

Product Master Data

Introduction of new mandatory fields

Questions & Answers (Q&A) – Version 1

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.

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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 the Product Master Data (PMD) uploaded by the On-Boarding Partners (OBPs) in the EU Hub has discrepancies for some medicinal products and data which must, as per the DR (EU) 2016/161, be uploaded to the EU Hub is not being uploaded consistently. EMVO performed a thorough investigation and gap-analysis of the requirements aiming to spot the irregularities in the data upload. Consequently, some

additional fields shall be made mandatory which will further strengthen the EU Hub and ensure the consistency and completeness of the data uploaded.

1.2 When will the new mandatory fields be introduced in the Product Master Data and Product Pack Data?

Answer: The new mandatory fields will be introduced with the deployment of the EU Hub Release 1.16 in Production Environment which is currently scheduled for Q1 2025. The exact date will be communicated later this year.

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

Answer: The deployment of the EU Hub Release 1.16 scheduled for Q1 2025, will have no interface impact on the OBP side. Nevertheless, the EU Hub will still undergo modifications such that if OBPs upload a PMD and PPD without filling in the specified fields, the transaction will be rejected with an A16 validation error.

With the deployment of the EU Hub Release 1.17 scheduled for Q2 2025, the EU Hub will undergo further modifications introducing a new OBP interface complementing the new mandatory fields. Consequently, if OBPs attempt to upload a PMD without filling in the indicated mandatory fields, the transaction will be rejected with a schema validation error¹.

Consequently, OBPs will need to update their interface connections to ensure the seamless continuation of their uploading transactions. Please contact your connection provider who will be able to assist you with this update. In case you are using the EMVO Gateway, please note that no actions are required from your side.

In case you do not update your interface connection or fail to fill in properly the indicated mandatory fields, you will be unable to upload the data to the EU Hub.

¹ A schema validation error occurs when data fails to be in line with the defined structure or rules specified by a schema.

1.4 What are the new mandatory fields?

Answer: The below table provides further information.

Field Name	Mandatory as per DR Article 33	Current behaviour of the EU Hub	Changes introduced with R.1.16
Common Name	Mandatory	Not Mandatory	Mandatory
MAH Address	Mandatory	Not Mandatory	Mandatory
Wholesaler Name	Mandatory*	Not Mandatory	Not Mandatory**
Wholesaler Street	Mandatory	Not Mandatory except if Postcode or Country is provided	Mandatory if a Wholesaler Name is provided. Empty if no Wholesaler Name is provided.
Wholesaler Postcode	Mandatory	Not Mandatory except if Street or Country is provided	Mandatory if a Wholesaler Name is provided. Empty if no Wholesaler Name is provided.
Wholesaler Country	Mandatory	Not Mandatory	Mandatory if a Wholesaler Name is provided. Empty if no Wholesaler Name is provided.
Manufacturer Address (PPD field)	Mandatory	Not Mandatory	Mandatory

* Wholesalers are designated by the marketing authorisation holder (MAH), by means of a written contract, to store and distribute the products covered by his marketing authorisation on his behalf (Article 33 DR (EU) 2016/161).

** Programmed as 'Not Mandatory' as the system cannot know if there is a contract in place. The EMVS Master Data Guide will be updated to specify that this field must be filled if a Wholesaler is designated by the MAH for a specific market.

1.5 Do we have to update the already uploaded Product Master Data and Product Pack Data?

Answer: Yes, you will be required to update the already uploaded Product Master Data. Please check the next section which provides further information regarding the update of the data.

2. Updating the Product Master Data & Product Pack Data

2.1 How can I update the Product Master Data and Product Pack Data?

Answer: You can easily input the missing information/data. If you have questions, please refer to the EMVS Master Data Guide [here](#).

2.2 Is there a deadline by which I should update the Product Master Data and Product Pack Data?

Answer: We advise you to update your PMD and PPD **as soon as possible**. Once the EU Hub Release 1.16 is deployed in Production Environment, the fields included in the table above will ultimately become mandatory. Therefore, you will be required to update all your priorly uploaded PMD with a new version and the PPD for the Manufacturer Address.

2.3 Are there any consequences of not updating the Product Master Data and Product Pack Data?

Answer: Should you not update the PMD and PPD on time, you will be unable to market your medicinal products.