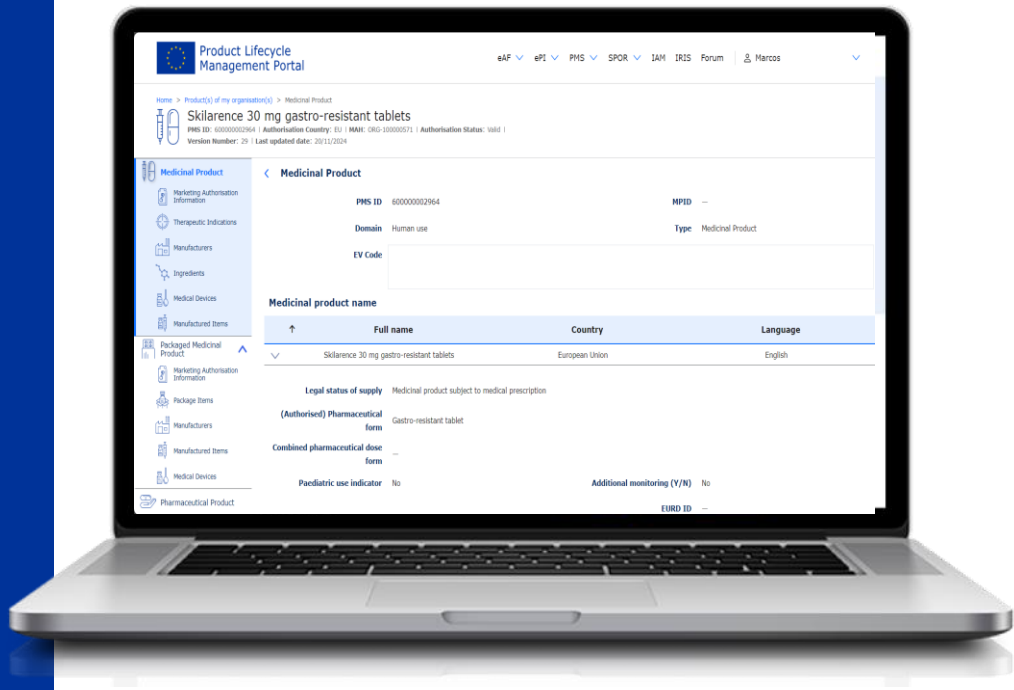
EMA
EUROPEAN MEDICINES AGENCY

Submission of Manufacturers, Manufacturing Business Operations (MBOs) and structured pack size data to PMS



25 November 2024, 10:00 – 11:30 (CET)

Presented by Marcos Fernandez Gomez and Veronica Lipucci di Paola
Product Management Service (PMS) Product Owners, EMA

Agenda

1 **Welcome**	**Marcos Fernández Gomez**, PMS Product Co-Owner, EMA	
2 **Background**	**Marcos Fernández Gomez**, PMS Product Co-Owner, EMA	
3 **Submission of structured data on pack sizes**	**Marcos Fernández Gomez**, PMS Product Co-Owner, EMA	
4 **Submission manufacturers and MBOs**	**Marcos Fernández Gomez**, PMS Product Co-Owner, EMA	
5 **Already answered questions**		**Marcos Fernández Gómez**, PMS Product Co-Owner, EMA
6 **Q&A** **30 mins**		**Moderator: Caterina Scarpati,** PMS Change Management Team
7 **Closing**		**Veronica Lipucci Di Paola**, PMS Product Co-Owner, EMA **Marcos Fernández Gómez**, PMS Product Co-Owner, EMA

For questions: www.slido.com Code: #PMSDATA

Housekeeping

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

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

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

For questions: www.slido.com Code: #PMSDATA

Housekeeping notes – Q&A

Join at
slido.com
#PMSDATA

- Join via **QR code** or **slido.com -** *please provide your questions and comments in Slido only*
- **Send or upvote the questions** you want to hear answered – *before raising a question check whether its has been raised already and vote for it*

Q&A Management

- Questions will be shown on the screen and managed live in the Q&A session
- EMA colleagues will **verbally address top voted questions** at the end in the live Q&A session.

Unanswered questions

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

2

Background

For questions: www.slido.com Code: #PMSDATA

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

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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.

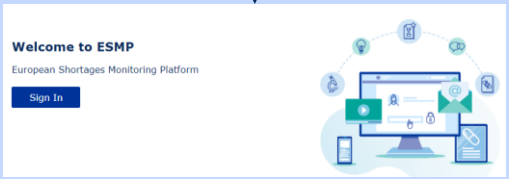
Member State data systems

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

ESMP



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

Packaged medicinal product data / Manufacturing sites

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

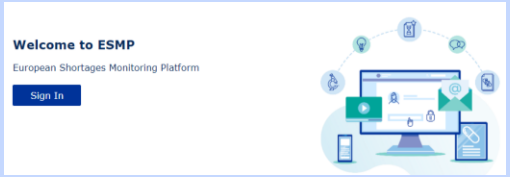
Measures to prevent, manage and mitigate shortages in EU/EEA, such as exploring MAHs supply capacity and possibility to increase production, regulatory support, etc.

Prevent, monitor and manage shortages

For questions: www.slido.com Code: #PMSDATA

Additional information in the ESMP essentials webinar

ESMP



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

Packaged medicinal product data / Manufacturing sites

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

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

ESMP consumes data from PMS.

More specifically, ESMP requires Medicinal Products, Packaged Medicinal Products, structured pack size data and Manufacturing Sites from PMS

For questions: www.slido.com Code: #PMSDATA

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

ESMP users see PMS information as the basis and have to provide additional information such as marketing status for each pack size.

ESMP pre-filled templates will show PMS data.

Product (PMS ID and name)

Manufacturers and MBOs

Product information				Representative product	Organisation information				
PMS ID (Medicinal product)	Full product name	Active substance SMS ID	Active substance	Representative product	Operation type ID	Operation type	ORG-ID (Manufacturer)	Manufacturer	LOC-ID (Manufacturer)
P1.1.2	P1.2.1	P1.3.1	P1.3.2	X1.1	O1.1	O1.2	O1.3	O1.4	O1.5
Mandatory	Optional	Mandatory	Optional	Optional	Mandatory	Optional	Conditional	Optional	Conditional
600000003161	Axzamol SUN 6.75 mg/0.9 ml - Solution for injection - 30 ml bottle/via	33456382;22345699	Paracetamol;Atosiban acetate		999999999999	Processing operations for the medicinal product	ORG-999999999	Sun Pharmaceutical Industries Limited	LOC-999999999
600000003161	Axzamol SUN 6.75 mg/0.9 ml - Solution for injection - 30 ml bottle/via	33456382	Paracetamol		1111111	Manufacturer of active substance	ORG-1000000000	Sun Pharmaceutical Industries Limited	LOC-999999999
600000003161	Axzamol SUN 6.75 mg/0.9 ml - Solution for injection - 30 ml bottle/via	22345699	Atosiban acetate		1111111	Manufacturer of active substance	ORG-1000000001	Sun Pharmaceutical Industries Limited	LOC-999999999

ESMP users see PMS information as the basis and have to provide additional information such as production capacity.

Data shown in this picture has been created for the purpose of this presentation and it is not real.

How is the required information included in PMS?

Medicinal products

Packaged medicinal products

Structured data on pack sizes

Manufacturers and MBOs

Medicinal Products in PMS

SIAMED II

- **CAPs** reflect consolidated data from SIAMED (EMA DB) and XEVMPD
- **Non-CAPs** are migrated from XEVMPD

- Review **EU IG Chapter 7 & 9** to get additional information on the business rules for this migration.
- **XEVMPD** business rules still apply

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XEVMPD

Medicinal Products in PMS

↑ PMS ID	Full Name	Authorised Dose Form	MA Holder	LOC ID	MA Nr.	Active substance	Authorisation Country	Authorisation Status	MRP / DCP / CP Nr.
700000137474	Sodor 30 mg comprimidos de liberación modificada EFG	Modified-release tablet	Uxa Farma S.A.	LOC-100005524	84501	Gliclazide	ES	Valid	
700000137475	Spiriva 18 microgrammes poudre pour inhalation en gélule	Inhalation powder, hard capsule	Boehringer Ingelheim International GmbH	LOC-100018243	200829707	Tiotropium	LU	Valid	NL/H/0299/001
700000137476	ACIDE ZOLEDRONIQUE SANDOZ 4 mg/100 ml, solution pour perfusion	Solution for infusion	Sandoz	LOC-100004447	34009 582 943 0 3	Zoledronic acid monohydrate	FR	Valid	AT/H/0411/002
700000137477	Neo-Ferro-Folgamma 114 mg/0,8 mg gyomornedv-ellenálló tabletta	Gastro-resistant tablet	Wörwag Pharma GmbH & Co.KG	LOC-100054619	OGYI-T-20273/01	DRIED FERROUS SULFATE, Folic acid	HU	Valid	
700000137478	SEVELAMER CARBONATE SANDOZ 2,4 g, poudre pour suspension buvable	Powder for oral suspension	Sandoz	LOC-100004447	34009 300 855 0 9	Sevelamer carbonate	FR	Valid	NL/H/5109/001
700000137479	Srivasso 18 microgrammes poudre pour inhalation en gélules	Inhalation powder, hard capsule	Boehringer Ingelheim International GmbH	LOC-100018243	2016040086	Tiotropium	LU	Valid	NL/H/3137/001
700000137480	Tramadol Retard EG 100 mg comprimés à libération prolongée	Prolonged-release tablet	EG	LOC-100000522	BE300221	Tramadol hydrochloride	BE	Valid	NL/H/0888/001
700000137481	Daptomicina Hikma 500 mg polvo para solución inyectable y para perfusión EFG	Powder for solution for injection/infusion	Hikma Farmaceutica (Portugal) S.A.	LOC-100002356	89.475	Daptomycin	ES	Valid	DE/H/7589/002
700000137482	Vancomycin Pharmline, 1000 mg, proszek do sporządzania koncentratu roztworu do infuzji	Powder for solution for infusion	Pharmline Company Sp. z o.o.	LOC-100085477	28675	Vancomycin hydrochloride	PL	Valid	HU/H/0668/001

Packaged medicinal products in PMS

SIAMED II

- **CAPs** reflect consolidated data from SIAMED (EMA DB) and XEVMPD
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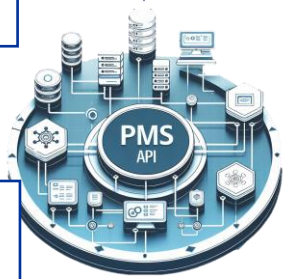

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XEVMPD

- Review **EU IG Chapter 7 and 9** to get additional information on the business rules for this migration.
- **XEVMPD** business rules still apply

Packaged medicinal products in PMS

SIAMED II

- Changes performed to **grouping elements** in XEVMPD will lead to the move of packages from one product to another or the creation of new Medicinal products.

Grouping elements depend on the auth country. They can be found in EU IG Ch 7 & 9.

- MAH
- Authorised dose form
- Active substance and strength
- Product name / MA number / Procedure number

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XEVMPD

Packaged medicinal products in PMS

Changes performed to **grouping elements** in XEVMPD will lead to the move of packages from one product to another or the creation of new Medicinal products.

EV Code	Full product name	Active substance	Strength	Auth dose form	MA number	Package ID	PMS ID
PRD123	Xariva 15 mg hard capsule	Rivaroxaban	15 mg/capsule	Hard capsule	1234	8765	600000111
PRD456	Xariva 15 mg hard capsule	Rivaroxaban	15 mg/capsule	Hard capsule	5678	8766	

MAH sends an update in XEVMPD

EV Code	Full product name	Active substance	Strength	Auth dose form	MA number	Package ID	PMS ID
PRD123	Xariva 15 mg hard capsule	Rivaroxaban	15 mg/capsule	Hard capsule	1234	8765	600000111
PRD456	Xariva 15 mg hard capsule**s**	Rivaroxaban	15 mg/capsule	Hard capsule	5678	8766	600000222

Package ID remains unchanged even if the pack size is moved to a different medicinal product.

Packaged medicinal products in PMS

Changes performed to **grouping elements** in XEVMPD will lead to the move of packages from one product to another or the creation of new Medicinal products.

EV Code	Full product name	Active substance	Strength	Auth dose form	MA number	Package ID	PMS ID
PRD123	Xariva 15 mg hard capsule	Rivaroxaban	15 mg/capsule	Hard capsule	1234	8765	600000111
PRD456	Xariva 15 mg hard capsules	Rivaroxaban	15 mg/capsule	Hard capsule	5678	8766	600000222

EMA validates and corrects the record

EV Code	Full product name	Active substance	Strength	Auth dose form	MA number	Package ID	PMS ID
PRD123	Xariva 15 mg hard capsule	Rivaroxaban	15 mg/capsule	Hard capsule	1234	8765	600000111
PRD456	Xariva 15 mg hard capsule	Rivaroxaban	15 mg/capsule	Hard capsule	5678	8766	

If the grouping element is changed again, packaged medicinal product is moved to previous PMS ID and extra medicinal product is nullified.

600000222 is nullified

Packaged medicinal products in PMS

SIAMED II

- Changes performed to **grouping elements** in XEVMPD will lead to the move of packages from one product to another or the creation of new Medicinal products.

- **Package IDs** are kept when moving them from one product to another.
- **Use this package ID in your mappings**. This Package ID will also be shown in the ESMP pre-filled templates.
- **Review 3rd AcKs** to make sure you agree and track the changes performed by EMA.

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XEVMPD

If changes are needed, perform them in bundle (all the EV codes at the same time) so they are propagated in PMS for all packaged medicinal products.

Packaged medicinal products in PMS

MA number	Package size(s)	PCID	EV code	Legal status of supply	Authorisation Status
041492113	—	—	PRD6666872	—	Valid
Package description	Packaging: BLISTER - PVC/PE/PVDC/ALU. Pack Size: 7 tablets			Language —	
041492125	—	—	PRD6666867	—	Valid
Package description	Packaging: BLISTER - PVC/PE/PVDC/ALU. Pack Size: 14 tablets			Language —	
041492137	—	—	PRD6666864	—	Valid
Package description	PACKAGING: BLISTER - PVC/PE/PVDC/ALU. PACK SIZE: 28 TABLETS			Language —	
041492149	—	—	PRD6666871	—	Valid
Package description	Packaging: BLISTER - PVC/PE/PVDC/ALU. Pack Size: 30 tablets			Language —	
041492152	—	—	PRD6666869	—	Valid
Package description	Packaging: BLISTER - PVC/PE/PVDC/ALU. Pack Size: 56 tablets			Language —	
041492164	—	—	PRD6666866	—	Valid
Package description	Packaging: BLISTER - PVC/PE/PVDC/ALU. Pack Size: 90 tablets			Language —	
041492176	—	—	PRD6666868	—	Valid
Package description	Packaging: BLISTER - PVC/PE/PVDC/ALU. Pack Size: 98 tablets			Language —	

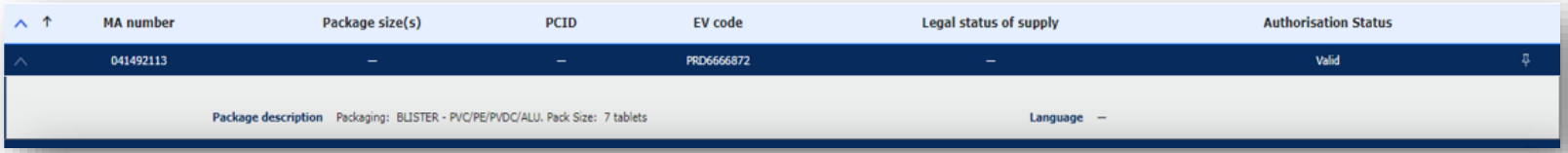
3

Submission of structured data on pack sizes

Structured data on pack sizes

MA number	Package size(s)	PCID	EV code	Legal status of supply	Authorisation Status
041492113	–	–	PRD6666872	–	Valid
Package description	Packaging: BLISTER - PVC/PE/PVDC/ALU. Pack Size: 7 tablets			Language –	
041492125	–	–	PRD6666867	–	Valid
Package description	Packaging: BLISTER - PVC/PE/PVDC/ALU. Pack Size: 14 tablets			Language –	
041492137	–	–	PRD6666864	–	Valid
Package description	PACKAGING: BLISTER - PVC/PE/PVDC/ALU. PACK SIZE: 28 TABLETS			Language –	
041492149	–	–	PRD6666871	–	Valid
Package description	Packaging: BLISTER - PVC/PE/PVDC/ALU. Pack Size: 30 tablets			Language –	
041492152	–	–	PRD6666869	–	Valid
Package description	Packaging: BLISTER - PVC/PE/PVDC/ALU. Pack Size: 56 tablets			Language –	
041492164	–	–	PRD6666866	–	Valid
Package description	Packaging: BLISTER - PVC/PE/PVDC/ALU. Pack Size: 90 tablets			Language –	
041492176	–	–	PRD6666868	–	Valid
Package description	Packaging: BLISTER - PVC/PE/PVDC/ALU. Pack Size: 98 tablets			Language –	

Structured data on pack sizes



MA number	Package size(s)	PCID	EV code	Legal status of supply	Authorisation Status
041492113	–	–	PRD6666872	–	Valid

Package description Packaging: BLISTER - PVC/PE/PVDC/ALU. Pack Size: 7 tablets Language –

The MA number of the packaged medicinal product is present:

The package description is also present:

The package description is a free text field so can't be used for analytical purposes.

That is why, the structured data of the pack size is required.

This data element is captured in EU IG Chapter 2 as Pack size (section 4.4)

Pack Size

Definition: the total number of units of the manufactured item or package item and represented per unit of presentation

Format: numeric value and unit (from the RMS list Units of presentation)

Repeatable: YES

Medicinal products with **one pharmaceutical product** the pack size shall indicate the unit of presentation of the manufactured item/package item

Structured data on pack sizes

Pack Size

Definition: the total number of units of the manufactured item or package item and represented per unit of presentation

Format: numeric value and unit (from the RMS list Units of presentation)

Repeatable: YES

One manufactured item

Quantity = 8
Units of presentation = Tablet (200000002152)

Structured data on pack sizes

Pack Size

Definition: the total number of units of the manufactured item or package item and represented per unit of presentation

Format: numeric value and unit (from the RMS list Units of presentation)

Repeatable: YES

One manufactured item

Quantity = 8
Units of presentation = Tablet (200000002152)

For medicinal products with **multiple pharmaceutical products** (e.g., tablet and cream) the pack size shall be differentiated and repeated by manufactured item/package item

Structured data on pack sizes

Pack Size

Definition: the total number of units of the manufactured item or package item and represented per unit of presentation

Format: numeric value and unit (from the RMS list Units of presentation)

Repeatable: YES

One manufactured item

Quantity = 8
Units of presentation = Tablet (200000002152)

Multiple manufactured items/package item

Quantity = 14 Units of presentation = Tablet (200000002152)
Quantity = 1 Units of presentation = Tube (200000002156)

Structured data on pack sizes

Pack Size

Definition: the total number of units of the manufactured item or package item and represented per unit of presentation

Format: numeric value and unit (from the RMS list Units of presentation)

Repeatable: YES

One manufactured item

Quantity = 8
Units of presentation = Tablet (200000002152)

Multiple manufactured items/package item

Quantity = 14 Units of presentation = Tablet (200000002152)
Quantity = 1 Units of presentation = Tube (200000002156)

For medicinal products in **solid dosage forms with multiple pharmaceutical products that present the same unit of presentation** (e.g., contraceptive tablets of different colours and formulation), the pack size shall be accounted as the total number of tablets.

Structured data on pack sizes

Pack Size

Definition: the total number of units of the manufactured item or package item and represented per unit of presentation

Format: numeric value and unit (from the RMS list Units of presentation)

Repeatable: YES

One manufactured item

Quantity = 8
Units of presentation = Tablet (200000002152)

Multiple manufactured items/package item

Quantity = 14 Units of presentation = Tablet (200000002152)
Quantity = 1 Units of presentation = Tube (200000002156)

Multiple manuf items and pharmaceutical products

Quantity = 12
Units of presentation = Tablet (200000002152)

Structured data on pack sizes

Pack Size

Definition: the total number of units of the manufactured item or package item and represented per unit of presentation

Format: numeric value and unit (from the RMS list Units of presentation)

Repeatable: YES

One manufactured item

Quantity = 8
Units of presentation = Tablet (200000002152)

Multiple manufactured items/package item

Quantity = 14 Units of presentation = Tablet (200000002152)
Quantity = 1 Units of presentation = Tube (200000002156)

Multiple manuf items and pharmaceutical products

Quantity = 12
Units of presentation = Tablet (200000002152)

For **liquid formulations requiring reconstitution** (e.g., powder and solvent for solution for injection), the unit of presentation shall be differentiated, and this data field is repeated per manufactured item.

Structured data on pack sizes

Pack Size

Definition: the total number of units of the manufactured item or package item and represented per unit of presentation

Format: numeric value and unit (from the RMS list Units of presentation)

Repeatable: YES

One manufactured item

Quantity = 8
Units of presentation = Tablet (200000002152)

Multiple manufactured items/package item

Quantity = 14 Units of presentation = Tablet (200000002152)
Quantity = 1 Units of presentation = Tube (200000002156)

Multiple manuf items and pharmaceutical products

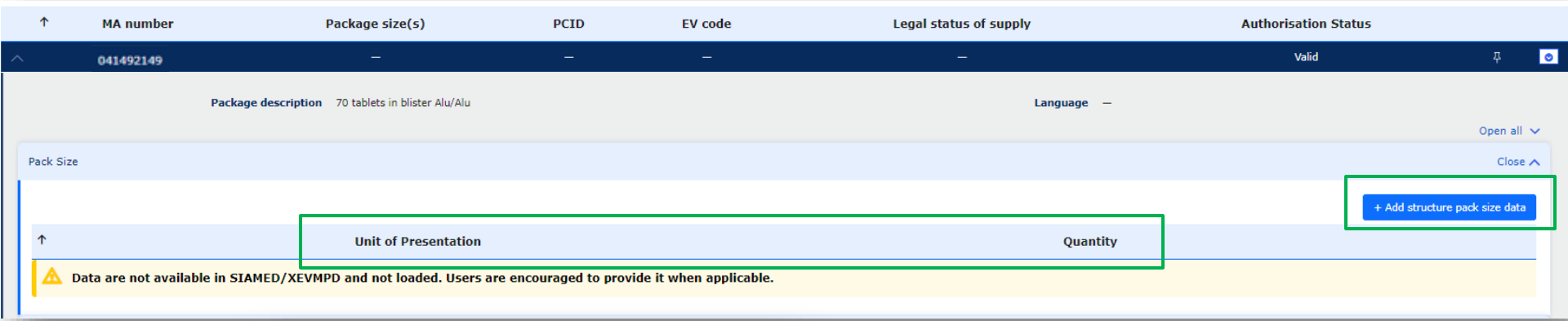
Quantity = 12
Units of presentation = Tablet (200000002152)

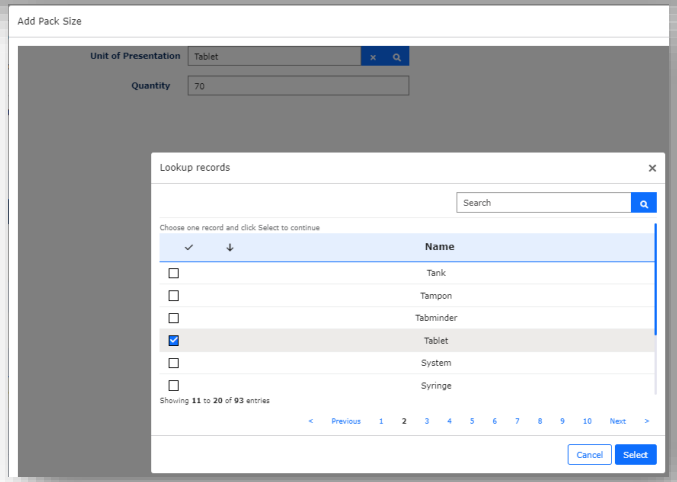
Multiple manufactured items, One (reconsitituted) pharmaceutical product

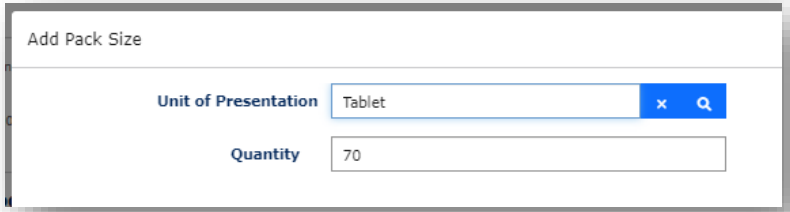
Quantity = 1 Units of presentation = Vial (200000002158)
Quantity = 1 Units of presentation = Ampoule (200000002164)

Structured data on pack sizes

Please, review **EU IG Chapters 2 & 8** for additional information







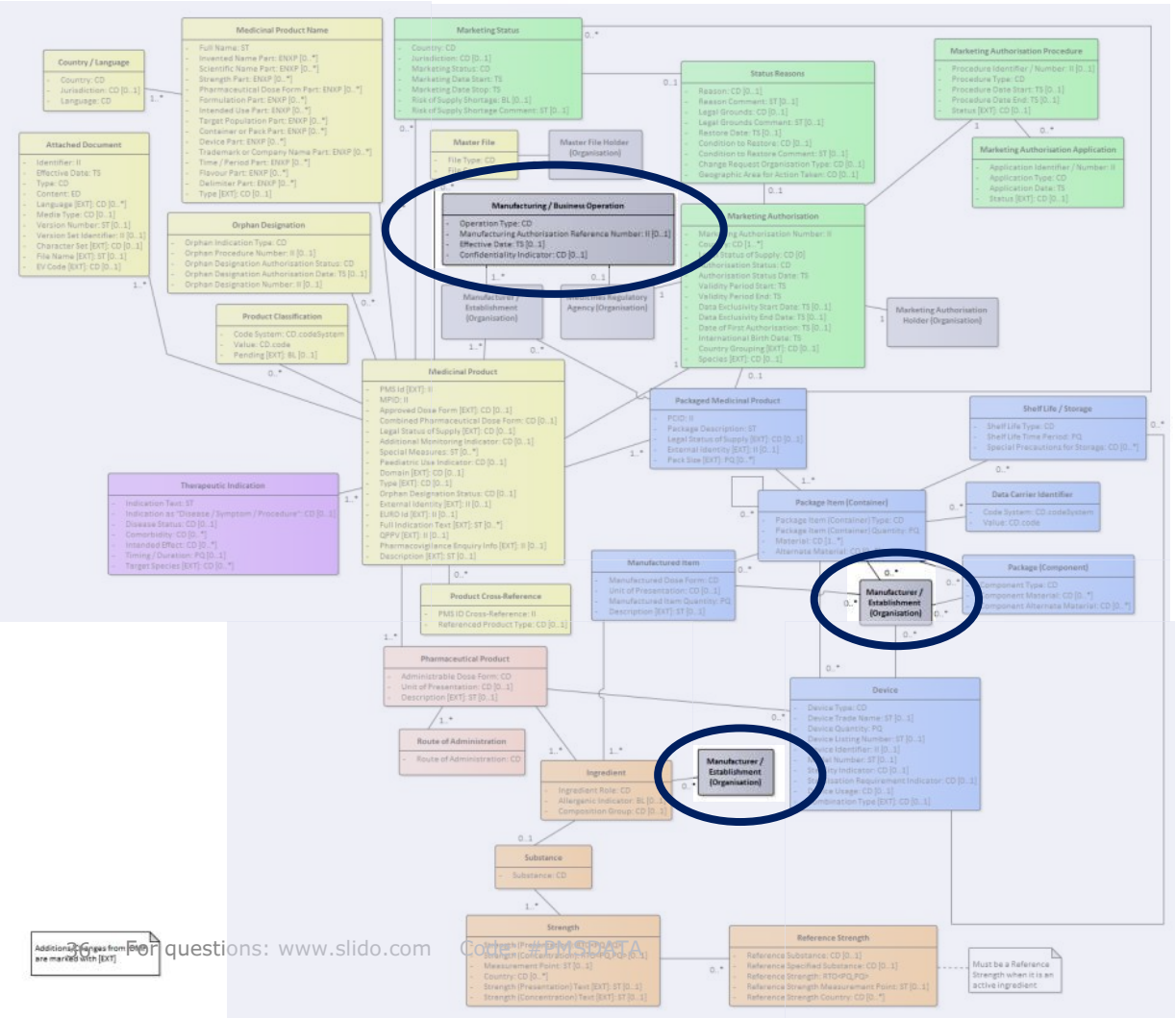
Applicant’s requirements for structured pack size data

- ***For CAPs:***
  - This data is already in PMS as it is **migrated from SIAMED.**
  - No need to provide this information but please review it. If mistakes are found, raise a ticket in Service Desk.

- ***For non-CAPs:***
  - This data will have to be submitted through the PMS API or the Product UI for the products under the ULCM and optionally for the rest.
  - There is no need to submit this information for invalid packaged medicinal products
  - For new pack sizes, include the information after submitting the record to XEVMPD
  - Split the packaged medicinal products in XEVMPD before updating the structured data in PMS.

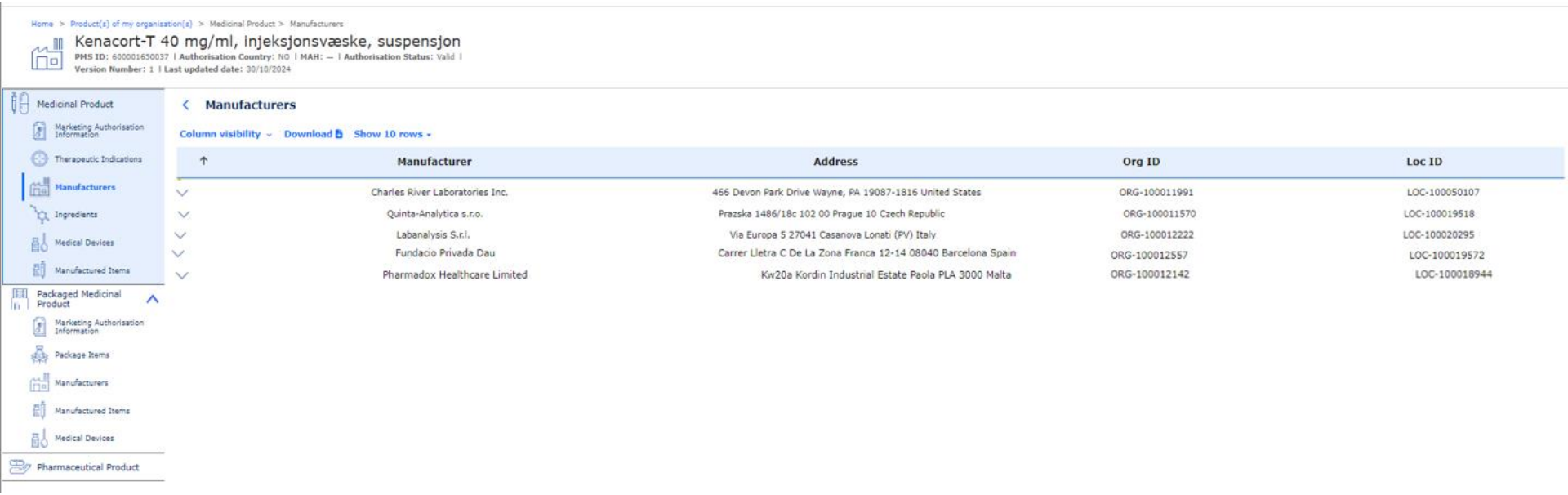
4

Submission of Manufacturers and MBOs



- Manufacturers are linked to:
  - Medicinal Product
  - Packaged Medicinal Product
  - Ingredients
  - Package items
  - Manufactured items
  - Devices

Manufacturers and MBOs



Data shown in this picture has been created for the purpose of this presentation and it is not real.

Manufacturers and MBOs

Manufacturer's ORG details as captured in OMS

Operation type / MBO
As in the RMS list: Manufacturing Activities

MBO start date
When the MBO is approved

MBO end date
When the MBO is discontinued

Confidentiality
Level of confidentiality of the MBO

Reference number
Reference number of the authorization (i.e. MIA number)

Effective date
The effective date of the Manufacturing Authorisation

Agency
Responsible for issuing the authorisation

Data shown in this picture has been created for the purpose of this presentation and it is not real.

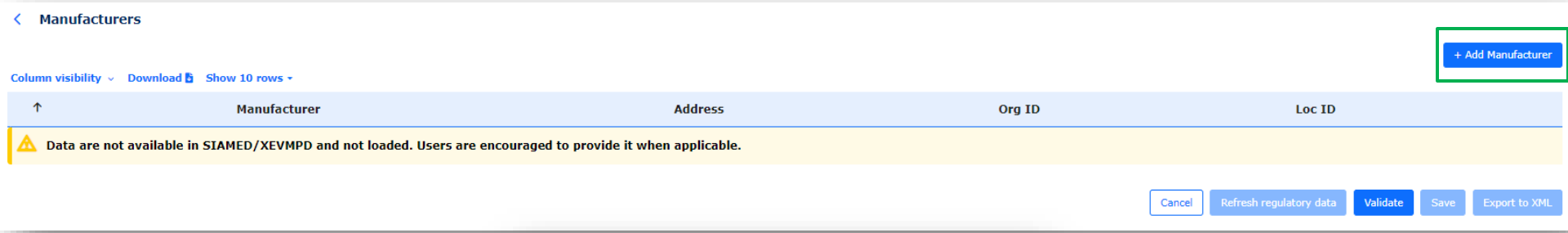
Manufacturers and MBOs

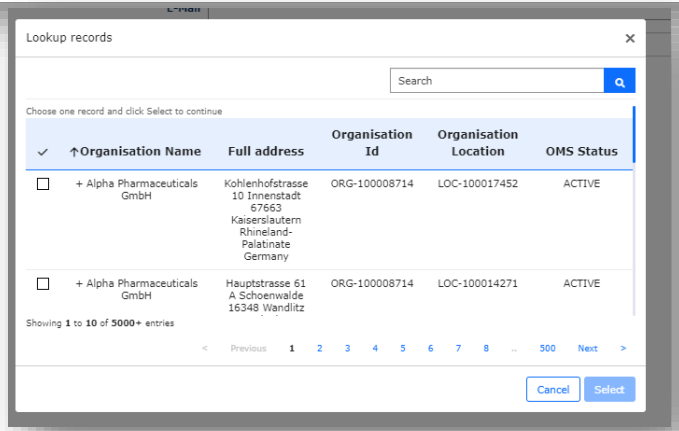
Manufacturer's ORG details as captured in OMS

- Select the LOC ID from OMS
- Include in OMS active ORGs if not present
- Inactive organisations can be selected if still registered
- All registered manufacturers should be included
- Manufacturers for which the MBOs have been deleted shall not be submitted

Operation type / MBO As in the RMS list: Manufacturing Activities	**MBO start date** When the MBO is approved	**MBO end date** When the MBO is discontinued	**Confidentiality** Level of confidentiality of the MBO	**Reference number** Reference number of the authorization (i.e. MIA number)	**Effective date** The effective date of the Manufacturing Authorisation	**Agency** Responsible for issuing the authorisation
For NAPs, same manufacturers and MBOs as the ones reported in the eAF shall be provided to PMS.	For legacy products, if the data is not known, same date as the initial marketing authorization date of the medicinal product can be included. For new products authorised as of 1s tof January 2025, accurate date shall be submitted.	Include this date if the activity is deleted for this specific MBO. Do not remove the MBO, just update this date.	Indicate if the MBO is public or confidential. Batch releaser & manufacturer of the biological active substance are public while the rest is confidential.	Not mandatory but can be provided to fulfill additional information. Highly recommended for manufacturers authorised as of 1st January 2025.	Not mandatory but can be provided to fulfill additional information. Highly recommended for new manufacturers authorised as pf 1st of January 2025.	Select the LOC ID of the NCA or agency who issued the authorisation.

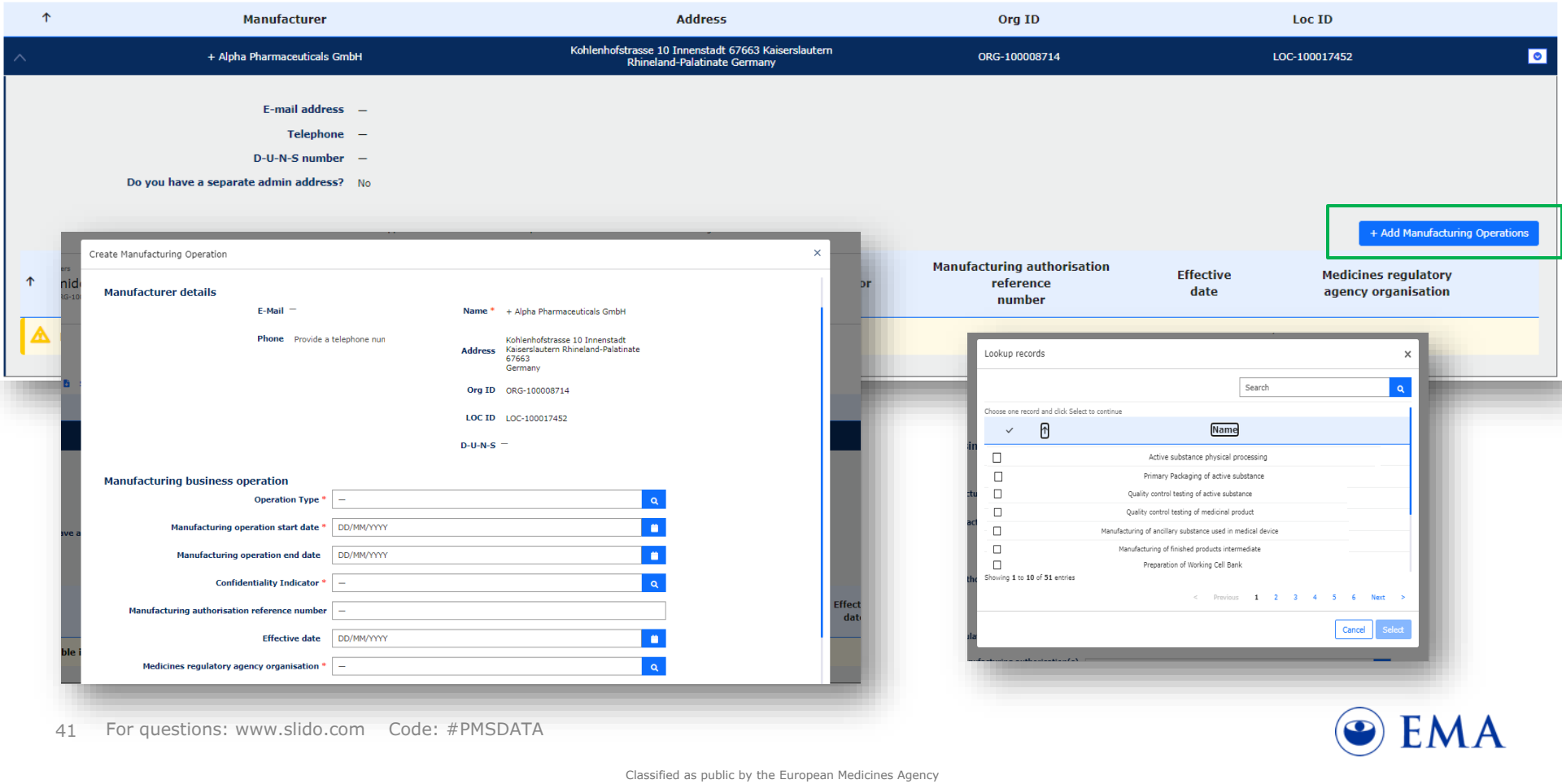
Manufacturers and MBOs



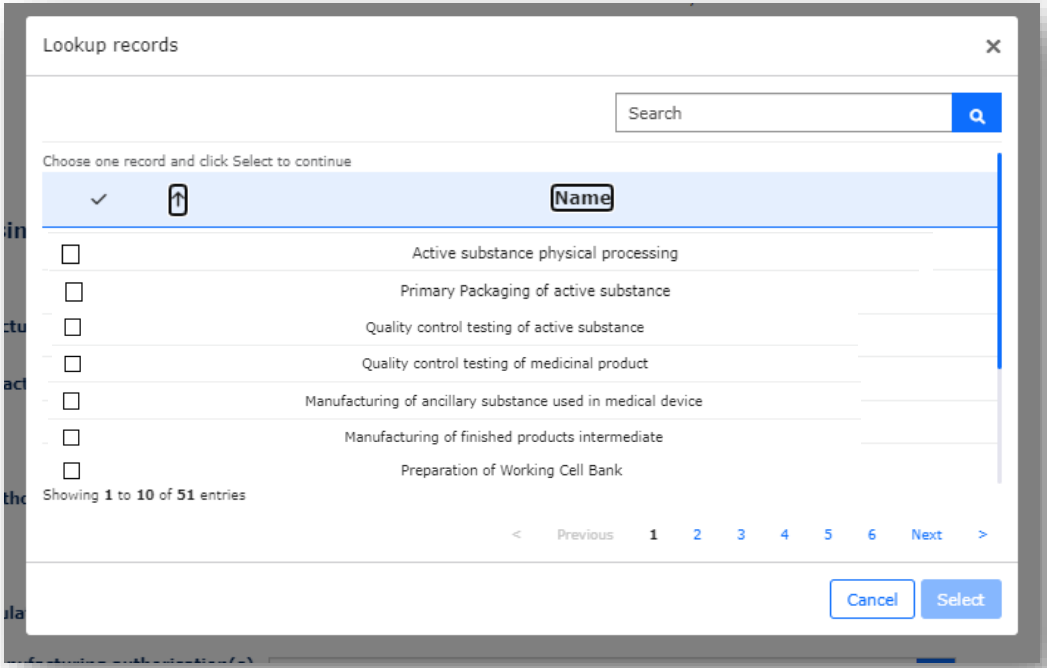


Searches can be done by all fields in the pop-up window.

Manufacturers and MBOs



Manufacturers and MBOs

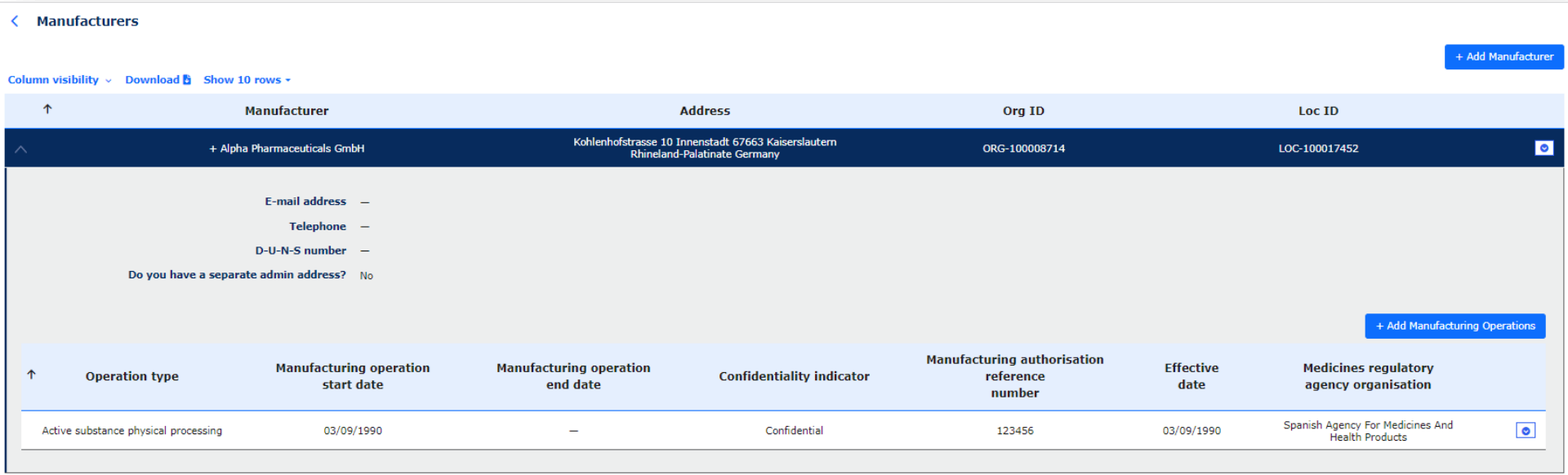


Short RMS names are shown in this window. (They will also be improved to reflect additional info – AS, finished product, etc)

The **list of MBOs** to be provided for non-CAPs takes into consideration the needs from **ESMP and eAF**.

List of operations applicable during the enrichment is described in **Annex II of EU IG Chapter 3.**

Manufacturers and MBOs



Applicant’s requirements for manufacturers and MBOs

- ***For CAPs:***
  - **Review** manufacturers’ details migrated from SIAMED
  - You can use the dynamic report “Manufacturing operation” in the Product UI
  - No need to submit additional information to PMS
  - If mistakes are found, raise a ticket so SIAMED can be amended
  - PMS will show the updated data in real time after every variation is approved in SIAMED

- ***For non-CAPs:***
  - **Gather the information** of manufacturers and MBOs
  - **Submit** them through the PMS API or Product UI
  - **Keep the data up to date** in case of changes

Data carrier identifiers

In order to connect PMS and ePI, the enrichment process has also been extended to the **Data Carrier Identifier**.

The data carrier identifier in the outer-most package should be specified using the Global Trade Item Number (GTIN) or National Trade Item Number (NTIN) identification system or the Pharmacy Product Number (PPN).

Example(s):

GTIN: 028901563801609

PPN: 30 A123456789 09

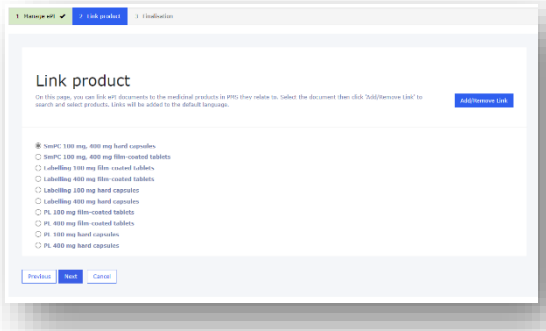
NTIN: 0 90 8985 391109 8

Note: Examples are fictitious

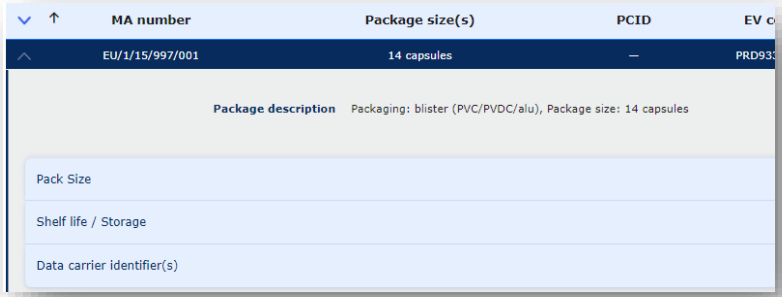
Submission of Data Carrier IDs is **optional** for all valid products, ideally to be submitted for products with ePIs created.

For **non-CAPs**, this data can be submitted through Product UI and PMS API.

For **CAPs**, temporarily this data will have to be submitted through Service Now. Additional information will be made available in Ch 3.



ePI will allow including the PMS ID of the medicinal product



PMS will contain the data carrier identifier

Medicinal product carrying GTIN

Scan data matrix code

ePI & structured product data displayed to patient

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Already answered questions

For questions: www.slido.com Code: #PMSDATA

Is the enrichment of manufacturers required at all levels of the product (packaged medicinal product, ingredients, etc) or only at medicinal product level?

Manufacturers and MBOs will only be submitted at the level of the medicinal product but comprises operations for active substances, intermediate medicinal products or devices. Links to other entities such as packaged medicinal products, ingredients or medical devices will be made in the future when the enrichment process is fully implemented.

Do we need to submit only the manufacturers actively used or all registered ones?

All registered manufacturers should be submitted.
So even if the manufacturer is not actively used, if it's registered, should be submitted.
Deleted manufacturers or MBOs should not be submitted during the initial enrichment.
If a valid manufacturer/MBO is deleted after the first enrichment, its data should be updated (i.e. the end date should be updated) → DO NOT remove the manufacturer (unless it was entered by mistake).

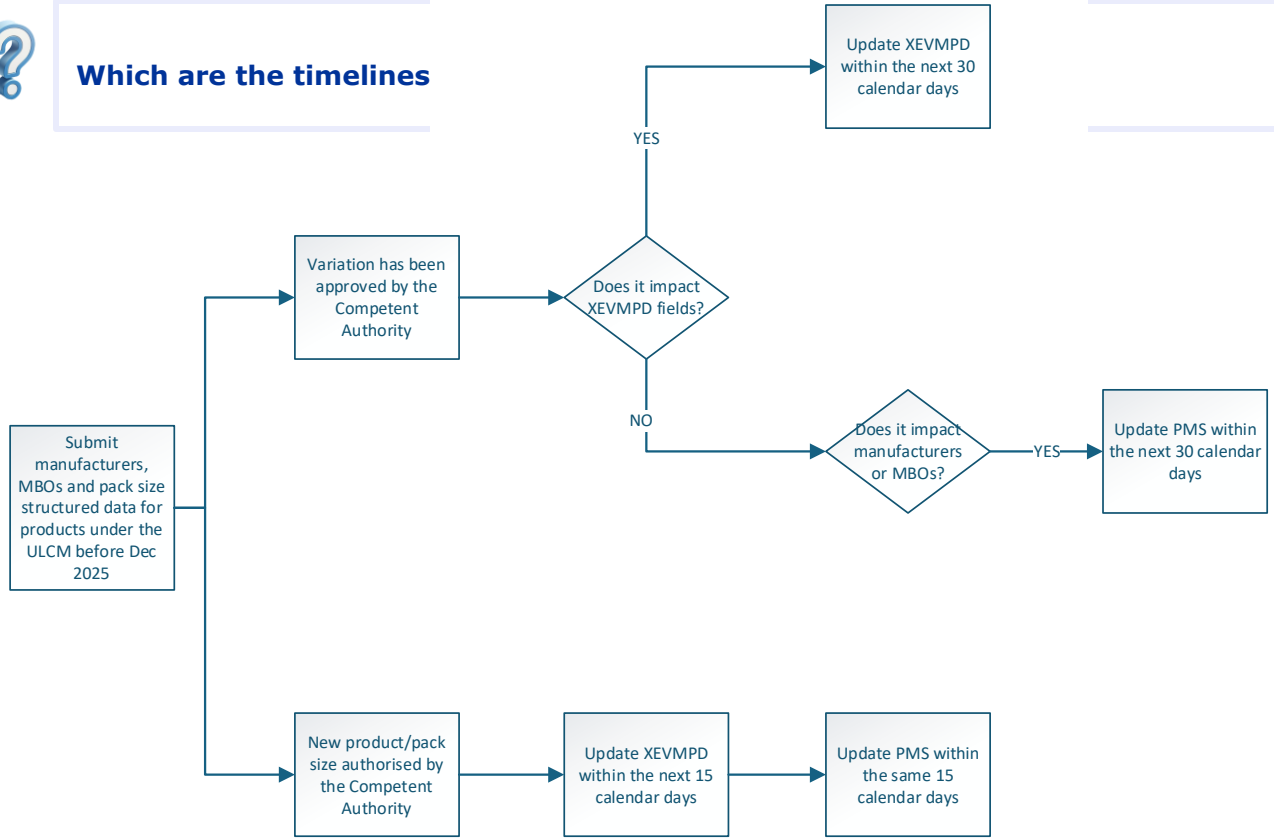
Can ‘inactive’ organisations be selected when submitting manufacturers to PMS?

For the moment, and based on a requirement from the PMS SMEs, inactive organisations from OMS can be chosen as manufacturers. Further analysis will be made in the future to restrict this capability.

When the write PMS API will be available to enrich product data?

The PMS team is working on the write PMS API. Documentation will be released before the end of the year so MAHs can prepare to access it. MAHs and software vendors need to integrate their RIM solutions with PMS API to be able to exchange /write data into PMS. This will be tested in UAT in early 2025 before a release date in production can be announced.

Which are the timelines



For the time being, EMA accepts that PMS is updated on a monthly basis.
XEVMPD should still be updated within the legal timelines (15 or 30 days).

For legacy products, the manufacturing start date might not be known. How do we fill this field?

Only for legacy products, when this date is not known, the initial MA approval date can be used.
For new products, the correct date shall be submitted.

Will the enrichment process allow the bulk update?

Yes.
The MVP of the Product UI will not allow the bulk update. Nevertheless, EMA is already working on its implementation and EMA is working to be able to release this functionality short after the go live of the MVP (end of Q1 – beginning of Q2 2025).

Which are the MBOs to be provided during the enrichment process? All manufacturers in M3? As in eAF?

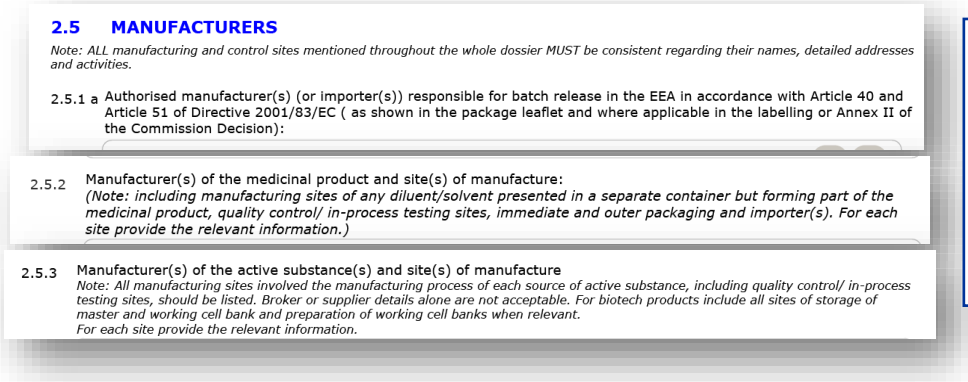
CAPs do not require enrichment – data is coming from SIAMED.

For non-CAPs, the list of MBOs to be provided takes into consideration the needs of ESMP and eAF.

Registered manufacturers and MBOs submitted within eAF are the ones to be provided to PMS.

Manufacturers/MBOs present in M3 but not in eAF are not required.

List of MBOs can be found in Annex II of EU IG Ch 3.



2.5 MANUFACTURERS

Note: ALL manufacturing and control sites mentioned throughout the whole dossier MUST be consistent regarding their names, detailed addresses and activities.

2.5.1 a Authorised manufacturer(s) (or importer(s)) responsible for batch release in the EEA in accordance with Article 40 and Article 51 of Directive 2001/83/EC (as shown in the package leaflet and where applicable in the labelling or Annex II of the Commission Decision):

2.5.2 Manufacturer(s) of the medicinal product and site(s) of manufacture:
(Note: including manufacturing sites of any diluent/solvent presented in a separate container but forming part of the medicinal product, quality control/ in-process testing sites, immediate and outer packaging and importer(s). For each site provide the relevant information.)

2.5.3 Manufacturer(s) of the active substance(s) and site(s) of manufacture
Note: All manufacturing sites involved the manufacturing process of each source of active substance, including quality control/ in-process testing sites, should be listed. Broker or supplier details alone are not acceptable. For biotech products include all sites of storage of master and working cell bank and preparation of working cell banks when relevant.
For each site provide the relevant information.

In eAF, different functions of the manufacturers are submitted in different sections:

- Batch releaser (2.5.1)
- Medicinal product (2.5.2)
- Active substance (2.5.3)
- Medical device (2.2.4)

In eAF, different functions of the manufacturers are submitted in different sections:

- Batch releaser (2.5.1)
  - Batch certification
- Medicinal product (2.5.2)
  - Manufacturing of solvent/diluent
  - Physical importation
  - Primary packaging
  - Processing operations
  - Quality control testing operations
  - Secondary packaging
  - Sterilisation operations
  - Storage and/or distribution
- Active substance (2.5.3)
  - Active substance intermediate physical processing
  - Active substance physical processing
  - Extraction of active substance from natural sources
  - Manufacturer of active substance operations
  - Preparation of working cell bank
  - Primary packaging of active substance
  - Quality control testing operations
  - Secondary packaging of active substance
  - Storage and/or distribution of active substance
  - Storage of Master Cell Bank and/or Working Cell Bank
- Medical device (2.2.4)
  - Manufacturing of medical device
  - Manufacturing of ancillary substance used in medical device
  - Notified Body of medical device

Same information as the one provided in the eAF should be provided to PMS.
EU IG Ch 3 Annex II contains a full list of the required terms in PMS.

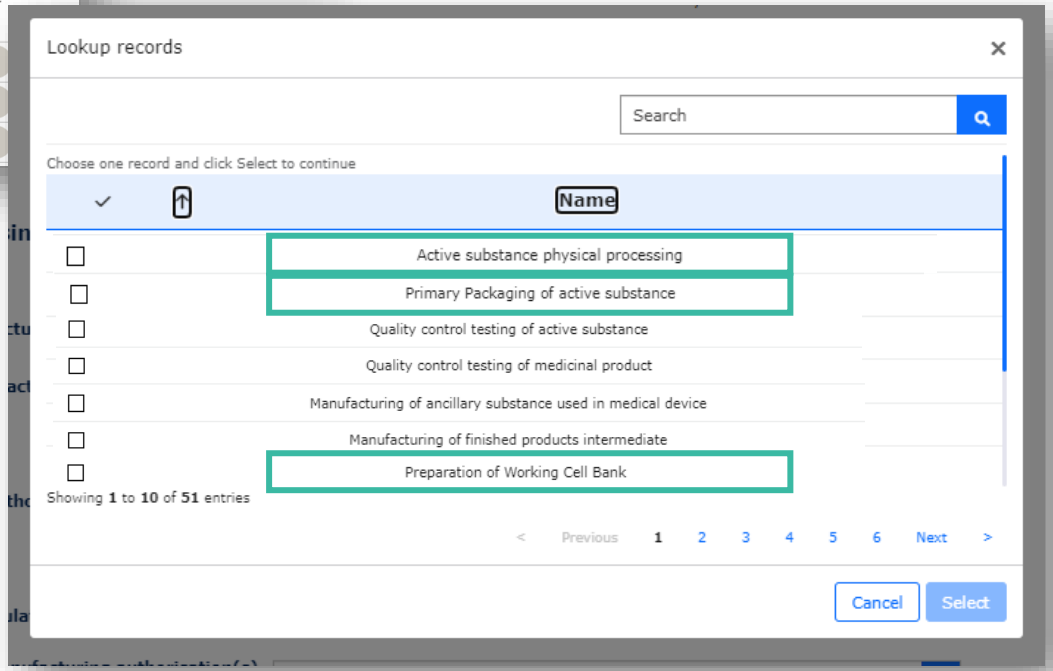
eAF section
RMS term

2.5.3 Manufacturer(s) of the active substance(s) and site(s) of manufacture

Note: All manufacturing sites involved the manufacturing process of each source of active substance, including quality control/ in-process testing sites, should be listed. Broker or supplier details alone are not acceptable. For biotech products include all sites of storage of master and working cell bank and preparation of working cell banks when relevant.
For each site provide the relevant information.

Brief description of manufacturing steps performed by manufacturing site:
(note: please see the `Compilation of Union Procedures on Inspections and Exchange of Information' document, (see pages - Interpretation of the Union Format for Manufacturer/Importer Authorisation): http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706.pdf

Active substance physical processing
Primary Packaging of active substance
Preparation of Working Cell Bank



What is the impact of not having the manufacturers if a preparedness/crisis is announced.

If manufacturers are not submitted and there is a crisis, they will all have to be submitted within 2 weeks.

Would it be possible to include the information directly in the excel template?

No. ESMP only uses data from PMS, it is not a portal to submit or update PMS information.
If changes are performed in the ESMP templates relating to product data, the ESMP will not consider them.

Where all this information can be found?

EU IG Chapter 3 will be released before the end of the year with full description of the data elements to be submitted. PMS Q&A document will also be updated to reflect general question in relation to the enrichment process..

Access to the ESMP portal: will the IRIS/PLM administrator grant access to the users for the go-live in Nov24. Any details on the available roles?

ESMP has its own process of assigning ESMP administrators and ESMP user roles, separately from IRIS. Please, check *European Shortages Monitoring Platform Frequently Asked Questions*

Are the requirements to support ESMP implementation also applicable for products registered in UK (Northern Ireland)?

ESMP does not include Northern Ireland for the needs of shortage management.

By when enrichment should be completed?

For products under ULCM enrichment should be completed by December 2025. Once enriched, product data should be also maintained.

For products not falling under ULCM enrichment is, for the moment, optional but highly recommended.

How to stay informed on PMS Work?

PMS News page

Check:

- News
- Events announcements
- Downtime comms

Check regularly

PLM Newsletter

- See planned PMS engagement activities for upcoming quarter
- **Subscribe** here

Receive via email quarterly after subscription

PMS webinars

Enter "PMS" in EMA website search bar to find all past and future PMS events

Announced via EMA's Website Events Pages - usually with registration

PMS FAQ Document

- Check FAQs on PMS (Document)

Check regularly

Quarterly System Demos

- See the latest developments
- Give your feedback on features and priorities
- **Next:** 12 Dec 2024

Announced via EMA's Website Events Pages - broadcast live

PMS Web Page

Find:

- PMS overview
- EU Implementation Guide

Check for general info on PMS

Subscribe to the PLM Newsletter

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

Next edition: mid-Jan 2025

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

PMS PUI Training materials

PMS Product User Interface guides page, including:

- PMS Product UI Registration Guidance
- PMS Product UI Navigation Guidance
- PUI - Known Issues

Latest training sessions:

- Webinar on PUI user & key actions for MAHs (29 Oct 2024)
- Pack sizes submissions webinar (11 Jul 2024)
- Access & use PMS API (8 Jul 2024)
- Access & use PMS PUI (3 Jun 2024)

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Q&A

 For questions: www.slido.com Code: #PMSDATA

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