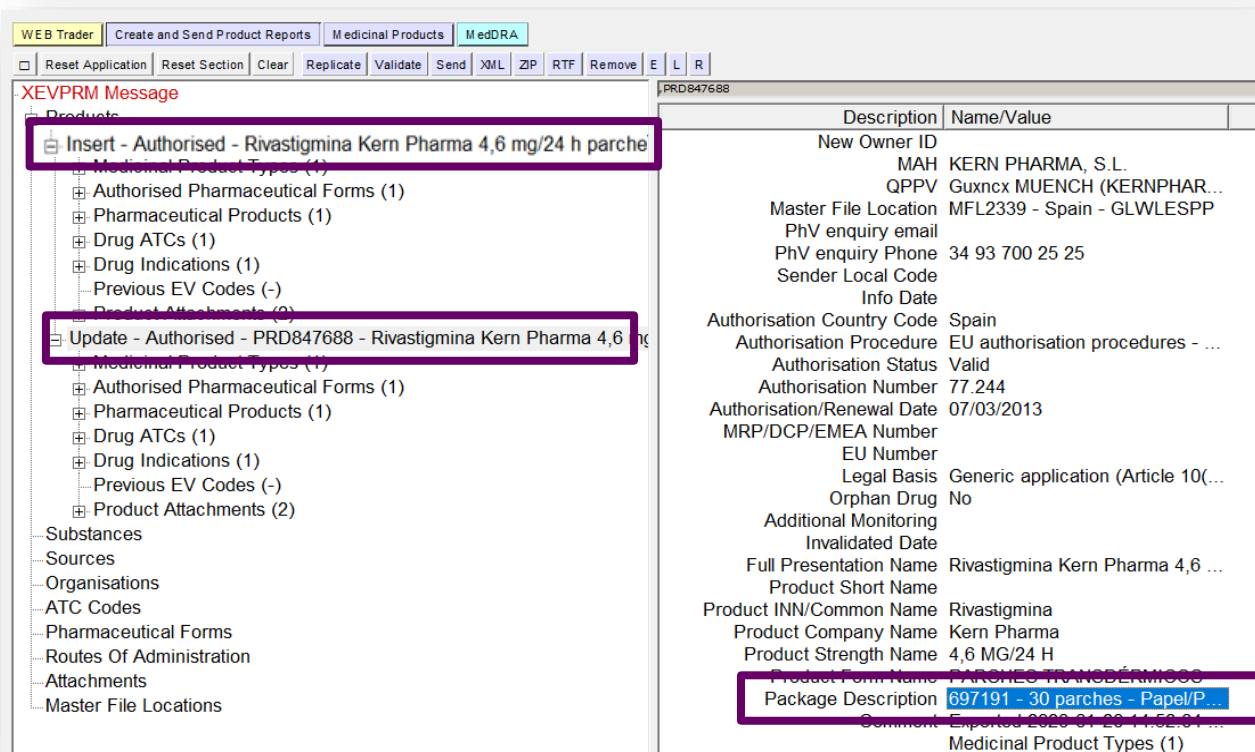
Num	Operation Type
☒ 0001	Update
☒ 0002	Insert
☐ New Authorised Product	
☐ New Development Product	

5b Change the package description in the product insert to reflect another pack size

- Product Attachments (2) - Insert - Authorised - Rivastigmina Kern Pharma 4,6 mg/24 h parches transdérmicos EFG - Medicinal Product Types (1) - Authorised Pharmaceutical Forms (1) - Pharmaceutical Products (1) - Drug ATCs (1) - Drug Indications (1) - Previous EV Codes (-) - Product Attachments (2) - Substances - Sources - Organisations - ATC Codes - Pharmaceutical Forms - Routes Of Administration - Attachments	<table><tr><td>Authorisation/Renewal Date</td><td>07/03/2013</td></tr><tr><td>MRP/DCP/EMA Number</td><td></td></tr><tr><td>EU Number</td><td></td></tr><tr><td>Legal Basis</td><td>Generic application (Article 10(...</td></tr><tr><td>Orphan Drug</td><td>No</td></tr><tr><td>Additional Monitoring</td><td></td></tr><tr><td>Invalidated Date</td><td></td></tr><tr><td>Full Presentation Name</td><td>Rivastigmina Kern Pharma 4,6 ...</td></tr><tr><td>Product Short Name</td><td></td></tr><tr><td>Product INN/Common Name</td><td>Rivastigmina</td></tr><tr><td>Product Company Name</td><td>Kern Pharma</td></tr><tr><td>Product Strength Name</td><td>4,6 MG/24 H</td></tr><tr><td>Product Form Name</td><td>PARCHES TRANSDÉRMICOS</td></tr><tr><td>Package Description</td><td>762697 - 60 parches - Papel/P...</td></tr></table> 762697 - 60 parches - Papel/PET/Al/Las Pol D	Authorisation/Renewal Date	07/03/2013	MRP/DCP/EMA Number		EU Number		Legal Basis	Generic application (Article 10(...	Orphan Drug	No	Additional Monitoring		Invalidated Date		Full Presentation Name	Rivastigmina Kern Pharma 4,6 ...	Product Short Name		Product INN/Common Name	Rivastigmina	Product Company Name	Kern Pharma	Product Strength Name	4,6 MG/24 H	Product Form Name	PARCHES TRANSDÉRMICOS	Package Description	762697 - 60 parches - Papel/P...
Authorisation/Renewal Date	07/03/2013																												
MRP/DCP/EMA Number																													
EU Number																													
Legal Basis	Generic application (Article 10(...																												
Orphan Drug	No																												
Additional Monitoring																													
Invalidated Date																													
Full Presentation Name	Rivastigmina Kern Pharma 4,6 ...																												
Product Short Name																													
Product INN/Common Name	Rivastigmina																												
Product Company Name	Kern Pharma																												
Product Strength Name	4,6 MG/24 H																												
Product Form Name	PARCHES TRANSDÉRMICOS																												
Package Description	762697 - 60 parches - Papel/P...																												

Now, we have the **two pack sizes ready to be submitted**:

- One as an update of the existing EV code
- A new one as an insert, containing the same information as the other product entry, except for the package description.



WEB Trader | Create and Send Product Reports | Medicinal Products | MedDRA

☐ Reset Application | ☐ Reset Section | | | | | XML | ZIP | RTF | | E | L | R

XEVPRM Message

Products

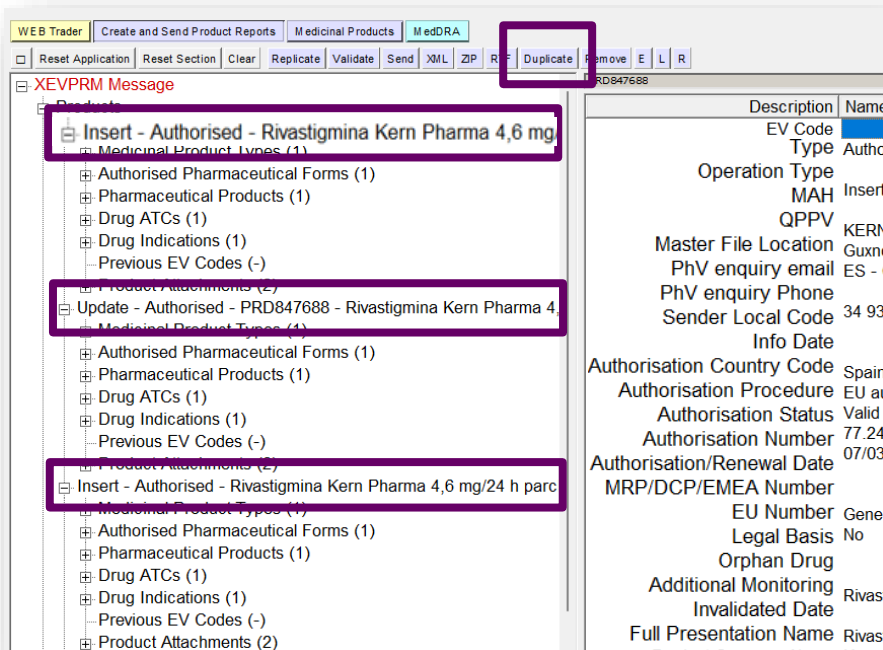
- ☒ **Insert - Authorised - Rivastigmina Kern Pharma 4,6 mg/24 h parche**
 - Medicinal Product Types (1)
 - Authorised Pharmaceutical Forms (1)
 - Pharmaceutical Products (1)
 - Drug ATCs (1)
 - Drug Indications (1)
 - Previous EV Codes (-)
 - Product Attachments (2)
- ☒ **Update - Authorised - PRD847688 - Rivastigmina Kern Pharma 4,6 mg/24 h parche**
 - Medicinal Product Types (1)
 - Authorised Pharmaceutical Forms (1)
 - Pharmaceutical Products (1)
 - Drug ATCs (1)
 - Drug Indications (1)
 - Previous EV Codes (-)
 - Product Attachments (2)
- Substances
- Sources
- Organisations
- ATC Codes
- Pharmaceutical Forms
- Routes Of Administration
- Attachments
- Master File Locations

PRD847688

Description	Name/Value
New Owner ID	MAH KERN PHARMA, S.L.
QPPV	Guxncx MUENCH (KERNPHAR...
Master File Location	MFL2339 - Spain - GLWLESPP
PhV enquiry email	
PhV enquiry Phone	34 93 700 25 25
Sender Local Code	
Info Date	
Authorisation Country Code	Spain
Authorisation Procedure	EU authorisation procedures - ...
Authorisation Status	Valid
Authorisation Number	77.244
Authorisation/Renewal Date	07/03/2013
MRP/DCP/EMEA Number	
EU Number	
Legal Basis	Generic application (Article 10(...
Orphan Drug	No
Additional Monitoring	
Invalidated Date	
Full Presentation Name	Rivastigmina Kern Pharma 4,6 ...
Product Short Name	
Product INN/Common Name	Rivastigmina
Product Company Name	Kern Pharma
Product Strength Name	4,6 MG/24 H
Product Form Name	PARCHES TRANSDÉRMICOS
Package Description	697191 - 30 parches - Papel/P...
Comment	Exported 2023-01-20 11:52:01 ...
	Medicinal Product Types (1)

6

If you need to create new records for additional pack sizes, you can create duplicates of the record and change the package descriptions accordingly in the newly created entries.



The screenshot displays the XEVMPD (eXtended European VMD Product) interface. The 'WEB Trader' tab is active, and the 'Create and Send Product Reports' section is selected. The 'Medicinal Products' and 'MedDRA' sub-sections are visible. The 'Duplicate' button is highlighted with a red box. The left pane shows a tree view of product data for 'Rivastigmina Kern Pharma 4,6 mg'. Three entries are highlighted with red boxes: 'Insert - Authorised - Rivastigmina Kern Pharma 4,6 mg', 'Update - Authorised - PRD847688 - Rivastigmina Kern Pharma 4,6 mg', and 'Insert - Authorised - Rivastigmina Kern Pharma 4,6 mg/24 h parc'. The right pane shows a list of fields for the selected entry, including 'Description', 'Name', 'EV Code', 'Type', 'Operation Type', 'MAH', 'QPPV', 'Master File Location', 'PhV enquiry email', 'PhV enquiry Phone', 'Sender Local Code', 'Info Date', 'Authorisation Country Code', 'Authorisation Procedure', 'Authorisation Status', 'Authorisation Number', 'Authorisation/Renewal Date', 'MRP/DCP/EMEA Number', 'EU Number', 'Legal Basis', 'Orphan Drug', 'Additional Monitoring', 'Invalidated Date', and 'Full Presentation Name'.

7

Validate and submit the message.

Wait for the 2nd ACK to confirm successful submission.

- Remember that now you need to **maintain these new EV codes** as well.
- In case one specific pack size is withdrawn, you need to perform an invalidation of that specific EV Code.
- Changes to the medicinal product should be reflected in all the EV Codes.

- You can check if these pack sizes have been updated and created in PMS.
- Allow time for the Deltas from XEVMPD to PMS to run (~5 min) and from PMS to the Product UI (~15 min)



Specific questions

Providing additional information on this process



Do I need to submit all pack sizes for all my authorised products?

- It depends:
 - If it's a CAP or a non-CAP with the authorisation number at pack size level:
YES, all pack sizes are required in XEVMPD. There is no change on the business rules.
 - If it's a non-CAP with the authorisation number at medicinal product level:
 - For the moment EMA has reduced the scope to products under the **Union List of Critical Medicines** and only for pack sizes in the market.
 - In case of a crisis, pack sizes that are not in the market will be required as well.
 - Sample pack sizes are not required.
 - Herbal and homeopathic are excluded from this list. So if they fall under this category, no need to submit pack sizes.
- These rules applies to newly authorised medicinal products and legacy products (products already in XEVMPD)



Do I need to submit all pack sizes for all my authorised products?

- For CAPs and non-CAPs authorised at pack size level → YES. This is an XEVMPD requirement.
- For non-CAPs authorised at medicinal product level → Mandatory for products on the **Union List of Critical Medicines** and optional for the rest.
- In order to support applicants, EMA will publish a list of products already authorised that falls under the Union List of Critical Medicines [here](#).
- This list is based on the ATC code of the product. Keep your records up to date to reflect the latest ATC Codes.

ATC code	ATC name	PMS id	Package PH	EV code	Full name	Author	MAH location id	Authorisation country	Procedure number	Authorisation number	Package authorisation number	Package description
A02BC05	esomeprazole	600000000033	74946	PRD86854	Nexium Control 20 mg gastro-resistant tablets	Gastro-re	LOC-100023097	European Union	EMEA/H/C/002618	EU/1/13/860	EU/1/13/860/001	Packaging:blister (alu), Package_size
A02BC05	esomeprazole	600000000033	74947	PRD86854	Nexium Control 20 mg gastro-resistant tablets	Gastro-re	LOC-100023097	European Union	EMEA/H/C/002618	EU/1/13/860	EU/1/13/860/002	Packaging:blister (alu), Package_size
A02BC05	esomeprazole	600000000033	74948	PRD86854	Nexium Control 20 mg gastro-resistant tablets	Gastro-re	LOC-100023097	European Union	EMEA/H/C/002618	EU/1/13/860	EU/1/13/860/004	Packaging:blister (alu), Package_size
A02BC05	esomeprazole	600000000068	58380	PRD86854	Nexium Control 20 mg gastro-resistant hard capsules	Gastro-re	LOC-100023097	European Union	EMEA/H/C/002618	EU/1/13/860	EU/1/13/860/003	Packaging:bottle (HDPE), Package_size
A02BC05	esomeprazole	600000000068	58381	PRD86854	Nexium Control 20 mg gastro-resistant hard capsules	Gastro-re	LOC-100023097	European Union	EMEA/H/C/002618	EU/1/13/860	EU/1/13/860/005	Packaging:bottle (HDPE), Package_size
A02BC05	esomeprazole	600001434371	31061001	PRD79746	Nexium, enterotabletlet	Gastro-re	LOC-100006949	Denmark	SE/H/0211/002		31490	
A02BC05	esomeprazole	600001434387	31061005	PRD79464	Nexium 40 mg enterotabletlet	Gastro-re	LOC-100006949	Norway	SE/H/0211/002	00-1995	00-1995	
A02BC05	esomeprazole	600001434521	31047813	PRD79621	Nexium 40 mg – magsenafresistente Tabletten	Gastro-re	LOC-100002222	Austria	SE/H/0211/002	1-23717	1-23717	
A02BC05	esomeprazole	600001435578	31726342	PRD74515	Esomeprazolo Germed 40 mg compresse gastroresistenti	Gastro-re	LOC-100001728	Italy	DE/H/2836/002		040002127/M	56 GASTRO-RESISTANT TABLETS IN BC
A02BC05	esomeprazole	600001435578	31726343	PRD74515	Esomeprazolo Germed 40 mg compresse gastroresistenti	Gastro-re	LOC-100001728	Italy	DE/H/2836/002		040002103/M	14 GASTRO-RESISTANT TABLETS IN BC
A02BC05	esomeprazole	600001435578	31726344	PRD74515	Esomeprazolo Germed 40 mg compresse gastroresistenti	Gastro-re	LOC-100001728	Italy	DE/H/2836/002		040002089/M	28 GASTRO-RESISTANT TABLETS IN BL
A02BC05	esomeprazole	600001435578	31726345	PRD74515	Esomeprazolo Germed 40 mg compresse gastroresistenti	Gastro-re	LOC-100001728	Italy	DE/H/2836/002		040002077/M	14 GASTRO-RESISTANT TABLETS IN BL
A02BC05	esomeprazole	600001435578	31726346	PRD74515	Esomeprazolo Germed 40 mg compresse gastroresistenti	Gastro-re	LOC-100001728	Italy	DE/H/2836/002		040002091/M	56 GASTRO-RESISTANT TABLETS IN BL
A02BC05	esomeprazole	600001435578	31726353	PRD74515	Esomeprazolo Germed 40 mg compresse gastroresistenti	Gastro-re	LOC-100001728	Italy	DE/H/2836/002		040002115/M	28 GASTRO-RESISTANT TABLETS IN BC
A02BC05	esomeprazole	600001435650	31301378	PRD95541	Esomeprazole Actavis, 20 mg gastroresistentis tabletid	Gastro-re	LOC-100003164	Estonia	DK/H/2131/001		805413	
A02BC05	esomeprazole	600001436579	31152716	PRD17361	Nexmezol 40 mg zarnās šķīstošās tabletes	Gastro-re	LOC-100002893	Latvia	DK/H/1457/002	09-0140	09-0140	
A02BC05	esomeprazole	600001436601	31545809	PRD95542	ESOMEPRAZOL ACTAVIS 40 MG ENTEROSOLVENTNÍ TABLETY	Gastro-re	LOC-100001873	Czechia	DK/H/2131/002	09/074/13-C	09/074/13-C	



Do I need to submit all pack sizes for all my authorised products?

- For CAPs and non-CAPs authorised at pack size level → YES. This is an XEVMPD requirement.
- For non-CAPs authorised at medicinal product level → Mandatory for products on the **Union List of Critical Medicines** and optional for the rest.
- In order to support applicants, EMA will publish a list of products already authorised that falls under the Union List of Critical Medicines [here](#).
- This list is based on the ATC code of the product. Keep your records up to date to reflect the latest ATC Codes.
- Check this list and update your EV records if needed/insert necessary pack sizes.
- For newly authorised products, if they fall under the ULCM (based on the ATC Code) submission of pack sizes is also mandatory.



For medicinal products with an authorisation number at product level it is important to include a national code in the package description.
Is there more information on these national codes?

We have received this information from the NCAs and we will publish this information.
 In case there is no national code, just include the pack size information. You can use national language or English.

Country	MA number level	National ID at pack
Austria	MP level	Packungsnummer (internal), Pharmazentralnummer for marketed packages (PIP code)
Belgium	between medicinal product level and packaging level	CTI Extended
Bulgaria	MP level	
Croatia	Both	Yes.
Cyprus	MP level	only internal
Czech Republic	MP level	yes: SUKL code.
Denmark	MP level	
Estonia	MP level	Yes. There is a national package code generated by our internal database. Package code
EU	Pack size	Ø
Finland	MP level	Yes
France	Both	The package number (CIP with 13 characters) from the SmPC should be used. as MA number.
Germany	MP level	yes
Greece	MP level	
Hungary	Pack size	
Iceland	MP level	Yes. Nordic article number and GTIN/NTIN but only for marketed packages
Ireland	MP level	No

Country	MA number level	National ID at pack
Italy	Pack size	Ø
Latvia	MP level	"Product ID" (in LV: Produkta ID).
Liechtenstein		
Lithuania	Pack size	Ø
Luxembourg	MP level	Yes. "Numero national" or national number (7 digits)
Malta	MP level	No additional identifier is given for each pack
Northern Ireland		
Norway	MP level	Yes. Nordic article number and GTIN/NTIN but only for marketed packages
Poland	MP level	
Portugal	MP level	Name in PT "Número de registo" (registration number).
Romania	Pack size	Ø
Slovakia	MP level	"ŠÚKL kód" (ŠÚKL code (SIDC code))
Slovenia	Pack size	Ø
Spain	MP level	Código nacional
Sweden	MP level	Yes. NPL pack id
The Netherlands	MP level	No



**For medicinal products with an authorisation number at product level it is important to include a national code in the package description.
Is there more information on these national codes?**

Just some examples on how the package description would be a useful field.
Some meaningful data would be:

National ID (if exists) + **pack size** (quantity and units of presentation) + **content** (units of measurement) + **material**

0053603	HEXTRIL SOL. BAIN BOUCHE 5 MG / 5 ML 1*1 FLACON 200 ML
0368339	HEXTRIL SOL. BAIN BOUCHE 5 MG / 5 ML 1*1 FLACON 400 ML

0053603 - 1 FLACON – 200 ml

0368339 - 1 FLACON – 400 ml

PRESENTACIONES EXPORTAR		COMERCIALIZADO	NO COMERCIALIZADO
ACETILCISTEINA CINFA 100 mg POLVO PARA SOLUCION ORAL EFG , 30 sobres		ACETILCISTEINA CINFA 100 mg POLVO PARA SOLUCION ORAL EFG , 500 sobres	
CÓDIGO NACIONAL: 650429		CÓDIGO NACIONAL: 600044	
AUTORIZADO(17/11/2004) COMERCIALIZADO		AUTORIZADO(17/11/2004) NO COMERCIALIZADO	
			
650429 - 30 sobres		600044 - 500 sobres	

Ibuprofen Zentiva - 400 mg

Pakninger

Tablett, filmdrasjert

200 mg

100 stk

400 mg

50 stk

100 stk

600 mg

10 stk

30 stk

100 stk

Tablett, filmdrasjert

[Pakningsvedlegg](#) [Lenke til Felleskatalogen](#) [Preparatomtale \(SPC\)](#)

Handelsnavn: Ibuprofen Zentiva
Virkestoff: Ibuprofen
Legemiddelform: Tablett, filmdrasjert
Styrke: 400 mg
Pakning: Blisterpakning 100 stk
Reseptpliktig: Ja
Reseptgruppe: C
Blå resept: [Ja](#)
Byttbar: [Ja](#)
ATC-Kode: M01AE01
Varenummer: 042298

Markedsføringstillatelse:

Pakning status: Markedsført
Markedsføringsdato: 15.12.2022
MT-status: Markedsført
Innehaver: Zentiva k.s.
MT-nummer: 22-14673
MT-dato: 16.06.2022

042298 – 100 film-coated tablet

382141 – 50 film-coated tablet

20160819100286 – 30 tabletter – blister

20160819100262 – 50 tabletter – blister

Förpackning	Försäljningsstatus	Restsituation	Visa mer
Blister, 2 tabletter	Aldrig såld i Sverige	Nej	▼
Blister, 4 tabletter	Aldrig såld i Sverige	Nej	▼
Blister, 6 tabletter	Aldrig såld i Sverige	Nej	▼
Blister, 8 tabletter	Aldrig såld i Sverige	Nej	▼
Blister, 10 tabletter	Aldrig såld i Sverige	Nej	▼
Blister, 20 tabletter	Aldrig såld i Sverige	Nej	▼
Blister, 30 tabletter	Säljs	Nej	▼
Blister, 40 tabletter	Aldrig såld i Sverige	Nej	▼
Blister, 50 tabletter	Säljs	Nej	▼
Blister, 60 tabletter	Aldrig såld i Sverige	Nej	▼



A medicinal product is authorised with different containers and materials. What is considered a pack size?

- Specific medicinal products are authorised with multiple sizes, materials and combinations of both:

Tamaño (x)	Capacidad geométrica (litros)	Presión de llenado (bar)	Cantidad nominal en litros (15°C) (y)	Cantidad de producto gaseoso a (15°C y 1 atm) en m ³ (y)	Peso de producto almacenado (kg)	Material de la bala de gas ⁽¹⁾	Tipo de válvula ⁽²⁾
X0,5S	0,5	200	107	0,11	0,14	Ac / Al	Man.
X1S	1	200	214	0,21	0,29	Ac / Al	Man.
X2S	2	200	429	0,43	0,58	Ac / Al	Man./ Int./ Dig.
X3S	3	200	643	0,64	0,87	Ac / Al	Man./ Int./ Dig.
X4S	4	200	857	0,86	1,16	Ac / Al	Man.
X5S	5	200	1072	1,07	1,45	Ac / Al	Man./ Int./ Dig.
X7S	7	200	1501	1,5	2,03	Ac / Al	Man.
X10S	10	200	2144	2,14	2,90	Ac / Al	Man.
X13S	13	200	2775	2,77	3,75	Ac	Man.
X15S	15	200	3215	3,21	4,35	Ac	Man.
X20S	20	200	4287	4,29	5,81	Ac	Man.
X25S	25	200	5359	5,36	7,26	Ac / Al	Man.
X30S	30	200	6431	6,43	8,71	Ac	Man.
X40S	40	200	8575	8,57	11,60	Ac	Man.
X50S	50	200	10718	10,72	14,51	Ac	Man.
Bloque 16	800	200	171488	171,49	232,2	Ac	Man. 1
Bloque 18	900	200	192924	192,92	261,2	Ac	Man. 2
Bloque 23	1150	200	246514	246,51	333,8	Ac	Man.

Nota al pie (1):
Ac: bala de gas de acero
Al: bala de gas de aluminio o de aluminio revestido de plástico

Man.: válvula manual
Int.: válvula integrada analógica
Dig.: válvula integrada digital
puede que no todos los tamaños se comercialicen.

6. Precauciones especiales de eliminación

o fumar.
o acercarse a una llama.
o engrasar.
En particular:
o introducir nunca este gas en un aparato que se sospeche puede ser a prueba de grasa.
o limpiar nunca con productos combustibles, en especial si son gases, ni las válvulas, las juntas, las guarniciones y los dispositivos.
o aplicar ninguna materia grasa (vaselina, pomadas, etc.) en el dispositivo.
o utilizar aerosoles (laca, desodorante, etc.) ni disolventes (alcohol, etc.).
Las balas de gas de oxígeno medicinal están reservadas exclusivamente para evitar cualquier incidente, es necesario respetar obligatoriamente las instrucciones de uso y verificar el buen estado del material antes de su utilización.
No agrupar las balas de gas de capacidad superior a 5 litros en un mismo contenedor.
Mantenerlas en posición vertical y evitar cualquier caída inesperada.
No utilizar las balas de gas si su presión es inferior a 10 bar.

Applicants are responsible to know how these products are authorised nationally and how many pack sizes are authorised.



A medicinal product is authorised with different containers and materials. How should it be submitted to XEVMPD?

- Specific medicinal products are authorised with multiple sizes, materials and combinations of both:

OXÍGENO MEDICINAL GAS CARBUROS METÁLICOS 99,5% V/V GAS COMPRIMIDO, 1 bala de gas de 0,5 l CÓDIGO NACIONAL: 62386G AUTORIZADO(01/08/2005) NO COMERCIALIZADO notifica	OXÍGENO MEDICINAL GAS CARBUROS METÁLICOS 99,5% V/V GAS COMPRIMIDO, 1 bala de gas de 1 l CÓDIGO NACIONAL: 62386G AUTORIZADO(01/08/2005) COMERCIALIZADO notifica
OXÍGENO MEDICINAL GAS CARBUROS METÁLICOS 99,5% V/V GAS COMPRIMIDO, 1 bala de gas de 10 l CÓDIGO NACIONAL: 62387G AUTORIZADO(01/08/2005) COMERCIALIZADO notifica	OXÍGENO MEDICINAL GAS CARBUROS METÁLICOS 99,5% V/V GAS COMPRIMIDO, 1 bala de gas de 13 l CÓDIGO NACIONAL: 62387G AUTORIZADO(01/08/2005) COMERCIALIZADO notifica
OXÍGENO MEDICINAL GAS CARBUROS METÁLICOS 99,5% V/V GAS COMPRIMIDO, 1 bala de gas de 15 l CÓDIGO NACIONAL: 62387G AUTORIZADO(01/08/2005) NO COMERCIALIZADO notifica	OXÍGENO MEDICINAL GAS CARBUROS METÁLICOS 99,5% V/V GAS COMPRIMIDO, 1 bala de gas de 20 l CÓDIGO NACIONAL: 62387G AUTORIZADO(01/08/2005) COMERCIALIZADO notifica
OXÍGENO MEDICINAL GAS CARBUROS METÁLICOS 99,5% V/V GAS COMPRIMIDO, 1 bala de gas de 25 l CÓDIGO NACIONAL: 62387G AUTORIZADO(01/08/2005) NO COMERCIALIZADO notifica	OXÍGENO MEDICINAL GAS CARBUROS METÁLICOS 99,5% V/V GAS COMPRIMIDO, 1 bala de gas de 30 l CÓDIGO NACIONAL: 62387G AUTORIZADO(01/08/2005) COMERCIALIZADO notifica

In this case, each combination of size, material and valve type is considered a pack size and has a national code assigned.



BE, FI and LU have more than one official language.
In XEVMPD, one record per official language should be submitted.
How do we handle pack size submission in XEVMPD in these cases?

Three EV codes are created in XEVMPD as there are three official languages (DE, NL and FR).
 The three EV codes refer to multiple pack sizes.

As-Is - 1 EV code per Language			
EV code	Name	Auth Number	pack sizes
EV code 1	Allopurinol Teva 100 mg tablets - DE	BE375575	20, 25, 28,50
EV code 2	Allopurinol Teva 100 mg tablets - NL	BE375575	20, 25, 28,50
EV code 3	Allopurinol Teva 100 mg tablets - FR	BE375575	20, 25, 28,50

In PMS, each EV code is considered a packaged medicinal product and therefore there is a medicinal product with 3 pack sizes and three names.

PMS ID	Name	Auth number	Pack sizes	PCID
PMS ID 1	Allopurinol Teva 100 mg tablets - DE	BE375575	20, 25, 28,50	PCID 1
	Allopurinol Teva 100 mg tablets - NL	BE375575	20, 25, 28,50	PCID 2
	Allopurinol Teva 100 mg tablets - FR	BE375575	20, 25, 28,50	PCID 3

As-Is - 1 EV code per Language			
EV code	Name	Auth Number	pack sizes
EV code 1	Allopurinol Teva 100 mg tablets - DE	BE375575	20, 25, 28, 50
EV code 2	Allopurinol Teva 100 mg tablets - NL	BE375575	20, 25, 28, 50
EV code 3	Allopurinol Teva 100 mg tablets - FR	BE375575	20, 25, 28, 50

EV code	Name	Auth Number	Pack size	package description
EV code 1	Allopurinol Teva 100 mg tablets - DE	BE375575	20	CTI Extended ID - 20 tablets - Blister Alu/Alu
EV code 2	Allopurinol Teva 100 mg tablets - NL	BE375575	20	CTI Extended ID - 20 tablets - Blister Alu/Alu
EV code 3	Allopurinol Teva 100 mg tablets - FR	BE375575	20	CTI Extended ID - 20 tablets - Blister Alu/Alu
EV code 4	Allopurinol Teva 100 mg tablets - DE	BE375575	25	CTI Extended ID - 25 tablets - Blister Alu/Alu
EV code 5	Allopurinol Teva 100 mg tablets - NL	BE375575	25	CTI Extended ID - 25 tablets - Blister Alu/Alu
EV code 6	Allopurinol Teva 100 mg tablets - FR	BE375575	25	CTI Extended ID - 25 tablets - Blister Alu/Alu
EV code 7	Allopurinol Teva 100 mg tablets - DE	BE375575	28	CTI Extended ID - 28 tablets - Blister Alu/Alu
EV code 8	Allopurinol Teva 100 mg tablets - NL	BE375575	28	CTI Extended ID - 28 tablets - Blister Alu/Alu
EV code 9	Allopurinol Teva 100 mg tablets - FR	BE375575	28	CTI Extended ID - 28 tablets - Blister Alu/Alu
EV code 10	Allopurinol Teva 100 mg tablets - DE	BE375575	50	CTI Extended ID - 50 tablets - Blister Alu/Alu
EV code 11	Allopurinol Teva 100 mg tablets - NL	BE375575	50	CTI Extended ID - 50 tablets - Blister Alu/Alu
EV code 12	Allopurinol Teva 100 mg tablets - FR	BE375575	50	CTI Extended ID - 50 tablets - Blister Alu/Alu

1. Update the current records (EV codes 1, 2 and 3) to the lower pack size.
2. Add additional pack sizes (1 EV code per language).
3. **Important:** For the package description use always the same language and info.

EV code	Name	Auth Number	Pack size	package description
EV code 1	Allopurinol Teva 100 mg tablets - DE	BE375575	20	CTI Extended ID - 20 tablets - Blister Alu/Alu
EV code 2	Allopurinol Teva 100 mg tablets - NL	BE375575	20	CTI Extended ID - 20 tablets - Blister Alu/Alu
EV code 3	Allopurinol Teva 100 mg tablets - FR	BE375575	20	CTI Extended ID - 20 tablets - Blister Alu/Alu
EV code 4	Allopurinol Teva 100 mg tablets - DE	BE375575	25	CTI Extended ID - 25 tablets - Blister Alu/Alu
EV code 5	Allopurinol Teva 100 mg tablets - NL	BE375575	25	CTI Extended ID - 25 tablets - Blister Alu/Alu
EV code 6	Allopurinol Teva 100 mg tablets - FR	BE375575	25	CTI Extended ID - 25 tablets - Blister Alu/Alu
EV code 7	Allopurinol Teva 100 mg tablets - DE	BE375575	28	CTI Extended ID - 28 tablets - Blister Alu/Alu
EV code 8	Allopurinol Teva 100 mg tablets - NL	BE375575	28	CTI Extended ID - 28 tablets - Blister Alu/Alu
EV code 9	Allopurinol Teva 100 mg tablets - FR	BE375575	28	CTI Extended ID - 28 tablets - Blister Alu/Alu
EV code 10	Allopurinol Teva 100 mg tablets - DE	BE375575	50	CTI Extended ID - 50 tablets - Blister Alu/Alu
EV code 11	Allopurinol Teva 100 mg tablets - NL	BE375575	50	CTI Extended ID - 50 tablets - Blister Alu/Alu
EV code 12	Allopurinol Teva 100 mg tablets - FR	BE375575	50	CTI Extended ID - 50 tablets - Blister Alu/Alu

PMS ID	Name	Auth number	Pack sizes	PCID	package description
PMS ID 1	Allopurinol Teva 100 mg tablets - DE Allopurinol Teva 100 mg tablets - NL Allopurinol Teva 100 mg tablets - FR	BE375575	20	PCID 4	CTI Extended ID - 20 tablets - Blister Alu/Alu
		BE375575	20	PCID 5	CTI Extended ID - 20 tablets - Blister Alu/Alu
		BE375575	20	PCID 6	CTI Extended ID - 20 tablets - Blister Alu/Alu
		BE375575	25	PCID 7	CTI Extended ID - 25 tablets - Blister Alu/Alu
		BE375575	25	PCID 8	CTI Extended ID - 25 tablets - Blister Alu/Alu
		BE375575	25	PCID 9	CTI Extended ID - 25 tablets - Blister Alu/Alu
		BE375575	28	PCID 10	CTI Extended ID - 28 tablets - Blister Alu/Alu
		BE375575	28	PCID 11	CTI Extended ID - 28 tablets - Blister Alu/Alu
		BE375575	28	PCID 12	CTI Extended ID - 28 tablets - Blister Alu/Alu
		BE375575	50	PCID 13	CTI Extended ID - 50 tablets - Blister Alu/Alu
		BE375575	50	PCID 14	CTI Extended ID - 50 tablets - Blister Alu/Alu
		BE375575	50	PCID 15	CTI Extended ID - 50 tablets - Blister Alu/Alu

- In PMS there will be as many pack size as records in XEVMPD: there will be duplicated / triplicated pack sizes.
- PMS team is designing a strategy to remove these duplicates or triplicates based on the package description.

Important: For the package description use always the same language and info.



French medicinal products can be submitted at pack size level or medicinal product level. How should they be updated?

- Based on the XEVMPD Q&A document, different strategies can be followed when submitting the data to XEVMPD.

3.17.1.8. Authorisation number: NAP in France

Question: For medicinal products nationally authorised in France; a "package number" is stated in section 8 of the SmPC but it does not correspond to the Marketing Authorisation number (i.e. NL number) stated in the marketing authorisation document.

Which number should be specified in the XEVPRM data element Authorisation number (AP.12.4)?

Answer: If you wish to submit only one XEVMPD product entity for all the pack sizes covered by the NL number, you should specify the NL number in the data element Authorisation number (AP.12.4).

If you wish to submit multiple XEVMPD product entities (i.e. one for each pack size) you may specify the NL number or the package number stated in section 8 of the SmPC in the data element AP.12.4.



French medicinal products can be submitted at pack size level or medicinal product level. How should they be updated?

- Package number (CIP) used for every pack size → **No action is required**

Full Presentation Name	Package Description	Authorisation Number
DES Loratadine Evolugen 5 mg, comprimé pelliculé	7 comprimés pelliculés sous plaquettes (OPA/ALU/PVCALUMINIUM)	34009 279 101 7 3
DES Loratadine Evolugen 5 mg, comprimé pelliculé	10 comprimés pelliculés sous plaquettes (OPA/ALU/PVCALUMINIUM)	34009 279 102 3 4
DES Loratadine Evolugen 5 mg, comprimé pelliculé	14 comprimés pelliculés sous plaquettes (OPA/ALU/PVCALUMINIUM)	34009 279 104 6 3
DES Loratadine Evolugen 5 mg, comprimé pelliculé	15 comprimés pelliculés sous plaquettes (OPA/ALU/PVCALUMINIUM)	34009 279 105 2 4
DES Loratadine Evolugen 5 mg, comprimé pelliculé	20 comprimés pelliculés sous plaquettes (OPA/ALU/PVCALUMINIUM)	34009 279 106 9 2
DES Loratadine Evolugen 5 mg, comprimé pelliculé	21 comprimés pelliculés sous plaquettes (OPA/ALU/PVCALUMINIUM)	34009 279 107 5 3
DES Loratadine Evolugen 5 mg, comprimé pelliculé	28 comprimés pelliculés sous plaquettes (OPA/ALU/PVCALUMINIUM)	34009 279 108 1 4

DES Loratadine Evolugen 5 mg, comprimé pelliculé							
PMS ID: 600000751966 Authorisation Country: FR MAH: ORG-100002031 Authorisation Status: Valid Version Number: -- Last updated date: --							
Medicinal Product	Packaged Medicinal Product						
Download							
MA number	Package size(s)	PCID	EV code	Legal status of supply		Authorisation Status	
34009 279 101 7 3	—	—	—	—		Valid	
34009 279 102 3 4	—	—	—	—		Valid	
34009 279 104 6 3	—	—	—	—		Valid	
34009 279 105 2 4	—	—	—	—		Valid	
34009 279 106 9 2	—	—	—	—		Valid	
34009 279 107 5 3	—	—	—	—		Valid	
34009 279 108 1 4	—	—	—	—		Valid	



French medicinal products can be submitted at pack size level or medicinal product level. How should they be updated?

- **NL number used for all pack sizes** → follow the process explained before to update the existing record with the lowest pack size and insert new records for additional pack sizes.
- In the Authorisation number you can either use the NL number or the package number.
Recommendation to use the package number. Otherwise include it in the package description.

Full Presentation Name	Package Description	Authorisation Number
AMOXICILLINE MYLAN PHARMA 1 g, comprimé dispersible	2, 6, 8, 10, 12, 14, 16...	NL xxx

AMOXICILLINE MYLAN PHARMA 1 g, comprimé dispersible

PMS ID: 600001127709 | Authorisation Country: FR | MAH: ORG-100001581 | Authorisation Status: Valid
Version Number: — | Last updated date: —

Medicinal Product

Marketing Authorisation Information

Therapeutic Indications

Manufacturers

Ingredients

Medical Devices

Packaged Medicinal Product

↑	MA number	Package size(s)	PCID	EV code
^	NL xxx	—	—	—
Package description 2, 6, 8, 10, 12, 14, 16, 20, 24, 30, 100 OU 1000 COMPRIMÉS SOUS PLAQUETTES				



**French medicinal products can be submitted at pack size level or medicinal product level.
How should they be updated?**

- Separate records are submitting per pack size but all of them reflect the same NL number in the authorisation number field.
- In this case, it would be a good approach to include the package number (CIP) in the package description or to update the NL number with the package number.



XEVMPD contains only the package description but there is no field to include the structured pack size information (quantity and units of presentation). How is this field going to be populated?

Repaglinide Aurobindo 2 mg compresse

PMS ID: 600001128171 | Authorisation Country: IT | MAH: ORG-100000589 | Authorisation Status: Valid
Version Number: — | Last updated date: —

Medicinal Product **< Packaged Medicinal Product**

Download

MA number	Package size(s)	PCID	EV code	Legal status of supply
041739196	—	—	—	—

Package description LE COMPRESSE DI REPAGLINIDE AUROBINDO SONO DISPONIBILI IN FLACONE HDPE | Language —

Pack Size

Unit of Presentation	Quantity
⚠ Data are not available in SIAMED/XEVMPD and not loaded. Users are encouraged to provide it when applicable.	

Shelf life / Storage Open

Data carrier identifier(s) Open

 **Repaglinide Aurobindo 2 mg compresse**
PMS ID: 600001128171 | Authorisation Country: IT | MAH: ORG-100000589 | Authorisation Status: Valid
Version Number: — | Last updated date: —

 Medicinal Product   **Packaged 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

[Download](#)

MA number

041739196

Package size(s)

—

PCID

—

EV code

—

Legal status of supply

—

Package description

LE COMPRESSE DI REPAGLINIDE AUROBINDO SONO DISPONIBILI IN FLACONE HDPE

Language

—

Pack Size

Close

Unit of Presentation

Quantity

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

Shelf life / Storage

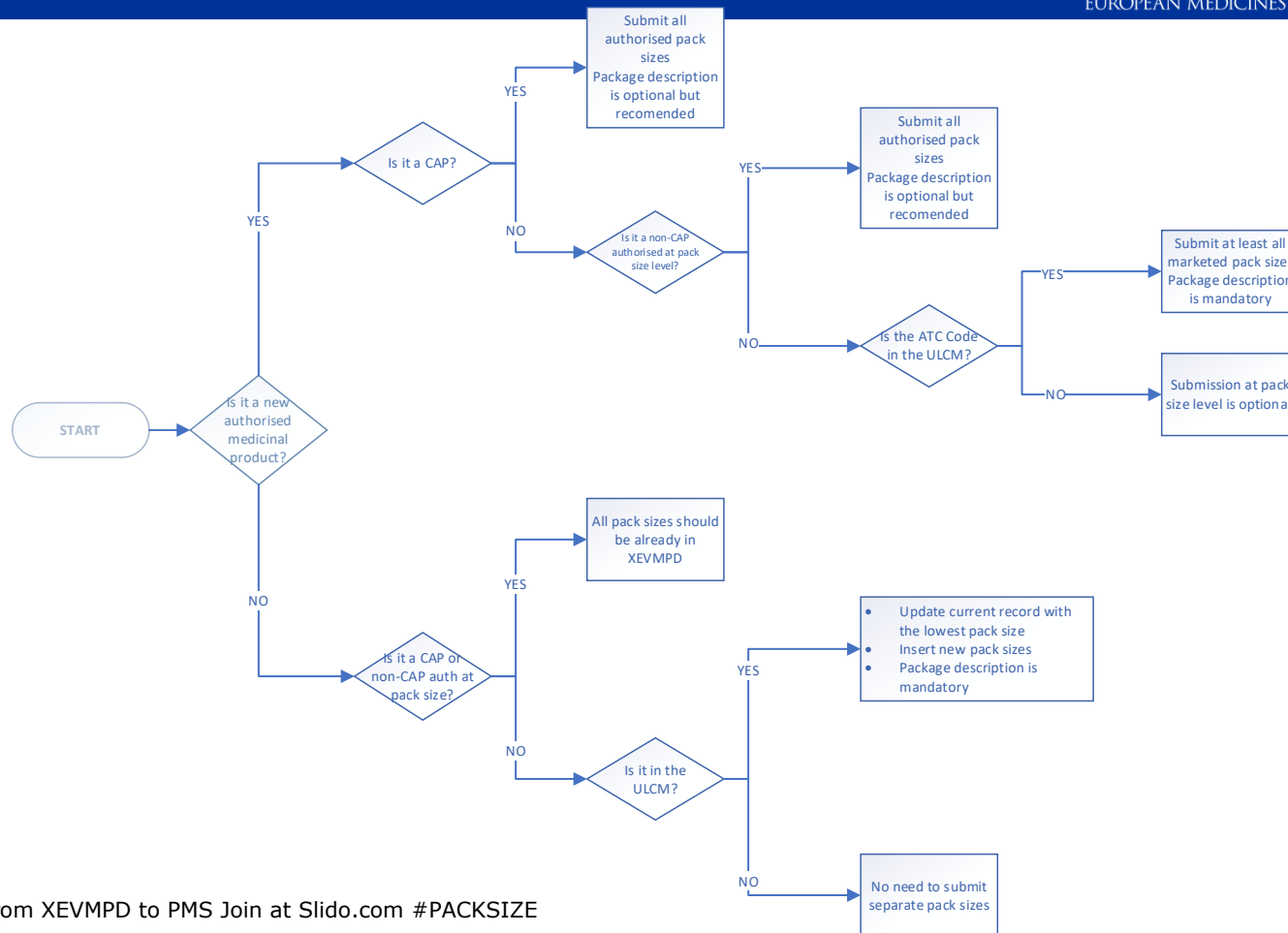
Open

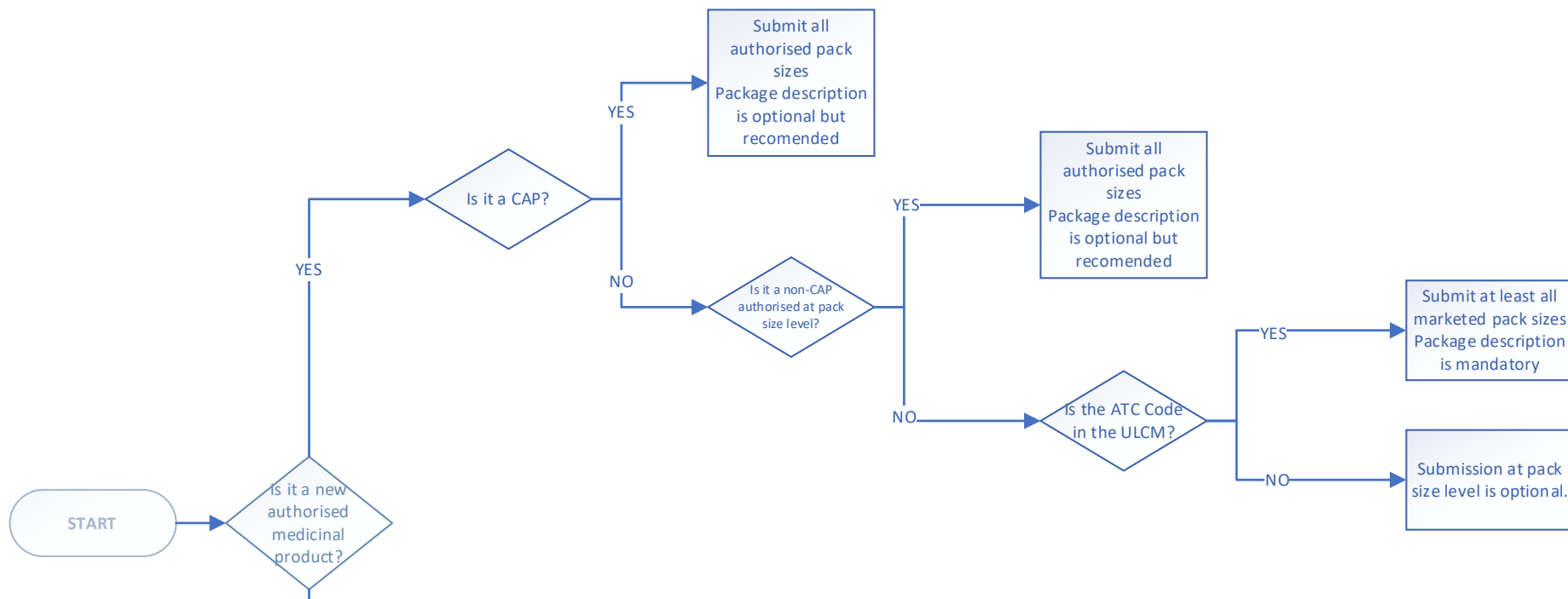
Data carrier identifier(s)

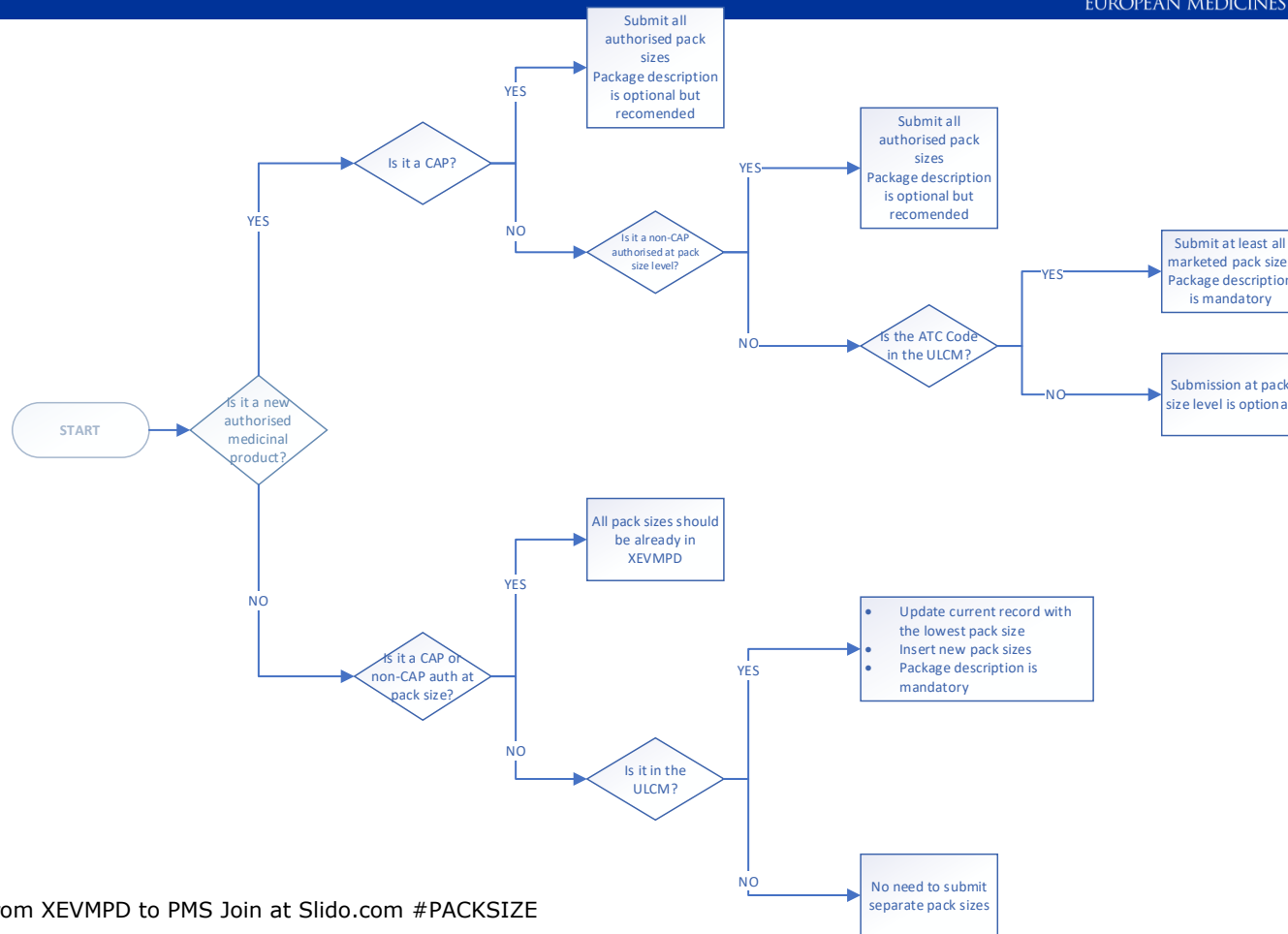
Open

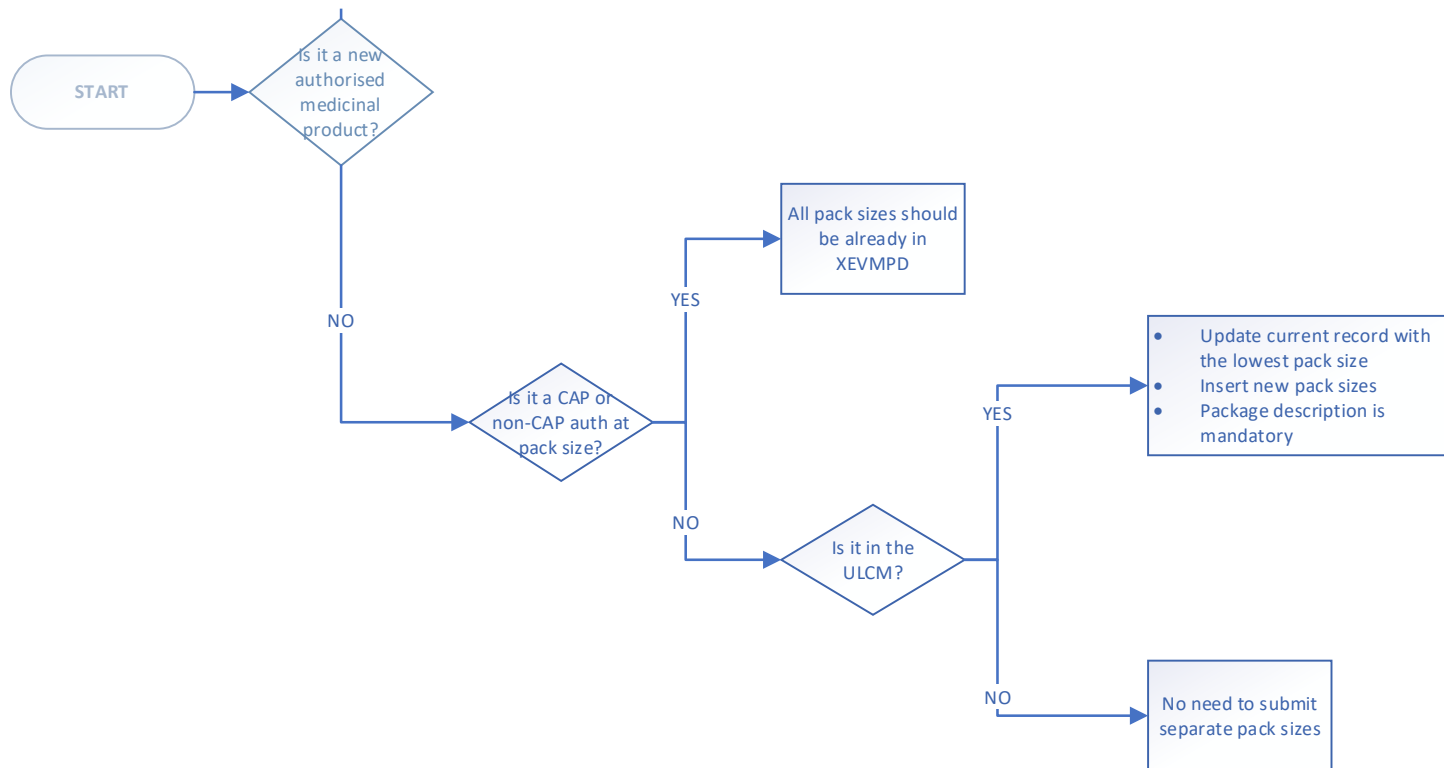
- Package description and structured pack size information are different fields in PMS.
- **Package description will be captured from XEVMPD and the structured data will have to be provided for non-CAPs via PMS API or Product UI from 2025.**

- This is why the package description is useful: to identify better each pack size once the capability to enrich the structure pack size information is available.
- Manufacturers for non-CAPs will be submitted at the same time. **Additional information will be provided in due course.**











Next steps



Quarterly System Demos (next: 18 September 2024)

- See and discuss the latest developments of the system
- Give your feedback on features and priorities

Announced via EMA's
Website Events Pages



PMS Web Page

Find:

- > PMS overview
- > EU Implementation Guide

Check regularly



PLM Portal Forum + PMS News page

- Check:
 - > News
 - > Release notes
 - > Downtime comms
- Ask questions (Forum)

Check regularly



Industry & Network SMEs

The Industry & Network SMEs are your connection to product development.

Engagement to be
determined by NPO & SMEs

Upcoming communication & engagement activities for PMS

Q3			Q4		
Jul	Aug	Sep	Oct	Nov	Dec
 EU IG Ch 7 update   API Go-live for Industry (All products view-only) PLM Newsletter publication    API training session Pack sizes training session Q&A clinics	 EU IG Ch 5 & PUI user guide update  PUI go-live for NAPs (view-only)   API Go-live for NCAs (All products view-only) API training session	  EU IG Ch 2 update Public system demo  API training session	 Training session on NAPs H var submissions in web-based eAF	  PLM Newsletter publication Training on write access to PMS	  EU IG Ch 3, 4 update Public system demo
Continuous enhancement to PUI layout & release of functionalities					
Discussion on Enrichment process and process to submit ESMP data via PMS					
Discussion on PMS Access Level 1 to expand the publicly available dataset via PUI					
PLM portal – continuous performance improvements					



Further details on **planned PMS engagement activities** provided on the **quarterly PLM Newsletter**.



Next edition to be published in mid-July 2024



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Q&A

Any questions?

Further information

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