EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PMS Webinar on Data Migration

23 February 2023, 14:00 – 15:30 (CET)

Welcome

Veronica Lipucci Di Paola, *PMS Product Co-owner, EMA*

Marcos Fernandez Gomez, *PMS Product Co-owner, EMA*

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Agenda

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1	**Welcome** **14:00 – 14:05 (5 min)**	**Veronica Lipucci Di Paola,** *PMS Product Co-Owner, EMA* **Marcos Fernandez Gomez,** *PMS Product Co-Owner, EMA*
2	**Background concepts** **14:05 – 14:15 (10 min)**	**Veronica Lipucci Di Paola,** *PMS Product Co-Owner, EMA* **Marcos Fernandez Gomez,** *PMS Product Co-Owner, EMA*
3	• **Data migration activities timelines** • **EU IG Chapter 7 release and contents** **14:15 – 14:55 (40 min)**	**Marcos Fernandez Gomez,** *PMS Product Co-Owner, EMA*
4	**Sources to stay updated** **14:55 – 15:00 (5 min)**	**Veronica Lipucci Di Paola,** *PMS Product Co-Owner, EMA* **Marcos Fernandez Gomez,** *PMS Product Co-Owner, EMA*
5	**Q&A Session** **15:00 – 15:25 (25 min)**	**Veronica Lipucci Di Paola,** *PMS Product Co-Owner, EMA* **Marcos Fernandez Gomez,** *PMS Product Co-Owner, EMA* **Moderator: Caterina Scarpati,** *PMS Change Management Team*
6	**Closing** **15:25 – 15:30 (5 min)**	**Veronica Lipucci Di Paola,** *PMS Product Co-Owner, EMA* **Marcos Fernandez Gomez,** *PMS Product Co-Owner, EMA*

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

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

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1. Join via the QR code or link

2. Send or upvote the questions you want to hear answered

3. Questions will be shown on the screen and managed live in the Q&A session

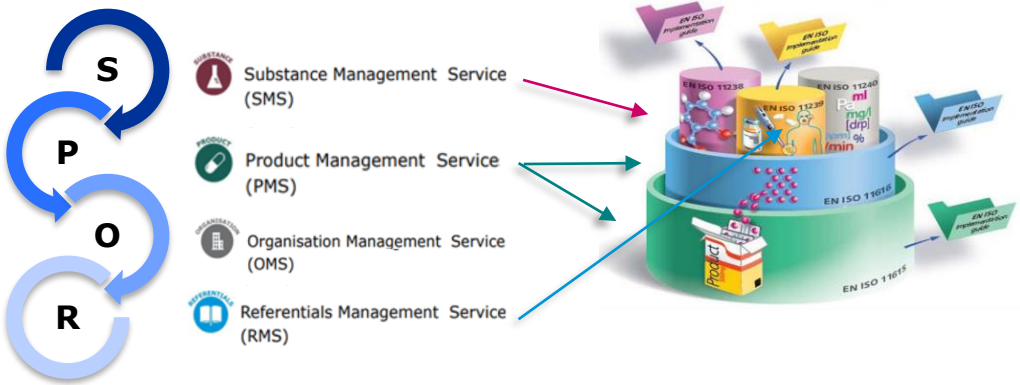
Background Concepts

Veronica Lipucci Di Paola, *PMS Product Co-owner, EMA*

Marcos Fernandez Gomez, *PMS Product Co-owner, EMA*

ISO IDMP & SPOR services

- **European Medicines Agency** is implementing the standards developed by the International Organization for Standardization (**ISO**) for the identification of medicinal products (**IDMP**)
- To comply with Commission Implementing **Regulation (EU) No 520/2012** (articles 25 and 26)
- ISO IDMP implementation in the EU in a step wise approach
- Four domains of master data used in pharmaceutical regulatory processes: **Substance**, **Product**, **Organisation** and **Referential** (SPOR) data



ISO IDMP	Description
ISO 11238	Data elements and structures for unique identification and exchange of regulated information on Substances
ISO 11239	Data elements and structures for unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging
ISO 11240	Data elements and structures for unique identification and exchange of units of measurement
ISO 11616	Data elements and structures for unique identification and exchange of regulated pharmaceutical Product information
ISO 11615	Data elements and structures for unique identification and exchange of regulated medicinal Product information

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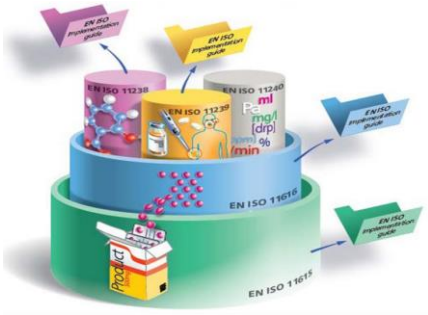
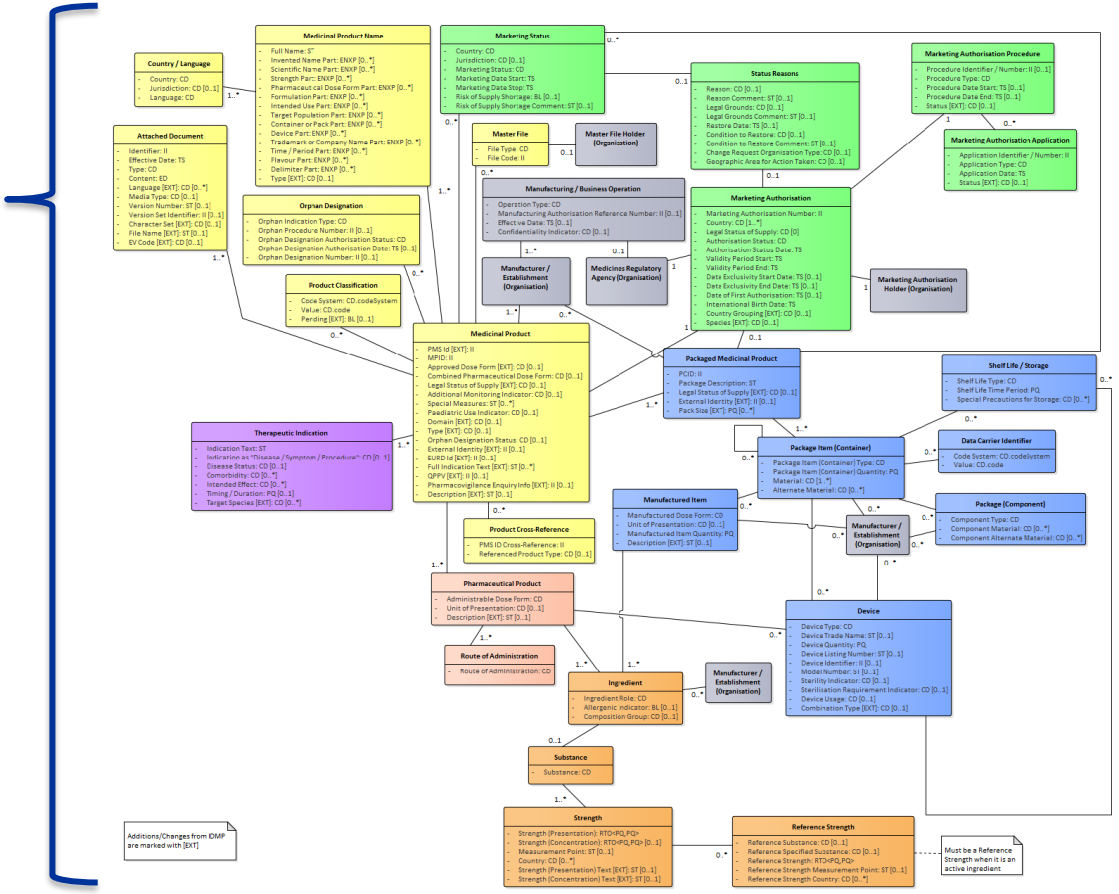
Product Management Service Data Model



Colour legend

- Medicinal Product definition
- Regulated Authorisation (Marketing Authorisation)
- Manufacturer / Organization definition
- Therapeutic indication
- Packaged Medicinal Product Definition
- Pharmaceutical Product
- Ingredient



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EU IG and Data Model

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EU IDMP Guidance Chapter 2 explains one by one the PMS data model fields including:

- Repeatability
- Conformance
- Data type
- Possible values
- ISO and FHIR information

5.1. Ingredient role

Tag	Description
User Guidance	The role of the ingredient as part of the manufactured item/pharmaceutical product shall be specified as a term ID. The applicable value(s) shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000072050
Value(s)	As listed in the Ingredient Role RMS list
ISO Element Name	Ingredient Role
ISO Path	For the Manufactured Item, the ISO path is: /MedicinalProduct/PackagedMedicinalProduct/PackageItem/ManufacturedItem/Ingredient/IngredientRole For the Pharmaceutical product, the ISO path is: /MedicinalProduct/PharmaceuticalProduct/Ingredient/IngredientRole
FHIR Element Name	Role
FHIR Path	Ingredient.role

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Other databases

SIAMED II

- Internal EMA's procedure management system
- Contains CAPs product data
- EMA maintains product data based on the outcome of the procedure

xEVMPD

- Authorised and Development Medicinal Products data base
- Contains CAPs and non-CAPs data
- MAHs are responsible for data maintenance (EMA data stewards validate data submitted)

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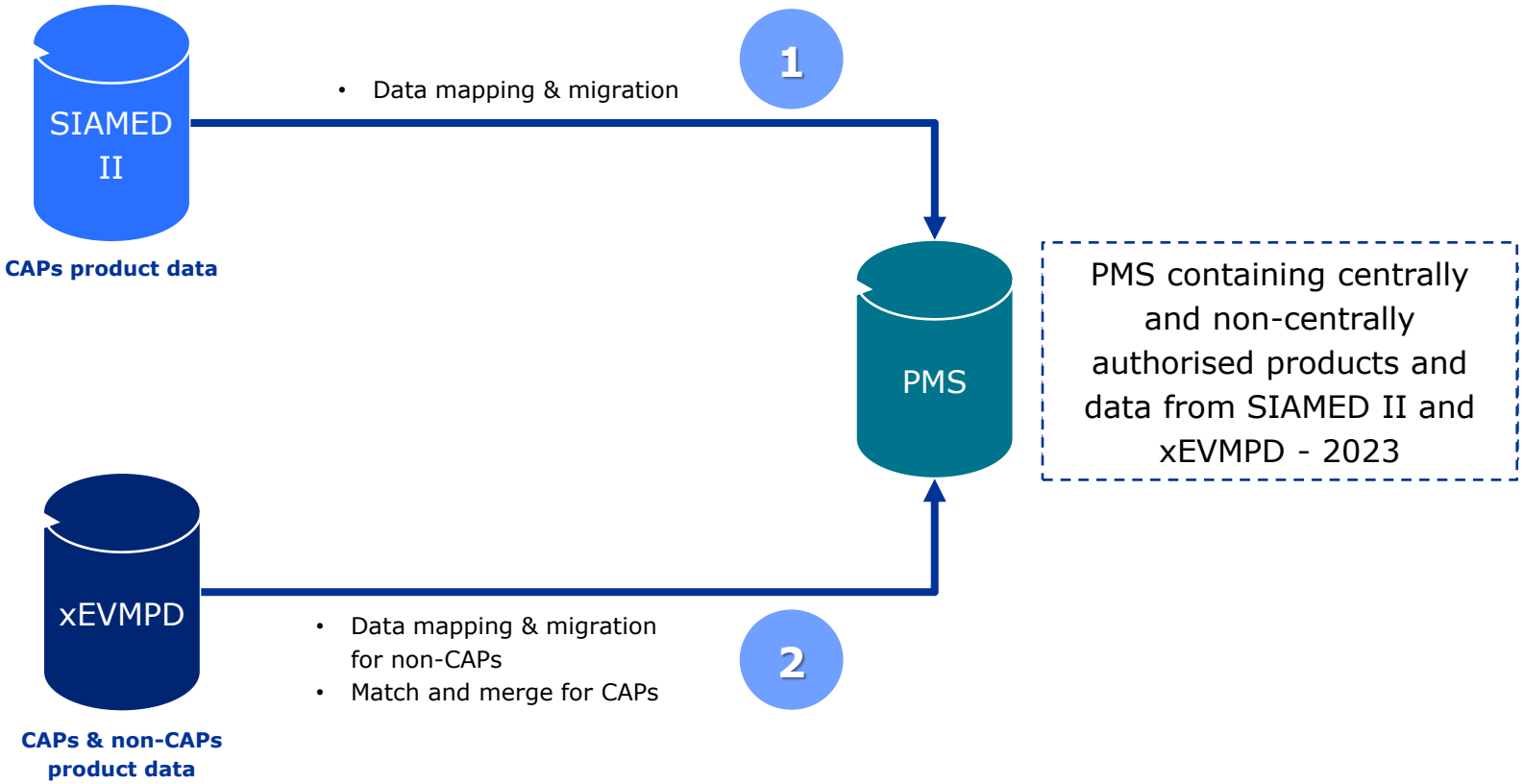
Data migration activities timelines, EU IG Chapter 7 release and contents

Marcos Fernandez Gomez, *PMS Product Co-owner, EMA*

Origin of existing product data in PMS: Initial data load



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Origin of existing product data in PMS: Initial data load

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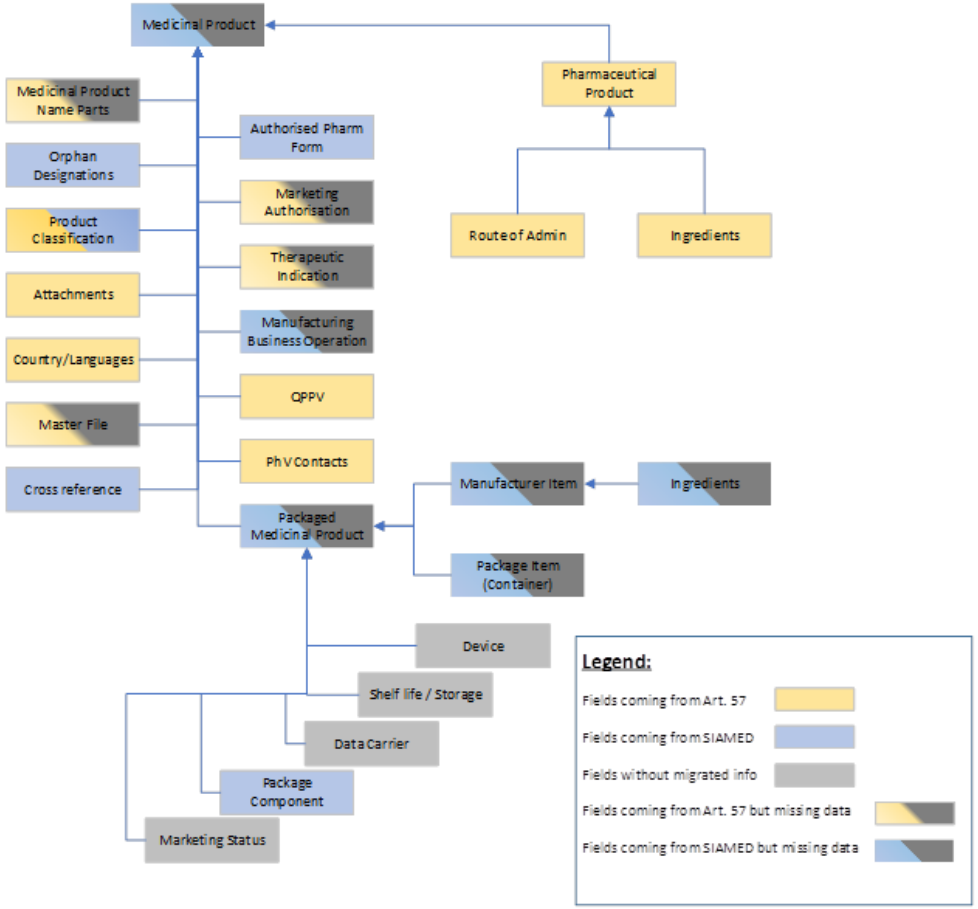
- **CAPs**: data sourced from SIAMED and XEVMPD
- **Non-CAPs**: limited data sourced only from XEVMPD
- Despite the initial data load from SIAMED and XEVMPD some PMS definitions & resources **will be missing** (e.g. non-CAP MBO, data carrier, device etc.)



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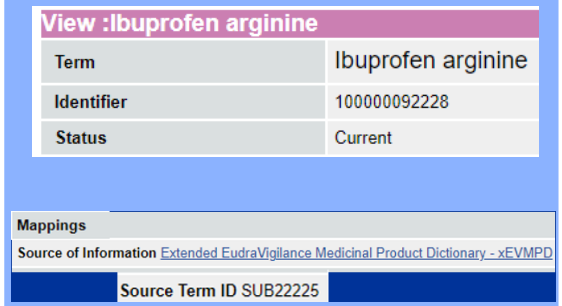
Data mapping

- SIAMED and xEVMPD contain **data** that can be **mapped to already existing terms** in other SPOR services.
- An exercise to map the terms in both databases to SPOR has been performed by EMA.

S



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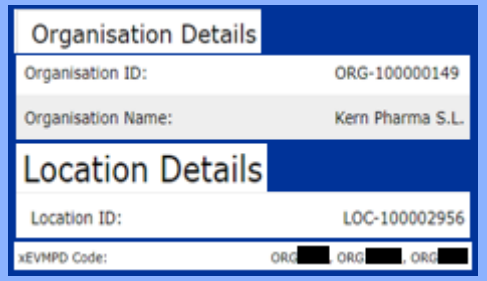

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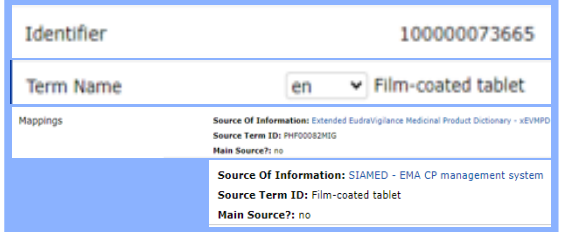

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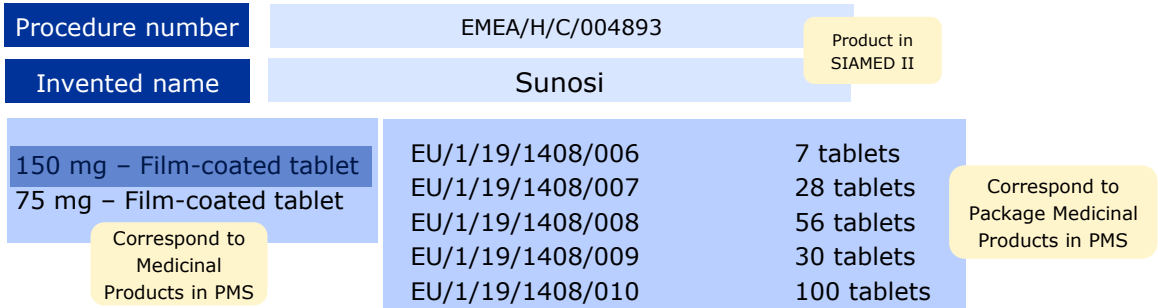
Migration of CAP data into PMS

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



PMS Currently in the PLM Portal as well

Full Name ↑	Authorised Dose Form	Active Substance	Authorisation Country	MA Holder	MA Nr.	MRP/CP Nr. ↑	PMS ID
Sunosi 150 mg - Film-coated tablet	Film-coated tablet	Solriamfetol hydrochloride	European Union	Tmc Pharma (EU) Limited	EU/1/19/1408	EMEA/H/C/004893	600000000651
Sunosi 75 mg - Film-coated tablet	Film-coated tablet	Solriamfetol hydrochloride	European Union	Tmc Pharma (EU) Limited	EU/1/19/1408	EMEA/H/C/004893	600000000173

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Migration of xEVMPD data into PMS

- xEVMPD contains **CAPs** data:
  - At presentation level (i.e. one EV code per presentation)
  - 4 records per presentation (i.e. 4 countries: EU, LI, NO, IS)
- Only EU records are migrated to PMS
- The **match and merge protocol** consists of the identification of:
  - Identifying a product in PMS migrated from SIAMED II with their respective presentation
  - Identifying the same presentation in xEVMPD and merge them

PMS	SIAMED II	MA number	xEVMPD
600000000651	Sunosi 150 mg - Film-coated tablet	EU/1/19/1408/006	Sunosi 150 mg film-coated tablets
		EU/1/19/1408/007	
		EU/1/19/1408/008	
		EU/1/19/1408/009	
		EU/1/19/1408/010	
600000000173	Sunosi 75 mg - Film-coated tablet	EU/1/19/1408/001	Sunosi 75 mg film-coated tablets
		EU/1/19/1408/002	
		EU/1/19/1408/003	
		EU/1/19/1408/004	
		EU/1/19/1408/005	

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Merge business rules

Once a record from SIAMED II *(now in PMS)* and a record from xEVMPD match, there are several **business rules** defined for the merge and are described in EU IG Chapter 7.

Depending on the data field, the final source of data might be different.

Is this field in SIAMED?	Is this field in xEVMPD?	Business rule	Example
NO	NO	This field will be empty	Storage conditions
YES	NO	Keep the data migrated from SIAMED	Manufacturers
NO	YES	Migrate the data from xEVMPD	MedDRA Codes
YES	YES	Define the source of data	Full name - overwritten by xEVMPD data

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Migration of xEVMPD data into PMS

xEVMPD contains **non-CAPs** product data:

- At presentation level (i.e. one EV code per presentation)
- At medicinal product level (i.e. no presentations are submitted to xEVMPD)
- BE, FI and LI authorised products are submitted in each official language

EV codes with the same data in the following **xEVMPD fields** are grouped under the same PMS Medicinal Product

*All countries except BE, FI and LI
**BE, FI and LI

Examples

Example 1

Owner HQ ID	Authorisation Country	Substance names	Pharmaceutical For	Full Presentation Nam	Authorisation Number
CHIESI	Romania	CROSPOVIDONE, LACTOSE MONOHYDRATE, MAGNESIUM STEARATE, SILICA, CO	TABLET	Flamexin, 20 mg, comprimate	7146/2006/03
CHIESI	Romania	CROSPOVIDONE, LACTOSE MONOHYDRATE, MAGNESIUM STEARATE, SILICA, CO	TABLET	Flamexin, 20 mg, comprimate	7146/2006/01
CHIESI	Romania	CROSPOVIDONE, LACTOSE MONOHYDRATE, MAGNESIUM STEARATE, SILICA, CO	TABLET	Flamexin, 20 mg, comprimate	7146/2006/02

3 EV codes in xEVMPD
(1 per presentation)

→

1 Medicinal product with
3 Package medicinal products

Example 2

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

3 EV codes in xEVMPD
(1 per product)

→

3 Medicinal product with
1 Package medicinal product each

PMS medicinal product data after migration

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CAPs

- Medicinal product is created from **SIAMED logic**
- Each medicinal product contains the presentations (package medicinal product) linked to it in SIAMED
- Package medicinal product and Medicinal product data is complemented with xEVMPD data after match and merge

Non-CAPs

- Medicinal product is created from **xEVMPD logic**
- Depending on the records submitted to xEVMPD, package medicinal products will be generated under the respective medicinal product
- Only xEVMPD data can be found in these PMS records

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Split of products from SIAMED II

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- There are some specific products in SIAMED II which are **not following the IDMP structure**
  - **PMS** defines a medicinal product based on the name as authorised in section 1 of the SmPC
  - **SIAMED II** does not capture the full name as authorised
- That situation leads to a case where in SIAMED II we only have one medicinal product but in PMS, more than one MP should be created
- A logic has been implemented to **split these products** before the match and merge protocol
- As advised by **eAF team**, these products should not be used until they have been split to avoid issues

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Split of products from SIAMED II - Example

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SIAMED STRUCTURE		PMS STRUCTURE	
Aimovig - 70 mg – solution for injection	EU/1/18/1293/001	Aimovig 70 mg solution for injection in pre-filled pen	EU/1/18/1293/001
	EU/1/18/1293/002		EU/1/18/1293/002
	EU/1/18/1293/003	Aimovig 70 mg solution for injection in pre-filled syringe	EU/1/18/1293/003
Aimovig - 140 mg – solution for injection	EU/1/18/1293/004	Aimovig 140 mg solution for injection in pre-filled pen	EU/1/18/1293/004
	EU/1/18/1293/005		EU/1/18/1293/005
	EU/1/18/1293/006	Aimovig 140 mg solution for injection in pre-filled syringe	EU/1/18/1293/006
2 products each of them with 3 presentations		**4 products each of the with different number of presentations**	

*As a general rule, if, for the same strength and dose form, there are **different full names authorised,** these products will be split in PMS.*

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Data quality issues

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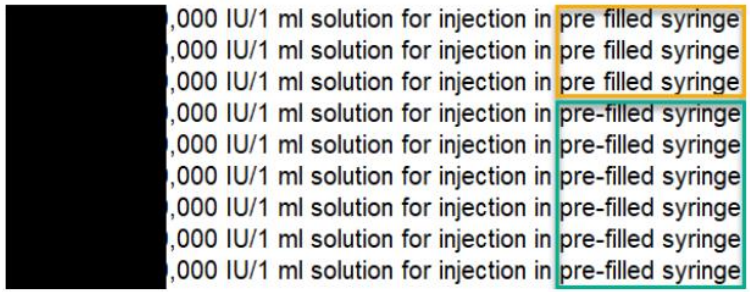
- There might be **data quality issues** in both SIAMED II and xEVMPD (visible via the PLM portal)
  - If coming **from SIAMED II**, applicants can submit a ticket through EMA Service Now (Report an Issue – SPOR – PMS)
  - If coming **from xEVMPD**, applicants can update their product data and it will be synchronised with PMS
- Any data quality issue present in xEVMPD and/or SIAMED II can result in an **incorrect migration of product data or generation of products into PMS**
- The **different scenarios** are described in EU IG Chapter 7

Data quality issues - Examples

Example 1



Different presentations of the same MP in xEVMPD with different names

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2 MPs in PMS will be created as the name is one of the grouping elements

Example 2

SIAMED II	xEVMPD	
EU/H/C/001	EU/H/C/001	Product 1
EU/H/C/003	EU/H/C/003	
EU/H/C/004	EU/H/C/004	
EU/H/C/005	EU/H/C/005	
EU/H/C/002	EU/H/C/002	Product 2
EU/H/C/006	EU/H/C/006	
EU/H/C/007	EU/H/C/007-0	

MA numbers from xEVMPD match with all presentations in SIAMED except the last one

→

Product 2 will have a duplicate in PMS with the presentation that has not matched with any presentation in SIAMED II

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Summary of the migration

- **SIAMED II data** is migrated first to PMS
  - It is already available in PMS and can be seen in the PLM Portal (only specific fields)
- **Some CAPs products** will be **split** to be IDMP Compliant
- **xEVMPD data** will be migrated to PMS
  - For CAPs: there will be a match and merge protocol to complement the products that already exist is PMS
  - For non-CAPs: there are several grouping rules depending on the country or MA number
- **Data quality issues** might lead to generation of wrong or incomplete products in PMS.

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Sources to stay updated

Veronica Lipucci Di Paola, *PMS Product Co-owner, EMA*

Marcos Fernandez Gomez, *PMS Product Co-owner, EMA*

How to stay updated on PMS

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System Demo

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

Next demo: 22 March 2023

Announced via EMA's Website Events Pages

Future Webinars

- SPOR Webinars Week (17-20 April 2023): all events listed here
- PMS Progress Webinar (Q2 2023): Date TBC

Announced via EMA's Website Events Pages

PLM Portal Forum

- News
- Release notes
- Down-time communications

Check regularly here

PMS Webpage

- Download EU Implementation Guide Updates
- Access Q&A documents

Check regularly here

eAF-PMS Newsletter

- Relevant updates on eAF and PMS
- Released quarterly

Available at EMA Corporate Website here

Q&A Session

Veronica Lipucci Di Paola, *PMS Product Co-owner, EMA*

Marcos Fernandez Gomez, *PMS Product Co-owner, EMA*

Moderator: Caterina Scarpati, *PMS Change Management Team*

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Closing

Veronica Lipucci Di Paola, *PMS Product Co-owner, EMA*

Marcos Fernandez Gomez, *PMS Product Co-owner, EMA*