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

Agenda

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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**.*

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

Housekeeping notes – Q&A

Join at
slido.com
#PACKSIZE

- 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 (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

Background

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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Improving the availability of medicines authorised in the EU is a key priority for the **European Medicines Regulatory Network** (EMRN)

Regulatory authorities - within and outside Europe - are increasingly **working together** to prevent shortages and to limit their impact whenever they occur

Background

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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.

Background

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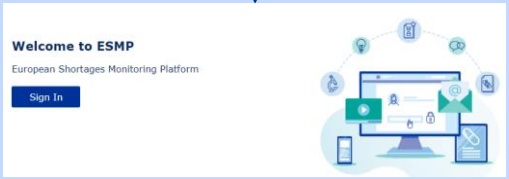
Member State data systems

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

ESMP



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

Packaged medicinal product data (PMS)

Prefilled in ESMP templates/machine-to-machine

Users **complete ESMP templates** with relevant information per product

Data analytics platform

Matching of supply and demand data

Regulatory coordination

SPOC WP, MSSG, and EC

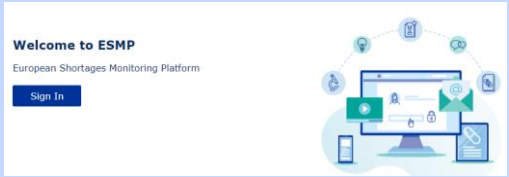
Measures to prevent, manage and mitigate shortages in EU/EEA, such as exploring MAHs supply capacity and possibility to increase production, regulatory support, etc.

Prevent, monitor and manage shortages

Additional information in the ESMP essentials webinar

Background

ESMP



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Packaged medicinal product data (PMS)

Prefilled in ESMP templates/machine-to-machine

	A	B	C	D	E	F	G	H	I	J	K
1	Packaged	Medicinal product - (Full medicinal	Medicinal product	Active Substance	Strength	Pharmaceutical form	Pack Size	Packaging	PCID	Country of authorisation	Marketing Status
2	55880	Brintellix 5 mg - Film-coated tablet	Brintellix	Vortioxetine hydrobromide	5 mg	Film-coated tablet	100 tablets	Bottle		AT	Temporarily unavailable
3	55880	Brintellix 5 mg - Film-coated tablet	Brintellix	Vortioxetine hydrobromide	5 mg	Film-coated tablet	100 tablets	Bottle		BG	Marketed
4	55880	Brintellix 5 mg - Film-coated tablet	Brintellix	Vortioxetine hydrobromide	5 mg	Film-coated tablet	100 tablets	Bottle		IS	Marketed
5	55880	Brintellix 5 mg - Film-coated tablet	Brintellix	Vortioxetine hydrobromide	5 mg	Film-coated tablet	100 tablets	Bottle		LI	Temporarily unavailable
6	55880	Brintellix 5 mg - Film-coated tablet	Brintellix	Vortioxetine hydrobromide	5 mg	Film-coated tablet	100 tablets	Bottle		NO	Marketed
7	55878	Brintellix 5 mg - Film-coated tablet	Brintellix	Vortioxetine hydrobromide	5 mg	Film-coated tablet	98 x 1 tablets (unit dose)	Blister		BG	Marketed
8											

Users **complete ESMP templates** with relevant information per product

ESMP consumes data from PMS.

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

Background

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

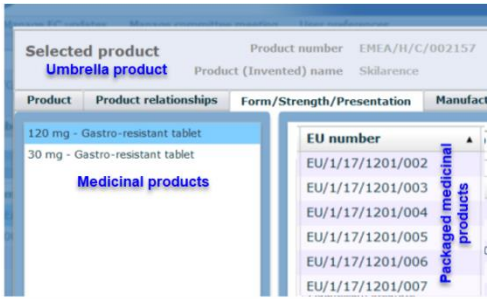
How is pack size information included in PMS?

From SIAMED and XEVMPD to PMS

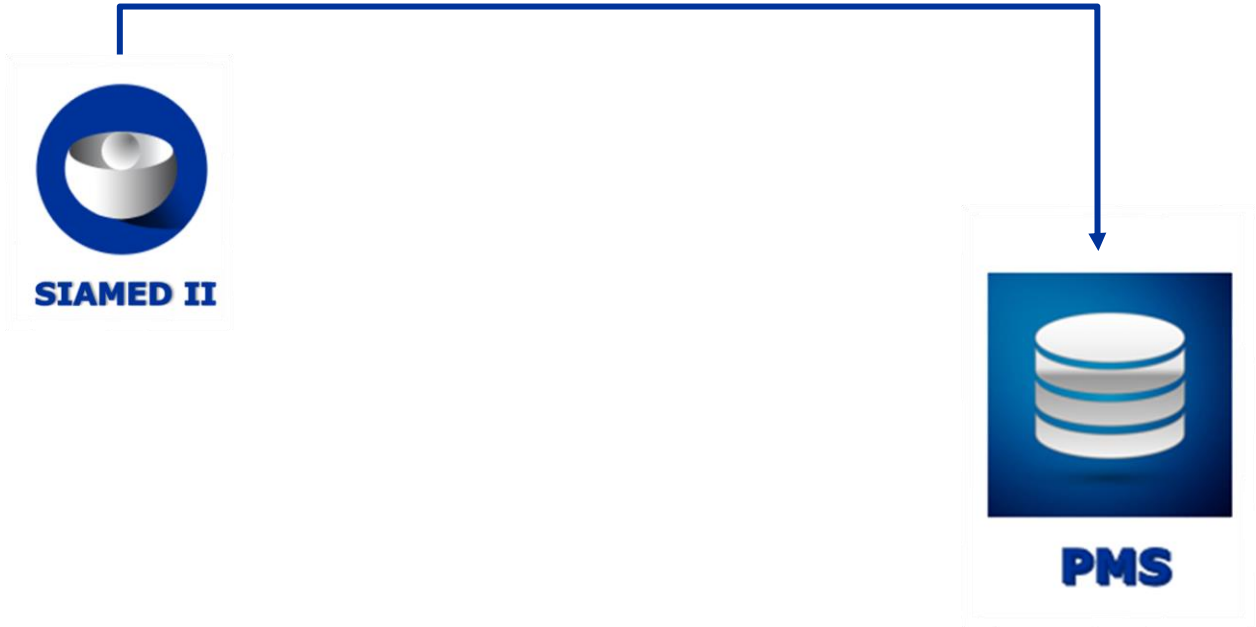
Data sources for PMS

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

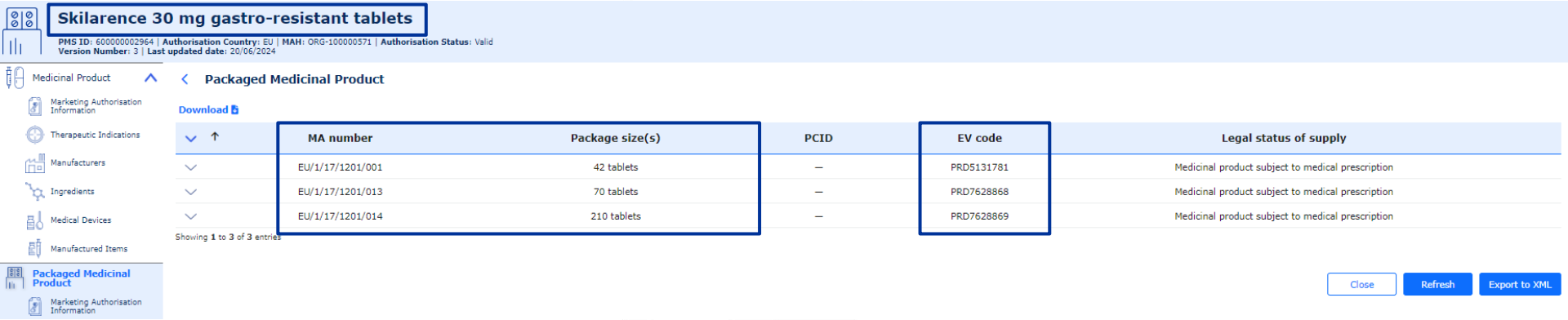
In SIAMED II, a "product" is an umbrella term which can contain several IDMP medicinal products, and each medicinal product can contain multiple presentations.



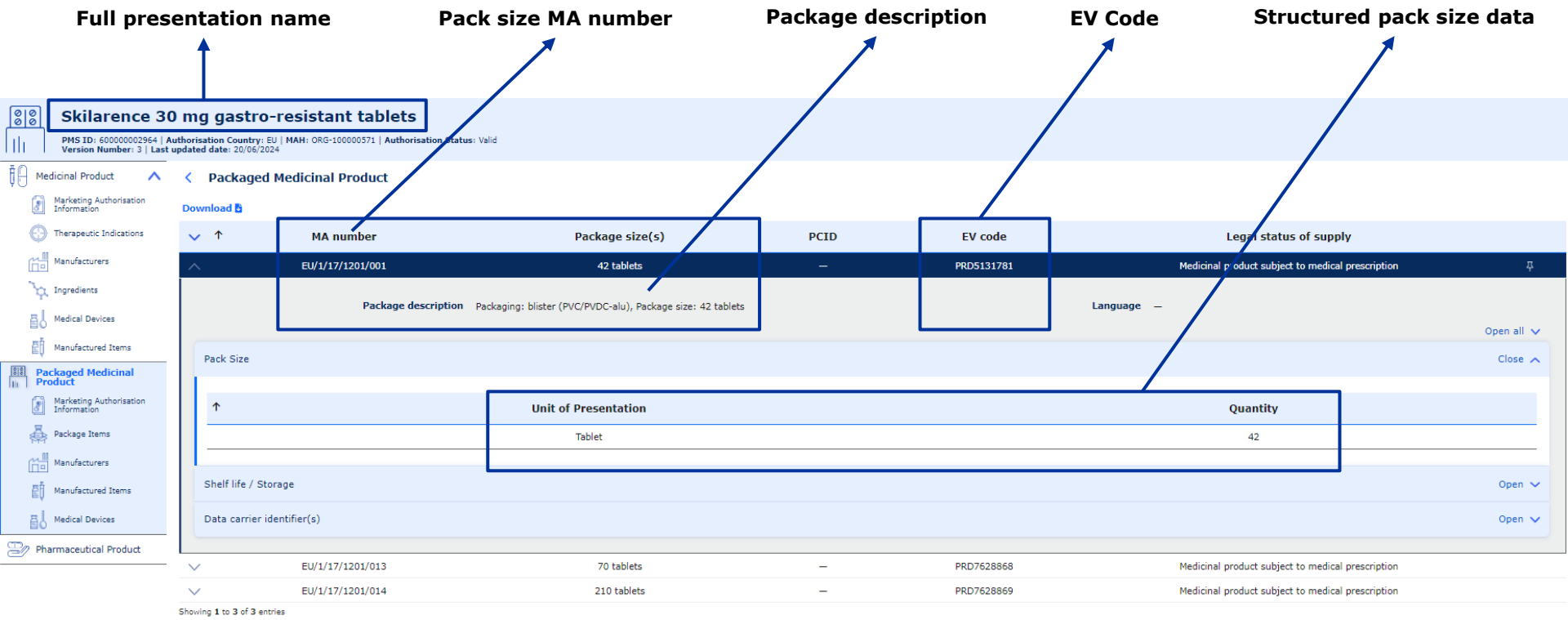
Initial data migration to PMS



Pack size data for CAPs



Pack size data for CAPs



Pack size data for CAPs

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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

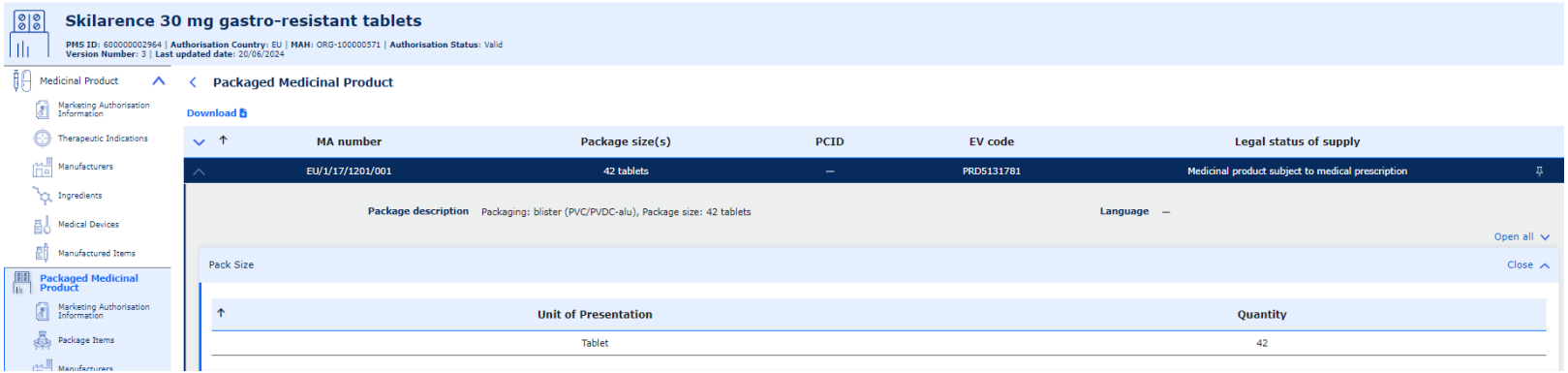
EV code
PRD5131781
PRD7628868
PRD7628869

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

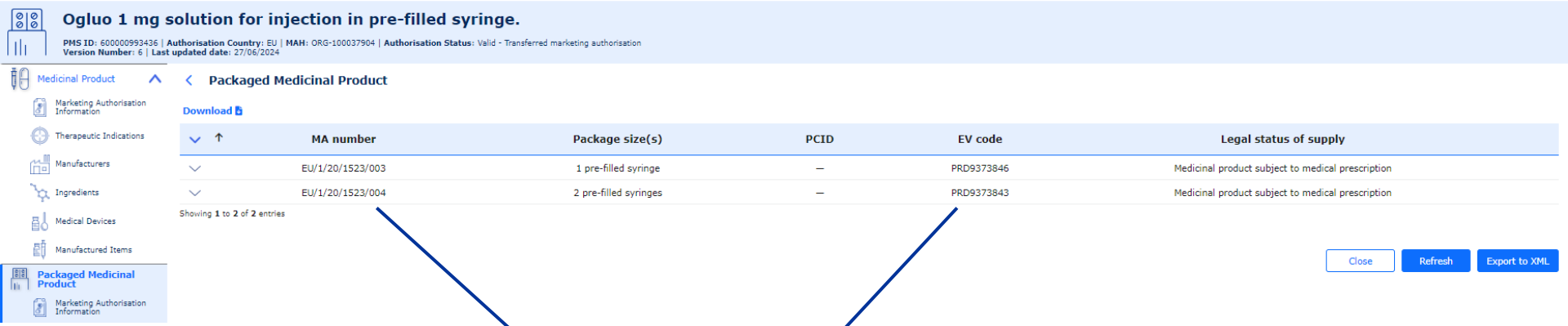
Package description	Packaging: blister (PVC/PVDC-alu), Package size: 42 tablets

- Structured pack size data comes from SIAMED

Unit of Presentation	Quantity
Tablet	42



Pack size data for CAPs



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

Pack size data for CAPs

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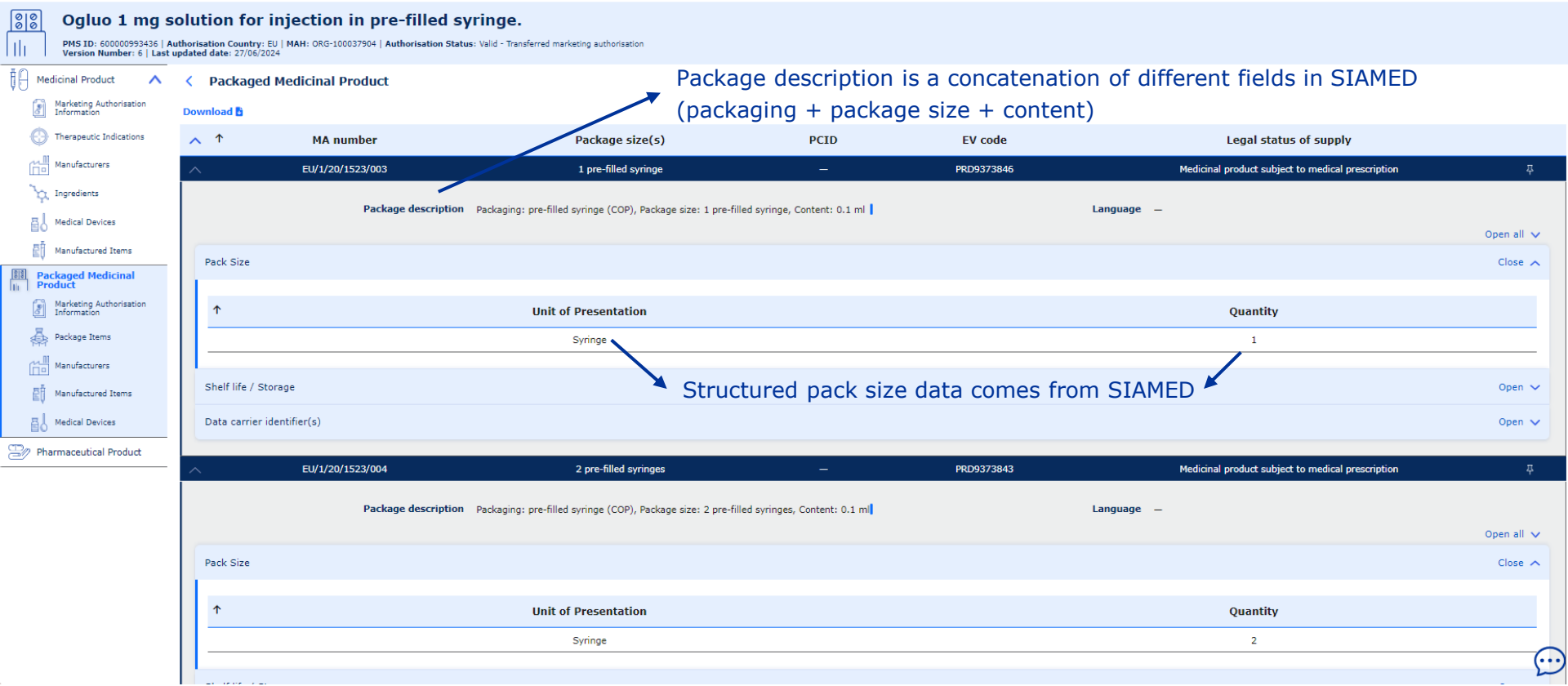
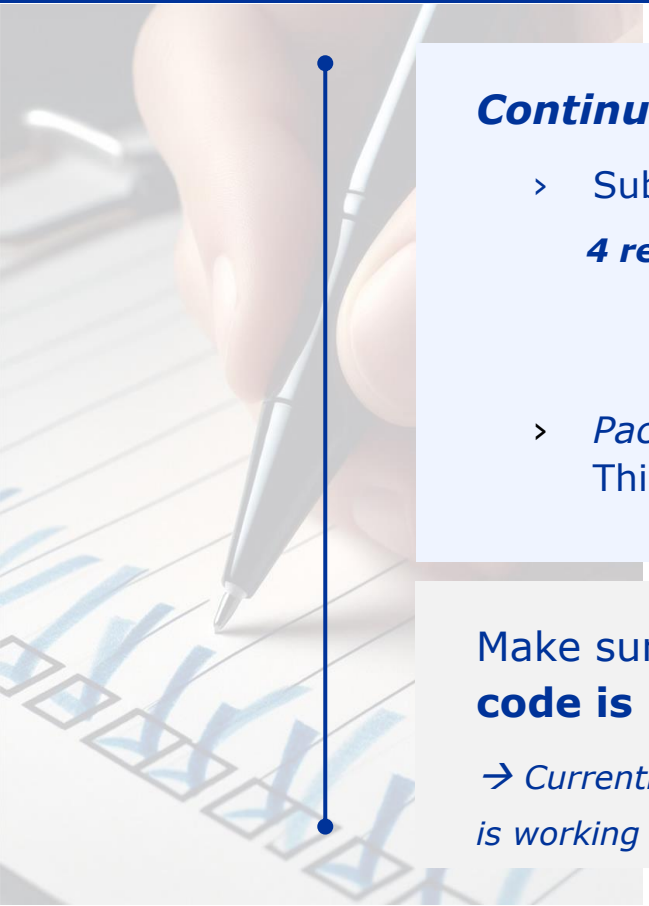


Applicant's requirements for CAPs



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.

Data sources for PMS

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EudraVigilance Human

XEVMPD

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 Fo	Full Presentation Nam	Authorisation Number
Romania	CROSPOVIDONE, LACTOSE MONOHYDRATE, MAGNESIUM STEARATE, SILICA, CO	TABLET	Flamexin, 20 mg, comprimate	7146/2006/03
Romania	CROSPOVIDONE, LACTOSE MONOHYDRATE, MAGNESIUM STEARATE, SILICA, CO	TABLET	Flamexin, 20 mg, comprimate	7146/2006/01
Romania	CROSPOVIDONE, LACTOSE MONOHYDRATE, MAGNESIUM STEARATE, SILICA, CO	TABLET	Flamexin, 20 mg, comprimate	7146/2006/02

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

Initial data migration to PMS

Please, review Chapter 7 of the EU IG or PMS Deep Dive Webinar

Non-CAPs

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

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

Non-CAPs

*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***

Non-CAPs

*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

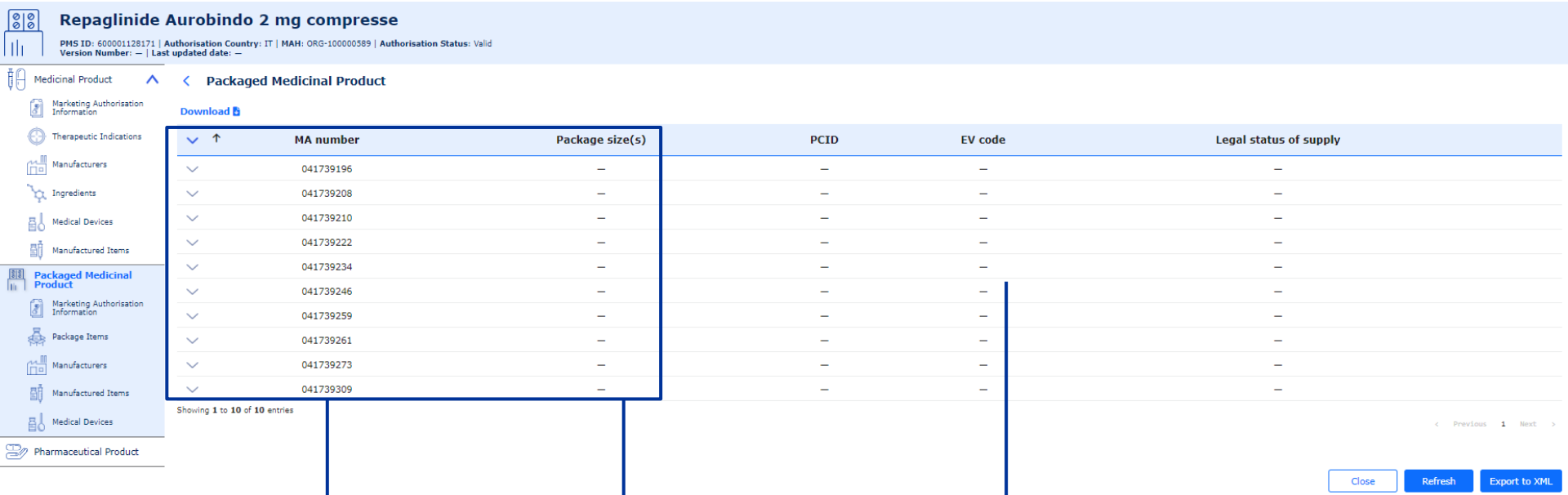
Comprimidos recubiertos con película

Blísteres 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.

Non-CAPs

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

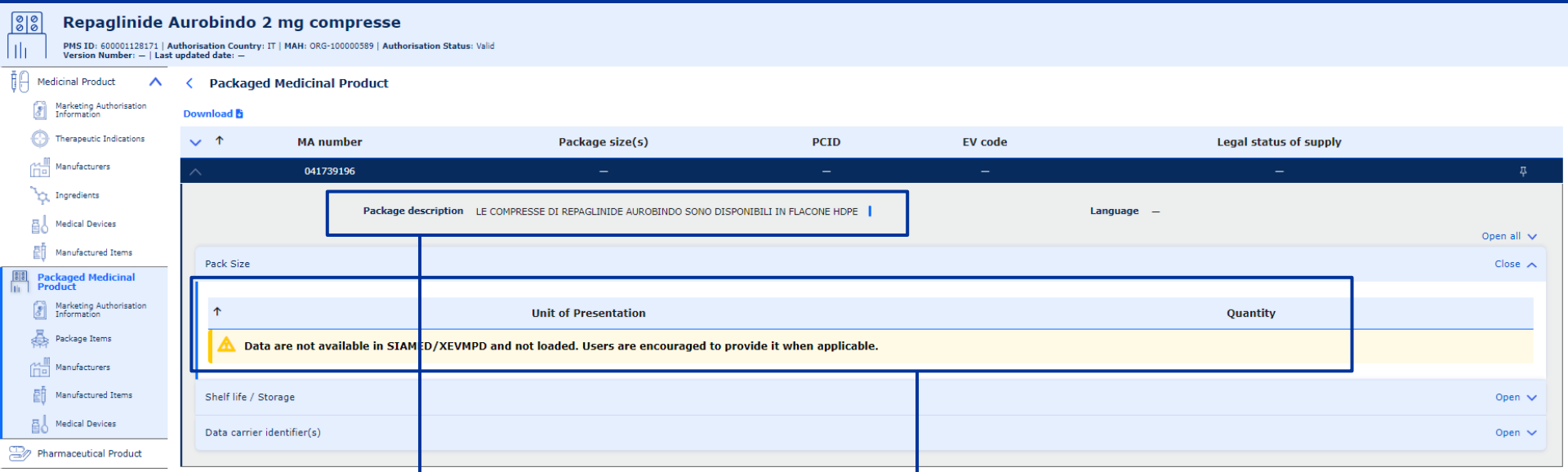


Different **MA number** per pack size

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

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

Non-CAPs



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.

Applicant's requirements for non-CAPs

*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.*

Non-CAPs

*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

Blísteres 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.

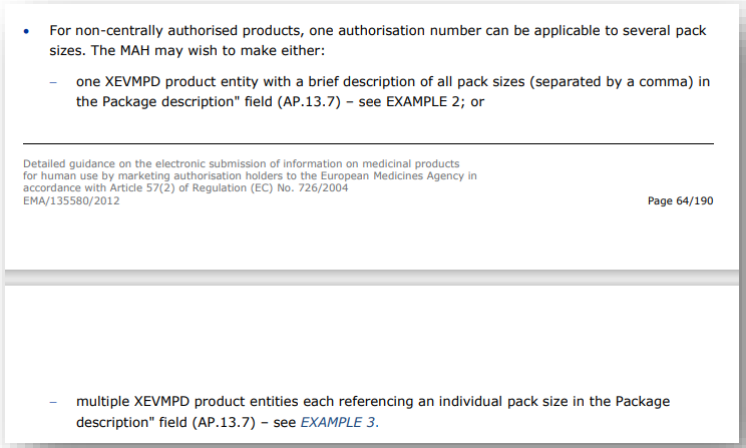
*Marketing Authorisation number is provided at **medicinal product level***

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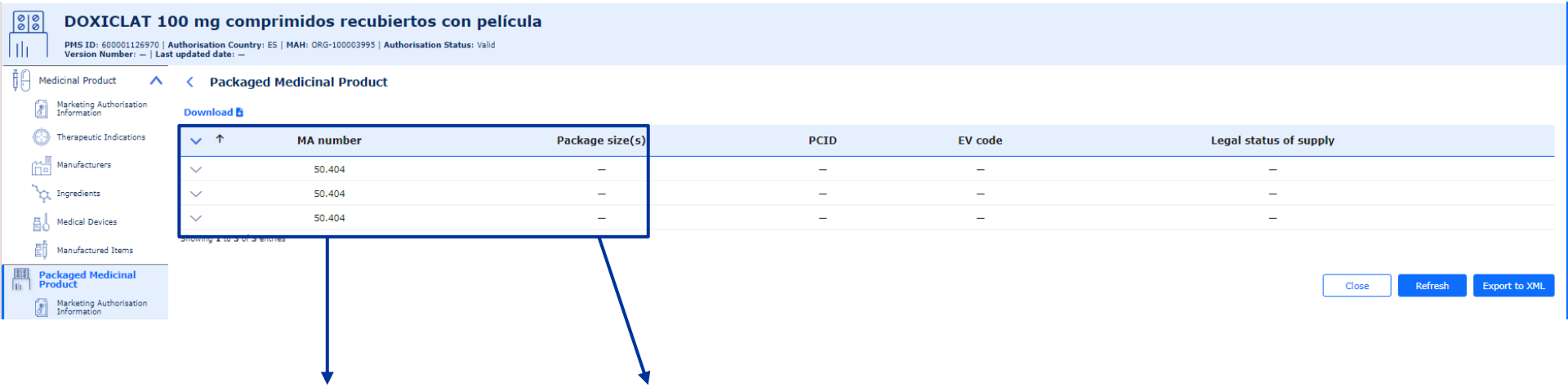
  - multiple XEVMPD product entities each referencing an individual pack size in the Package description" field (AP.13.7) – see *EXAMPLE 3*.

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***

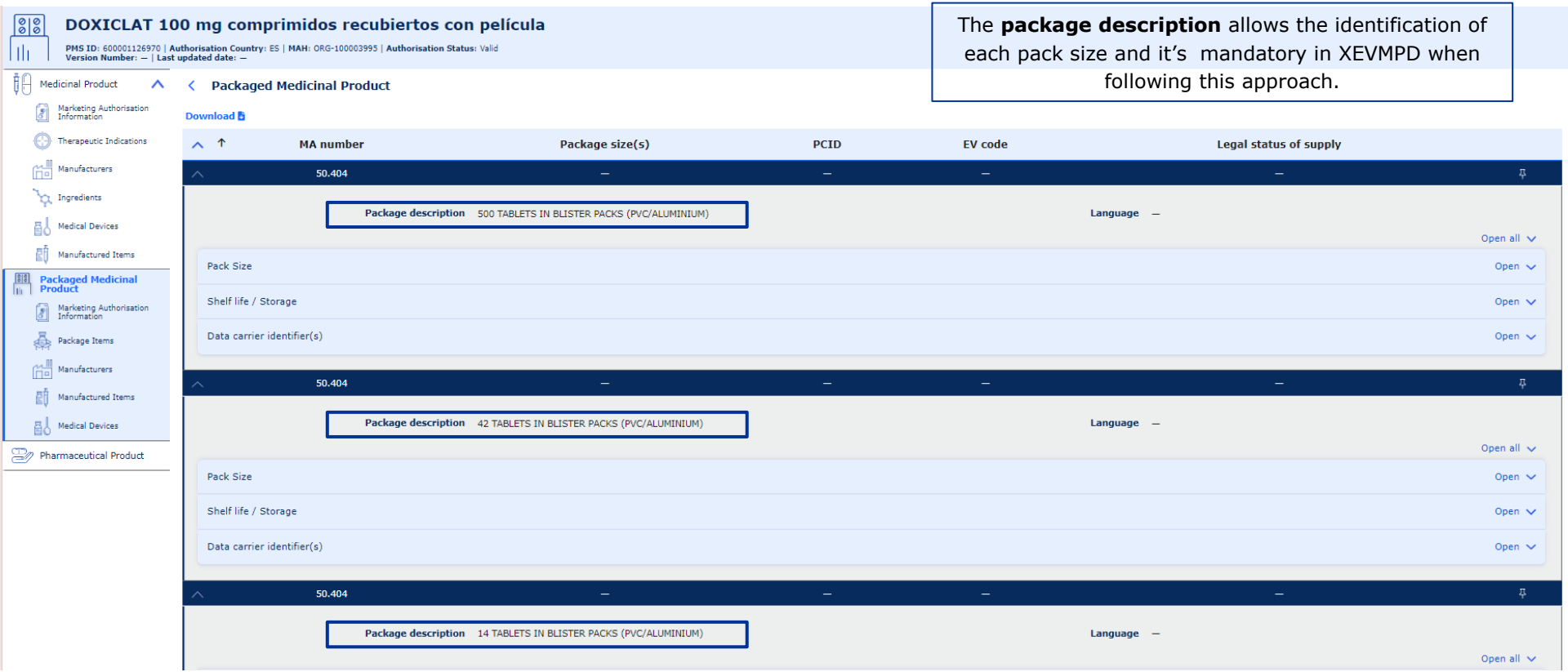
One XEVMPD record per pack size



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

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



Applicant's requirements for non-CAPs

*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

TIPS

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

*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:

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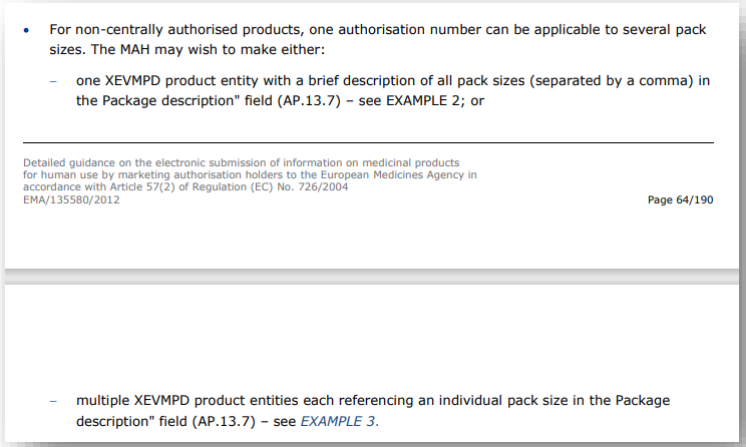

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Detailed guidance on the electronic submission of information on medicinal products for human use by marketing authorisation holders to the European Medicines Agency in accordance with Article 57(2) of Regulation (EC) No. 726/2004
EMA/135580/2012 Page 64/190

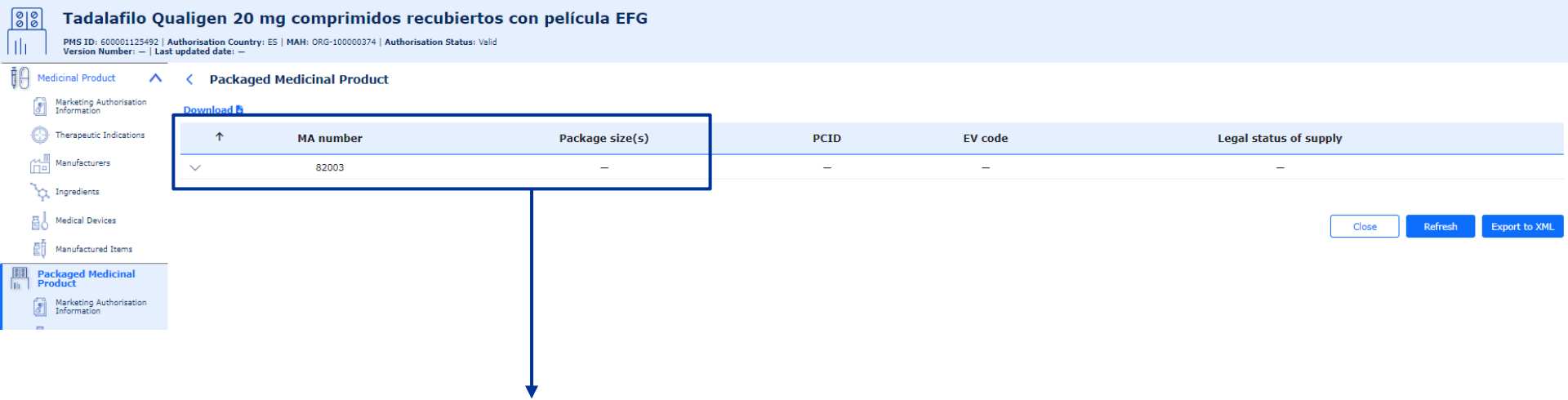
  - multiple XEVMPD product entities each referencing an individual pack size in the Package description" field (AP.13.7) – see *EXAMPLE 3*.

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)

Non-CAPs

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

One XEVMPD record for all pack sizes



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

Non-CAPs

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

One XEVMPD record for all pack sizes

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

Applicant's requirements for non-CAPs

*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.

Process to submit pack sizes through XEVMPD

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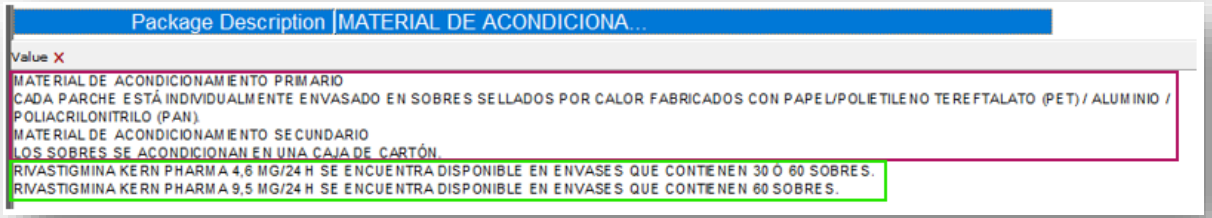
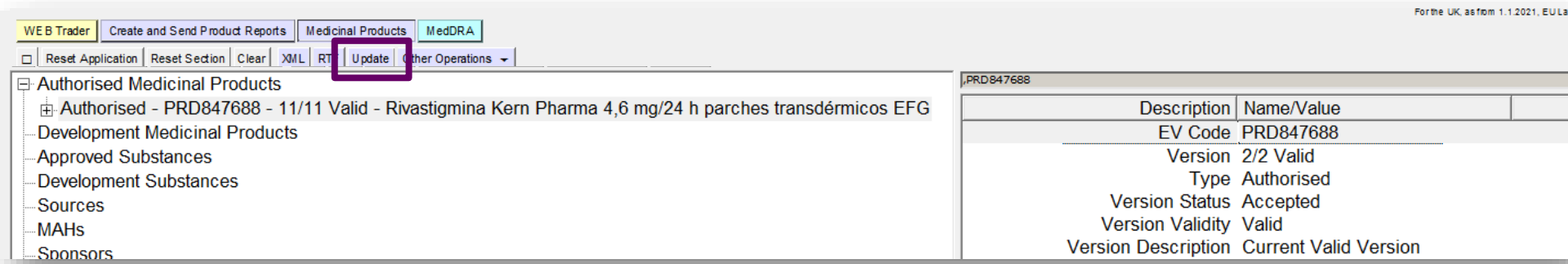
1 Identify the EV code to be updated



Process to submit pack sizes through XEVMPD

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



Process to submit pack sizes through XEVMPD

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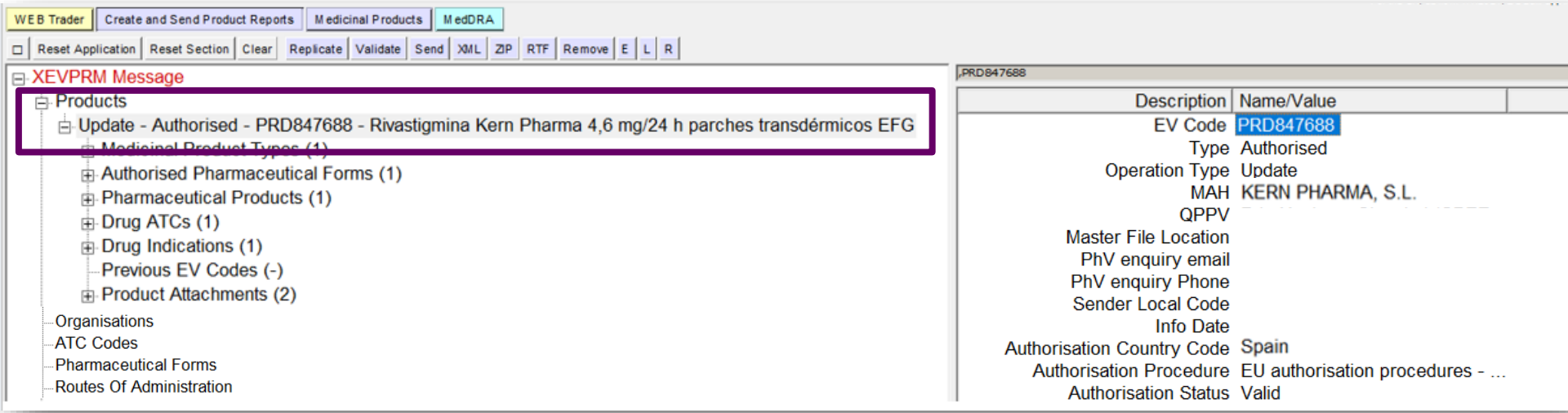
2b The product is now moved in the 'Create and Send Product Reports' section and ready for update



Process to submit pack sizes through XEVMPD

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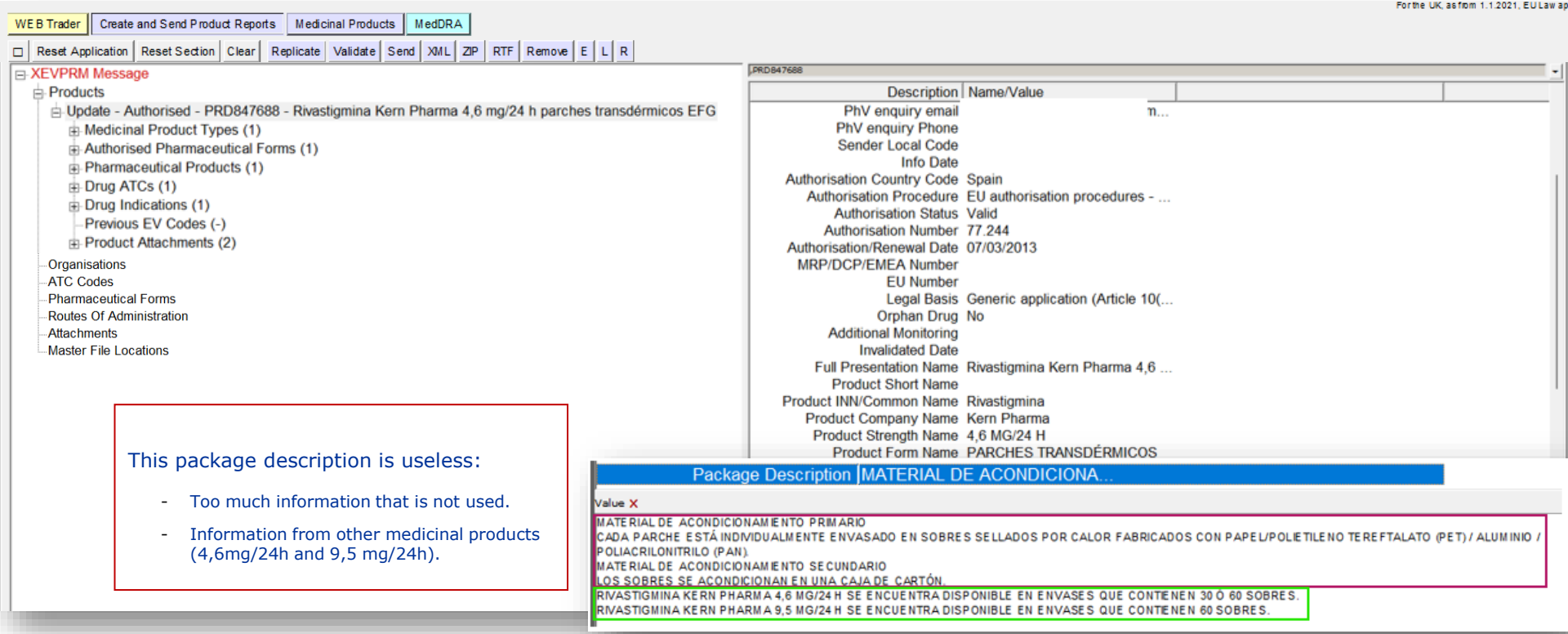
3a Identify the lowest pack size



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).

Process to submit pack sizes through XEVMPD

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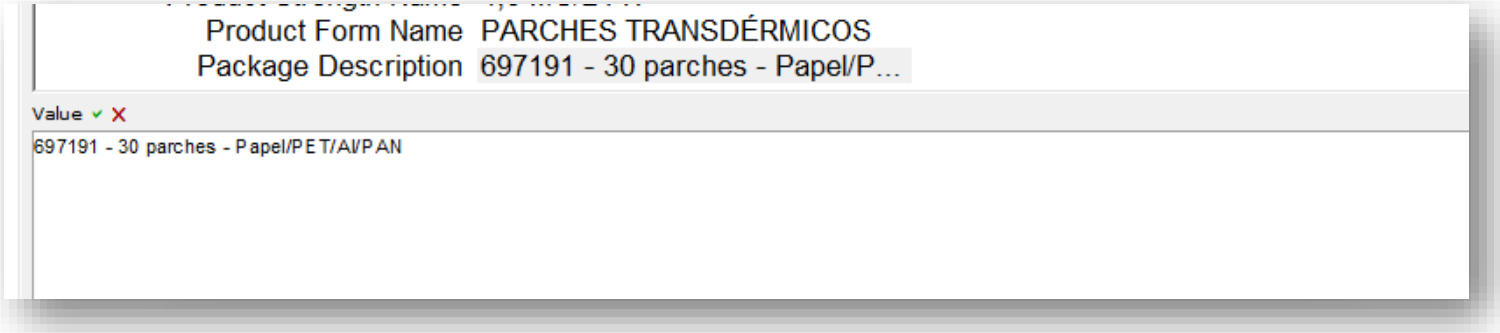
3b Change the package description to the lowest pack size

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



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

The additional pack sizes should be created now.

Process to submit pack sizes through XEVMPD

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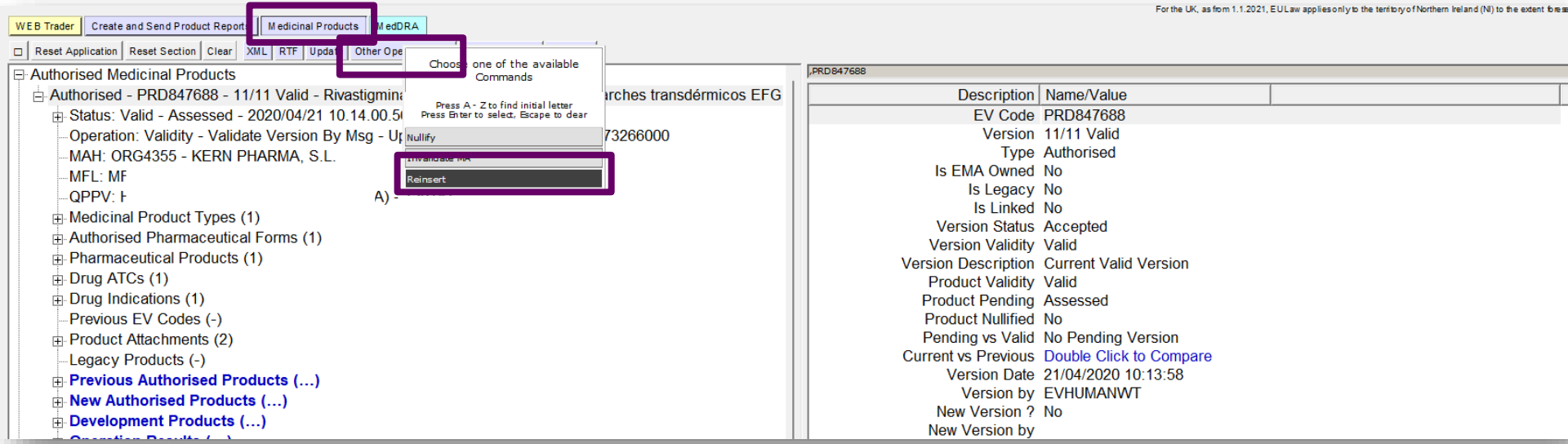
4 Go back to the 'Medicinal Products' section and, in 'Other Operations' select 'Reinsert'

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



Process to submit pack sizes through XEVMPD

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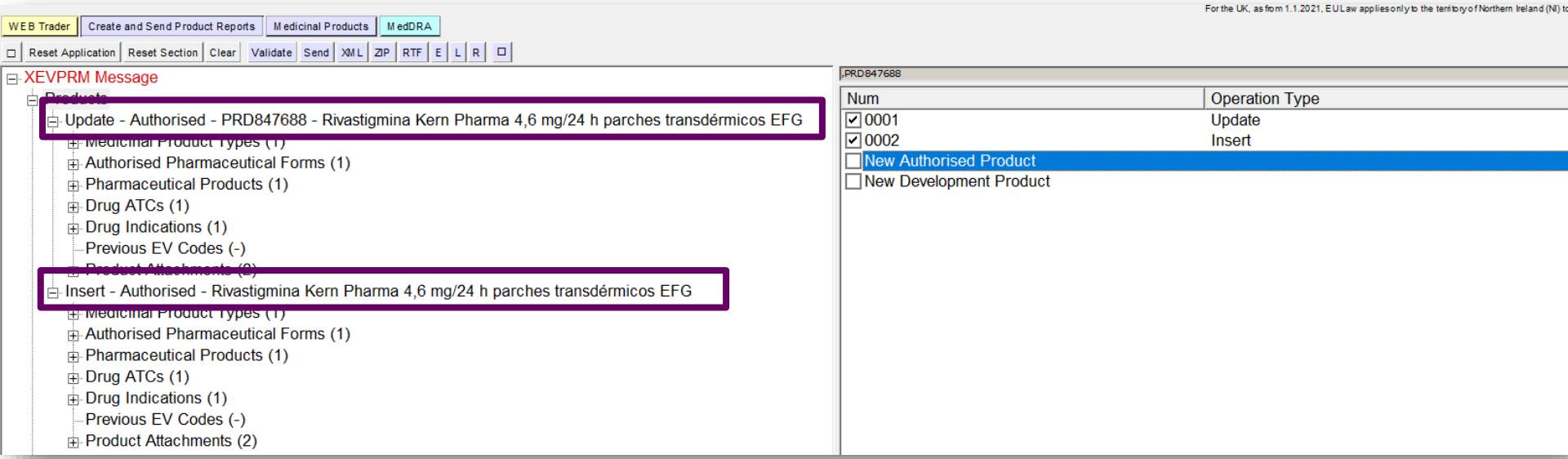
5a The XEVPRM now references two AMP records:

- 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



Process to submit pack sizes through XEVMPD

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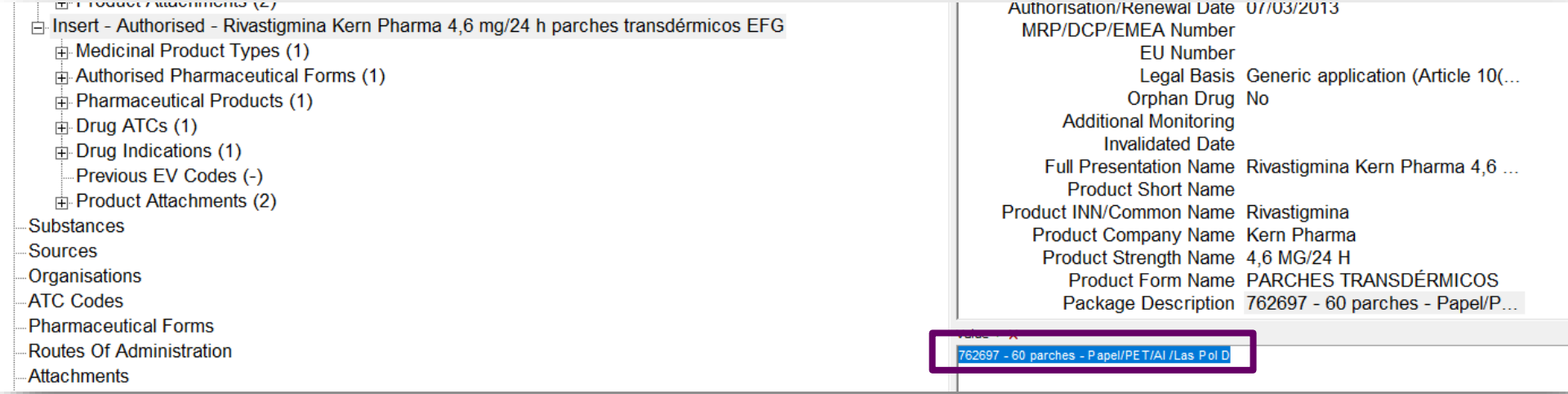
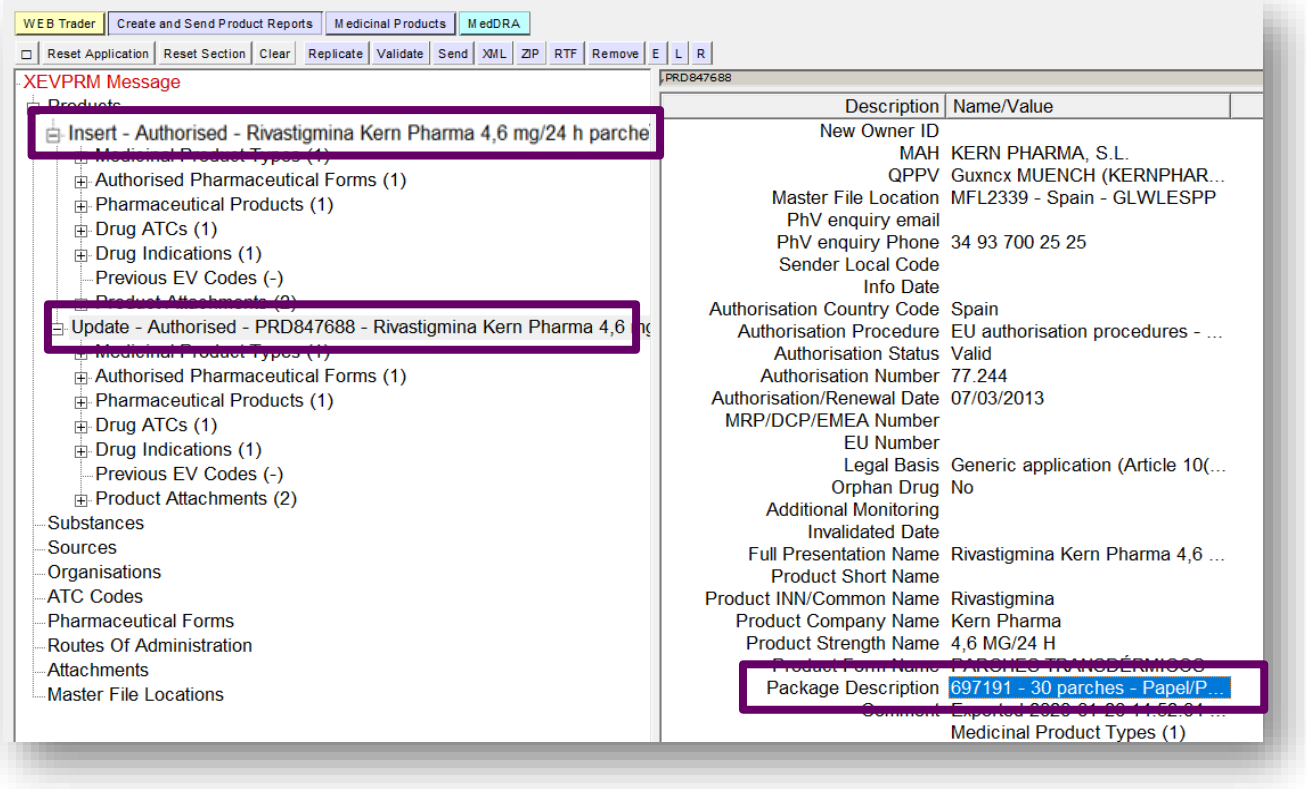
5b Change the package description in the product insert to reflect another pack size



Process to submit pack sizes through XEVMPD

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.



Process to submit pack sizes through XEVMPD

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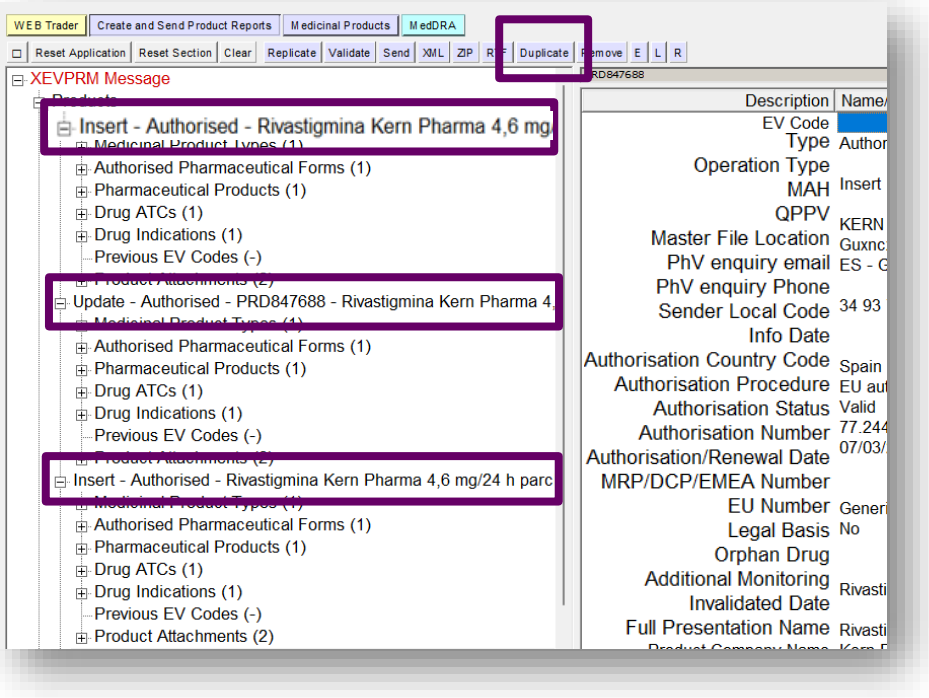
6 If you need to create new records for additional pack sizes, you can create duplicates of the record and change the package descriptions accordingly in the newly created entries.



Process to submit pack sizes through XEVMPD

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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 co	ATC name	PMS id	Package PN	EV cod	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_si
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_si
A02BC05	esomeprazole	600001434371	31061001	PRD79746	Nexium, enterotabletter	Gastro-re	LOC-100006949	Denmark	SE/H/0211/002	31490	31490	
A02BC05	esomeprazole	600001434387	31061005	PRD79464	Nexium 40 mg enterotabletter	Gastro-re	LOC-100006949	Norway	SE/H/0211/002	00-1995	00-1995	
A02BC05	esomeprazole	600001434521	31047813	PRD79621	Nexium 40 mg – magensaftresistente 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 gastroresistentsed tabletid	Gastro-re	LOC-100003164	Estonia	DK/H/2131/001	805413	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
Luxemburg	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	Codigo nacional
Sweden	MP level	Yes. NPL pack id
The Netherlands	MP level	No

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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

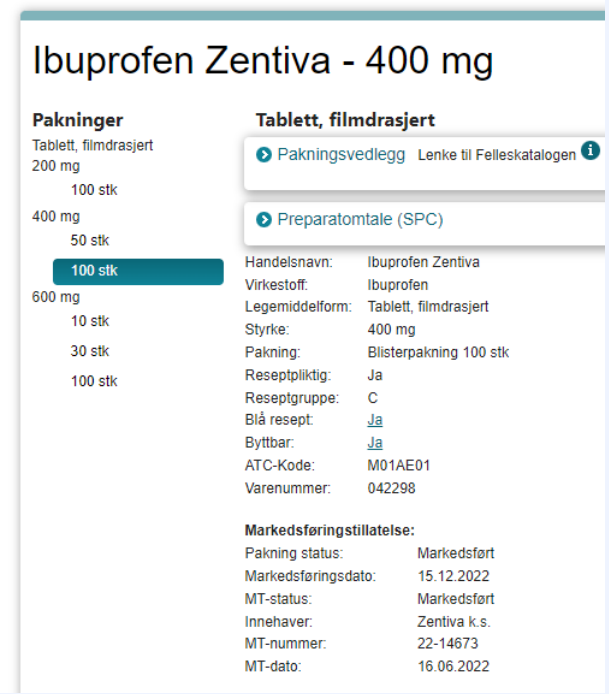
0053603 - 1 FLACON – 200 ml

0368339 - 1 FLACON – 400 ml

650429 - 30 sobres

600044 - 500 sobres

Q&A



042298 – 100 film-coated tablet

382141 – 50 film-coated tablet

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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	⌄

EUROPEAN MEDICINES AGENCY

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 (15ºC) (y)	Cantidad de producto gaseoso a (15ºC y 1atm) en m³ (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.
Bloque 18	900	200	192924	192,92	261,2	Ac	Man.
Bloque 23	1150	200	246514	246,51	333.8	Ac	Man.

ota al pie (1):
c: bala de gas de acero
l: bala de gas de aluminio o de aluminio revestido de plástico

Man.: válvula manual
at.: válvula integrada analógica
ig.: válvula integrada digital

uede que no todos los tamaños se comercialicen.

.6. Precauciones especiales de eliminació

o fumar.
o acercar a una llama.
o engrasar.

n particular:

o introducir nunca este gas en un aparato que se sospeche pue
aturaleza grasa.
o limpiar nunca con productos combustibles, en especial si so
as ni las válvulas, las juntas, las guarniciones y los dispositivos
o aplicar ninguna materia grasa (vaselina, pomadas, etc.) en el
o utilizar aerosoles (laca, desodorante, etc.) ni disolventes (alc

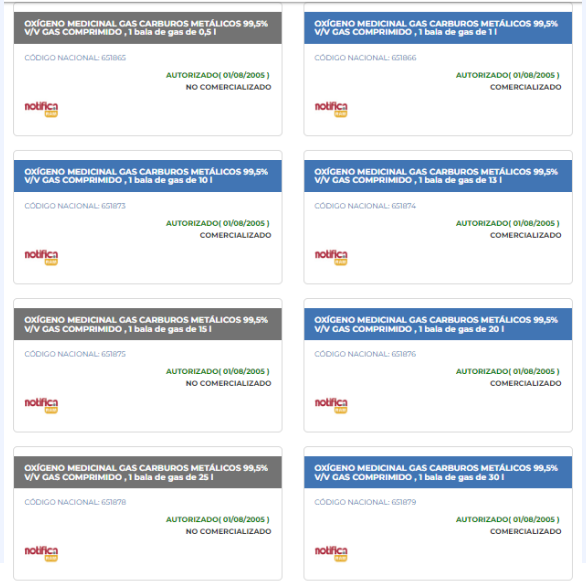
as balas de gas de oxígeno medicinal están reservadas exclu
ara evitar cualquier incidente, es necesario respetar obligatoria
erificar el buen estado del material antes de su utilización.
grupar las balas de gas de capacidad superior a 5 litros
antenerlas en posición vertical y evitar cualquier caída inesper
o 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.

EUROPEAN MEDICINES AGENCY

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:



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. **<u>Important</u>: For the package description use always the same language and info.**

Q&A

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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.

<u>Important</u>: 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.

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SCENARIO 1

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
DESLORATADINE EVOLUGEN 5 mg, comprimé pelliculé	7 COMPRIMÉS PELLICULÉS SOUS PLAQUETTES (OPA/ALU/PVCALUMINIUM)	34009 279 101 7 3
DESLORATADINE EVOLUGEN 5 mg, comprimé pelliculé	10 COMPRIMÉS PELLICULÉS SOUS PLAQUETTES (OPA/ALU/PVCALUMINIUM)	34009 279 102 3 4
DESLORATADINE EVOLUGEN 5 mg, comprimé pelliculé	14 COMPRIMÉS PELLICULÉS SOUS PLAQUETTES (OPA/ALU/PVCALUMINIUM)	34009 279 104 6 3
DESLORATADINE EVOLUGEN 5 mg, comprimé pelliculé	15 COMPRIMÉS PELLICULÉS SOUS PLAQUETTES (OPA/ALU/PVCALUMINIUM	34009 279 105 2 4
DESLORATADINE EVOLUGEN 5 mg, comprimé pelliculé	20 COMPRIMÉS PELLICULÉS SOUS PLAQUETTES (OPA/ALU/PVCALUMINIUM)	34009 279 106 9 2
DESLORATADINE EVOLUGEN 5 mg, comprimé pelliculé	21 COMPRIMÉS PELLICULÉS SOUS PLAQUETTES (OPA/ALU/PVCALUMINIUM)	34009 279 107 5 3
DESLORATADINE EVOLUGEN 5 mg, comprimé pelliculé	28 COMPRIMÉS PELLICULÉS SOUS PLAQUETTES (OPA/ALU/PVCALUMINIUM)	34009 279 108 1 4

DESLORATADINE EVOLUGEN 5 mg, comprimé pelliculé

PMS ID: 600000751966 | Authorisation Country: FR | MAH: ORG-100002031 | 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

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

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SCENARIO 2

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

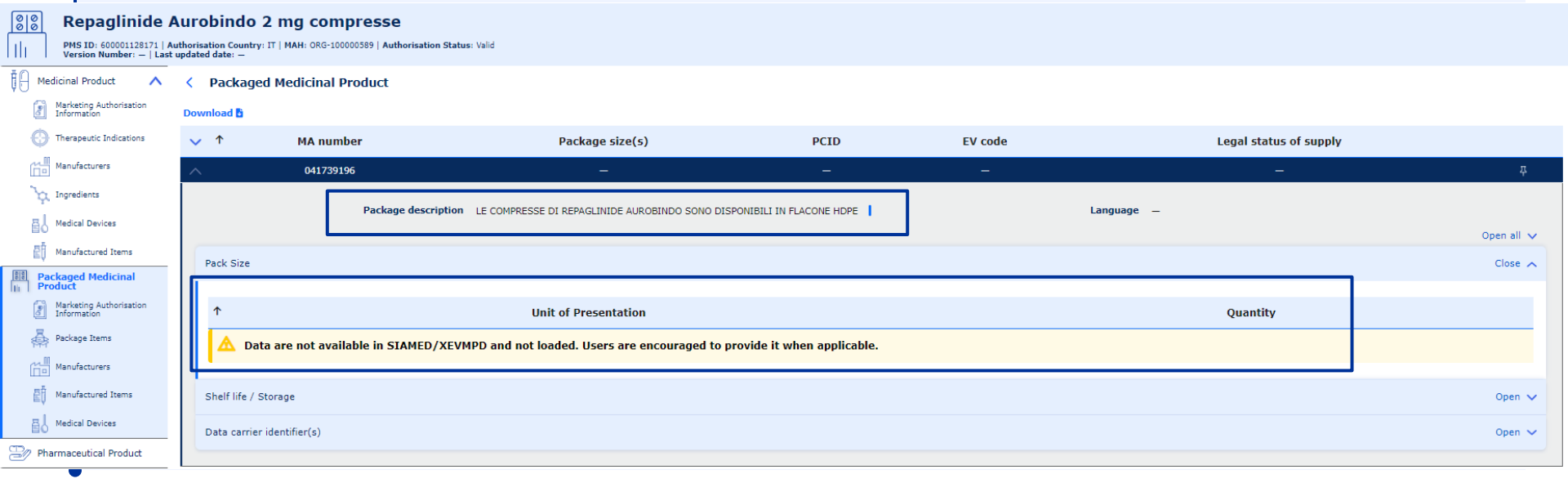
SCENARIO 3

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

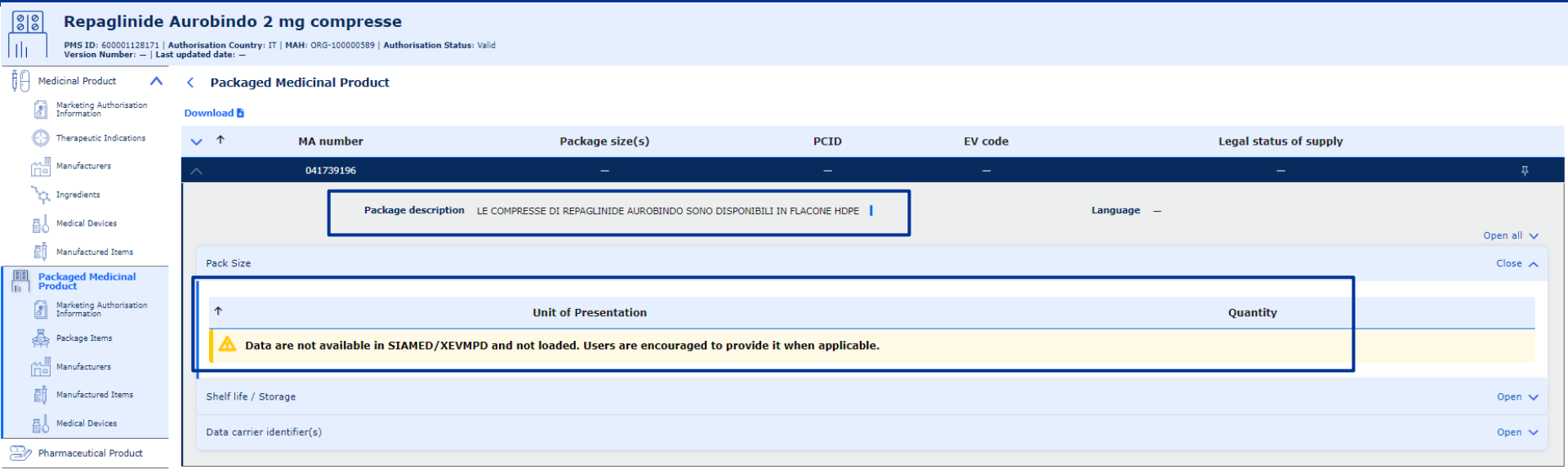
- Separete records are submitting per pack size but all of them reflect the same NL number in the authorisation number field.
- In this case, it would be a good approach to include the package number (CIP) in the package description or to update the NL number with the package number.

Q&A

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?



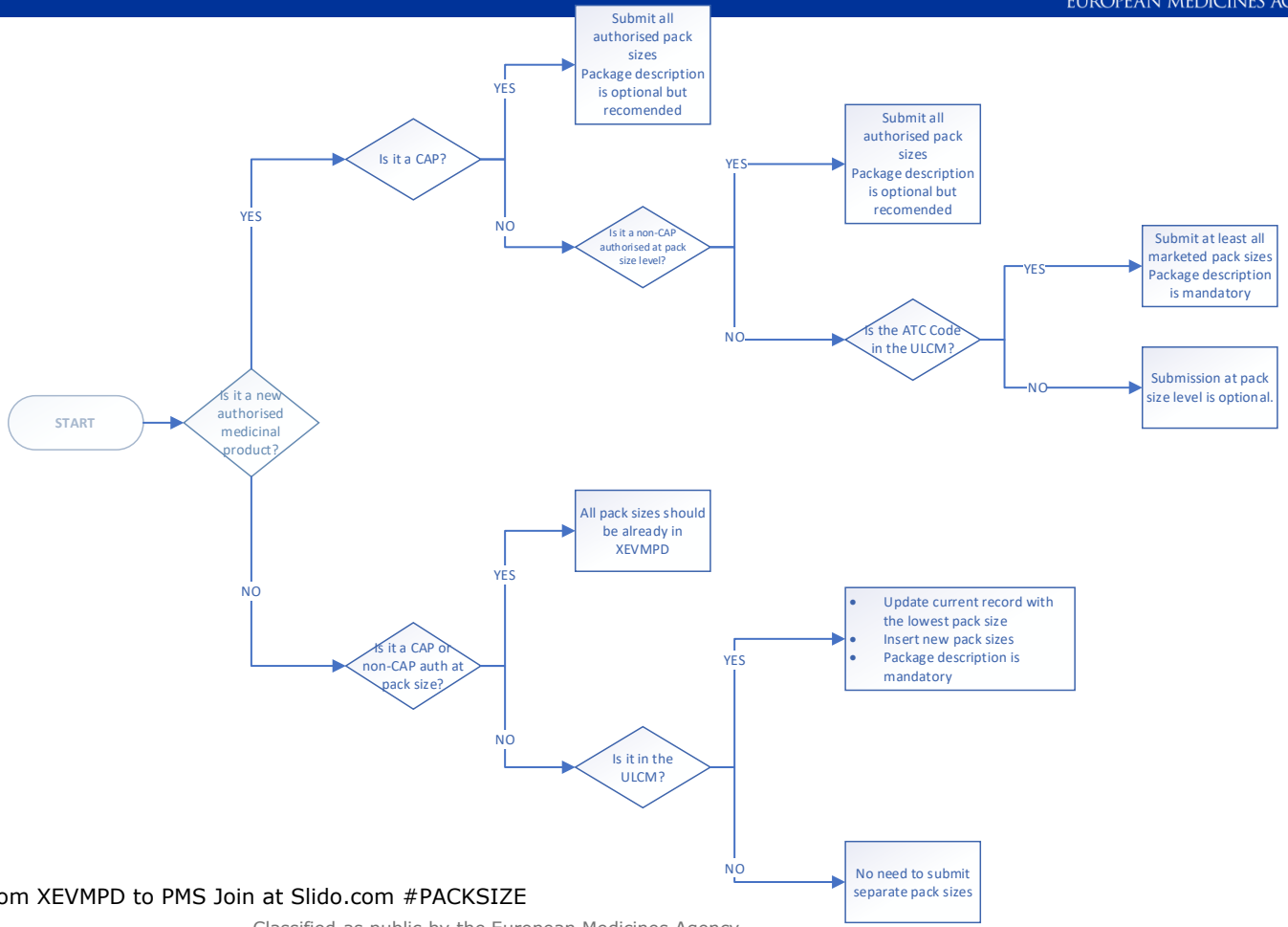
Q&A



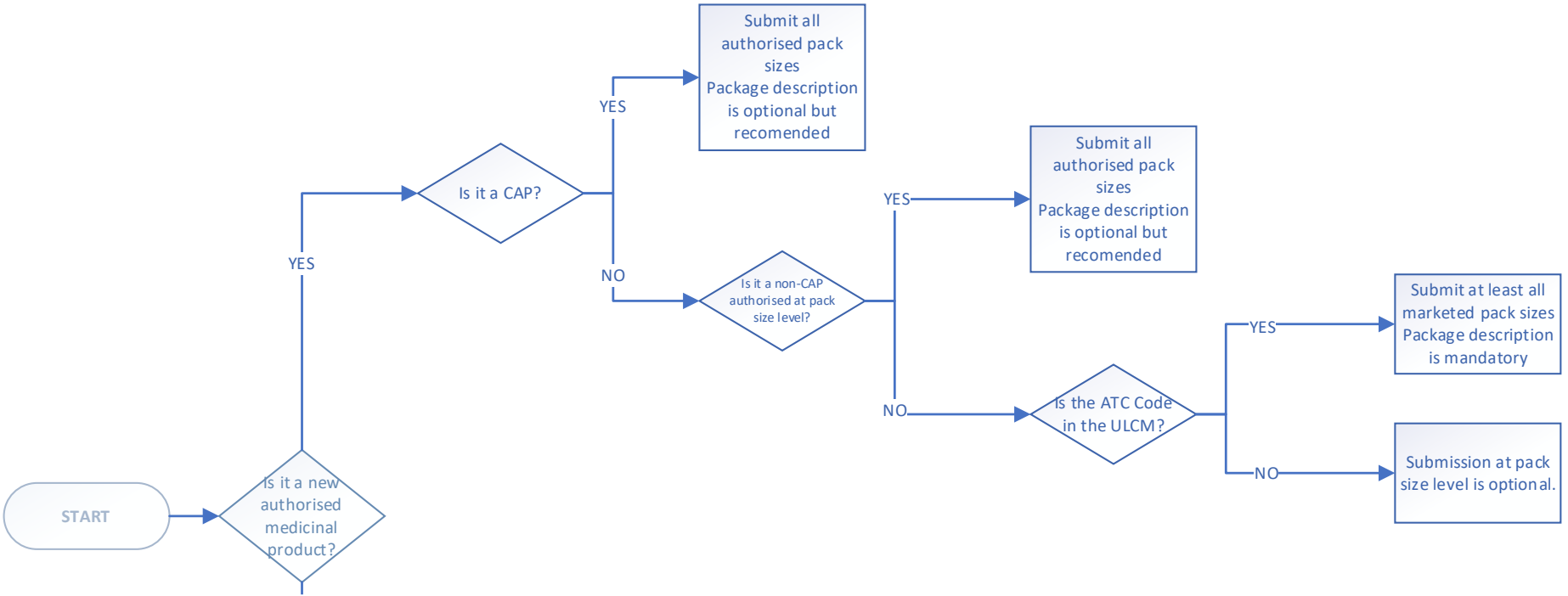
- Package description and structured pack size information are different fields in PMS.
- **Package description will be captured from XEVMPD and the structured data will have to be provided for non-CAPs via PMS API or Product UI from 2025.**

- 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.**

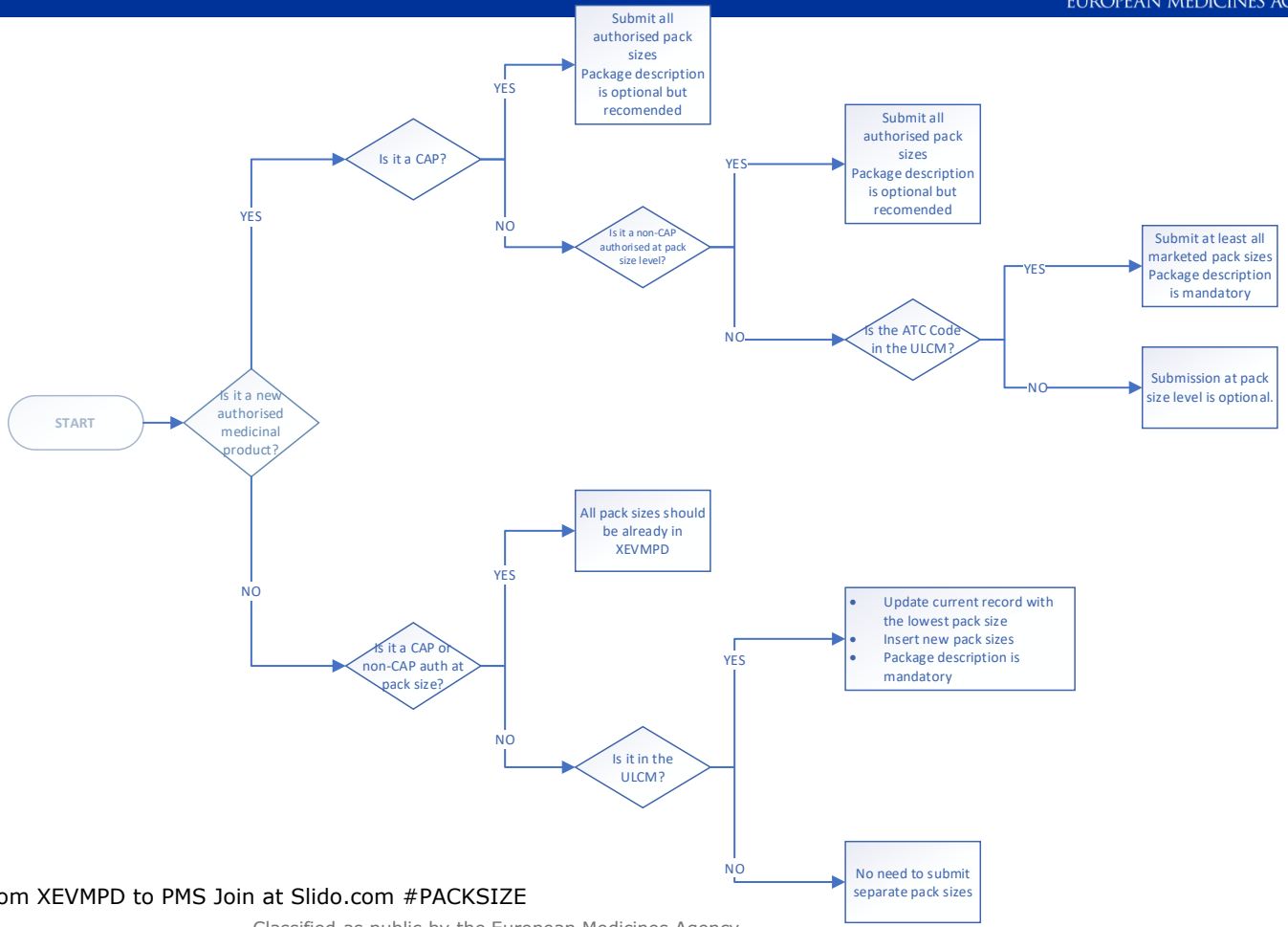
Summary



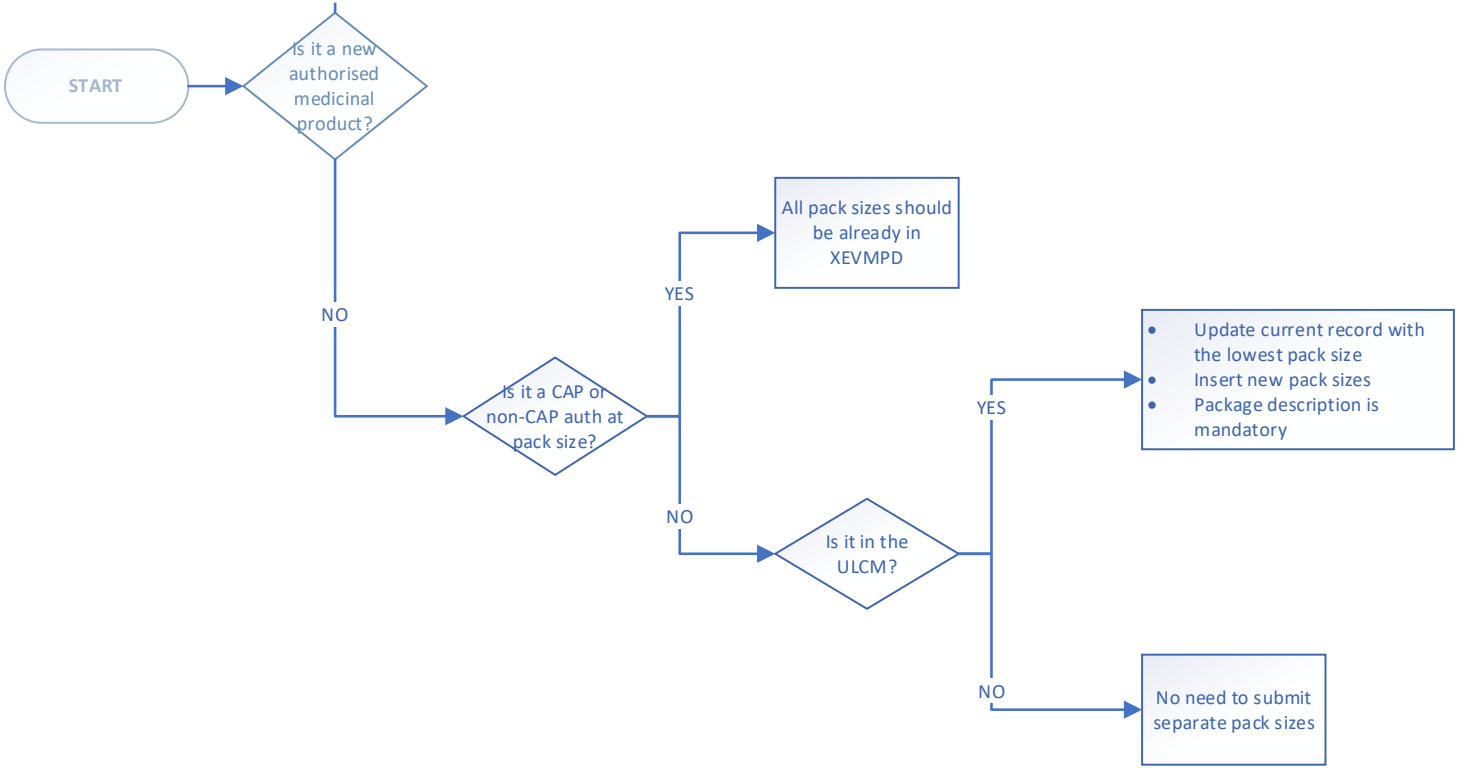
Summary



Summary



Summary



Next steps

How to stay informed on PMS Work

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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

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Q3			Q4		
Jul	**Aug**	**Sep**	**Oct**	**Nov**	**Dec**
EU IG Ch 7 update	*EU IG Ch 5 & PUI user guide update*	*EU IG Ch 2 update*			*EU IG Ch 3, 4 update*
Public system demo		*Public system demo*			*Public system demo*
API Go-live for Industry (All products view-only)		*PUI go-live for NAPs (view-only)*			
PLM Newsletter publication					
API training session		*API Go-live for NCAs (All products view-only)*	*Training session on NAPs H var submissions in web-based eAF*	*PLM Newsletter publication*	
Pack sizes training session		*API training session*		*Training on write access to PMS*	
Q&A clinics					

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

Pack Size Submissions: from XEVMPD to PMS Join at Slido.com #PACKSIZE

Development activities

Subscribe to quarterly PLM Insights newsletter

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

Next edition to be** published in **mid-July 2024

Subscribe by scanning the **QR code** or through this link.

Q&A

Any questions?

Further information

[Insert relevant information sources or contact details as applicable.]

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