BEST PRACTICE: PMS DATA ENRICHMENT

1 Revision History

When Ennov releases a new version of Ennov InSight, they issue Release Notes which explain the new features and updates. The Ennov Business Consulting Team reviews the Release Notes against each Best Practice to determine any impact to the document:

- Impact = Release notes-documented upgrade changes this Best Practice
- No Impact = Release notes-documented upgrade changes do not affect this Best Practice

When Release Notes impact Best Practice documentation, Ennov recommends that clients review the entire Release Notes for a full understanding of all changes associated with this Best Practice documentation.

Software Version	Release/ Revision Date	Summary of Change(s) (Refer to Release Notes for Full Description)
v7.3.3	7 April 2025	First released

2 Contents

3 Document Purpose

The purpose of this document is to provide a Best Practice to support enrichment of medicinal product data in the EMA's Product Management Service (PMS).

4 Scope

The scope of this Best Practice is limited to the data points that the EMA have made mandatory for enrichment by December 2025 for medicines on the Union List of Critical Medicines and by December 2026 for all other registered products.

The following data is currently mandatory:

- Structured pack size
- Manufacturer
- Manufacturer business operations

This Best Practice describes where the data can be stored in Ennov InSight Registrations. Submission to PMS is out of the scope of this Best Practice.

5 Manufacturer and Manufacturer Business Operations

Manufacturers and manufacturer business operations (manufacturer functions) that are submitted within the eAF should be submitted to PMS. This is required for products that have not been authorised via a centralised procedure (i.e. national, MRP or DCP products/non-CAP products). CAP products will already have this information populated due to the integration with SIAMED.

Manufacturers should be submitted if they are currently registered – i.e. there is no need to submit a manufacturer that has been withdrawn. Manufacturers that are not currently used but which are registered in the dossier should be submitted.

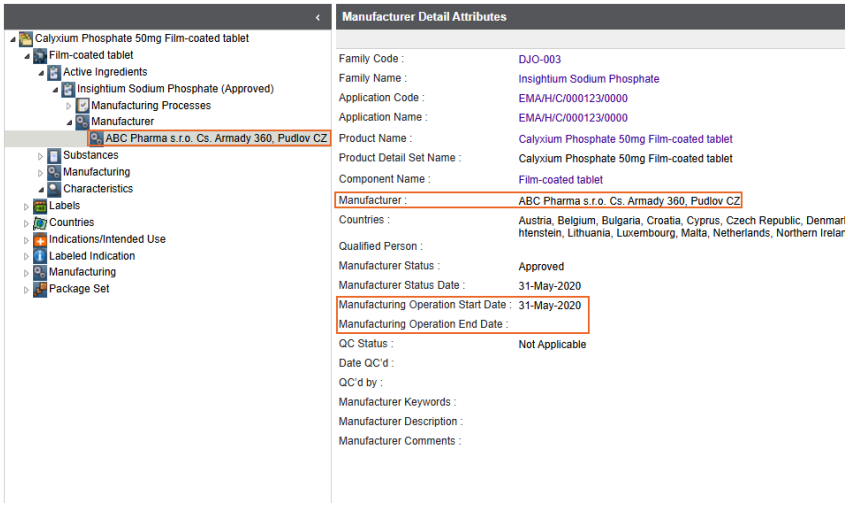
Manufacturer and manufacturer function data as it relates to a specific registered product is stored in the Product Detail Set. Additional manufacturer information, such as the confidentiality indicator and manufacturing authorisation reference number, is stored on the Manufacturer value in Data Administration.

5.1 Manufacturer and Manufacturing Business Operation information

Field	Definition	Location of data in InSight
Manufacturer	The manufacturer shall be specified using the location identifier (LOC ID) linked to the organisation as listed in OMS. All manufacturers that are specified in the eAF should be submitted to PMS. Manufacturers should all be submitted at the level of the medicinal product.	Manufacturers are stored in the Product Detail Set. The manufacturer may be associated with the appropriate OMS value in Data Administration by following the instructions in the Best Practice: Associating SPOR values in Data Admin.
Manufacturing Business Operation Type	The type of manufacturing operation shall be specified as a term ID from the Manufacturing Activity RMS list.	Manufacturer functions are stored in the Product Detail Set. Manufacturers should be added underneath a Manufacturing Process node so that a Manufacturing Function may be associated. The function may be associated with the appropriate RMS value in Data Administration by following the instructions in the

Field	Definition	Location of data in InSight
		Best Practice: Associating SPOR values in Data Admin.
Manufacturing Operation Start Date	The date when the manufacturing operation is approved or included in the terms of the marketing authorisation. Where this information is not available (e.g. for legacy products), the date of the MAA first approval may be given.	The manufacturing operation start date should be populated on the appropriate manufacturer detail in the PDS. The date should be populated in the field 'Manufacturing Operation Start Date'.
Manufacturing Operation End Date	The date when the manufacturing operation is discontinued and removed from the terms of the marketing authorisation – i.e. the manufacturer is withdrawn. Manufacturers that have been withdrawn before data enrichment begins do not need to be submitted. This field is therefore not relevant for the initial enrichment, but will be required going forward.	The manufacturing operation end date should be populated on the appropriate manufacturer detail in the PDS once the manufacturer is withdrawn. The date should be populated in the field 'Manufacturing Operation End Date'.

Information on active manufacturers is entered in the appropriate location in the PDS. The field 'Manufacturing Operation Start Date' is populated on the Manufacturing Detail node. The 'Manufacturing Operation End Date' will be populated when the manufacturer is withdrawn.



5.2 Confidentiality indicator

The confidentiality indicator is populated on the Manufacturer Value in Data Administration using the Global Product Details tab.

Field	Definition	Location of data in InSight
Confidentiality indicator	Whether the manufacturing operation performed by a manufacturing site is classified as confidential or public information.	Data Administration > Product Detail Set Maintenance > Manufacturer Values > Global Product Details > Confidentiality indicator

The Confidentiality Indicator is populated for each manufacturer in Data Administration:

5.3 Manufacturing Authorisation information

The manufacturing authorisation reference number is populated on the Manufacturer Value in Data Administration using the Manufacturing Authorisation Reference Number tab.

Field	Definition	Location of data in InSight
Manufacturing authorisation reference number	The reference number of the authorisation issued for the manufacturing of medicinal products by the relevant National Competent Authority.	Data Administration > Product Detail Set Maintenance > Manufacturer Values > Manufacturing Authorisation Reference Number >

Field	Definition	Location of data in InSight
	e.g. the Manufacturing and Importation authorisation, GMP certificate or equivalent.	Manufacturing Authorisation Reference Number
Effective date	The effective date of the manufacturing authorisation listed above.	Data Administration > Product Detail Set Maintenance > Manufacturer Values > Manufacturing Authorisation Reference Number > Effective Date
(Manufacturing business operation) Medicines Regulatory Agency Organisation	The applicable medicines regulatory agency or national competent authority responsible for issuing the manufacturing authorisation listed above.	Data Admin > Product Detail Set Maintenance > Manufacturer Values > Manufacturing Authorisation Reference Number > Regulatory Agency The agency may be associated with the appropriate OMS value in Data Administration by following the instructions in the Best Practice: Associating SPOR values in Data Admin.

The Manufacturing Authorisations for each Manufacturer are stored in Data Administration. They can be disabled when no longer valid.

Manufacturing Authorisation Reference Number

Agent e-mail:	
Site License Number:	
Site Certificate Filed:	No
DMV/CEP Number:	
US Agent:	
FEI Number:	
Parent Company Name:	
Other Firms :	
Comments:	
Keywords:	
Description:	
Last User Updated:	Darren Oakes
Last Changed Date:	21-Aug-2024
Manufacturing Authorisation Reference Number:	* BE-250123
Manufacturing Authorisation Type:	* Good Manufacturer Practice
Effective Date:	* 01-Jan-2020
Country:	Belgium
Regulatory Agency:	Direction Générale Médicaments

6 Structured Pack Size

Structured pack size information should be submitted for products that have not been authorised via a centralised procedure (i.e. national, MRP or DCP products/non-CAP products). CAP products will already have this information populated due to the integration with SIAMED.

Pack size information is stored in the Product Detail Set in the Pack Size detail.

Field	Definition	Location of data in InSight
Pack size	The total number of units of the manufacturing item or package item, represented per unit of presentation.	This information is split across three fields in InSight: • PDS Details > Pack Size > Quantity Operator • PDS Details > Pack Size > Pack Size Value • PDS Details > Pack Size > Unit of Presentation

A package of 5 tablets would be entered as follows: