LMVO LUXEMBOURG MEDICINES VERIFICATION ORGANISATION

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BELGIUM – LUXEMBOURG Loading specifications for MAH data

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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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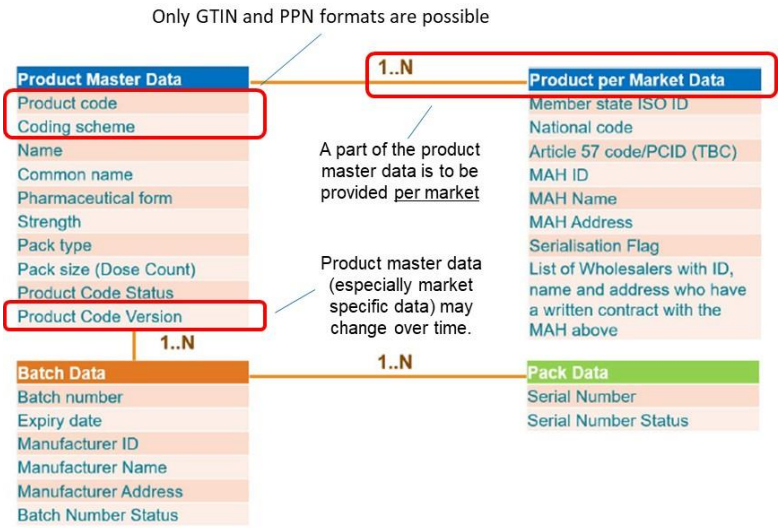
3. Country Specific Master data

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.

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.

Only one record: 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.

Designated Wholesalers: An exception to this principle of prevailing Belgian information is the information to be provided in the "List of designated Wholesalers." In case a different designated wholesaler is used in Belgium and Luxembourg for the same product, then both designated wholesalers need to be listed in this field.

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. **Therefor it is critical that**:

The MAH Name is identical with each load for each product of the MAH

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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 **(1) officially registered, (2) in FMD scope and (3) 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**.

Detailed specifications

a. 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,
except if the product/pack data where already loaded for Luxembourg prior to the Belgian load (eg cases where the BeLux pack is on the market in LU before the pack is on the market in BE):
Member state ISO ID: **BE**

b. Load of Packs in scope for Luxembourg

All packs officially registered and on the market in Luxembourg, and in scope for FMD in Luxembourg, need to be loaded, except if the product/pack data have already been loaded for Belgium.
So, there are 2 possible cases:

a) **Case 1:** The product code (PC) with product and pack data (batch and SN), is already loaded for Belgium
Load : No records need to be loaded

b) **Case 2:** The product code (PC) with product and pack data (batch and SN), is not loaded for Belgium
Load : Load the records with product and pack data for Luxembourg with Member state ISO ID: **BE**

Note: In case the product and pack data that are loaded (for Belgium and Luxembourg) were already loaded for the other country, then the system will generate an error message indicating that the data were already loaded. Equally, an error message will be returned in case product/pack data are loaded with member state ISO ID "LU".

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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” under Product code for Belgium;
   Load 1 record for Luxembourg with Member state ISO ID “BE” under Product code for Luxembourg

6. Product PQR registered, active and in Belgian FMD scope; Product PQR registered in Luxembourg based on the French registration, and active and in Luxembourg FMD scope; and Product code for product PQR in Belgium is the same as the Product code for product PQR 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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5. National Code

The Product per Market data contains also the field “National Code”.
The load of this information for the Belgian repository (Belgium and Luxembourg) **is NOT mandatory**. There will be no problem if the information is loaded, but not required as this might create confusion at the level of the end users.
If the code is loaded, it should be the CNK for Belgian products, PZN for German products, CIP13 for French products and the Luxembourg national code (or left blank) for any other product.

6. Retro-active loading

We insist that MAH/OBPs are loading the product and pack data as soon as possible, i.e., when the Belgian repository is connected to the Live environment of the EU Hub.

Users in Belgium will start scanning 2D information as from month 8/2018. Because the scanning of 2D codes that are not loaded in the system will generate alerts at the level of the end users, this might create confusion at the level of these end users and might lead to reluctance from some users to deliver the products from the concerned MAH.

7. GTIN – CNK conversion

All systems in Belgium will continue to work with the national code CNK as the unique product identifier. This is valid for the end users (pharmacies, wholesalers, hospitals), for the communications between these stakeholders (eg pharmacy to wholesaler orders), for reimbursement coding of the delivered products, for the insurance instances, for the different NCA departments receiving data from the supply chain stakeholders.

To that extend, a conversion table GTIN-to-CNK is being maintained by the Belgian national pharmacist association (APB). The information will also be inserted in other NCA product databases. **It is therefore critical that MAHs communicate this link GTIN-CNK to APB as soon as possible**. Products not available in that conversion table will cause many problems at the level of the end users and the other stakeholders involved.

The early communication of the GTIN codes by pack to APB is critical for ensuring a smooth distribution of the MAHs products on the market in Belgium.
The information must be communicated to GTIN@apb.be

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8. Quality of the 2D matrix print

The quality of the print of the 2D matrix on the packages is of equal importance.

It is clear that bad quality will create serious problems when your packs are moving through the supply chain. In the extreme case, such packs can even be considered not compliant with FMD by the relevant competent authorities and be requested for a recall of the batch.

MAHs have the responsibility to pay particular attention to this element and implement the necessary quality procedures (see also DR art. 14). It is strongly advised to ask GS1 to verify the quality of the 2D matrix prints before releasing the batches.

In case of doubt on any of the above elements, contact:

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