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Information Management

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

Chapter 9: Process for submitting existing data on medicinal products authorised for human use – SIAMED II & XEVMPD to PMS deltas

Version 2

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Summary of changes.

Version 2 of this guidance provides an update on the deltas for products authorised in LU. On December 2024, the grouping criteria for the products authorised in Luxemburg changed to be the same as the products in Belgium and not as the products authorised in Finland.

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 to further complete the product dataset 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 compatible 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;
- facilitate transparency and comprehension of the data transformed into the new format by stakeholders and owner of the data.

Additional information on how this data is initially migrated can be found in Chapter 7 of the EU IG. Once this data is migrated to PMS, it has to be maintained. The scope of this guidance is to provide marketing authorisation holders with the necessary information on how to keep this data up to date.

EMA's vision in this respect is to allow the updating of data directly in PMS. Nevertheless, in order to achieve this goal, there are several enablers that shall be in place such as, among others, a Product User Interface and a direct connection to the PMS API.

Therefore, until all these enablers are delivered, PMS data base can only be updated using the sources of information that were used for the initial migration of data (i.e. SIAMED II and XEVMPD). This approach is a temporary solution until direct submissions to PMS are allowed taking also into account that SIAMED II and XEVMPD are still central systems for EMA internal processes.

The basic idea being explained in this chapter of the ISO IDMP EU IG is that any change performed to SIAMED II or XEVMPD is going to be propagated to PMS, keeping its IDMP compliance. This process to update PMS based on the changes performed in the other two databases is known as deltas.

2. SIAMED II to PMS Deltas

As explained in other chapters of this ISO IDMP EU IG, SIAMED II is an internal EMA database that contains centrally authorised products. More information on how this data was initially migrated to PMS can be found in Chapter 7 of the EU IG.

SIAMED II is maintained by EMA and once the regulatory procedures (variations, transfers of marketing authorisation holder, line extensions, etc) are approved, the relevant data is updated or included as new.

Any change performed to the product data is then propagated to the PMS taking into account the mapping rules described in section 7 Mapping and migration rules of Chapter 7.

A couple of examples of the changes that can happen in SIAMED II can be found hereafter.

- Addition of a new presentation to an existing medicinal product

  Once a new presentation is authorised, the relevant data is included in SIAMED II: authorisation number, pack size, etc. After this information is included, PMS receives this information and generates a new packaged medicinal product under the relevant medicinal product.

- Addition or removal of a manufacturer/manufacturer business operation

  SIAMED II contains the information on manufacturers and manufacturer business operations. Any change or insertion to these entities is performed in SIAMED II after the relevant variation has been approved. Once this information is included in the database, PMS is updated to reflect the same changes.

- Transfer of Marketing Authorisation Holder

  As soon as the transfer of MAH is authorised, the relevant medicinal product in SIAMED II is updated to reflect the new MAH. This change is therefore propagated to PMS, where the medicinal product is assigned to the new MAH.

Chapter 7 of the EU IG contains, at the end of the document, a table reflecting which data elements from PMS are migrated from SIAMED II. Once the full dataset from PMS is visible to the applicants (via a user interface or the PMS API), if any data element coming from SIAMED II is wrong, either from the initial migration or from any of the deltas, users will be able to request a correction (supported by the relevant information) via Service Now.

For example, once the PMS product data is visible, if an applicant, while reviewing their product data, realise that a manufacturer that was authorised is missing in PMS, can request the addition of this manufacturer providing the relevant documents such as the notification of approval of a specific variation. This way, data will be corrected in SIAMED II, and thanks to the SIAMED II deltas, the same information is reflected in PMS.

Nevertheless, not all the data in PMS is coming from SIAMED II. Next section describes the rules applying to the product data pushed to PMS during the product life cycle coming from the other source of information: XEVMPD.

3. XEVMPD to PMS Deltas

The eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) is a database designed to support the collection, reporting, coding and evaluation of medicinal product data in a standardised and structured way. This database is maintained by marketing authorisation holders following Chapter 3.II XEVPRM User Guidance.

Business rules describing the initial load of data in PMS from XEVMPD can be found in Chapter 7 of the EU IG. Nevertheless, in this section, the different business operations that can be performed in XEVMPD are described to explain which would be the input in PMS after the delta.

These operations can be used to keep the normal lifecycle of a medicinal product, and to follow Art. 57 legislation which states that marketing authorisation holders are responsible to keep the product data up to date. Moreover, deltas can also be used to correct discrepancies in PMS. Chapter 7 provides some examples of data quality issues that might lead to incorrect migration of data from XEVMPD. These deltas can be used to correct the data in one database (XEVMPD) and reflect the change in the other (PMS).

3.1. General principles of XEVMPD to PMS deltas

The set of rules driving the XEVMPD to PMS deltas are summarised below:

1) Only XEVPRMs with a positive 2nd acknowledgement are processed. Meaning that, if after submission of an XEVPRM to XEVMPD, the system provides a negative 2nd acknowledgement, this message is not be sent to PMS.

2) EMA data stewards oversee data validation in XEVMPD. They might perform changes to standardise the data. In these cases, a 3rd acknowledgement is generated and submitted to the applicant. Those changes performed by the EMA are also considered updates and therefore, submitted to PMS. Additional information on the AcKs from XEVMPD can be found in Chapter 5: eXtended EudraVigilance Product Report Acknowledgement Message.

3) EMA intends to process the deltas almost in real time. Nevertheless, as soon as the XEVMPD data is migrated and the deltas are captured by PMS, the performance might not be the desired one. The deltas are sent to a queue and are processed in that order. That means, that changes performed in XEVMPD might take some time to appear in PMS. Please, only if the changes take more than a day to arrive to PMS, raise a ticket in Service Now including as much information as possible (XEVPRM number, EV Codes impacted, etc) so we can track the issue. EMA is working to increase the performance of the deltas.

4) If a medicinal product in PMS is composed by several packaged medicinal products (and therefore EV codes from XEVMPD), product data is overwritten by every EV code. This behaviour is explained in the following sections.

5) If a term in XEVMPD is not mapped to a SPOR term, the value in PMS is then 0 until the mapping is created.

6) For the time being, the only way to update PMS data is through SIAMED and XEVMPD. EMA's goal is to decommission XEVMPD submissions, but in order to allow users to update their product data directly in PMS, several enablers such as the product UI and the edit functionality or the write API connection should be in place. Therefore, until those enablers are in place, applicants shall keep submitting new products and updates to XEVMPD. Deltas to PMS are in charge of keeping the system aligned with the data in SIAMED and PMS.

3.2. Nullifications

Chapter 3.II describes in section 2.4.7. that marketing authorisation holders should flag as "nullified" AMP entities created by mistake, e.g., duplicated entities (the same medicinal product information was submitted multiple times, multiple EV Codes were assigned) or entities provided erroneously (e.g., they were not supposed to be submitted).

Nullifications submitted to XEVMPD are also sent to PMS, but it is recommended to read Chapter 3.II before a nullification is submitted to understand the process.

3.2.1. Nullifying a presentation

A medicinal product in PMS can be composed by different packaged medicinal products. Each of those packages correspond to an EV code in XEVMPD. This can be the case of products authorised in e.g., Italy, where the marketing authorisation is provided at package level and therefore, XEVMPD contains one EV code per presentation.

Nullifying one of those EV codes will nullify the specific packaged medicinal product in PMS, but the medicinal product will still be Valid.

This nullification can be used for example, if there are duplicate packages created in PMS after the XEVMPD migration.

Table 1. nullification of one presentation in XEVMPD and the delta in PMS

EV code	Package description - Status	PMS ID - Status	Packaged Medicinal Product - Status
PRD123	20 tablets - Nullified	60000789 - Valid	Pack1 - Nullified
PRD456	40 tablets - Valid		Pack2 - Valid

3.2.2. Nullifying all presentations of a medicinal product

Following the example above, if all EV codes (i.e., presentations) related to a medicinal product in PMS are nullified in XEVMPD, not only the presentations are nullified in PMS but also the medicinal product.

Please, take into account that, after the initial migration, some medicinal products in PMS may contain only one packaged medicinal product for all the presentations. This can be the case of e.g., Spanish products as they receive the same MA number for all the presentations and therefore, in XEVMPD, only one record is submitted. In this case, the nullification of the relevant EV code would lead to the nullification of the medicinal product.

Table 2. nullification of all the presentations in XEVMPD and the delta in PMS

EV code	Package description - Status	PMS ID - Status	Packaged Medicinal Product - Status
PRD123	20, 40 and 60 tablets - Nullified	60000789 - Nullified	Pack1 - Nullified

3.2.3. Nullifying a multilingual medicinal product

In section 4 of Chapter 7 it is stated that medicinal products authorised in BE, LU and FI will have as many packages as languages have been submitted to XEVMPD.

In order to nullify this type of products, all the EV codes related to that medicinal product (i.e., all the records reflecting the names in approved languages) should be nullified. If only one record for one language is nullified in XEVMPD, then, only one package is nullified in PMS while the medicinal product will still be valid.

Table 3. nullification of a multilingual product in XEVMPD and the delta in PMS

EV code	Package description - Status	PMS ID - Status	Packaged Medicinal Product - Status
PRD123	Record with name in Finish - Nullified	60000789 - Nullified	Pack1 - Nullified
PRD456	Record with name in Swedish - Nullified		Pack2 - Nullified

3.3. Invalidations

Chapter 3.II states that invalidations allow the sender organisation to submit a notification about the withdrawal of an authorised medicinal product from the market in an XEVPRM. The 'Invalidate MA' operation type covers several scenarios including but not limited to the transfer of an authorised medicinal product to a third party or a renewal of the marketing authorisation (MA) by the marketing authorisation holder (MAH) if the marketing authorisation number changes.

An invalidation means that the authorisation status is changing from a valid value to a non-valid one. In this case, different invalidations can be submitted to different packages of the same medicinal product. As stated in Chapter 2 of the EU IG, PMS contains two authorisation status fields. One at medicinal product level and another one at package medicinal product level.

The authorisation status values submitted to XEVMPD are mapped with the RMS list Regulatory Entitlement Status (100000072049) and therefore, after the invalidation is submitted, PMS is also updated with the relevant information.

- Only if all package medicinal products (EV codes) of a medicinal product contain the same non-valid authorisation status, then, the same value is reflected at medicinal product level.

Table 4. same authorisation status in XEVMPD for all records lead to the same status in PMS

EV code	Authorisation Status	PMS ID – Auth. Status	Packaged Medicinal Product – Auth. Status
PRD123	Not valid - Revoked by Competent Authority	60000789 - Revoked	Pack1 - Revoked
PRD456	Not valid - Revoked by Competent Authority		Pack2 - Revoked

- If different authorisation statuses are referred in different packages, then, a logic has been implemented in PMS to reflect only one value at medicinal product level. Please, check section Authorisation status of Chapter 2 of the EU IG.

Table 5. the authorisation status in PMS depends on the authorisation status of the packs

EV code	Authorisation Status	PMS ID – Auth. Status	Packaged Medicinal Product – Auth. Status
PRD123	Not valid - Revoked by Competent Authority	60000789 - Expired due to Sunset Clause	Pack1 - Revoked
PRD456	Not valid - Expired due to Sunset Clause		Pack2 - Expired due to Sunset Clause

3.4. Transfers of MAH and renewals

Transfers of marketing authorisation holder and renewals are two specific use cases that should follow a defined process as described in Chapter 3.II. (sections 2.4.3 for transfers and 2.4.4 for renewals).

In Chapter 7 of the EU IG, it is stated that during the initial migration from XEVMPD, records with the authorisation status *Not Valid - Superseded by Marketing Authorisation Transfer* or *Not Valid - Superseded by Marketing Authorisation Renewal/Variation* are not migrated to PMS.

In the following sections, users can find the behaviour of PMS when the process to submit a renewal or a transfer is followed in XEVMPD.

3.4.1. Transfer of marketing authorisation holder

There are two steps to follow in XEVMPD to notify a transfer of MAH:

- The former MAH should invalidate the records in XEVMPD.
- The new MAH should insert a new record with the Authorisation Status Valid - Transferred Marketing Authorisation and the previous EV code in the relevant section of the XEVPRM.

There are some business rules that EMA has implemented in the deltas to make sure a correct transfer is performed in PMS.

1) There is no generation of a new medicinal product in PMS when the new MAH inserts the new records. From an IDMP perspective, the medicinal product is still the same, the only difference, is on the marketing authorisation holder and therefore, the PMS record with its PMS ID should remain the same.

2) If the invalidation of the medicinal product is received before the insert, the medicinal product is invalidated in PMS. Once the insert is received, the authorisation status changes to valid – transferred and the new MAH is referred.

3) If the insert is received before the invalidation, then, the authorisation status and the MAH are updated in PMS and the invalidation is not processed. This way, an invalidation is avoided after the transfer has been performed in the PMS record.

4) Any change included in the new XEVMPD record will be reflected in PMS. That means, that, the new QPPV, PSMFL, (and any other value, different from the former record) will be overwritten in PMS.

Either way, PMS is keeping the reference to both EV Codes: the invalidated and the inserted one.

IMPORTANT: whenever a medicinal product in PMS contains more than one packaged medicinal product, which means that is referring more than one EV code from XEVMPD, as soon as the transfer of MAH is submitted to XEVMPD for one EV code, the full medicinal product in PMS will reflect the new

MAH. Nevertheless, it is still mandatory for the applicant, to submit the transfer for all the EV codes impacted by the transfer.

Please, take also into account that not following the XEVMPD process for transfers of marketing authorisations (i.e., submitting a new record with authorisation status valid – transferred and making reference to the previous EV Code) will lead to the generation of a new PMS record with a different PMS ID where the lifecycle of the product is lost as well as the previous information captured in PMS.

3.4.1.1. Transfer of MAH for centrally authorised products

As explained before, SIAMED II is updated right after the regulatory procedure is approved. That also involves transfers of marketing authorisation holders.

That means that for centrally authorised products, as soon as the transfer is approved, SIAMED II is updated to reflect the new holder, and following the deltas to PMS, the record is updated accordingly.

The fact that PMS is updated as soon as SIAMED II records the change, does not mean that both the former and the new MAHs shall not follow the XEVMPD process.

The only difference in this case, is that the insert message from XEVMPD will only be processed if the MAH in the XEVPRM is the same as the MAH reflected in PMS after the update in SIAMED II.

Table 6. transfer of MAH in SIAMED leads to the change of MAH in PMS

SIAMED Status	MAH LOC ID in SIAMED	PMS ID - MAH
Before MA transfer	LOC-123456 (MAH 1)	60000789 – MAH 1
After MA transfer	LOC-567890 (MAH 2)	60000789 – MAH 2

Table 7. only if the MAH in XEVMPD and PMS are the same, the delta is processed

MAH in insert XEVPRM	Delta from XEVMPD
MAH 2 (mapped in OMS to LOC-567890)	Processed
MAH 3 (NOT mapped in OMS to LOC-567890)	Not processed

3.4.2. Renewal of marketing authorisation

Chapter 3.II. defines in section 2.4.4 the process after a renewal of a marketing authorisation has been granted.

If the marketing authorisation number changes after the renewal or after a variation, a similar process to the transfer of MAH should be followed. In this case, the two steps are:

- The MAH must retire the authorised medicinal product for which the marketing authorisation number is no longer valid by using the operation type 'Invalidate MA'.
- A new AMP entity must be submitted in the XEVMPD using the operation type 'Insert' where the value "Valid – Renewed/Varied Marketing Authorisation" must be specified in the data element "Authorisation status".

There are some business rules that EMA has implemented in the deltas to make sure a correct renewal is performed in PMS.

1) There is no generation of a new medicinal product in PMS when the MAH inserts the new records. From an IDMP perspective, the medicinal product is still the same, the only difference, is on the marketing authorisation number and therefore, the PMS record with its PMS ID should remain the same.

2) If the invalidation of the medicinal product is received before the inserts, the medicinal product is invalidated in PMS. Once the insert is received, the authorisation status changes to valid – renewed and the new MA number is referred.

3) If the insert is received before the invalidation, then, the authorisation status and the MA number are updated in PMS and the invalidation is not processed. This way, an invalidation is avoided after the renewal has been performed in the PMS record.

4) Any change included in the new XEVMPD record is then reflected in PMS. That means, that, the new MA number and authorisation /renewal date is overwritten in PMS.

Either way, PMS is keeping the reference to both EV Codes: the invalidated and the inserted one.

Inserts

After a marketing authorisation has been granted by a competent authority, marketing authorisation holders shall submit these new medicinal products in XEVMPD.

XEVMPD deltas are taking each new record and based on the defined business rules, a new medicinal product is created in PMS.

The business rules that have been defined are the ones used for the initial migration of data from XEVMPD to PMS and that are described in Chapter 7 of the EU IG. Those business rules are again explained in this chapter providing some examples.

3.4.3. Insert of non-CAP products in all countries except BE, LU and FI

In those cases, 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
- Strength of active substance
- Authorised pharmaceutical dose form
- Product full name

In this case, we can have one or more EV codes belonging to the same medicinal product. Some countries for example, assign a different MA number per presentation, which means that MAHs have to submit as many presentations as authorised to XEVMPD. Nevertheless, as all the previous fields are the same for all EV codes, all the presentations will be migrated as different packaged medicinal products of the same medicinal product.

Table 8. insert of a medicinal product with several presentations (EV codes)

EV code	Product full name	Authorisation Number	Package description	PMS ID	Packaged medicinal product ID
PRD123	Test 50 mg tablets	12.345	10 tablets	6000000123	ID111
PRD456	Test 50 mg tablets	67.890	20 tablets		ID222
PRD789	Test 50 mg tablets	98.765	30 tablets		ID333

Other countries assign only one MA number for all the presentations. In this case, MAHs can decide whether they submit one record for all presentations to XEVMPD or one record per presentation. In case they follow the first option, only one packaged medicinal product is created in PMS. Enrichment of data in PMS will be enabled in the future and applicants will be able to provide information of all the presentations.

Table 9. insert of a medicinal product with only one EV code

EV code	Product full name	Authorisation Number	Package description	PMS ID	Packaged medicinal product ID
PRD123	Test 50 mg tablets	12.345	10,20 and 30 tablets	6000000123	ID111

Insert of non-CAP products in FI

Finland has two 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.

Therefore, EV codes with the same product data in the following XEVMPD fields will be grouped under the same PMS Medicinal Product:

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

Finland assign the same marketing authorisation number to all the presentations and therefore, this is the value PMS will use to merge records belonging to the same medicinal product.

Please, take into account that each EV code is reflected in PMS as a separate packaged medicinal product. This duplication of packages will have to be corrected by the applicant as soon as the enrichment capability is made available in PMS.

Table 10. insert of a multilingual medicinal product

EV code	Product full name	Authorisation Number	Package description	PMS ID	Packaged Medicinal Product
PRD123	Testi 50 mg tabletit Finnish	12.345	10 tabletit	60000789	ID111
PRD456	Test 50 mg tabletter Swedish	12.345	10 tabletter		ID222

In case the applicant is submitting all the presentations to XEVMPD, then the insert in PMS will be reflected as follows:

Table 11. insert of a multilingual medicinal product

EV code	Product full name	Authorisation Number	Package description	PMS ID	Packaged Medicinal Product
PRD123	Testi 50 mg tabletit Finnish	12.345	10 tabletit	60000789	ID111
PRD456	Testi 50 mg tabletit Finnish	12.345	30 tabletit		ID222
PRD789	Test 50 mg tabletter Swedish	12.345	10 tabletter		ID333
PRD001	Test 50 mg tabletter Swedish	12.345	30 tabletter		ID444

Insert of non-CAP products in BE and LU

Belgium has three official languages and Luxemburg has two. 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 and Luxemburg and Finland is that the competent authorities from Belgium and Luxemburg 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 specific 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. In the example below, 6 records submitted to XEVMPD for two different presentations (10 tablets in Alu/Alu and 10 tablets in Alu/PVC) would generate only one medicinal product. In this case, as well as in the case for LU and FI, each EV code from XEVMPD would generate a different packaged medicinal product in PMS.

This duplication of packages will have to be corrected by the applicant as soon as the enrichment capability is made available in PMS.

Table 12. insert of a multilingual medicinal product

EV code	Auth procedure and number	Product full name	Authorisation Number	Package description	PMS ID	Packaged Medicinal Product
PRD123	DCP – ES/H/1111/222	Test 50 mg tablette French	12.345	10 tablets – Alu/Alu	60000789	ID111
PRD456	DCP – ES/H/1111/222	Testi 50 mg tabletten Dutch	12.345	10 tabletten – Alu/Alu		ID222
PRD789	DCP – ES/H/1111/222	Test 50 mg tabletten German	12.345	10 tabletten – Alu/Alu		ID333
PRD987	DCP – ES/H/1111/222	Test 50 mg tablette French	67.890	10 tablets – Alu/PVC		ID444
PRD654	DCP – ES/H/1111/222	Testi 50 mg tabletten Dutch	67.890	10 tabletten – Alu/PVC		ID555
PRD321	DCP – ES/H/1111/222	Test 50 mg tabletten German	67.890	10 tabletten – Alu/PVC		ID666

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, as soon as the records are created in XEVMPD and pushed to PMS, only one medicinal product will be created as there is no way to differentiate both products. As explained in the PMS Q&A document, updates to any of the grouping elements can be submitted to XEVMPD to make the system aware that there are differences on the grouping elements and therefore, different medicinal products should be created.

3.4.4. Insert of CAP products

As explained in Section 2 of this chapter, SIAMED II is the EMA's database for Centrally Authorised Products which is updated after a regulatory procedure is approved.

Therefore, once the initial marketing authorisation application is approved, the product is included in SIAMED II with the status authorised. Once the product is created in SIAMED II, the deltas to PMS will generate the medicinal product with the respective packaged medicinal products.

Once the approval of this marketing authorisation has been received by the applicant, they shall submit the relevant information to XEVMPD. This means, that the medicinal product will be always created first in SIAMED and therefore in PMS before any information arrives from XEVMPD.

As stated in Chapter 3.II, for Centrally Authorised Products, the MAH shall submit four records per presentation (one with authorisation country EU and other three for NO, IS and LI). Only the records where the authorisation country is EU are matched with the already existing ones in PMS (created from the SIAMED deltas). The other records for the EEA countries are following the same business rules as described in section 3.5.1.

In order for the match and merge of records coming from XEVMPD and records existing in PMS (coming from SIAMED II) to happen, there are two necessary conditions.

- LOC ID of the MAH in the PMS record and the XEVMPD record should be the same
- Authorisation number in PMS and XEVMPD should be the same

Taking into account these two conditions, we can grant that the correct record (presentation) from the correct MAH (LOC ID) is linked to the relevant information in PMS.

If any of those conditions are not met, then, a new medicinal product is created in PMS. It is therefore important to make sure that the MAH is correctly included and that there are no mistakes in the authorisation number.

A representation of these two business cases can be found in the following table.

Table 13. different scenarios for match and merge between SIAMED and XEVMPD

SIAMED II TO PMS				XEVMPD TO PMS		Outcome
PMS ID	**Name & MAH**	**MA number in PMS**	**EV Code**	**MAH**	**MA number in XEVMPD**	**Outcome of the match & merge**
6000000123	Test 50 mg tablets & LOC1000123	EMEA/1/22/001	PRD123	LOC1000123	EMEA/1/22/001	Match & merge with 6000000123
		EMEA/1/22/002	PRD456		EMEA/1/22/002	Match & merge with 6000000123
		EMEA/1/22/003	PRD789		EMEA/1/22/**03**	New product created as MA number cannot be

SIAMED II TO PMS			XEVMPD TO PMS			Outcome
						matched 6000000456

3.4.5. Data quality issues when inserting records in XEVMPD

Please, take into account that any difference in any of the values used to group EV codes under the same medicinal product, will trigger the generation of different records in PMS.

In the example below you can see that three different names for different presentations of the same medicinal product would generate three different medicinal products in PMS.

Table 14. different scenarios for match and merge between SIAMED and XEVMPD

EV code	Product full name – Authorisation country	Authorisation Number	Package description	PMS ID	Packaged medicinal product ID
PRD123	Test 50 mg tablet - IT	12.345	10 tablets	6000000123	ID111
PRD456	Test 50 mg tablet**s** - IT	67.890	20 tablets	6000000456	ID222
PRD789	Test 50 mg tablets**.** **-** IT	98.765	30 tablets	6000000789	ID333

The discrepancy can also be found in the ingredients or the strength of the active substance as represented in the table below. In this case, as the substance(s) and strength(s) are grouping elements, this discrepancy would lead to the generation of three different medicinal products in PMS.

Table 15. differences in the active substance(s) or strength would lead to different PMS IDs

EV code	Product full name – Authorisation country	Active substance - strength	Package description	PMS ID	Packaged medicinal product ID
PRD123	Test 50 mg tablet - IT	Ibuprofen – 50 mg / tablet	10 tablets	6000000123	ID111
PRD456	Test 50 mg tablet - IT	Ibuprofen **sodium – 62 mg** / tablet	20 tablets	6000000456	ID222
PRD789	Test 50 mg tablet **-** IT	Ibuprofen – 50 mg / **capsule**	30 tablets	6000000789	ID333

As explained in the previous section, wrong authorisation numbers in XEVMPD might also lead to the generation of wrong CAP medicinal products in PMS.

In case these data quality issues are submitted to XEVMPD and therefore, medicinal products or packaged medicinal products that should not exist in PMS are created, the XEVMPD data should be

amended to support the correct generation of products in PMS. These amendments should be submitted as updates to XEVMPD and these submission types are explained in section 3.6 of this guidance.

3.4.6. Insert of medicinal products where the national phase is still pending

MRPs and DCPs are procedures where a medicinal product is first authorised by a reference member state and afterwards by the concerned member state(s).

While the national phases are taking place, MAHs might need to submit a variation for the medicinal product which also impacts the medicinal products to be authorised in the concerned member states. Being that a requirement from the web-based eAF, PMS shall allow the creation of pending medicinal products. The only way to submit nationally-authorised data to PMS is through the deltas from XEVMPD to PMS, and therefore, XEVMPD shall allow the submission of pending medicinal products so they will appear in PMS and therefore can be used in the eAF.

Please, take into account that pending medicinal products can only be sent for MRP and DCP procedures. Pure national medicinal products shall be submitted to XEVMPD only when the marketing authorisation is approved.

Based on the most recent timelines delivered by the eAF team, NAPs will not be available in the PLM portal before Q4 2024, therefore, there is no need to submit this type of products at the moment. Chapter 3.II of XEVMPD and this guidance will be updated as soon as these submissions are required.

3.5. Updates

Marketing authorisation holders are required to amend the authorised medicinal product entities submitted in the XEVPRM format in compliance with the requirements of Article 57(2) of Regulation (EC) 726/2004 to reflect any changes to the terms of the marketing authorisations.

Updates to a specific EV code can also be submitted in order to amend data quality issues as the ones described in section 3.5.5 of this document.

EMA data stewards can also update XEVMPD records as part of the data validation and standardisation. EMA encourage MAHs to review the 3rd AcK but more important if the MAH is a gateway submitter as any change performed by EMA will be overwritten with the next submission if the change is not performed in the MAHs system. In case of discrepancies with the changes performed by EMA, a ticket can be opened via the Service Desk.

These changes to the product data submitted to XEVMPD can impact data elements used by the grouping business rules in the inserts (see section 3.5) or to other data elements. Whether the field that is changing is used or not by the grouping rules, the outcome of the deltas might be different.

3.5.1. Updates on data elements not used for grouping

Example of these data elements are for example MedDRA codes, ATC codes or QPPV among others.

Any change performed to these fields will be reflected in PMS. In section 7 of Chapter 7, the mapping rules are explained. Therefore, PMS will reflect the new RMS, OMS or SMS ID after the update has

been submitted to XEVMPD. In the case, the mapping does not exist, PMS is not going to reflect anything in that specific field and as soon as the mapping is created, PMS will be updated.

It is important to understand that PMS overwrites its data after every update with the latest data received. For example, if a medicinal product in PMS is formed by several packaged medicinal products (several EV Codes from XEVMPD), the data at medicinal product level will be updated every time a pack (EV Code) is updated. Therefore, in case of discrepancies among EV codes, the data captured in the latest EV code received will be shown.

An example can be seen below.

Table 16. updates to data fields not used for grouping

EV code	Product full name – Authorisation country	Indications	Package description	PMS ID	Packaged medicinal product ID
PRD123	Test 50 mg tablet - IT	Pain Fever	10 tablets	6000000123	ID111
PRD456	Test 50 mg tablet - IT	Pain	20 tablets		ID222
PRD789	Test 50 mg tablets - IT	Fever	30 tablets		ID333

In this example, each package contains different information on the indications section in XEVMPD. The last updated EV code received in PMS will overwrite the data from the other updates. That is the reason why users shall make sure that the data is consistent among all the records belonging to the same medicinal product.

3.5.2. Updates on data elements used for grouping

Example of these data elements are for example full product name, marketing authorisation number, ingredients, etc.

Changes performed in these data elements could result in the generation of a new medicinal product in PMS or in movement to an already existing product. After the initial load from XEVMPD to PMS, if data quality issues are present in XEVMPD, wrong products are created in PMS. If these issues are related to discrepancies in the data elements used for groupings, then, by updating the relevant EV codes in XEVMPD, these issues will be solved.

An example can be found below:

Table 17. wrong generation of a medicinal product due to data quality issues in XEVMPD

EV code	Product full name – Authorisation country	Ingredients	Package description	PMS ID	Packaged medicinal product ID	Status
PRD123	Test 50 mg tablet - IT	Ibuprofen – 50 mg / tablet Excipient 1 Excipient 2	10 tablets	6000000123	ID111	Valid
PRD456	Test 50 mg tablet - IT	Ibuprofen – 50 mg / tablet Excipient 1	20 tablets		ID222	

EV code	Product full name – Authorisation country	Ingredients	Package description	PMS ID	Packaged medicinal product ID	Status
		Excipient 2				
PRD789	Test 50 mg tablets - IT	Ibuprofen **sodium** – 50 mg / tablet Excipient 1 Excipient 2	30 tablets	6000000456	ID111	Valid

In this case, there is a discrepancy in one of the EV codes because the active substance used in PRD789 is different from the other two EV codes, which means that a new medicinal product is created.

Once the active substance is amended, PRD789 will be merged with the already existing medicinal product 6000000123 as the grouping fields will match and the medicinal product 6000000456 will be nullified in PMS.

Table 18. scenario when data quality issue is corrected in XEVMPD

EV code	Product full name – Authorisation country	Ingredients	Package description	PMS ID	Packaged medicinal product ID	Status
PRD123	Test 50 mg tablet - IT	Ibuprofen – 50 mg / tablet Excipient 1 Excipient 2	10 tablets	6000000123	ID111	Valid
PRD456	Test 50 mg tablet - IT	Ibuprofen – 50 mg / tablet Excipient 1 Excipient 2	20 tablets		ID222	
PRD789	Test 50 mg tablets - IT	Ibuprofen – 50 mg / tablet Excipient 1 Excipient 2	30 tablets		ID333	
PRD789	Test 50 mg tablets - IT	Ibuprofen **sodium** – 50 mg / tablet Excipient 1 Excipient 2	30 tablets	6000000456	ID111	Nullified

For a CAP where one of the Authorisation numbers is not correct and therefore cannot be matched with an existing record in PMS, a new medicinal product is created with the information on that presentation.

Table 19. wrong generation of a medicinal product due to data quality issues in XEVMPD

SIAMED II TO PMS		XEVMPD TO PMS				
PMS ID	**Name & MAH**	**MA number in PMS**	**EV Code**	**MAH**	**MA number in XEVMPD**	**Outcome of the match & merge**
6000000123		EMEA/1/22/001	PRD123	LOC1000123	EMEA/1/22/001	Match & merge with 6000000123
	Test 50 mg tablets & LOC1000123	EMEA/1/22/002	PRD456		EMEA/1/22/002	
		EMEA/1/22/003	PRD789		EMEA/1/22/**03**	New product created as MA number cannot be matched 6000000456

As soon as the authorisation number is amended, the medicinal product created in PMS with the incorrect information (i.e. 6000000456) will be nullified and the correct packaged medicinal product will be created under the already existing and correct medicinal product in PMS (i.e. 6000000123) .

Table 20. scenario when data quality issue is corrected in XEVMPD

SIAMED II TO PMS		XEVMPD TO PMS				
PMS ID	**Name & MAH**	**MA number in PMS**	**EV Code**	**MAH**	**MA number in XEVMPD**	**Outcome of the match & merge**
6000000123		EMEA/1/22/001	PRD123	LOC1000123	EMEA/1/22/001	Match & merge with 6000000123
	Test 50 mg tablets & LOC1000123	EMEA/1/22/002	PRD456		EMEA/1/22/002	
		EMEA/1/22/003	PRD789		EMEA/1/22/**003**	