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Information Management

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

Annex I to Chapter 7: Migration rules between SIAMED and PMS for centrally authorised products

Version 1

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1. Introduction

Annex I of Chapter 7 is intended to support the first release of the DADI variation form for centrally authorised products (CAPs).

As part of this release in October 2022, only data stored in SIAMED II, which is an internal database of the European Medicines Agency (EMA) and contains information on centrally authorised products, will be available in PMS. This document explains the structure of a medicinal product in SIAMED II and how the data is migrated to PMS.

As part of the second release of DADI, containing information on centrally authorised products and non-centrally authorised products (non-CAPs) from SIAMED II and the eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD), a new version of Chapter 7 will be released.

2. Migration of SIAMED II data into PMS

2.1. SIAMED II migration

In SIAMED II a product is an umbrella which can contain several medicinal products and each medicinal product can contain multiple presentations within.

An example can be found in Figure 1.

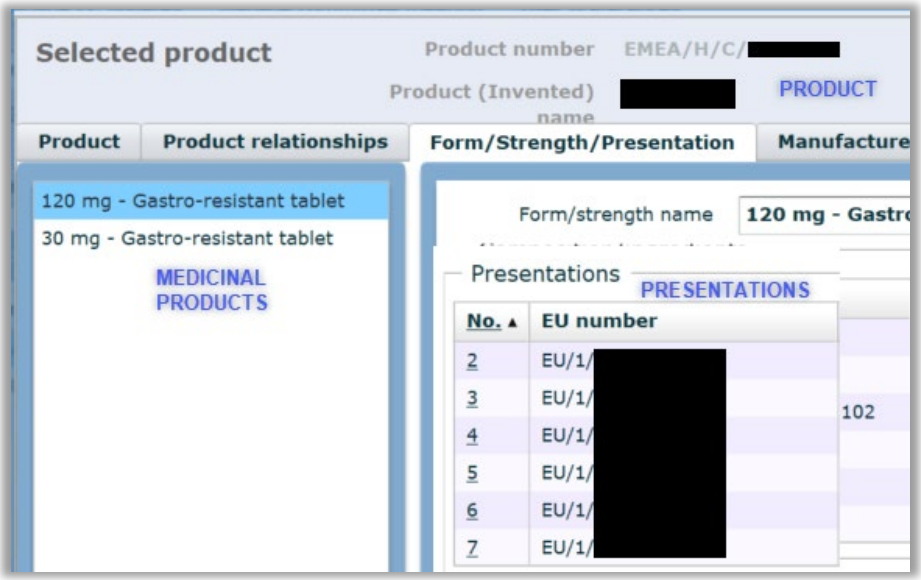

Figure 1

SIAMED II is built to split the medicinal products based on the strength and authorised pharmaceutical dose form.

Considering the example in Figure 1, two medicinal products can be expected in PMS: one for 120 mg gastro-resistant tablets and another one for 30 mg gastro-resistant tablets.

Under each medicinal product, the relevant presentations are captured. Those presentations will be migrated to PMS as packaged medicinal products using the rules established in Chapter 2 of the EU IG.

2.2. Mapping and migration rules

A diagram with a summary of the sections that will contain data as part of the initial migration from SIAMED II to PMS can be found in Figure 2.

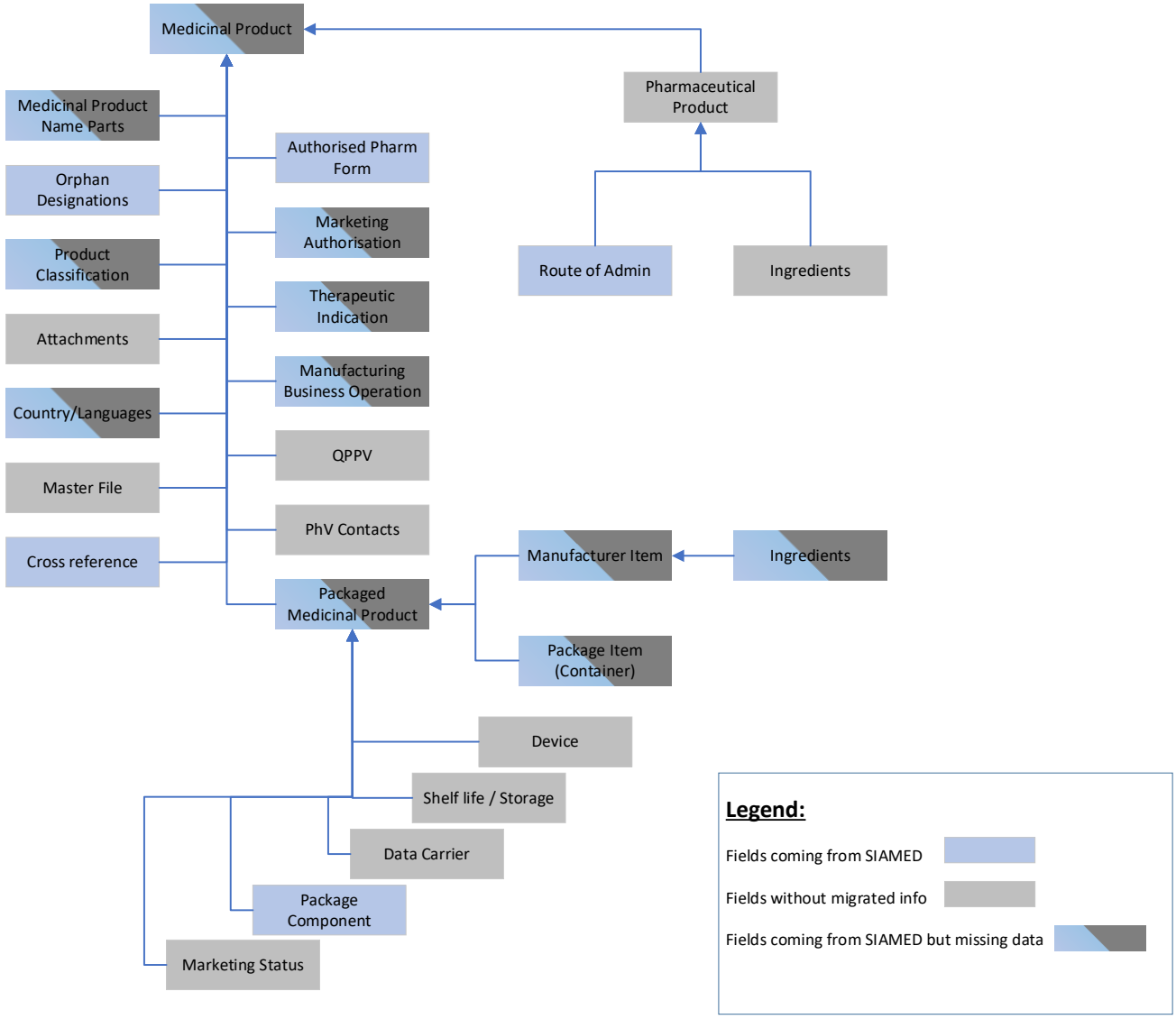

Figure 2

In section 1 of this document, it is stated that this Annex is intended to support the first release of DADI Variation form.

At the time of DADI going-live, PMS will contain centrally authorised medicinal product information as available in SIAMED II and with the sections completed as represented in Figure 2. Nevertheless, the DADI variation form will only be able to show 15 of the fields coming from PMS which have been explained in the following sections.

The following sections shall be read together with Chapter 2 of the EU IG to understand the Referentials Management Service (RMS) lists used to map SIAMED II data. This information will also be updated to reflect the final source when xEVMPD data is used in the second release of the DADI variation form.

2.2.1. Medicinal Product Information

2.2.1.1. Product Management System Identifier (PMS ID)

Source	None
Business rule	This value is generated by the system following EU IG Ch.2

2.2.1.2. Medicinal Product Identifier (MPID)

Source	None
Business rule	This value is generated by the system following EU IG Ch.2

2.2.1.3. Domain

Source	None
Business rule	Only medicinal products authorised for human use are migrated and this value is set by default.

2.2.1.4. Authorised pharmaceutical form

Source	SIAMED II
Business rule	This term is mapped to RMS following EU IG Ch. 2 and migrated to PMS.

2.2.1.5. Name of the medicinal product

Source	SIAMED II
Business rule	Product (invented) name is migrated to PMS as free text.

2.2.2. Marketing Authorisation Information

2.2.2.1. Marketing Authorisation Number

Source	SIAMED II
Business rule	At medicinal product level, the "root number" is indicated in this section in PMS as free text. Please check for information at package level. Example of MA number at medicinal product level: *EU/1/13/016*

2.2.2.2. Country of authorisation

Source	SIAMED II
Business rule	This term is mapped to RMS and migrated to PMS. Only EU products in the first DADI release.

2.2.2.3. Authorisation status

Source	SIAMED II
Business rule	This term is mapped to RMS following EU IG Ch. 2 and migrated to PMS.

2.2.2.4. Marketing authorisation holder

Source	SIAMED II
Business rule	MAH captured in SIAMED II is mapped to OMS and the LOC ID is migrated to PMS.

2.2.2.5. Procedure Identifier

Source	SIAMED II
Business rule	Product number from SIAMED II is migrated to PMS.

2.2.2.6. Procedure type

Source	SIAMED II
Business rule	Only centrally authorised products for the first release.

2.2.3. Packaged medicinal product

2.2.3.1. Pack size

Source	SIAMED II
Business rule	Data in this field is migrated to PMS as free text.

2.2.3.2. Marketing authorisation number

Source	SIAMED II
Business rule	At packaged medicinal product Level, the marketing authorisation number assigned to each presentation is migrated to PMS as free text. Example of MA number at package medicinal product level: *EU/1/13/016/001*

2.2.3.3. Authorisation status

Source	SIAMED II
Business rule	This term is mapped to RMS following EU IG Ch. 2 and migrated to PMS.

2.2.4. Ingredient

2.2.4.1. Substance

Source	SIAMED II
Business rule	Substances captured in SIAMED II are mapped to SMS and the code is migrated to PMS for the manufacturer item.

For the second release, CAP and non-CAP data from the xEVMPD is also migrated and will complement the PMS data model. A match and merge step will occur during the migration for CAP data whereas for non-CAPs, data will only be migrated from the xEVMPD, and therefore, those records will contain less information.

The representation of the full PMS data model can be found in Figure 1 of Chapter 2 of the EU IG. This data model is bigger than SIAMED II and xEVMPD data models, which means that, as part of the initial migration to PMS, the full dataset cannot be completed.

The match and merge process, as well as every business rule used during the migration of data from SIAMED II and xEVMPD to PMS, will be described in version 2 of Chapter 7 that is intended to be released before the second release of DADI variation form.