1 July 2024
EMA/676106/2019
Information Management

Products Management Services (PMS) - Implementation of International Organization for Standardization (ISO) standards for the identification of medicinal products (IDMP) in Europe

Chapter 7: XEVMPD and SIAMED II to PMS – Initial migration guide

Version 3.1

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Table of Contents

1. Introduction

The EMA intends to migrate the Centrally Authorised Products (CAPs) and non-Centrally Authorised Products (non-CAPs) data held in the eXtended Eudravigilance Medicinal Product Dictionary (XEVMPD) and submitted by marketing authorisation holders (MAHs) under the Art.57 (2) legal obligations into the ISO IDMP-compliant data format and terminologies.

In addition to the data stored in XEVMPD, EMA intends to migrate the Centrally Authorised Products (CAPs) data held in its internal database called SIAMED II ultimately building the new ISO IDMP compatible repository [i.e. Product Management Services (PMS)] in PMS.

The transformed data will be loaded into the Product Management Service (PMS) hub with the following approach:

- allow the building of the new ISO IDMP compliant repository [i.e. Product Management Services (PMS)] from the data submitted under the Art.57 legal obligation and the data collected by EMA for Centrally Authorised Products;
- provide external stakeholders with services for the access and retrieval of the data previously submitted in Art.57 data format [i.e. via the eXtended Eudravigilance Medicinal Product Report message (XEVPRM)] and stored in SIAMED II, transformed and remapped into the new data format (FHIR) and terminologies for further processes such as enrichments, corrections, updates, etc.;
- facilitate business continuity ensuring that PMS contains data comparable with what is available in the XEVMPD database and currently supports the EMA business and regulatory processes until integration with PMS will be implemented;
- provide transparency and comprehension of the data transformed into the new format by EMA.

The present chapter provides information on the approach followed by the European Medicines Agency (EMA) to enable the transformation and migration of the data to the PMS. Specifically, this chapter aims at describing the following aspects:

- migration of CAP data into PMS;
- migration of non-CAP data into PMS;
- match and merge of CAP data from SIAMED II and XEVMPD;
- the Art.57 - SIAMED II - PMS data mapping;
- the transformation rules that will be applied to the data during the migration into PMS.

This chapter is purely for information and transparency, it does not require or oblige individual stakeholders to implement this approach in their in-house systems.

The illustrated mapping and migration rules are based on the XEVMPD, SIAMED II and PMS logical data model, which may be different from the individual stakeholder database architecture, and it is beyond EMA's remit to advice stakeholders on how to migrate the data recorded in their internal system to fulfil new legal requirements. However, the Agency is committed to share its own strategy and experience and encourages stakeholders to reflect and transpose the transformation rules provided in section 7 Mapping and migration rules in their in-house system when transforming product data into the IDMP-compatible format.

Version 2 of this guidance provided a meaningful update compared to version 1. SIAMED II was included as a new source of information and, therefore, the business rules provided in version 1 might be no longer applicable.

Annex I to Chapter 7 was released as a transitional document to explain the data migration from SIAMED II to PMS in support of the first release of the variation electronic Application Form (eAF) occurred in November 2022 for Centrally Authorised Products (CAPs). The information provided in Annex I is now included in this chapter for completeness.

Version 3 of this chapter contains information on centrally authorised products (CAPs) and non-centrally authorised products (non-CAPs) loaded from the eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) and SIAMED II database to support the future release of the web-based variation eAFs for CAPs and non-CAPs.

Version 3 of this document also provides major updates on the business rules defined for the initial migration of data from XEVMPD and SIAMED II. It is out of scope of this guidance to explain the synchronisation between XEVMPD and SIAMED with PMS as this information can be found in Chapter 9 of the EU IG. This version also includes revision to sections previously published and examples for each scenario.

Version 3.1 of this document includes a minor update specifying that the source of the package description for CAPs is SIAMED.

2. Scope and strategy of the initial migration of SIAMED II and Article 57 product data into PMS

In order to establish a baseline of data in the PMS database, it was agreed that medicinal product data would be migrated from two different sources: SIAMED II and XEVMPD. This would be achieved by performing a onc-time migration (referred to as "initial migration"). After this initial migration is done, data in PMS is maintained through the SIAMED II and XEVMPD to PMS Deltas until direct submissions to PMS are available. Information on how these deltas work can be found in Chapter 9 of the EU IG.

The strategy to migrate the authorised product data into PMS is described in this section and outlined in the following figure.

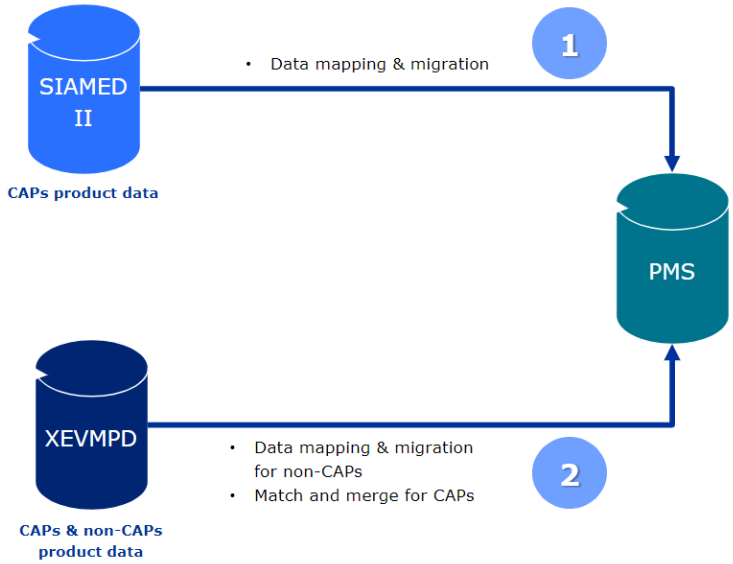

Figure 1: Strategy for initial migration to PMS

The steps describing how authorised data is migrated to PMS are reported below and are based on the procedure type of the medicinal product:

- Centrally Authorised Products (CAPs):
  - Initial product data load performed from SIAMED II to PMS;
  - Subsequent product data load performed from XEVMPD to PMS;
  - Consolidation of product data resulting from the migration from SIAMED II and XEVMPD into PMS. The data consolidation consists in the implementation of the match and merge process.
- Non-Centrally Authorised Products (Non-CAPs):
  - Initial product data load performed from XEVMPD to PMS only.

  This strategy applies to any product authorised through the Decentralised Procedure (DCP), Mutual Recognition Procedure (MRP), National Procedure (NAP) and any other authorisation procedure type.

3. SIAMED II product data migration

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

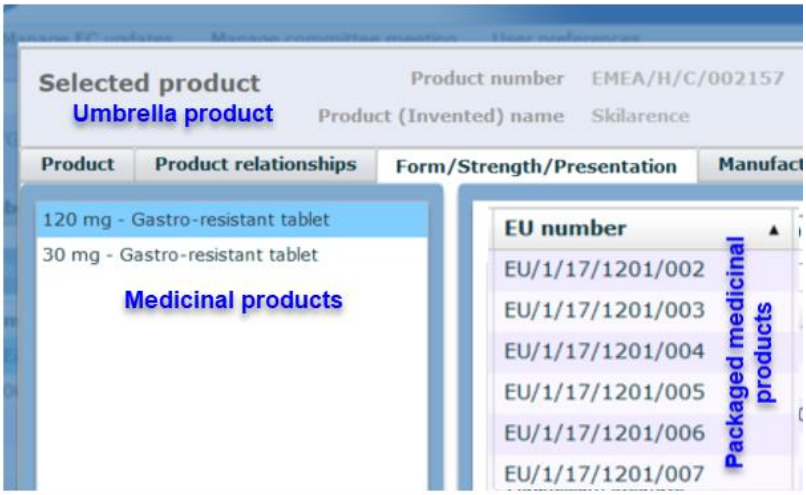

Figure 2: SIAMED II product structure

Business rules are built so that the parent product as stored in SIAMED II is split into the relevant IDMP compliant medicinal products following the rules established in Chapter 2 of the EU IG.

Considering the example in the figure above, two Medicinal Product entities can be expected in PMS: one referring to "120 mg gastro-resistant tablets" and the other one referring to "30 mg gastro-resistant tablets". For each medicinal product created in PMS, a PMS ID and a MPID will be assigned by the system based on the business rules in Chapter 2 of the EU IG.

Additionally, the relevant presentations are captured under each medicinal product entity created. These presentations will be migrated to PMS as Packaged Medicinal Products. According to Chapter 2 of the EU IG, each packaged medicinal product should be identified by the Packaged Medicinal Product Identifier (PCID). For this initial load, PCIDs are not generated, as there are defining elements needed for its creation that are missing. PCIDs will be generated when all the defining elements are available in PMS once data enrichment is available.

In the following table, a representation of the medicinal products created in PMS based on the data available in SIAMED II for the example above can be found.

Table 1. Medicinal products in PMS after SIAMED migration

PMS ID	Medicinal product name	Packaged medicinal product
600000001234	Skilarence - 30 mg – Gastro-resistant tablet	EU/1/17/1201/002 EU/1/17/1201/003 EU/1/17/1201/004
600000005678	Skilarence - 120 mg – Gastro-resistant tablet	EU/1/17/1201/005 EU/1/17/1201/006 EU/1/17/1201/007

SIAMED II contains all centrally authorised medicinal products authorised in the EU. Nevertheless, not all of them are migrated to PMS. Only medicinal product groups (i.e. SIAMED product) with one of the following statuses are migrated to PMS:

- Valid: Application for Marketing Authorisation approved.
- Revoked: Withdrawn after Marketing Authorisation by the Regulatory Authority.
- Expired: Renewal application not received.
- Suspended: Marketing authorisation is still valid, but the medicinal product must not, for some reason, be placed on the market, in the meantime.
- Surrendered: Regulatory entitlement withdrawn by the holder after it has been granted.

That means that refused or invalid medicinal products stored in SIAMED II are not migrated into PMS.

3.1. Split of specific CAPs in PMS

As explained in the section above, in SIAMED II, medicinal products are structured in a way that an umbrella product contains several IDMP compliant medicinal products based on product strength. As stated in Chapter 2 of the EU IG, a medicinal product in PMS is defined by different attributes, one example being the full product name in section 1 of the authorised SmPC.

In most cases, medicinal products with the same strength have the same product full name. However, in some cases, the medical device used for the administration might be included in the medicinal product name and therefore, for the same strength, more than one product name is used. That means that more than one medicinal product should be created in PMS.

During the first step of the initial migration, i.e. the migration of data from SIAMED II, medicinal products are created in PMS based on the structure that SIAMED II is following. In this case, for the SAIMED II Product: *Aranesp - 20 mg - solution for injection*, only one medicinal product is created in PMS. Depending on the presentation, we have two different names authorised in the SmPC: *Aranesp 20 micrograms solution for injection in pre-filled pen* and *Aranesp 20 micrograms solution for injection in pre-filled syringe*.

Therefore, the initially migrated product will be split into two medicinal products, and each presentation will be moved to the corresponding newly created medicinal product.

Table 2. Medicinal product in PMS after SIAMED migration, not split

Initially migrated CAP product		
PMS ID	Medicinal product name	Presentations
600000001234	Aranesp - 20 mg - solution for injection	EU/1/01/185/059 EU/1/01/185/047 EU/1/01/185/005 EU/1/01/185/006 EU/1/01/185/035 EU/1/01/185/078 EU/1/01/185/079

Table 3. Medicinal products in PMS after SIAMED migration and split

Split CAP		
PMS ID	Full presentation name	Presentations
600000004567	Aranesp 20 micrograms solution for injection in pre-filled pen	EU/1/01/185/059 EU/1/01/185/047
600000008900	Aranesp 20 micrograms solution for injection in pre-filled syringe	EU/1/01/185/005 EU/1/01/185/006 EU/1/01/185/035 EU/1/01/185/078 EU/1/01/185/079

The split of this medicinal product in PMS will be followed by the match and merge protocol which is explained in section 5 of this guidance.

As part of this split, the initially created medicinal product (600000001234 in this case) will be nullified and only the newly created medicinal product will be available.

SIAMED II and PMS teams have performed an exercise to identify the impacted CAP products that should be split during the initial load. In the case of the MAH finding a discrepancy after this activity is performed, please, contact EMA through Service Desk so the corrective actions are performed.

4. XEVMPD product data migration

As part of the initial load from XEVMPD, only the last version of a non-nullified record is migrated to PMS. Since there is no defined timeline for validation of updates submitted to XEVMPD, a non-validated version of a record may be migrated to the PMS at the time of data migration.

Only authorised medicinal products with data in the following fields in XEVMPD are migrated:

- Authorised Pharmaceutical Form
- Legal basis
- Medicinal product type
- Authorisation status different from Not Valid - Superseded by Marketing Authorisation Transfer or Not Valid - *Superseded by Marketing Authorisation Renewal/Variation*

NOTE: Development medicinal products available in the XEVMPD are not migrated as they are out of scope of the PMS implementation for the moment.

In XEVMPD, products are submitted following Chapter 3.II. Depending on the country of authorisation, XEVMPD can contain one or multiple EV codes for the same medicinal product (as described in Chapter 2 of the EU IG).

- Centrally Authorised Products (**CAPs**):
  - The Marketing Authorisation (MA) number is assigned at **package level**. Moreover, as stated in the XEVMPD guidelines, for each presentation, 4 records shall be submitted to XEVMPD:

    - one corresponding to EU as country of authorisation
    - three additional EV codes for each of the EEA countries: Iceland (IS), Liechtenstein (LI) and Norway (NO).

- Non-Centrally Authorised Products (**non-CAPs**):
  - If the country of authorisation assigns the MA number at **package level**, several EV codes belonging to the same medicinal product are available in XEVMPD. In this case, one EV code is assigned to each presentation in XEVMPD.
  - If the country of authorisation assigns the MA number at **product level**, one EV code is assigned to the medicinal product unless the Marketing Authorisation Holder (MAH) submits one record per package in XEVMPD in which case, one EV code corresponds to one presentation in XEVMPD.

Based on the scenarios described above, different business and grouping rules have been implemented in order to have a successful initial migration generating IDMP compliant products. These business rules can be found in the following sections.

As already mentioned in section 2, for each medicinal product created in PMS, a PMS ID and a MPID will be assigned by the system based on the business rules in Chapter 2 of the EU IG. PCIDs, assigned at packaged medicinal product are not generated until all the defining elements are submitted to PMS as part of the enrichment process.

4.1. Initial migration of non-CAP products in all countries except BE, LU and FI

For XEVMPD records where the authorisation procedure is not "EU authorisation procedure - Centralised Procedure", and the country of authorisation is not BE, LU or FI, a grouping logic is established to group and migrate different EV codes belonging to the same medicinal product. This logic would cover the scenario where different presentations with different EV codes belong to the same Medicinal Product but also in the case where only one record is submitted to XEVMPD.

EV codes with the same product data in the following XEVMPD fields are grouped under the same PMS Medicinal Product:

- Marketing Authorisation Holder (MAH)
- Authorisation country
- Active substance(s)
- Strength of active substance(s)
- Authorised pharmaceutical dose form
- Full presentation name

In the case, where multiple EV codes are grouped as they shared the same data in the above-mentioned fields, each EV code will be migrated as a packaged medicinal product in PMS.

An example of this grouping logic can be found in the table below.

Table 4. grouping logic for NAP

Auth Country	MAH Name	Authorised dose form	EV Code	Full Presentation Name	Active substance and strength
IT	LABIANA PHARMACEUTICALS S.L.U.	Granules for oral solution	PRD111111 PRD222222	Fosfomicina Reddy Bambini 2 g granulato per soluzione orale	Fosfomicin – 2 g

In this case, all grouping fields for these two EV codes contain the same information. Therefore, they will be grouped into the same medicinal product in PMS, and two packaged medicinal products will be created under it.

In the following case, as full presentation name and the strength of active substance are different in each record, one Medicinal Product per EV code will be created in PMS with one packaged medicinal product under each of them.

Table 5. grouping logic for NAP

Auth Country	MAH Name	Authorised dose form	EV Code	Full Presentation Name	Active substance and strength
ES	KERN PHARMA, S.L.	Capsules	PRD111111	Alprazolam Kern Pharma 1 mg comprimidos EFG	Alprazolam – 1 mg
			PRD222222	Alprazolam Kern Pharma 2 mg comprimidos EFG	Alprazolam – 2 mg
			PRD333333	Alprazolam Kern Pharma 0,5 mg comprimidos EFG	Alprazolam – 3 mg
			PRD444444	Alprazolam Kern Pharma 0,25 mg comprimidos EFG	Alprazolam – 0,25 mg

Based on the business rules that have been defined for the initial migration, the packages that have been submitted to XEVMPD will be migrated to PMS as packaged medicinal products under one medicinal product record. The package description field from XEVMPD will be migrated to PMS as stated in Annex I of this document and will be useful to identify each package in PMS.

In the cases where all presentations are submitted under the same record in XEVMPD, only one packaged medicinal product will be created in PMS. MAHs will have the possibility to enrich this information either directly in PMS once the enrichment capability is deployed, or through XEVMPD by submitting one record per presentation as already described in Chapter 3.II of XEVMPD.

4.2. Initial migration of non-CAP products in FI and LU

Finland (FI) and Luxemburg (LU) have more than one official language. Following Chapter 3. II, one record per official name in its official language shall be submitted to XEVMPD.

That exceptional situation makes it impossible to use the same business rules that had been defined in the previous use case. As there are different names for the same medicinal product, the full presentation name cannot be used to group all the records under the same PMS medicinal product.

EV codes with the same product data in the following XEVMPD fields are grouped under the same PMS Medicinal Product:

- Marketing Authorisation Holder (MAH)
- Authorisation country
- Active substance(s)
- Strength of active substance(s)
- Authorised pharmaceutical dose form
- Marketing authorisation number

The marketing authorisation number, which is the same for all the records in XEVMPD independently of the name, is used as a grouping element.

An example of this grouping logic can be found hereafter:

Table 6. grouping logic for NAP in FI and LU

Auth Country	Authorised dose form	MA number	EV Code	Full Presentation Name	Active substance and strength
LU	Tablets	138115	PRD111111	Diamox 250 mg Tabletten	Acetazolamide – 250 mg
			PRD222222	Diamox 250 mg Comprimés	Acetazolamide – 250 mg

In this case, even if the name of the two product EV codes are different, as the MA number is the same, these two records will be migrated as two packaged medicinal products in PMS.

NOTE: Please, take into account that, each EV code from XEVMPD that belongs to the same medicinal product in PMS will be migrated as a packaged medicinal product. Therefore, medicinal products authorised in countries with more than one official language will contain as many packages as EV codes have been submitted in the different languages. This duplication of packages will have to be corrected by the applicant as soon as the enrichment capability is made available in PMS.

4.3. Initial migration of non-CAP products in BE

Belgium has three official languages. Based on Chapter 3.II, applicants shall submit the product in all languages to XEVMPD. In this case, only one medicinal product should be created in PMS with more than one product name.

The difference between Belgium, Luxembourg and Finland is that Belgium competent authority might assign different marketing authorisation numbers to different presentations. Therefore, the marketing authorisation number cannot be used to group EV codes belonging to the same medicinal product in PMS. In this case, these are the values used for the grouping.

- Marketing Authorisation Holder (MAH)
- Authorisation country

- Active substance
- Strength of active substance
- Authorised pharmaceutical dose form
- Authorisation procedure
- MRP/DCP/EMEA number

Taking into account these fields, the system is able to group all the EV codes with different names (official names) and different MA numbers (different presentations) under the same medicinal product.

Table 7. grouping logic for NAP in BE

Full presentation name – Language	Package description	MA number	MRP/DCP number	Procedure type
Gabapentine Pfizer 600 mg comprimés pelliculés - French	20 tablets – Alu/Alu blister	BE399463	DE/H/2852/004	DCP
Gabapentine Pfizer 600 mg comprimés pelliculés - French	20 tablets – PVC/Alu blister	BE399454		
Gabapentine Pfizer 600 mg filmomhulde tablet - Dutch	20 tablets – Alu/Alu blister	BE399463		
Gabapentine Pfizer 600 mg filmomhulde tablet - Dutch	20 tablets – PVC/Alu blister	BE399454		

In this example, different presentations of the same medicinal product get different MA number based on the material of the immediate package.

Using the MRP/DCP number and the procedure type as grouping elements, these four records will be grouped under the same PMS medicinal product and four packaged medicinal products will be created.

IMPORTANT: Pure national procedures do not have a procedure number, and therefore MRP/DCP/EMEA number field in XEVMPD is empty.

That means that in case an MAH has duplicated pure national medicinal products, only one medicinal product will be created as part of the initial migration as there is no way to differentiate both products. MAHs will have to open a ticket in Service Desk requesting the split of those products in PMS. Please, provide as much information as possible such as the EV codes from XEVMPD and which records should belong to which medicinal product.

4.4. Initial migration of CAP products from XEVMPD

For centrally authorised medicinal products, separate authorisation numbers (EU numbers) are assigned to each presentation. Following Chapter 3.II, for each presentation (each EU number) a separate record should be submitted to XEVMPD.

Moreover, for each presentation, 4 records should be submitted to XEVMPD. One with authorisation country EU, and three more for the EEA countries (Iceland, Norway and Liechtenstein) with the respective country of authorisation.

All these records will follow the business rules described in section 4.1 for the grouping and migration logic. Only after the grouping, those records where the authorisation country is EU, will follow the match and merge protocol as described in section 5 below.

5. Match and merge of SIAMED II and XEVMPD product data

Match and merges rules apply only to Centrally Authorised Products where the authorisation country is EU. As explained in section 3 and 4, Centrally Authorised Product data is migrated from two different sources, i.e. SIAMED II and XEVMPD.

As reported in Figure 1, the first step of the initial data load is the migration of SIAMED II product data. Afterwards, XEVMPD data is migrated. A match and merge protocol is applied to prevent the duplication of CAP products.

The match and merge protocol consists of the identification of XEVMPD records that matches with a CAP record initially migrated from SIAMED II to PMS followed by a merge of both and where applicable overwrite the values from SIAMED II with the product data available from XEVMPD. That is why the match and merge protocol only applies to centrally authorised products with authorisation country EU. CAPs where the authorisation country is NO, IS or LI are just migrated from XEVMPD but not matched nor merged with products coming from SIAMED II.

Two or more medicinal products will be matched if the following conditions are all met:

- All records on package level must match for that medicinal product (all MA numbers must match)
- MAH in SIAMED II and XEVMPD shall be the same
- Only EU records from XEVMPD will be matched
- The match is only viable if there is a least one record from SIAMED II and another one from XEVMPD

The Marketing Authorisation Number (reported at packaged medicinal product level in both databases) is the data element considered to identify matches between SIAMED II and XEVMPD CAP product data. The following tablet represents an example of a perfect match between SIAMED II and XEVMPD:

Table 8. match strategy between SIAMED and XEVMPD

SIAMED II product name	SIAMED II authorisation numbers	XEVMPD product name	XEVMPD authorisation numbers
BindRen (SRD) 3 g - Granules	EU/1/12/804/014	BindRen 3 g granules	EU/1/12/804/014
	EU/1/12/804/015		EU/1/12/804/015
	EU/1/12/804/016		EU/1/12/804/016

After the match and merge protocol, depending on the data element, SIAMED II data or XEVMPD data survives. More information on the source of information as well as more details regarding the mapping rules can be found in section 7 of this guidance.

6. Data quality issues that may affect the initial migration

Some of the data submitted to XEVMPD is provided as free text and entered manually into the system. Free text and manual processes may lead to inconsistencies of data and despite the efforts EMA data quality team is putting into standardisation some records in XEVMPD might present discrepancies.

These data discrepancies might result in incorrect product generation in PMS as part of the initial migration. In this section, some examples are provided and the PMS team encourages MAHs to review their XEVMPD data to spot these mistakes before the initial migration to PMS is performed.

In case these data quality issues are not solved at the moment of the initial migration, and therefore, wrong products are generated in PMS, please, read Chapter 9 of the EU IG to know how those issues can be solved by the XEVMPD to PMS deltas.

6.1. Data discrepancies in grouping fields

As described in the previous sections, there are some XEVMPD terms that are used to group records under the same medicinal product. Inconsistencies on these terms will lead to the generation of multiple PMS medicinal products.

For example, in the example below, three EV codes have been submitted to XEVMPD for the three presentations of the same medicinal product but in each of the records the name might contain different characters (a dot (.) in PRD111111 and a hyphen (-) in PRD222222). Even if the rest of the grouping fields contain the same information, as the name of the medicinal product is different, three different medicinal products will be generated in PMS.

Table 9. example of data discrepancies in grouping fields

Auth Country	MAH Name	Authorised dose form	EV Code	Full Presentation Name	Active substance and strength
IT	ALMIRALL HERMAL GMBH	Capsule, soft	PRD111111	Aknenormin 10 mg capsule molli.	Isotretinoin – 10 mg
			PRD222222	Aknenormin 10 mg capsule-molli	

Auth Country	MAH Name	Authorised dose form	EV Code	Full Presentation Name	Active substance and strength
			PRD333333	Aknenormin 10 mg capsule molli	

This example is making reference to the name of the product, but the same situation could happen to other grouping elements such as the active substance(s) and strength(s), the MA number, etc.

6.2. Discrepancies in data not used for grouping logic

There are data elements which will be migrated from XEVMPD and will not be use for grouping purposes, for example: ATC Code, MedDRA Codes, and QPPV Codes, among others. These data elements are part of the Medicinal Product PMS data model, not the Packaged Medicinal Product part.

When several EV codes from XEVMPD are grouped to create one medicinal product, some of the information is migrated to each packaged medicinal product such as the authorisation status but other information is migrated to the medicinal product section such as the MedDRA codes. Every time one package is added to the medicinal product, the data belonging to the medicinal product section overwrites the data that was present at the beginning.

That means that, in case two records from XEVMPD belonging to the same medicinal product contain different data for example in the indications section, the data of the first one will be overwritten by the data in the second one.

Table 10. example of data discrepancies in non-grouping fields

Auth Country	MAH Name	Authorised dose form	EV Code	Full Presentation Name	MedDRA Codes
IT	ALMIRALL HERMAL GMBH	Capsule, soft	PRD111111	Aknenormin 10 mg capsule molli	10000496
			PRD222222	Aknenormin 10 mg capsule molli	10000496
			PRD333333	Aknenormin 10 mg capsule molli	10000496 & 10000498

In this case, two records have the same indication, but the third one contains two indications. In this case, the medicinal product in PMS will reflect the indications in PRD333333 as it is the last one to be part of the grouping.

6.3. Discrepancies in XEVMPD for CAPs

Within this document, it is explained how centrally authorised products are migrated from two different sources (SIAMED II and XEVMPD) to PMS.

As outlined in section 2, medicinal products from SIAMED II have been migrated to PMS. Those products are already present in PMS and the next step is to run the match and merge protocol with the products from XEVMPD.

Data discrepancies in XEVMPD might affect the correct migration and generation of products in PMS.

As stated in section 5, the marketing authorisation number is one of the data elements used to match and merge two records.

In case the discrepancy is not in the MA number, but for example in the name of the medicinal product, the business rule establishes that if the MA numbers from two different medicinal products migrated from XEVMPD matches the MA numbers of the medicinal product migrated from SIAMED II, both products will be merged as the Marketing Authorisation number will result in a 1:1 match. The name displayed in PMS will be the name of the last presentation migrated from XEVMPD as one product will overwrite the data from the previous one in the medicinal product section.

Table 11. example of data quality issue in the full presentation name for CAPs

SIAMED II MA number	XEVMPD – Full medicinal product name	XEVMPD – MA number
EU/1/18/1287/008	Hefiya 80 mg solution for injection in pre-filled pen	EU/1/18/1287/008
EU/1/18/1287/009	Hefiya 80 mg solution for injection in pre-filled pen	EU/1/18/1287/009
EU/1/18/1287/010	Hefiya 80 mg solution for injection in pre-filled pen	EU/1/18/1287/010
EU/1/18/1287/011	Hefiya 80 mg solution for injection in pre filled pen	EU/1/18/1287/011

Any change in the full presentation name can be done directly in XEVMPD and will be reflected in PMS. Please, refer to EU IG Chapter 9 for further information on the deltas from XEVMPD to PMS functionality.

In addition to the example above, in case of data quality issues reported at the level of the EU number field in XEVMPD, the applied match and merge rules in SIAMED II and XEVMPD will have a negative outcome.

Table 12. example of data quality issue in the EU number for CAPs

SIAMED II MA number	XEVMPD – Full medicinal product name	XEVMPD – EU number
EU/1/04/279/014	Lyrica 100 mg hard capsules	EU/1/04/279/014
EU/1/04/279/015	Lyrica 100 mg hard capsules	EU/1/04/279/015
EU/1/04/279/016	Lyrica 100 mg hard capsules	EU/1/04/279/016

SIAMED II	MA number	XEVMPD – Full medicinal product name	XEVMPD – EU number
EU/1/04/279/039		Lyrica 100 mg hard capsules	EU/1/04/279/39

In this case, as not all the packages can be matched between SIAMED II and XEVMPD, the medicinal product from XEVMPD cannot be fully matched and merged with the corresponding SIAMED II medicinal product, triggering the creation of a duplicate medicinal product in PMS; one from SIAMED II and another one from XEVMPD.

In this situation, data corrections shall be performed in XEVMPD. Additional information can be found in chapter 9 of the EU IG.

7. Mapping and migration rules

This section describes the mapping and migration rules applicable to the different data elements in the PMS data model.

7.1. Migration rules

A representation of the PMS data model can be found in Chapter 2 of the EU IG with the description of all the data elements that are part of PMS. Having a look at the number of data elements in PMS, it is obvious that this number is higher than the number of data elements that are present in XEVMPD and/or SIAMED II.

Therefore, as part of the initial migration from SIAMED II and XEMPVD to PMS, some fields will contain data, but some other fields will be missing information as it is not present in the source.

As centrally authorised product data is migrated from two separate sources: SIAMED II and XEVMPD, the PMS product entity resulting from the applied data migration will contain more data than the one generated for non-CAP products with only one source of information (i.e.: XEVMPD).

PMS can contain data elements:

- shared across the two databases (i.e.: name of the medicinal product, marketing authorisation holder, authorisation number, etc)
- contained in one single database (i.e.: MedDRA codes in XEVMPD but full indication text in SIAMED II)
- not captured in either SIAMED II or XEVMPD (i.e.: storage conditions)

A representation of the PMS data model and the source of their data elements can be found in section 8 of this document.

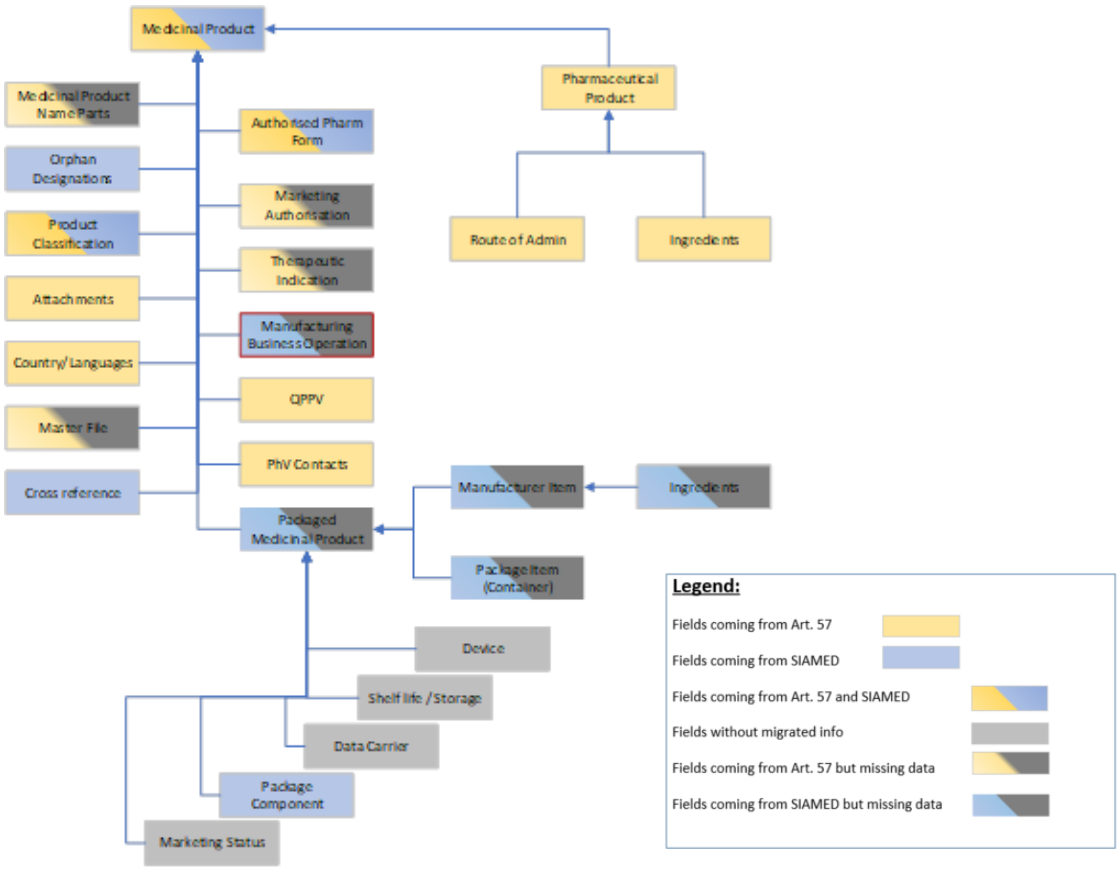

Figure 3: Representation of sources of data in the PMS data model

As explained in section 5, in case the same PMS attribute is available in both source databases, only the information migrated from one source will survive upon completion of the match and merge protocol.

The table available in section 8 provides full visibility on the migration rules that apply to the PMS data model when migrating product data from SIAMED II and XEVMPD.

The third column, named "Migration rules applied to PMS", captures the survival source when the data is present in both databases (SIAMED II and XEVMPD).

The migration rules reported in the table applies to CAP and non-CAP products. However, considering that SIAMED II database only captures centrally authorised product data, non-CAP product data can only be migrated from XEVMPD. Hence the term "SIAMED II" reported in the column "Migration rules applied to PMS" only refers to CAP products, while non-CAP product data will result in an empty field due to the lack of information available from XEVMPD.

The term "Default" means that the value is not migrated from any source database, and it is included by default. The default value is specified in the table where applicable.

"Ø" means that no value can be migrated from any source as the information does not exist in the available systems where the data is coming from.

It is recommended that the table below is read along with Chapter 2 of the EU IG to understand which RMS lists are used in PMS and mapped against SIAMED II and/or XEVMPD data, where applicable.

7.2. Mapping rules

Independently of the source of the data, SIAMED II, XEVMPD and PMS contain information in different formats:

- SIAMED II captures product data as free text
- XEVMPD, depending on the field, is supported by EV codes or free text
- PMS captures product data as controlled vocabularies, boolean and free text

In consideration of the above different formats, a mapping exercise has been performed to correctly map the different terms from SIAMED II and XEVMPD, to the relevant PMS controlled vocabularies. The outcome of this exercise has been used to update the mapping sections of Referentials Management Service (RMS), Organisation Management Service (OMS) and Substance Management Service (SMS).

An example of RMS data mapping can be found in the RMS "Pharmaceutical Dose Form" list (RMS ID: 200000000004) and in figure 4 below.

In this list, each term is mapped against the relevant EV codes used in XEVMPD and/or the SIAMED II free text term. As a result of the data mapping exercise, the information migrated is mapped to the correct term needed in PMS.

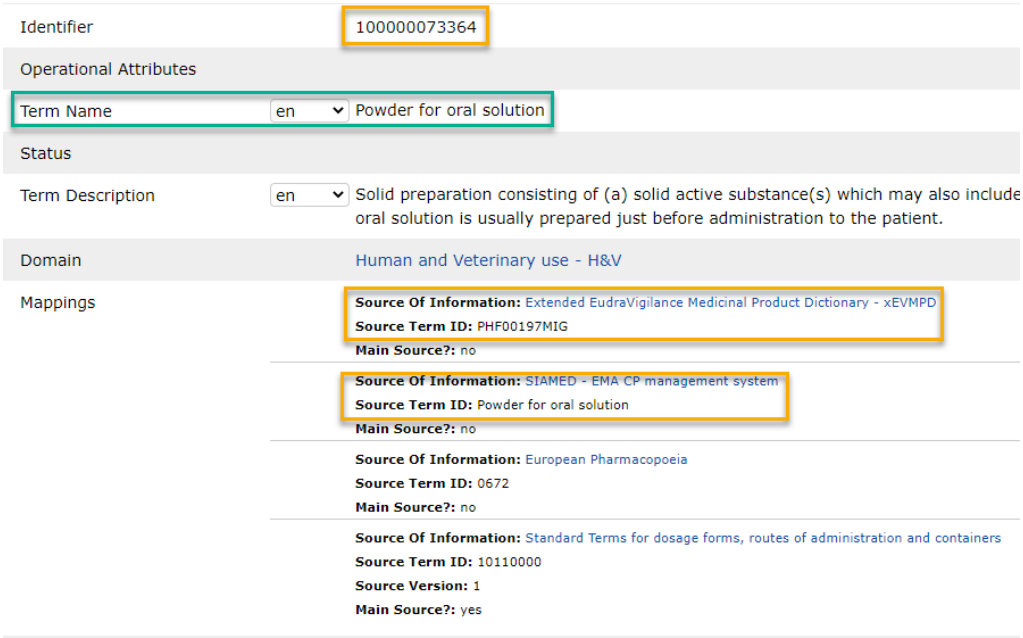

Figure 4: Example of RMS term mapped against the relevant XEVMPD EV code and SIAMED II term

The different lists consumed by the Product Management Service (PMS) can be found in Chapter 2 of the EU IG. The data mappings to the different terms can be found in each relevant RMS list available from the RMS portal.

A similar data mapping exercise is performed with OMS data. In this case, information can be found linked to the relevant LOC ID as shown in figure 5.

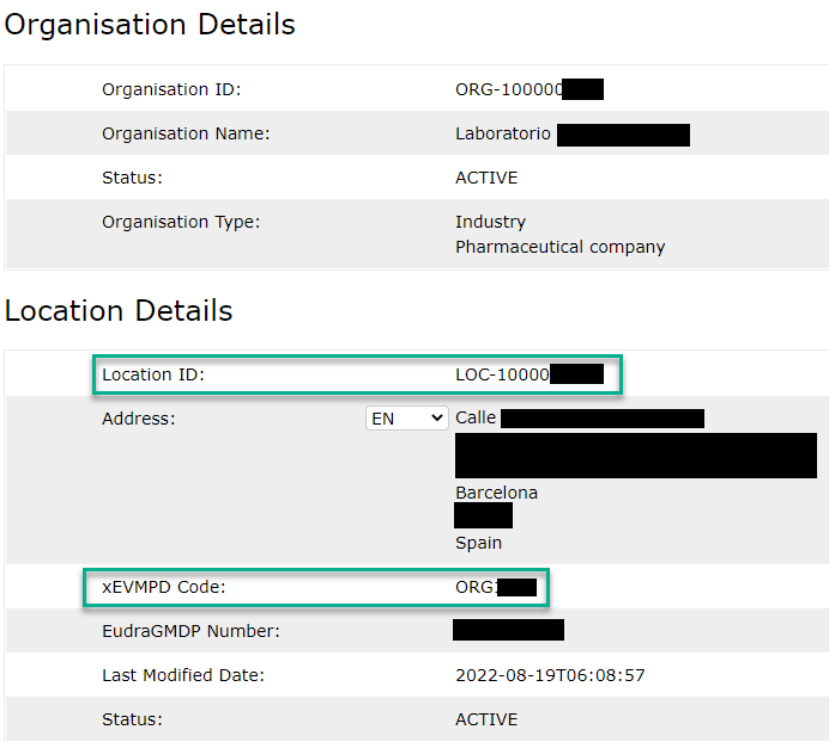

Figure 5: Example of OMS organisation mapped against the relevant XEVMPD EV code

A similar exercise was conducted to map the substances to SMS. The relevant information in this case can be found in the SMS Export CSV file that is available in the SMS section of SPOR. Figure 6 shows an example of the EV codes and the SMS IDs.

#SMS_ID	Substance_Name	Is_Preferred_Name	Language	External_Code_XEVMPD
100000075987	HUMAN MEASLES IMMUN	TRUE	English	SUB12039MIG
100000075987	IMMUNOGLOBULINE HUM	FALSE	French	SUB12039MIG
100000075987	IMMUNOGLOBULINUM HU	FALSE	Latin	SUB12039MIG
100000075988	HUMAN PLASMA FOR FRA	TRUE	English	SUB12043MIG
100000075988	PLASMA HUMAIN POUR F	FALSE	French	SUB12043MIG
100000075988	PLASMA HUMANUM AD S	FALSE	Latin	SUB12043MIG
100000075989	HYDROCHLORIC ACID, CO	TRUE	English	SUB12050MIG
100000075989	CONCENTRATE HCL	FALSE	English	SUB12050MIG
100000075989	CONCENTRATED HYDROC	FALSE	English	SUB12050MIG
100000075989	HYDROCHLORIC ACID CON	FALSE	English	SUB12050MIG

Figure 6: Example of substances in SMS mapped against the relevant XEVMPD EV code

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

8. Annex 1. Source of data for PMS data elements

EU IG Section	PMS EU IG Data element	Migration rules applied to PMS
	Medicinal product	
1. Medicinal product	1.1. Product Management Service Identifier (PMS ID)	Ø
1. Medicinal product	1.2. Medicinal product identifier (MPID)	Ø
1. Medicinal product	1.3. Domain	SIAMED II for CAP; Default *Human* for non-CAP
1. Medicinal product	1.4. Type	Default *Authorised Medicinal Product*
1. Medicinal product	1.5. (Authorised) pharmaceutical form	SIAMED II for CAPs and XEVMPD for non-CAPs
1. Medicinal product	1.6. Combined pharmaceutical dose form	If (Authorised) pharmaceutical form is a combined one, it is copied in this field
1. Medicinal product	1.7. Legal status of supply	SIAMED II
1. Medicinal product	1.8. Additional monitoring indicator	XEVMPD
1. Medicinal product	**1.9. Orphan Designation**	**NA**
1. Medicinal product	1.9.1. Regulatory Authorisation Type	SIAMED II
1. Medicinal product	1.9.2. Orphan designation Status	SIAMED II
1. Medicinal product	1.9.3. Orphan designation number	SIAMED II
1. Medicinal product	1.9.4. Orphan designation status date	SIAMED II
1. Medicinal product	1.9.5. Market Exclusivity start date	Ø

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

EU IG Section	PMS EU IG Data element	Migration rules applied to PMS
1. Medicinal product	1.10. Paediatric use indicator	XEVMPD
1. Medicinal product	1.11. Full Indication text	SIAMED II
1. Medicinal product	1.11.1. Language	Default – English for CAPs
1. Medicinal product	1.12. EURD ID	Ø
1. Medicinal product	**1.13. Product Classification**	**NA**
1. Medicinal product	1.13.1. XEVMPD product type information	XEVMPD
1. Medicinal product	1.13.2. Legal basis	XEVMPD
1. Medicinal product	1.13.3. ATC Code(s)	XEVMPD
1. Medicinal product	1.13.3.1. ATC Code – Flag	Ø
1. Medicinal product	1.13.4. Medicinal product category	Ø
1. Medicinal product	1.13.5. Genetically Modified Organisms (GMOs)	SIAMED II
1. Medicinal product	**1.14. Medicinal product name**	**NA**
1. Medicinal product	1.14.1. Full name	XEVMPD
1. Medicinal product	1.14.2.1. Country	XEVMPD
1. Medicinal product	1.14.2.2. Language	Mapping Country with language
1. Medicinal product	1.14.3.3.1. Invented Name part (text)	XEVMPD
1. Medicinal product	1.14.3.3.2. Scientific name part (text)	XEVMPD
1. Medicinal product	1.14.3.3.3. Strength part (text)	XEVMPD
1. Medicinal product	1.14.3.3.4. Pharmaceutical dose form part (text)	XEVMPD
1. Medicinal product	1.14.3.3.5. Formulation part (text)	Ø
1. Medicinal product	1.14.3.3.6. Intended use part (text)	Ø
1. Medicinal product	1.14.3.3.7. Target population part (text)	Ø
1. Medicinal product	1.14.3.3.8. Container or pack part (text)	Ø
1. Medicinal product	1.14.3.3.9. Device part (text)	Ø
1. Medicinal product	1.14.3.3.10. Trademark or company name part (text)	Ø
1. Medicinal product	1.14.3.3.11. Time/period part (text)	Ø

EU IG Section	PMS EU IG Data element	Migration rules applied to PMS
1. Medicinal product	1.14.3.3.12. Flavour part (text)	Ø
1. Medicinal product	1.14.3.3.13. Delimiter Part	Ø
1. Medicinal product	**1.15. (Pharmacovigilance) master file**	**NA**
1. Medicinal product	1.15.1. File type	Default – PSMFL
1. Medicinal product	1.15.2. File code	XEVMPD
1. Medicinal product	**1.16. Contact (QPPV)**	**NA**
1. Medicinal product	1.16.1. Identifier [Contact (QPPV)]	XEVMPD
1. Medicinal product	1.16.2. Role	Default – QPPV
1. Medicinal product	**1.17. Pharmacovigilance enquiry information**	**NA**
1. Medicinal product	1.17.1. Email address	XEVMPD
1. Medicinal product	1.17.2. Phone number	XEVMPD
1. Medicinal product	1.17.3. Role	Default – Pharmacovigilance enquiry information
1. Medicinal product	**1.18. Attached document**	**NA**
1. Medicinal product	1.18.1. Master (Attached Document) Identifier	Ø
1. Medicinal product	1.18.1.1. Identifier value	Ø
1. Medicinal product	1.18.1.2. Identifier system	Ø
1. Medicinal product	1.18.2. Alternative (Attached Document) Identifier	XEVMPD
1. Medicinal product	1.18.2.1 Identifier value;	XEVMPD
1. Medicinal product	1.18.2.2. Identifier system	XEVMPD
1. Medicinal product	1.18.3. (Attached Document) Type	Ø
1. Medicinal product	1.18.4. (Attached Document) Effective Date	XEVMPD
1. Medicinal product	1.18.5. (Attached Document) Language	XEVMPD
1. Medicinal product	1.18.6. URL value (New)	Ø
1. Medicinal product	1.18.7. (Attached document) Status (New)	Ø
1. Medicinal product	**1.19. Product cross-reference**	**NA**
1. Medicinal product	1.19.1. Product cross-reference type	Ø

EU IG Section	PMS EU IG Data element	Migration rules applied to PMS
1. Medicinal product	1.19.2. Product Cross-Reference resource identifier	Ø
1. Medicinal product	1.20. Manufacturer	SIAMED II
Manufacturing Business Operation		
2. Manufacturing Business Operation	2.1. Manufacturer (Manufacturing Business Operation)	SIAMED II
2. Manufacturing Business Operation	2.2. Operation type	SIAMED II
2. Manufacturing Business Operation	2.3. Manufacturing operation Start date	SIAMED II
2. Manufacturing Business Operation	2.4. Manufacturing Operation End date	SIAMED II
2. Manufacturing Business Operation	2.5. Confidentiality indicator	Default – YES
2. Manufacturing Business Operation	2.6. Manufacturing Authorisation Reference Number	Ø
2. Manufacturing Business Operation	2.7. Effective date	Ø
2. Manufacturing Business Operation	2.8. (Manufacturing Business Operation) Medicines Regulatory Agency Organisation	Ø
Marketing authorisation information		
3. Marketing authorisation information	3.1. Regulatory Authorisation Type	XEVMPD
3. Marketing authorisation information	3.2. Marketing Authorisation Number	XEVMPD

EU IG Section	PMS EU IG Data element	Migration rules applied to PMS
3. Marketing authorisation information	3.3. Country	XEVMPD
3. Marketing authorisation information	3.4. Authorisation status	XEVMPD
3. Marketing authorisation information	3.5. Authorisation status date	XEVMPD
3. Marketing authorisation information	3.6. Date of first authorisation	SIAMED II
3. Marketing authorisation information	3.7. International birth date	SIAMED II
3. Marketing authorisation information	3.8. Marketing authorisation holder (organisation)	XEVMPD
3. Marketing authorisation information	3.9. (Marketing Authorisation) Regulator	Default – Mapping with the Country of Authorisation
3. Marketing authorisation information	**3.10. Marketing authorisation procedure**	**NA**
4. Marketing authorisation information	3.10.1. Procedure Identifier (Marketing authorisation procedure)	XEVMPD
4. Marketing authorisation information	3.10.2. Procedure Type – Medicines approval system	XEVMPD
2. Marketing authorisation information	23.10.3. Procedure Submission Start date	SIAMED II
2. Marketing authorisation information	2.10.4 Procedure end date	SIAMED II
3. Marketing authorisation information	**3.10.5. Regulatory application**	**NA**

EU IG Section	PMS EU IG Data element	Migration rules applied to PMS
2. Marketing authorisation information	3.10.5.1. Regulatory application Identifier/Number	Ø
2. Marketing authorisation information	3.10.5.2. Regulatory application type	Ø
2. Marketing authorisation information	3.10.5.3. Regulatory application end date	Ø
Therapeutic (product) indication		
4. Therapeutic (product) Indication	4.1. Indication as "Disease/Symptom/Procedure"	XEVMPD
4. Therapeutic (product) Indication	4.2. Co-morbidity	Ø
4. Therapeutic (product) Indication	4.3. Intended effect	Ø
Packaged medicinal product		
5. Packaged medicinal product	5.1. Packaged Medicinal Product Identifier (PCID)	Ø
5. Packaged medicinal product	5.2. Package description	SIAMED for CAPs and XEVMPD for non-CAPs
5. Packaged medicinal product	5.2.1. Language	Default – mapping with country of authorisation
5. Packaged medicinal product	5.3. Manufacturer	SIAMED II
5. Packaged medicinal product	5.4. Pack size	SIAMED II

EU IG Section	PMS EU IG Data element	Migration rules applied to PMS
5. Packaged medicinal product	5.4.1. Quantity operator	Ø
5. Packaged medicinal product	5.5. Legal status of supply	SIAMED II
5. Packaged medicinal product	**5.6. Marketing Status**	**NA**
5. Packaged medicinal product	5.6.1. Country	Ø
5. Packaged medicinal product	5.6.2. Marketing Status	Ø
5. Packaged medicinal product	5.6.3. (Marketing Status) Start date	Ø
5. Packaged medicinal product	5.6.4. (Marketing Status) End date	Ø
5. Packaged medicinal product	5.6.5. Risk of supply shortage	Ø
5. Packaged medicinal product	5.6.6. Risk of supply shortage comment	Ø
5. Packaged medicinal product	5.6.7. Status reasons	Ø
5. Packaged medicinal product	5.6.7.1. Reason	Ø
5. Packaged medicinal product	5.6.7.2. Restore date	Ø
5. Packaged medicinal product	**5.7. Marketing Authorisation (Pack level)**	**NA**

EU IG Section	PMS EU IG Data element	Migration rules applied to PMS
5. Packaged medicinal product	5.7.1. Regulatory Authorisation Type (Marketing Authorisation (Package level))	XEVMPD
5. Packaged medicinal product	5.7.2. Marketing Authorisation Number (Package Level)	XEVMPD
. Packaged medicinal product	5.7.3. Country	XEVMPD
5. Packaged medicinal product	5.7.4. Authorisation status	XEVMPD
5. Packaged medicinal product	5.7.5. Authorisation status date (Package Medicinal Product)	XEVMPD
5. Packaged medicinal product	**5.8. Package item (container)**	**NA**
5. Packaged medicinal product	5.8.1. Package item (container) type	SIAMED II
5. Packaged medicinal product	5.8.2. Package item reference(s)	Ø
5. Packaged medicinal product	5.8.3. Manufactured item reference(s)	Ø
5. Packaged medicinal product	5.8.4. Device reference(s)	Ø
5. Packaged medicinal product	5.8.5. Package item (container) quantity	SIAMED II
5. Packaged medicinal product	5.8.5.1 Quantity Operator	Ø
5. Packaged medicinal product	5.8.6. Data carrier identifier	Ø

EU IG Section	PMS EU IG Data element	Migration rules applied to PMS
5. Packaged medicinal product	5.8.6.1. Identifier value	Ø
5. Packaged medicinal product	5.8.6.2. Identifier system	Ø
5. Packaged medicinal product	5.8.7. Material	SIAMED II
5. Packaged medicinal product	5.8.8. Manufacturer	Ø
5. Packaged medicinal product	**5.9. Package Component**	**NA**
5. Packaged medicinal product	5.9.1. Component type	SIAMED II
5. Packaged medicinal product	5.9.2. Component material	SIAMED II
5. Packaged medicinal product	5.9.3. Manufacturer	
5. Packaged medicinal product	**5.10. Medical Device**	**NA**
5. Packaged medicinal product	5.10.1. Type of medical device used in combination with medicinal product	Ø
5. Packaged medicinal product	5.10.2. Medical device type	Ø
5. Packaged medicinal product	5.10.3. Medical device identification	Ø
5. Packaged medicinal product	5.10.4. Medical device trade name	Ø

EU IG Section	PMS EU IG Data element	Migration rules applied to PMS
5. Packaged medicinal product	5.10.5. Medical device quantity	Ø
5. Packaged medicinal product	5.10.5.1. Quantity operator	Ø
5. Packaged medicinal product	5.10.6. Medical device description	Ø
5. Packaged medicinal product	5.10.6.1 Language	Ø
5. Packaged medicinal product	5.10.7. Medical device description of intended purpose	Ø
5. Packaged medicinal product	5.10.7.1 Language	Ø
5. Packaged medicinal product	5.10.8. Medical device classification	Ø
5. Packaged medicinal product	5.10.9. Medical device manufacturer	Ø
5. Packaged medicinal product	**5.11. Manufactured item**	**NA**
5. Packaged medicinal product	5.11.1. Unit of presentation	SIAMED II
5. Packaged medicinal product	5.11.2. Manufactured item quantity	SIAMED II
5. Packaged medicinal product	5.11.2.1. Quantity operator	Ø
5. Packaged medicinal product	5.11.3. Manufactured dose form	SIAMED II

EU IG Section	PMS EU IG Data element	Migration rules applied to PMS
5. Packaged medicinal product	5.11.4. Ingredient	SIAMED II
5. Packaged medicinal product	5.11.5. Manufactured item description	Ø
5. Packaged medicinal product	5.11.5.1. Language	Ø
5. Packaged medicinal product	**5.12. Shelf life / Storage**	**NA**
5. Packaged medicinal product	5.12.1. Shelf Life Type	Ø
5. Packaged medicinal product	5.12.2. Shelf Life Time Period and Units	Ø
5. Packaged medicinal product	5.12.3. Special Precautions for Storage	Ø
Ingredient		
6. Ingredient	6.1. Ingredient role	SIAMED II for Manufactured Item Ingredients. Art 57 for Pharmaceutic Product Ingredients.
6. Ingredient	6.2. Origin of the substance	Ø
6. Ingredient	6.3. Composition grouping description	Ø
6. Ingredient	6.4. Manufacturer	SIAMED II
6. Ingredient	**6.5. Substance**	**NA**
6. Ingredient	5.5.1. Substance	SIAMED II for Manufactured Item Ingredients. XEVMPD for Pharmaceutic Product Ingredients.
6. Ingredient	6.5.2. Substance Strength (quantitative composition)	SIAMED II for Manufactured Item Ingredients. XEVMPD for Pharmaceutic Product Ingredients.

EU IG Section	PMS EU IG Data element	Migration rules applied to PMS
6. Ingredient	6.5.2.1. Quantity operator	SIAMED II for Manufactured Item Ingredients. XEVMPD for Pharmaceutic Product Ingredients.
6. Ingredient	6.5.2.2. Strength (Presentation)	SIAMED II for Manufactured Item Ingredients. XEVMPD for Pharmaceutic Product Ingredients.
6. Ingredient	6.5.2.2.1. Quantity operator	SIAMED II for Manufactured Item Ingredients. XEVMPD for Pharmaceutic Product Ingredients.
6. Ingredient	6.5.2.2.2. Strength (presentation single value or low limit)	SIAMED II for Manufactured Item Ingredients. XEVMPD for Pharmaceutic Product Ingredients.
6. Ingredient	6.5.2.2.3. Strength (presentation high limit)	SIAMED II for Manufactured Item Ingredients. XEVMPD for Pharmaceutic Product Ingredients.
6. Ingredient	6.5.2.3. Strength (Concentration)	SIAMED II for Manufactured Item Ingredients. XEVMPD for Pharmaceutic Product Ingredients.
6. Ingredient	6.5.2.3.1. Quantity operator	SIAMED II for Manufactured Item Ingredients. XEVMPD for Pharmaceutic Product Ingredients.
6. Ingredient	6.5.2.3.2. Strength (concentration single value or low limit)	SIAMED II for Manufactured Item Ingredients. XEVMPD for Pharmaceutic Product Ingredients.
6. Ingredient	6.5.2.3.3. Strength (concentration high limit)	SIAMED II for Manufactured Item Ingredients. XEVMPD for Pharmaceutic Product Ingredients.
6. Ingredient	6.5.3. Substance Reference strength (quantitative composition)	SIAMED II for Manufactured Item Ingredients. XEVMPD for Pharmaceutic Product Ingredients.
6. Ingredient	6.5.3.1. Reference substance	SIAMED II for Manufactured Item Ingredients. XEVMPD for Pharmaceutic Product Ingredients.
6. Ingredient	6.5.3.2. Quantity operator	SIAMED II for Manufactured Item Ingredients. XEVMPD for Pharmaceutic Product Ingredients.
6. Ingredient	6.5.3.3. Reference strength (Presentation)	SIAMED II for Manufactured Item Ingredients. XEVMPD for Pharmaceutic Product Ingredients.

EU IG Section	PMS EU IG Data element	Migration rules applied to PMS
6. Ingredient	6.5.3.3.1. Quantity operator	SIAMED II for Manufactured Item Ingredients. XEVMPD for Pharmaceutic Product Ingredients.
6. Ingredient	6.5.3.3.2. Reference strength (Presentation single value or low limit)	SIAMED II for Manufactured Item Ingredients. XEVMPD for Pharmaceutic Product Ingredients.
6. Ingredient	6.5.3.3.3. Reference strength (Presentation high limit)	SIAMED II for Manufactured Item Ingredients. XEVMPD for Pharmaceutic Product Ingredients.
6. Ingredient	6.5.3.4. Reference strength (Concentration)	SIAMED II for Manufactured Item Ingredients. XEVMPD for Pharmaceutic Product Ingredients.
6. Ingredient	6.5.3.4.1. Quantity operator	SIAMED II for Manufactured Item Ingredients. XEVMPD for Pharmaceutic Product Ingredients.
6. Ingredient	6.5.3.4.2. Reference strength (Concentration single value or low limit)	SIAMED II for Manufactured Item Ingredients. XEVMPD for Pharmaceutic Product Ingredients.
6. Ingredient	6.5.3.4.3. Reference strength (Concentration high limit)	SIAMED II for Manufactured Item Ingredients. XEVMPD for Pharmaceutic Product Ingredients.
6. Ingredient	6.5.4. (Certificate) master file	Ø
6. Ingredient	6.5.4.1. File type	Ø
6. Ingredient	6.5.4.2. File code	Ø
6. Ingredient	6.5.4.2.1. File identifier type	Ø
6. Ingredient	6.5.4.2.2. File Identifier	Ø
6. Ingredient	6.5.4.3. Submission date	Ø
6. Ingredient	6.5.4.4. Date of last update	Ø
6. Ingredient	6.5.4. Manufacturer	SIAMED II
Pharmaceutical Product		
7. Pharmaceutical Product	7.1. Pharmaceutical Product Description	Ø
7. Pharmaceutical Product	7.1.1. Language	Ø

EU IG Section	PMS EU IG Data element	Migration rules applied to PMS
7. Pharmaceutical Product	7.2. Administrable Dose Form	XEVMPD
7. Pharmaceutical Product	7.3. Unit of Presentation	Ø
7. Pharmaceutical Product	7.4. Ingredient	XEVMPD
7. Pharmaceutical Product	7.5. Device	Ø
7. Pharmaceutical Product	7.6. Route of Administration	XEVMPD