

BELGIUM – LUXEMBOURG Loading specifications for MAH data

BMVS_DataLoad	Version 1.2	22/01/2018	BeMVO
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1. Purpose

The purpose of this document is to provide additional information regarding the product data that have to be loaded by the On Boarding Partner (OBP) in the EU Hub in the Country Specific Product Master for Belgium and Luxembourg.

The National Verification System (NMVS) that is set up for these countries is a Supra-National system where both the end users from Belgium and from Luxembourg will connect. This means that the Belgian NMVS will contain all packs that are officially registered in Belgium and/or in Luxembourg.

For this reason, and also because a large number of products that are in FMD scope for Luxembourg are also covered in the FMD scope for Belgium, specific rules are to be considered which are explained hereafter.

2. Scope of FMD in Belgium and Luxembourg

The products that are in scope for Belgium and Luxembourg for carrying the 2D matrix with the Unique Identifier (UI) are defined by the relevant authorities of both countries.

Belgium

The products that need to carry the 2D matrix with UI for Belgium are the medicines that have been officially registered on the market in Belgium and that belong to the following definition:

1. All medicines under medical prescription
2. All medicines that are defined in Annex II of the Delegated Regulation (Black list)
3. All non-prescription medicines that are reimbursable and that are carrying a serialized unique barcode (UBC) today in Belgium
4. Excluding the prescription medicines (item 1.) and non-prescription UBC medicines (item 3.) that are covered by Annex I of the Delegated Regulation (White list)

Luxembourg

The products that need to carry the 2D matrix with UI for Luxembourg are the medicines that have been officially registered on the market in Luxembourg and that belong to the following definition:

1. All medicines under medical prescription
2. All medicines that are defined in Annex II of the Delegated Regulation (Black list)
3. Excluding the prescription medicines (item 1.) that are covered by Annex I of the Delegated Regulation (White list)

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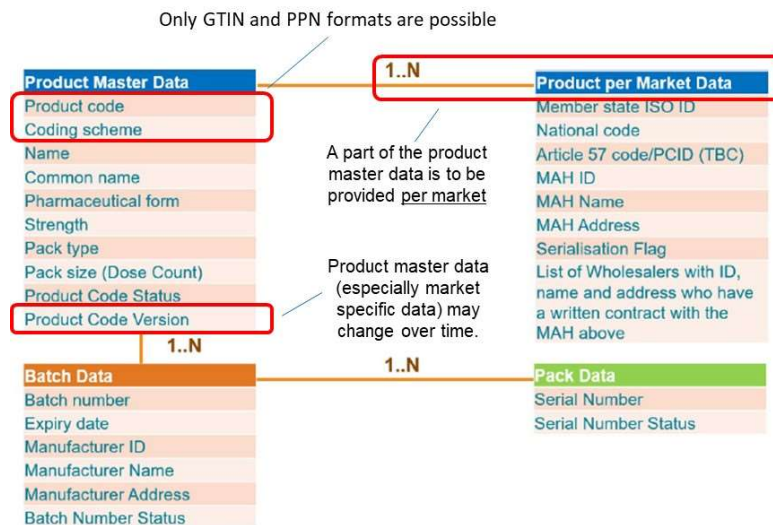
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3. Country Specific Master data

As shown in the schematic overview of the data model used for loading data coming from the OBP's, besides the Product Master data, Batch data and Pack data, a specific table with information per Market needs to be provided.



Because the NMVS needs to contain the product data that are in scope for both Belgium and Luxembourg, specific guidelines for this 'Product per Market Data' are to be applied.

The general principle is that for each product, identified with the unique Product Code in the Product Master Data, on the market and in scope FMD for Belgium and/or Luxembourg, only one record can be loaded in the Product per Market Data.

In case the same Product Code is applicable for Belgium and Luxembourg but with a different Country Specific information (eg a different MAH), then the Belgian information is prevailing.

A 'Product' is defined as a unique Product Code (Gtin) in the Product Master Data. If the same product is present in both Belgium and Luxembourg, but with a different Product Code, then these are considered as 2 different products.

According the EMVO guidelines, the MAH ID is left blank for the moment. This implies that the MAH will be identified based on the MAH Name. **Therefore it is critical that:**

- The MAH Name is identical with each load for each product of the MAH
- The OBP (or MAH) must communicate the MAH Name that will be loaded before loading the data to the BeMVO (mail to mah@bemvo.be)

If not, the data will bounce back and an error message will be generated.

(note: this communication request will change in later versions of the verification system)

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4. Loading instructions

As explained, the basic loading principle for is that both for Belgium and Luxembourg the Product Master data (and more specific the Product per Market data) are loaded with Member state ISO code BE and that the same Product Code is not loaded twice.

In summary, this means:

A product that is **officially registered, in FMD scope and active** on the market in **Belgium AND/OR Luxembourg**, needs to be loaded with **Member state ISO ID “BE”**, where the **same Product Code cannot be loaded twice**.

Some examples

1. Product ABC registered, active and in Belgian FMD scope; Product ABC registered, active and in Luxembourg FMD scope:
Load only 1 record in the Product master with Member state ISO ID “BE”
2. Product DEF registered, active and in Belgian FMD scope; Product DEF registered and active in Luxembourg, but NOT in Luxembourg FMD scope:
Load only 1 record in the Product master with Member state ISO ID “BE”
3. Product GHI registered and active in Belgium, but NOT in Belgian FMD scope; Product GHI registered, active and in Luxembourg FMD scope:
Load only 1 record in the Product master with Member state ISO ID “BE”
4. Product JKL not registered in Belgium; Product JKL registered in Luxembourg based on the German registration, and active and in Luxembourg FMD scope:
Load only 1 record in the Product master with Member state ISO ID “BE”
5. Product MNO registered, active and in Belgian FMD scope; Product MNO registered in Luxembourg based on the German registration, and active and in Luxembourg FMD scope; and Product code for product MNO in Belgium is different from Product code for product MNO in Luxembourg (and Germany):
Load 1 record for Belgium with Member state ISO ID “BE”;
Load 1 record for Luxembourg with Member state ISO ID “BE”
6. Product PQR registered, active and in Belgian FMD scope; Product PQR registered in Luxembourg based on the German registration, and active and in Luxembourg FMD scope; and Product code for product MNO in Belgium is the same as the Product code for product MNO in Luxembourg (multimarket pack):
Load only 1 record in the Product master with Member state ISO ID “BE”
7. Product STU registered and active in Belgium, but not in FMD scope for Belgium; Product STU registered in Luxembourg based on the French registration, and active and in Luxembourg FMD scope;
Load only 1 record in the Product master with Member state ISO ID “BE”

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Detailed specifications

Load of Packs in scope for Belgium

All packs officially registered and on the market in Belgium, and in scope for FMD, need to be loaded, ie, all packs with a 2D matrix containing a serial code.

Data elements in the Product per Market data to be loaded:

Member state ISO ID: **BE**

The National code to load in the field “National Code” is the CNK

Load of Packs in scope for Luxembourg

The loading specifications for Luxembourg are dependent on the concepts

- Is the product (= Product Code in the Product Master) already loaded for Belgium?
If yes, no records are allowed to be loaded for Luxembourg.
- ‘Country of Origin’: this indicates the country that was used as reference for registering the product for the Luxembourg Market. The Luxembourg name is “Pays de provenance du conditionnement” filled by the MAH when applying for the AMM (registration of the pack).

Depending on this ‘Country of Origin’ a different guideline needs to be followed for submitting data for the Product per Market data.

There are 4 possible cases:

1) Country of Origin is “Belgium”

This implies that the same Product Code (in the Product Master) is used for both countries.

- a) The product is also active on the market in Belgium and in scope for Belgium.
In that case the Product per Market record was already loaded with the Belgian data.
NO record can be loaded for Luxembourg to avoid double records.
- b) The product is not active on the market in Belgium or not in Scope in Belgium.
This can be the case when eg the registration in Luxembourg was faster than the registration in Belgium; or when for commercial reasons it was decided not to market the product in Belgium; or that the product status is different between the two countries (eg under prescription in Luxembourg but not in Belgium).

In that case a **record needs to be loaded** for Luxembourg with data elements:

Member state ISO ID: **BE**

The National code to load in the field “National Code” is the Code National Luxembourg (National number)

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- 2) Country of Origin is “Germany”
- a. and the Product Code (in the Product Master) is different from the Product Code for that product in Belgium (ie, it is NOT a multimarket pack shared with Belgium).

In that case a **record needs to be loaded** for Luxembourg with data elements:

Member state ISO ID: **BE**

The National code to load in the field “National Code” is the PZN (National number Germany)

- b. If the **same Product Code** is used for Germany and Belgium (ie, it IS a multimarket pack shared with Germany and Belgium):
NO record can be loaded for Luxembourg to avoid double records.

- 3) Country of Origin is “France”

- a. and the Product Code (in the Product Master) is different from the Product Code for that product in Belgium (ie, it is NOT a multimarket pack shared with Belgium).

In that case a **record needs to be loaded** for Luxembourg with data elements:

Member state ISO ID: **BE**

The National code to load in the field “National Code” is the CIP13 (National number France)

- b. If the **same Product Code** is used for France and Belgium (ie, it IS a multimarket pack shared with France and Belgium):
NO record can be loaded for Luxembourg to avoid double records.

- 4) Country of Origin is any other country (including country “Luxembourg”)

- a. and the Product Code (in the Product Master) is different from the Product Code for that product in Belgium (ie, it is NOT a multimarket pack shared with Belgium).

In that case a **record needs to be loaded** for Luxembourg with data elements:

Member state ISO ID: **BE**

The National code to load in the field “National Code” is the Code National Luxembourg (National number)

- b. If the **same Product Code** is used for Belgium (ie, it IS a multimarket pack shared with Belgium):
NO record can be loaded for Luxembourg to avoid double records.

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Overview of the different cases

Product in scope for	Country of Origin AMM Luxembourg	Same Product Code as Belgium*	On Market & in scope in BE	Load data	Country ISO ID	National code
Belgium	<i>na.</i>	<i>na.</i>	Yes	Yes	BE	CNK
Luxembourg	Belgium	Yes	Yes	No ⁽¹⁾	<i>na.</i>	<i>na.</i>
Luxembourg	Belgium	<i>Yes or No</i>	No	Yes	BE	CNK**
Luxembourg	Germany	Yes	Yes	No ⁽¹⁾	<i>na.</i>	<i>na.</i>
Luxembourg	Germany	Yes	No	Yes	BE	PZN
Luxembourg	Germany	No	<i>Yes or No</i>	Yes	BE	PZN
Luxembourg	France	Yes	Yes	No ⁽¹⁾	<i>na.</i>	<i>na.</i>
Luxembourg	France	Yes	No	Yes	BE	CIP
Luxembourg	France	No	<i>Yes or No</i>	Yes	BE	CIP
Luxembourg	Any other	Yes	Yes	No ⁽¹⁾	<i>na.</i>	<i>na.</i>
Luxembourg	Any other	Yes	No	Yes	BE	Lux.Nat.Num.
Luxembourg	Any other	No	<i>Yes or No</i>	Yes	BE	Lux.Nat.Num.

No⁽¹⁾: Because these records are loaded for Belgium, they cannot be loaded for Luxembourg to avoid double records

* Product Code = code used to identify the product in the Product Master Data

** If no CNK available, then use Lux.Nat.Number

In case of doubt, contact the Belgian Medicines Verification Organisation:

BeMVO

Jean-Pierre Engels

info@bemvo.be