

## Product Master Data

### Introduction of additional mandatory fields

#### Questions & Answers (Q&A) – Version 3

<b>Document history:</b>	
Date of publication:	09/09/2024
Supersedes:	Version 2
Changes compared to superseded version:	New Q&As: 1.7; 2.1 Revised Q&As: 1.2; 2.2; 4.4

**Important disclaimer:** The answers may include recommendations or advice. You are solely and exclusively responsible for deciding any particular course of action or omission and for implementing any actions or taking any decision on this basis. EMVO disclaims all liability with regard to such actions or decisions and their consequences.

This document sets out the main questions regarding the introduction of new mandatory fields within the Product Master Data (PMD) and Product Pack Data (PPD) fields of the EU Hub. The document shall be updated in case further questions and/or information come to EMVO's attention.

Regularly consult EMVO's website and Knowledge Database ([here](#)) to follow up on the latest communication.

## Contents

1. General .....	2
2. Existing Product Master Data .....	5
3. New (or new versions of) Product Master Data (PMD) and Product Pack Data (PPD) .....	7
4. Helpful Scenarios as of EU Hub Release 1.16 .....	7

## 1. General

### 1.1 Why are some fields becoming mandatory, and what is the background behind their implementation?

**Answer:** The European Commission Delegated Regulation (EU) 2016/161 specifies in Article 33 section 2 the information that must be uploaded in the repositories system by the marketing authorization holder (MAH) or, in case of parallel imported or parallel distributed medicinal products bearing an equivalent unique identifier for the purposes of complying with Article 47a of Directive 2001/83/EC, the person responsible for placing those medicinal products on the market.

Following a Federal Agency for Medicines and Health Products (FAHMP) inspection of EMVO in the summer of 2023, it was spotted that required information (e.g. common name, address of the Marketing Authorisation Holder, etc.) is not always uploaded to the repositories system. EMVO was requested to enforce the upload of the missing information.

EMVO performed a thorough investigation and gap-analysis of the requirements, aiming to spot the irregularities in the data upload. Consequently, some existing fields shall additionally be made mandatory to further strengthen the EU Hub and ensure the consistency and completeness of the data uploaded.

### 1.2 When will the fields be made mandatory in the Product Master Data (PMD) and Product Pack Data (PPD)?

**Answer:** Additional existing fields will be made mandatory with the deployment of the EU Hub Release 1.16 in the Production Environment which is currently planned for 24<sup>th</sup> January, 2025 (*this date could change following the outcome of the Interoperability testing (IOT)*).

### 1.3 Are there any changes to the interface? If yes, what should I do and how will I be affected?

**Answer:** The deployment of the EU Hub Release 1.16, scheduled for 24<sup>th</sup> January 2025, will have no interface impact on the OBP side. Nevertheless, the EU Hub will still undergo modifications to ensure that, if OBPs upload PMD and PPD without filling in the specified fields, the transaction will be rejected with an A16 Data validation error. Further changes with an impact on the OBP interface will be communicated timely providing sufficient time to prepare.

In case you fail to fill in properly the indicated mandatory fields, you will be unable to upload the data to the EU Hub.

## 1.4 What are the new mandatory fields?

**Answer:** The below table provides further information.

Field name	Mandatory as per DR Article 33 (Legal Assessment)	Current EU Hub Implementation	EU Hub Implementation from Q1 2025
<b>Common Name<sup>1</sup></b>	Mandatory	Not Mandatory	Mandatory (not whitespace)
<b>MAH Address</b> <i>(separator, not a field)</i>			
<b>MAH Address – Street</b>	Mandatory	Not Mandatory, except if address provided	Mandatory (not whitespace)
<b>MAH Address - Street2</b>	Not Mandatory	Not Mandatory, except if address provided	Not Mandatory
<b>MAH Address - City</b>	Mandatory	Not Mandatory, except if address provided	Mandatory (not whitespace)
<b>MAH Address - PostCode</b>	Mandatory	Not Mandatory, except if address provided	Mandatory (not whitespace)
<b>MAH Address - Country</b>	Mandatory	Not mandatory	Mandatory (not whitespace)
<b>Wholesaler Name</b>	Mandatory for the Wholesalers that are designated by the MAH by contract	Not Mandatory (No discrepancy on this field)	Not Mandatory (No discrepancy on this field)
<b>Wholesaler Address</b> <i>(separator, not a field)</i>			
<b>Wholesaler Street</b>	Mandatory for the Wholesalers that are designated by the MAH by contract	Not Mandatory, except if address provided	Mandatory (not whitespace) if a Wholesaler Name is provided. Empty if Wholesaler Name is not provided
<b>Wholesaler Street2</b>	Not Mandatory	Not Mandatory, except if address provided	Not Mandatory
<b>Wholesaler City</b>	Mandatory for the Wholesalers that are designated by the MAH by contract	Not Mandatory, except if address provided	Mandatory (not whitespace) if a Wholesaler Name is provided. Empty if Wholesaler Name is not provided.
<b>Wholesaler Postcode</b>	Mandatory for the Wholesalers that are designated by the MAH by contract	Not Mandatory, except if address provided	Mandatory (not whitespace) if a Wholesaler Name is provided. Empty if Wholesaler Name is not provided.

<sup>1</sup> Also referred to as ‘generic name’ by some solution providers.

<b>Wholesaler Country</b>	Mandatory for the Wholesalers that are designated by the MAH by contract	Not Mandatory	Mandatory (not whitespace) if a Wholesaler Name is provided. Empty if Wholesaler Name is not provided.
<b>Manufacturer Address</b> ( <i>separator, not a field</i> )			
<b>Manufacturer Address – Street</b>	Mandatory	Not Mandatory, except if address provided	Mandatory (not whitespace)
<b>Manufacturer Address - Street2</b>	Not Mandatory	Not Mandatory, except if address provided	Not Mandatory
<b>Manufacturer Address - City</b>	Mandatory	Not Mandatory, except if address provided	Mandatory (not whitespace)
<b>Manufacturer Address - PostCode</b>	Mandatory	Not Mandatory, except if address provided	Mandatory (not whitespace)
<b>Manufacturer Address - Country</b>	Mandatory	Not Mandatory	Mandatory (not whitespace)

Table 1: Overview of mandatory fields

### 1.5 Do we have to update the already uploaded PMD?

**Answer:** Yes, in order to be fully compliant with the Delegated Regulation (EU) 2016/161, you are required to update the already uploaded PMD. Please check section 2 of this document which provides further information.

### 1.6 Do we have to update the already uploaded PPD to add the Manufacturer Address (Street, City, PostCode, Country)?

**Answer:** No, however, you need to populate the Manufacturer Address field for **any new PPD** that you will be uploading from now on.

### 1.7 Do I need to add the MAH/wholesaler/manufacturer address even if I already provided the corresponding ID?

**Answer:** Yes.

### 1.8 Can guidance be provided on determining the common name, especially for products with several active substances?

**Answer:** When multiple active substances are part of the common name, all the active substances should be listed.

More information, about the common name can be found in EMVO-00122 EMVS Master Data Guide [here](#) (currently under review).

## 1.9 What guidance will be provided for CMOs and secondary packagers regarding manufacturer identification?

**Answer:** The EMVS Master Data Guide [here](#) states: "Enter the Registered address of the manufacturer placing the safety features".

## 2. Existing Product Master Data

### 2.1 Which version of the existing PMD should I update?

**Answer:** If your SPOC<sup>2</sup> or SPOC Assistant received a communication from the EMVO Helpdesk in the past months (from February 2024 onwards) that any of your uploaded PMD have missing fields, you are requested to update **at least the last version of the affected PMD** (if you wish to update all the versions of the affected PMD, you are free to do so).

### 2.2 How can I update existing PMD?

**Answer:** You can update the existing versions of the affected PMD.

- a) If you use the EMVO Gateway to upload PMD in the EU HUB, the action is performed by updating the PMD and enabling the "Retrospective Override".

Code **scheme required**



✓ Enable Retrospective Override

Version **required**

This allows you to choose a version, already uploaded, that you want to update.

If you do not know which is the last version of your product code, you can request a Master Data Report of the Product Code through your solution provider<sup>3</sup> or direct connection, which shows all the versions that were uploaded.

<sup>2</sup> SPOC: Single Point of Contact

<sup>3</sup> Can also be referred to as provider, L4 platform, L5, hub provider, software provider, serialization provider...

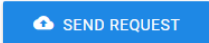
Report Type

PMR - Master Data Report

Product Details

Scan Barcode

Code *scheme required*

 SEND REQUEST

- b) In case you are using a different solution provider<sup>4</sup> or a direct connection to upload PMD to the EU HUB, and you need assistance on how to update existing version of the affected PMD(s), contact your solution provider.

If you do not know which is the latest version of the affected Product Master Data, you can request a 'Master Data Report' of that Product Code, which shows all the versions that were uploaded.

Note that, instead, if you wish to generate a 'Master Data Report' for all product codes, you might require the assistance of the EMVO Helpdesk (helpdesk@emvo-medicines.eu).

If you have questions on what information is to be inserted in the PMD fields, please contact EMVO's Helpdesk (helpdesk@emvo-medicines.eu).

### 2.3 Is there a deadline by which the PMD should be updated?

**Answer:** To be fully compliant with the Delegated Regulation (EU) 2016/161, we advise you to update your PMD **as soon as possible**. Once the EU Hub Release 1.16 is deployed in the Production Environment (PRD), the fields included in Table 1 above will become technically mandatory.

### 2.4 Can I update the PMD in bulk?

**Answer:** Please check with your OBP connection provider whether that option is available in your system.

Note: the EMVO Gateway does not permit this functionality.

---

<sup>4</sup> Can also be referred to as provider, L4 platform, L5, hub provider, software provider, serialization provider...

### 3. New (or new versions of) Product Master Data (PMD) and Product Pack Data (PPD)

#### 3.1 For any PMD or PPD (or new versions) created between now and the deployment of the EU Hub Release 1.16, do we already need to populate the fields indicated in Table 1?

**Answer:** Yes, to be compliant with the Delegated Regulation (EU) 2016/161, you should populate all the fields indicated in Table 1.

### 4. Helpful Scenarios as of EU Hub Release 1.16

#### 4.1 As an OBP I need to UPDATE an existing PMD version

**Answer:** If the mandatory fields are not populated, the EU Hub will send back an A16 Data Validation Error and the update will be rejected.

#### 4.2 As an OBP I need to UPLOAD a new PMD version

**Answer:** If the mandatory fields are not populated, the EU Hub will send back an A16 Data Validation Error and the upload will be rejected.

#### 4.3 As an OBP I need to UPLOAD a new PMD

**Answer:** If the mandatory fields are not populated, the EU Hub will send back an A16 Data Validation Error and the upload will be rejected.

#### 4.4 As an OBP I need to UPLOAD a new PPD associated to a PMD version with missing data

**Answer:** If the mandatory fields of the PPD are not populated, the EU Hub will send back an A16 Data Validation Error and the upload will be rejected.

#### 4.5 As an OBP I need to UPLOAD a new PPD associated to a PMD version with complete data

**Answer:** If the mandatory fields of the PPD are not populated, the EU Hub will send back an A16 Data Validation Error and the upload will be rejected.

#### 4.6 As an OBP I need to UPDATE an existing PPD to change the expiry date/Batch IDs/add new SN but the Manufacturer Address was not filled in in the existing PPD

**Answer:** If the mandatory fields of the PPD are not populated, the EU Hub will send back an A16 Data Validation Error and the update will be rejected.