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Information Management

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

Chapter 3: Process for the electronic submission of medicinal product information

Version 3.4

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Summary of changes

After the release of version 2 of this guideline, important discussions took place which led to significant changes in the information provided. As a result, version 3 of this document has been completely revised, and previous versions should no longer be taken into consideration. This update reflects changes that have been made based on feedback and new developments in the field, with the aim of providing the most up-to-date and accurate guidance possible.

It's important to note that this guideline will continue to be updated as necessary to reflect any changes to the processes described below. This ensures that the guidance remains current and relevant to industry and NCAs practices, and that users are always working with the latest information available.

Version 3.1 of this guidance provides the full list of MBOs to be submitted to PMS as part of the enrichment process.

Version 3.2 includes an additional MBO that was missing in the previous version. This MBO (Bioequivalence Contract Research Organisation (CRO)) is part of the eAF but will also be used to support the referrals process. Additionally, some notes were included on the manufacturers and Data Carrier ID sections to provide some useful information to MAHs.

Version 3.3 includes the change of the conformance of the Medicines Regulatory Agency Organisation. It changed from mandatory to conditional. It shall be provided when the Manufacturing Authorisation Reference number is provided, otherwise, it is optional. Additionally, some notes were included on the MBO start and end dates.

Furthermore, version 3.4 includes an improvemed MBOs section with additional information clarifying which business operations should be submitted by MAHs as part of the enrichment process.

1. Introduction

This chapter provides guidance on the process governing the electronic submission of human medicinal products in the European Economic Area (EEA), in accordance with ISO IDMP standards i.e. using the FHIR message containing PMS data.

This guidance covers the entire process from the initial submission of the marketing authorisation application to the maintenance activities (e.g. variations and renewals) performed during the lifecycle of the medicinal product. This guidance also covers the process to provide new data or to correct data of already authorised medicinal products.

ISO IDMP standards specify the use of standardised definitions and structures for the identification and description of medicinal products for human use. The use of ISO IDMP is required in accordance with Articles 25 and 26 of Commission Implementing Regulation (EU) No 520/2012. These provisions mandate Member States, marketing authorisation holders and the European Medicines Agency (EMA) to use ISO IDMP standards for the exchange and communication of information on medicinal product.

The Article 57(2) of Regulation (EC) No 726/2004, as amended by Regulation (EU) 1235/2010 and Regulation (EU) 1027/2012, requires:

- *the Agency to publish the format for the electronic submission of information on medicinal products for human use by 2 July 2011;*
- *marketing authorisation holders to submit information to the Agency electronically on all medicinal products for human use authorised in the European Union by 2 July 2012, using this format; marketing authorisation holders to inform the Agency of any new or varied marketing authorisations granted in the EU as of 2 July 2012, using this format.*

2. Target Operating Model (TOM)

The Target Operating Model is a business process model to ensure high data quality and consistency and to optimise the exchange of medicinal product data between regulators and applicants.

The overall goal of the EU TOM is to integrate the submission of medicinal product data as referred to in the Article 57(2) of Regulation (EC) No 726/2004 with the applicable regulatory activities (including the activities of validation, assessment and approvals).

The implementation of the TOM and the use of PMS is expected to benefit the following areas:

- enable the digital transformation of the EU Network regulatory activities reducing administrative burdens,
- harmonise data governance processes for management of medicines data and documents resulting in:
  - higher quality of data fulfilling different regulatory and non-regulatory needs,
  - enhancing data interoperability and data re-usability,
  - minimizing data maintenance costs.

The Target Operating Model (TOM) is currently under discussion. This discussion involves assessing the roles of various enablers (such as eAF, PMS or APIs) and stakeholders (such as EMA, NCAs, and Industry) and how they interact with each other.

These discussions not only include insert of new data and the same being re-used, which ties into improving data interoperability and re-usability as previously mentioned but also validation of legacy data.

3. Current Operating Model

This guideline outlines the current processes that Marketing Authorization Holders (MAHs) should follow to ensure that data for medicinal products remains up to date throughout its lifecycle.

If any changes are made to these processes, this guidance will be updated accordingly to reflect new procedures or systems to be used. The following processes have been identified during the lifecycle of a medicinal product:

- Initial submission of an authorised medicinal product
- Maintenance of medicinal product data
    - Variations
    - Renewals
    - Transfers of Marketing Authorisation
    - Invalidation of medicinal products
    - Notifications
    - Enrichment of PMS missing data
    - Correction of data migrated

The following image depicts the current operating model. This diagram illustrates the data flow and outlines the systems that are involved, as well as the processes that take place within each system/platform.

In the following sections, each process is described along with explanations of the corresponding systems or platforms to be utilized.

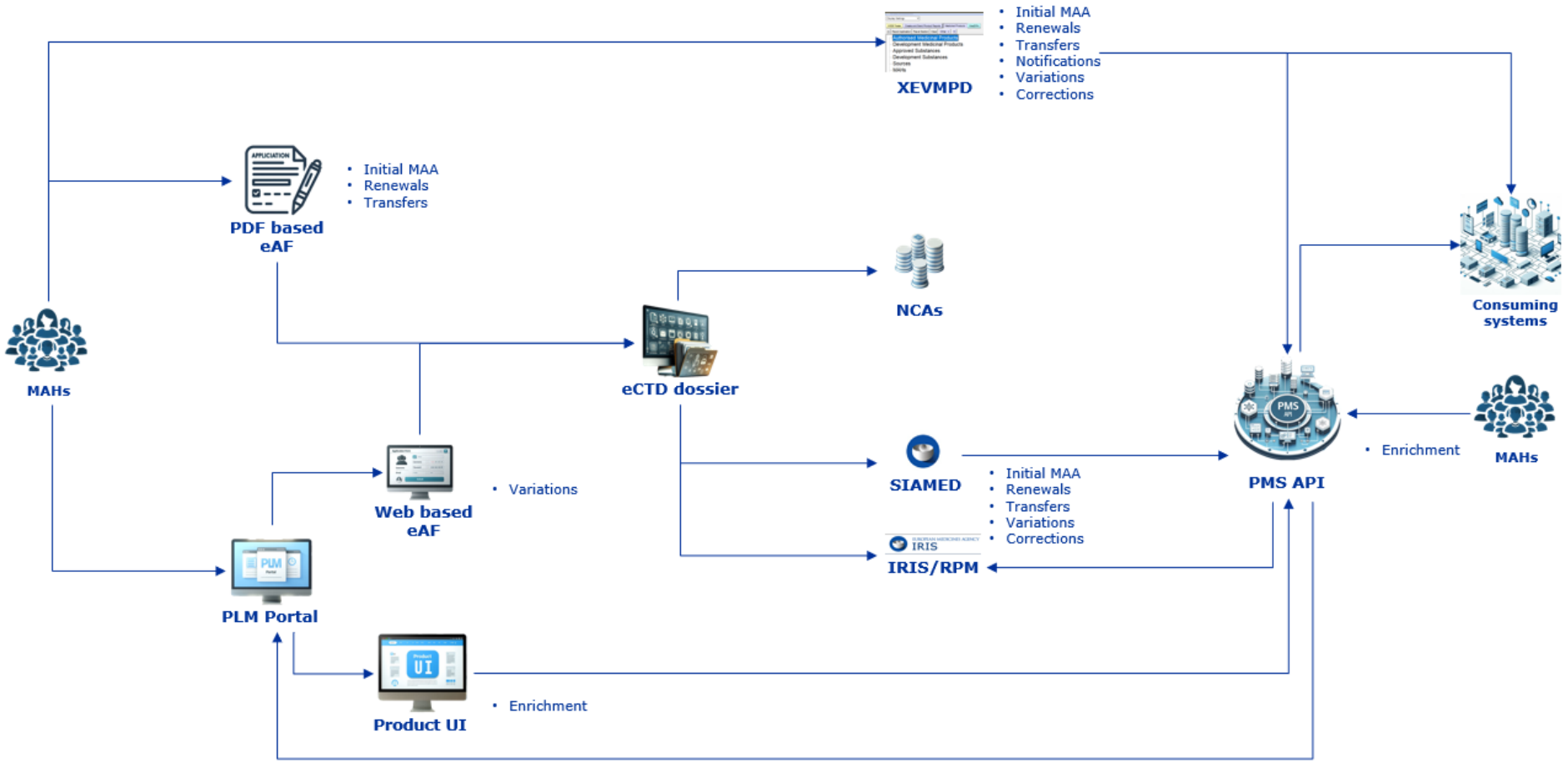

Diagram 1: Current Operating Model

4. Initial submission of an authorised medicinal product

This section covers the initial submission of marketing authorisation applications and line extensions. In essence, applications that will ultimately trigger the generation of new business IDs (i.e. PMS ID(s), MPID(s) and PCID(s)) based on the defining elements described in EU IG Chapter 2.

For both centrally authorized products (CAPs) and non-centrally authorized products (non-CAPs), a PDF eAF must be submitted to either EMA or the National Competent Authority (NCA) for assessment. However, there is a difference in the process for these two types of products following initial marketing authorization.

For centrally authorized products, once the marketing authorization has been granted, EMA enters the product data into their database (SIAMED). Once this information is stored in SIAMED, an integration routine sends the necessary data to the PMS API, as specified in EU IG Chapter 7 (for initial migration) and EU IG Chapter 9 (for new products).

MAHs must also submit information on newly authorized products to XEVMPD within 15 days of approval, as per point (b) of Article 57(2) of Regulation (EC) 726/2004. Once this information is submitted, the deltas from XEVMPD send the data to PMS, and the match and merge protocol links the product created in PMS with the SIAMED data and the data submitted in XEVMPD. Additional information on this protocol can be found in EU IG Chapter 7 (for initial migration) and EU IG Chapter 9 (for new products).

For non-centrally authorized products, only data submitted to XEVMPD by MAHs is sent to PMS. In this case, information from National Competent Authorities is not synchronized.

To guarantee that data submitted to XEVMPD for non-centrally authorized products contains accurate information, it is recommended to review EU IG Chapter 9. This will help to ensure that the EV codes related to the same medicinal product contain consistent data in the grouping elements, thereby facilitating their grouping under the same medicinal product.

5. Maintenance of medicinal product data

Marketing authorisation holders should notify the Agency about amendments to the terms of marketing authorisations which require a revision of the information on medicinal products as referred to in paragraph 3 and 4 of the Legal Notice on the Implementation of Article 57(2) of Regulation (EC) No. 726/2004.

This section outlines the post-authorization lifecycle of a medicinal product. After marketing authorization has been granted, various changes may occur to the product data, and depending on the type of update, different processes should be followed.

5.1. Variations

Whenever amendments are made to the terms of a marketing authorization, Marketing Authorization Holders (MAHs) must use the web-based eAF to submit these changes for assessment by EMA or NCAs. Additional information on how to utilize the web-based variation form can be found on the eSubmission webpage.

Following approval of the variation(s), changes to centrally authorized products (CAPs) are performed in SIAMED by EMA, which results in an update of PMS data.

For both CAPs and non-centrally authorized products, MAHs are responsible for updating XEVMPD. If any changes impact data elements captured in XEVMPD, MAHs are required to notify the Agency of subsequent changes to marketing authorization terms using the electronic XEVPRM format no later than 30 calendar days after authorization. Deltas from XEVMPD will subsequently update PMS as outlined in EU IG Chapter 9.

As illustrated in the diagram in section 3, after changes have been made in either SIAMED or XEVMPD, PMS will be updated. Once PMS is updated, the new data will be reflected in the PLM Portal and displayed in the Product UI, as well as in any new variation form created.

As explained in section 5.6 of this guidance, enrichment of specific data is required in PMS. After a variation affecting the enriched data has been approved, for CAP products, the data will be updated in SIAMED and therefore in PMS. For non-CAPs, the same enrichment process should be followed to update the relevant information.

5.2. Renewals

Renewals of marketing authorizations must be submitted using the PDF eAF. For CAPs, any required changes are entered in SIAMED, which subsequently updates PMS if necessary.

Similarly to variations, for CAPs and non-CAPs, updates should be submitted to the Art. 57 database by MAHs, as outlined in Chapter 3.II of XEVMPD, with changes reflected in PMS thereafter.

5.3. Transfers of Marketing Authorisations

Transfers of marketing authorizations shall be submitted following national requirements. Sometimes using the eAF but some NCAs might require some national procedures were an eAF is not needed.

For centrally authorized products (CAPs), after the transfer has been completed, the new MAH is referred in the medicinal product in SIAMED leading to an update in PMS. With this change, the former MAH will lose access to the medicinal product through both the PMS API and Product UI, while the new MAH will be able to view the product under their organization.

Regardless of the procedure type (CAP or non-CAP), both the former and new MAHs must follow the transfer process outlined in Chapter 3.II of XEVMPD.

For CAPs, new EV codes entered in XEVMPD will only be merged into the PMS product if the MAH in XEVMPD (ORG EV Code) and the new MAH in PMS (LOC ID) are mapped together in OMS.

For non-CAPs, it is the responsibility of the MAHs to follow the process as described in Chapter 3.II of XEVMPD to ensure a successful transfer of the product in PMS.

Failure to follow the process as described may result in the creation of new medicinal products, with the consequence of being unable to track the correct lifecycle of a medicinal product.

5.4. Invalidation of Marketing Authorisations

MAHs shall notify the revocation or withdrawal of a marketing authorization, either for the full medicinal product or for specific pack sizes to EMA or NCAs. Depending on the type of change, this could be considered as a variation, in which case the web-based eAF should be used, or a different communication should be submitted. Either way, the result will be a change in the authorization status of the medicinal product or a specific packaged medicinal product in PMS.

For CAPs, the change will come from SIAMED after EMA has updated it. MAHs should also submit the change in authorization status to XEVMPD to maintain accurate lifecycle records.

For non-CAPs, MAHs are responsible for updating XEVMPD with the relevant information, leading to an update of PMS data.

5.5. Notifications

Notifications refer to changes made to the medicinal product data that are not triggered by a regulatory procedure. Currently, notifications only apply to changes in

- the name and contact details of the qualified person responsible for pharmacovigilance (QPPV) in accordance with Article 4(4) of Commission Implementing Regulation (EU) No. 520/2012,
- the location of the Pharmacovigilance system master file (PSMF),
- the contact information for Pharmacovigilance enquiries.

As per Chapter 3.II of XEVMPD, as of February 1, 2016, MAH organizations no longer need to notify EMA or the national competent authorities of changes to QPPV, PSMFL, or Pharmacovigilance enquiry information, as the Article 57 database is considered functional for this purpose. Updates to this data should be submitted to XEVMPD and will be reflected in PMS thereafter.

In the future, as additional information is captured and managed in PMS, updates to other fields might be considered notifications. It's important to note that direct submissions of these updates to PMS are not yet allowed, as this data is still used in XEVMPD for pharmacovigilance purposes (QPPVs, PSMFLs, etc.). As represented in the diagram in section 3, updates made in XEVMPD are pushed to PMS, but not the other way around. Therefore, management of this data should remain, for now, in XEVMPD.

5.6. Enrichment of missing PMS data

According to EU IG Chapter 7, during the initial migration from SIAMED and XEVMPD to PMS, some fields will contain data, while others will have missing information as it was not captured in the source.

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

Enrichment refers to the submission of data that was missing from the initial load of data from SIAMED or XEVMPD to PMS, and currently, enrichment also refers to maintaining this missing data as part of the product lifecycle. It's important to note that fields to be enriched may differ between

CAPs and non-CAPs since data from SIAMED is migrated to PMS for CAPs, resulting in additional information for these products.

As shown in section 3 of this guidance, enrichments can be submitted through the Product UI or directly through the PMS API. The reason why this information can be submitted directly to PMS is because it is not present in the sources (either SIAMED or XEVMPD), so there is no need to sync the data from PMS back to SIAMED or XEVMPD.

For now, the enrichment process will only be opened for specific products and specific fields that are not captured in the source of data. From Q1 2025, the enrichment process was opened to support ESMP, covering manufacturers and manufacturing business operations, as well as structured data on pack sizes.

This data is already available in PMS for CAPs, so no enrichment of this data is required. On the other hand, XEVMPD does not hold this data, and therefore, it has to be enriched in PMS. This means that, for non-CAPs, information on these fields can be submitted either by using the Product UI or submitting the information directly through the PMS API. These fields should be maintained in PMS, meaning that, after a variation impacting manufacturers or manufacturing business operations has been approved for non-CAP products, MAHs should update this data in PMS.

One additional field that can be maintained through the enrichment process is the data carrier identifier. For non-CAPs, this data can be submitted directly to PMS through the PMS API or Product UI. For CAPs, for the time being, this information is not required. EMA will let users know once this data can be sent for CAPs.

All the information provided with the enrichment process should be submitted in line with guidance provided in EU IG Chapter 2. Additional information on how to use the Product UI for this purpose will be available in the PLM Portal, and further documentation will be released for the PMS API.

In the future, the Agency will open the enrichment capability to other fields based on priorities, giving MAHs enough time to gather and submit this information.

5.7. Corrections of migrated data

Corrections are meant to amend data that is already present in the source of information (either SIAMED or XEVMPD).

As MAHs don't have access to SIAMED, corrections of CAP product data from this database should be requested via Service Desk. Examples of corrections needed from SIAMED could include correcting missing manufacturers or incorrect manufacturing business operations for a specific medicinal product.

On the other hand, XEVMPD is accessible by MAHs, so they can directly submit corrections for data from this database. Please refer to section 3.5.5 of EU IG Chapter 9 to understand how data quality issues in XEVMPD can affect their products.

If the data is correct in the source (SIAMED and XEVMPD), but an incorrect term is shown in PMS, the issue might be with the mappings between the data in the source and S, O, and R. Please refer to section 7.2 of EU IG Chapter 7 to understand how these mappings are generated. Any corrections needed on these mappings should be raised via Service Now.

Additional information related to known issues can be found in the PMS Q&A document.

6. Annex I: Product Data Submission Paths

In the following table the different processes and which system should be used to keep the data in PMS up to date can be found.

Process	Procedure type	Submission path
Initial MAA	CAPs	SIAMED & XEVMPD
	Non-CAPs	XEVMPD
Variation	CAPs	XEVMPD data impacted: SIAMED & XEVMPD
		Enriched data impacted: SIAMED
	Non-CAPs	XEVMPD data impacted: XEVMPD
		Enriched data impacted: PMS
Transfer or Renewal	CAPs	SIAMED & XEVMPD
	Non-CAPs	XEVMPD
Notification	CAPs	XEVMPD
	Non-CAPs	XEVMPD
Enrichment	CAPs	NA
	Non-CAPs	PMS API and Product UI
Correction	CAPs	XEVMPD data impacted: XEVMPD
		SIAMED data impacted: Service Desk
	Non-CAPs	XEVMPD data impacted: XEVMPD
		Enriched data impacted: PMS

7. Annex II: Data elements subject to be enriched

Section 5.6 of the guidance specifies that only certain fields for specific products will be subject to data enrichment starting from Q1 2025. The details on which fields and data are supposed to be provided can be found in this Annex.

7.1. Structured data of pack sizes

For non-CAPs, the only information we have in relation to the pack size might be captured in the package description that comes from XEVMPD. Nevertheless, this field is submitted as a free text field and therefore this can't be used for analytical purposes. That is why, the structured data of the pack size is required. This data element is captured in EU IG Chapter 2 as Pack size (section 5.5).

For CAPs, this information is captured from SIAMED and here is no need to enrich this information on CAPs.

For each Packaged Medicinal Product, the pack size defined as the total number of units of the manufactured item or package item and represented per unit of presentation shall be provided. For the moment, the quantity operator is not required. These two fields (number of units and units of presentations) for each packaged medicinal product can be submitted directly to PMS either through the PMS API or through the Product UI.

This information must be submitted for all packaged medicinal products under the Union List of Critical Medicines (ULCM) and in case of an MSSG preparedness exercise before end of June 2026 (the previous deadline was December 2025 but it has been extended).

Please, take into account that, as described in Chapter 3.II of XEVMPD, for products under the ULCM, one EV code per pack size shall be submitted. Structured data on pack sizes cannot be enriched for packaged medicinal products referring to multiple pack sizes.

For products that are not under the ULCM, the enrichment of structured pack size data should be provided by the end of December 2027.

It is important to note that this data cannot be enriched for packaged medicinal products that refer to multiple pack sizes.

Therefore, before submitting this information through the PMS API or the Product UI, packages shall be splitted in XEVMPD. More information about this process can be found in Chapter 3.II of XEVMPD.

Tag	Description
Repeatable	Yes
Conformance	Mandatory
Data Type	Quantity
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/200000000014
Value(s)	Numeric value and unit. The units shall be specified as a Term ID listed in RMS Units of Presentation list as applicable
FHIR Element Name	containedItemQuantity
FHIR Path	PackagedProductDefinition.extension.containedItemQuantity Note: Please refer to Chapter VI – SPOR API Technical Specification for the details of the extension URL.

7.2. Manufacturers and Manufacturing Business Operations

The European Shortage Monitoring Platform (ESMP) requires information on manufacturers and manufacturing business operations so additional information such as production capacity can be provided in case of a crisis or a MSSG preparedness exercise to prevent, monitor and manage shortages.

For Centrally Authorised Products:

For CAPs, this data has already been migrated from SIAMED and it is maintained with the changes performed in SIAMED. Therefore, MAHs are just required to review the information stored in PMS and make sure it is kept up to date. In case a correction is needed, a Service Desk ticket should be raised providing as much information as possible so the data can be amended.

For Non-Centrally Authorised Products:

For non-CAPs, this information has to be provided either through the PMS API or the Product UI.

Manufacturers and MBOs shall be provided for products under the ULCM before the end of June 2026 (previous deadline was December 2025). This data, once submitted shall be kept up to date.

For non-CAPs, whenever the provided data has undergone any change, MAHs should update the information following the same enrichment process not later than 30 days after the approval of the change.

In order to support ESMP, but also, taking into account that in the near future, structured changes will be submitted through the web-based variation form, the same information as provided via eAF, should be provided to PMS. Additional manufacturers or MBOs reported in the dossier but not in the eAF are not required for the moment.

In the table below, the list of MBOs to be submitted to PMS as part of the enrichment can be found.

In version 3.2 of this guideline, the MBO for Bioequivalence Contract Research Organisation (CRO)' has been added to the table below. This MBO is part of the eAF and will be consumed by it when the structured changes are implemented but will also be used by the referrals team at EMA.

Capturing this information will ensure that MAHs are promptly identified and contacted at the beginning of any referral procedure that affects products for which studies have been performed at a specific site and so have the opportunity to exercise their right of defence during the procedure and submit relevant data in relation to their product for consideration by the CHMP. Submission of this MBO follows the same approach as the submission of the rest of manufacturers and MBOs for products under the ULCM.

In version 3.4 of this guideline, the list of MBOs to be submitted as part of the enrichment was improved. The RMS list for manufacturing activities is a hierarchical list and some terms are related to a high-level term.

For example, the term 'Quality control testing of medicinal product' is the high-level term for other terms such as 'Microbiological testing: sterility' or 'Chemical/Physical testing'.

Whenever possible, the lower term from the RMS list should be provided (i.e. Microbiological testing: sterility) to be aligned with the granularity submitted through the eAF.

Nevertheless, for legacy products (medicinal products that were authorized many years ago, often before current regulatory standards (like ISO IDMP) were established. They may lack structured or complete data but remain on the market so different approaches might apply in some processes),

the eAFs submitted for the authorisation had a different granularity than the information provided nowadays and only the high-level term can be provided. In those specific cases, the high-level terms from RMS are accepted. For the rest of the products, when the information has been provided in the most granular level, the lower-level terms should be provided.

Please, review EU IG Chapter 2 for additional information on the conformance or FHIR paths for all the terms related to the manufacturer and the MBOs.

The following table captures the information required to be submitted together with the MBOs.

Field	Description
Manufacturer's ORG details	The relevant LOC ID should be selected. If the organisation is not registered in OMS, it can be created following the OMS processes. All registered manufacturers should be submitted during the enrichment process. Manufacturers for which the MBOs have been deleted shall not be submitted during the initial enrichment.
Operation type	Coming from the RMS list 100000160406: manufacturing activity
MBO start date	For new products, accurate date shall be submitted. For legacy products, if the date is not known, same date as the initial marketing authorization date of the medicinal product can be included.
MBO end date	This date should be included only if the activity linked to the specific MBO is discontinued or deleted. Do not remove the MBO record itself; instead, update the End Date field to reflect the discontinuation of the activity.
Confidentiality	Indicate if the MBO is public or confidential. Batch releaser is public while the rest is confidential.
Manuf. Auth. Reference number	Conditional based on the information provided in EU IG Ch 2.
Effective date	Conditional based on the information provided in EU IG Ch 2.
Medicines Regulatory Agency Organisation	Conditional field. Only to be provided if the reference number is also submitted. Select the LOC ID of the NCA or agency who issued the authorisation.

Note: please, take into account that the granularity of the MBOs captured in SIAMED is not the same as the required for non-CAPs. The manufacturing business operations RMS list is hierarchical and SIAMED only captures the high-level terms from RMS. Therefore, please, do not request corrections in those cases, as this is the way SIAMED is capturing the data for CAPs. Internal discussions will take place at EMA on how this discrepancy will be solved.

As a summary for the table below:

High-level terms – should only be provided for legacy products or if the more granular data is not known.
Low-level terms – should be provided for all the products where the data has been submitted at this level.
Terms without hierarchy – should be provided for all medicinal products.

Manufacturing business operation	RMS short name	RMS ID
Authorised manufacturer responsible for batch release		
Manufacturer responsible for batch certification	Batch certification	100000160407
Manufacturer(s) of the medicinal product		
Manufacturing of solvent / diluent	Manufacturing of solvent/diluent	100000160415
Physical Importation	Physical Importation	100000160465
Primary packaging	Primary packaging	100000160463
Processing operations for the medicinal product	Processing operations for the medicinal product	100000160413
Processing of non-sterile medicinal product	Processing of non-sterile medicinal product	100000163618
Processing of sterile medicinal product - aseptically prepared	Processing of sterile medicinal product - aseptically prepared	100000163709
Processing of sterile medicinal product - terminally sterilised	Processing of sterile medicinal product - terminally sterilised	100000163737
Quality control testing of medicinal product	Quality control testing of medicinal product	100000160408
Microbiological testing: sterility	Quality Control Testing - Medicinal product - Microbiological - sterility	100000160409
Microbiological testing: non-sterility	Quality Control Testing - Medicinal product - Microbiological - non-sterility	100000160410
Chemical/Physical testing	Quality Control Testing - Medicinal product - Chemical/Physical	100000160411
Biological testing	Quality Control Testing - Medicinal product - Biological	100000160412
Secondary packaging	Secondary packaging	100000160464
Sterilisation	Sterilisation	100000160456
Filtration	Sterilisation - Filtration	100000160457
Dry heat	Sterilisation - Dry heat	100000160458
Moist heat	Sterilisation - Moist heat	100000160459
Chemical	Sterilisation - Chemical	100000160460
Gamma irradiation	Sterilisation - Gamma irradiation	100000160461
Electron beam	Sterilisation - Electron beam	100000160462
Storage and/or distribution of medicinal product	Storage and/or distribution of medicinal product	100000160466
Manufacturer(s) of the active substance(s)		

Manufacturing of active substance	Manufacturing of active substance	100000160467
Active substance physical processing	Active substance physical processing	100000163846
Extraction of active substance from natural sources	Extraction of active substance from natural sources	100000163844
Manufacturing of active substance by chemical synthesis	Manufacturing of active substance by chemical synthesis	100000163843
Manufacturing of active substance using biological processes	Manufacturing of active substance using biological processes	100000163845
Manufacturing of active substance intermediate	Manufacturing of active substance intermediate	100000160453
Active substance intermediate physical processing	Active substance intermediate physical processing	100000163715
Manufacturing of active substance intermediate by chemical synthesis	Manufacturing of active substance intermediate by chemical synthesis	100000163713
Manufacturing of active substance intermediate using biological processes	Manufacturing of active substance intermediate using biological processes	100000163714
Packaging of active substance	Packaging of active substance	100000160454
Primary Packaging of active substance	Primary Packaging of active substance	100000163716
Secondary Packaging of active substance	Secondary Packaging of active substance	100000163717
Preparation of Working Cell Bank	Preparation of Working Cell Bank	100000160476
Quality control testing of active substance	Quality control testing of active substance	100000160448
Microbiological testing: sterility	Quality Control Testing - Active substance - Microbiological - sterility	100000160449
Microbiological testing: non-sterility	Quality Control Testing - Active substance - Microbiological - non-sterility	100000160450
Chemical/Physical testing	Quality Control Testing - Active substance - Chemical/Physical	100000160451
Biological testing	Quality Control Testing - Active substance - Biological	100000160452
Storage and/or distribution of active substance	Storage and/or distribution of active substance	100000160455
Storage of Master Cell Bank and/or Working Cell Bank	Storage of Master Cell Bank and/or Working Cell Bank	100000160477
Contract companies used for all clinical trial(s)		
Bioequivalence Contract Research Organisation (CRO)	Bioequivalence Contract Research Organisation (CRO)	100000160478

Note: during the initial enrichment (when the product is enriched for the first time with the full list of manufacturers and MBOs), only authorised manufacturers and MBOs should be submitted. If a manufacturer or MBO was authorised during the lifecycle of the product but then it was discontinued or deleted, it should not be submitted to PMS during the initial migration. If, once submitted, the MBO is discontinued, then, the end date should be updated.

7.3. Data carrier ID

EMA has identified a use case that involves the link between ePI and PMS. The proposed approach is that ePI will reference the PMS ID of a medicinal product, while PMS will capture the Data Carrier ID for each packaged medicinal product. When all the relevant enablers are in place, scanning the data matrix on the outer package of a medicinal product can provide access to the electronic product information thanks to the connection between PMS and ePI.

The data carrier identification number of the outer-most packaging of the packaged medicinal product shall be specified using the Global Trade Item Number (GTIN) or National Trade Item Number (NTIN) identification system as recorded in the European Medicines Verification System (EMVS) or the Pharmacy Product Number (PPN).

For non-CAPs, MAHs can submit this information through the PMS API or the Product UI. For CAPs, this information is not required for the moment. As soon as this information is needed, EMA will let the users know.

It is important to note that data carrier IDs cannot be enriched for packaged medicinal products that refer to multiple pack sizes.

While submission of Data Carrier ID is currently optional, it is highly recommended for products that already have an ePI.

Tag	Description
Repeatable	Yes
Conformance	Conditional
Data Type	String and URI
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000000009
Value(s)	String and RMS term.
FHIR Element Name	Value and system
FHIR Path	PackagedProductDefinition.package.identifier.value PackagedProductDefinition.package.identifier.system

Please, refer to EU IG Chapter 2 and EU IG Chapter 8 for additional information and examples, and also the webinar Submission of Manufacturers, Manufacturing Business Operations (MBOs) and structured pack size data to Product Management Service (PMS) | European Medicines Agency (EMA) can be consulted for further information.