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Information Management

Product Management Service (PMS) - Implementation of International Organization for Standardization (ISO) standards for the Identification of Medicinal Products (IDMP) in Europe

Chapter 1: Registration requirements

Version 2.0

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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Summary of changes

Following the publication of version 1 in February 2020, the following sections were added:

- Introduction;
- Scope of this document;l
- Scope of PMS;
- On-boarding of users to SPOR data services, access to data;
- Training.

Introduction

In accordance with the obligations laid down by the Commission Implementing Regulation (EU) No 520/2012 (articles 25 and 26) the European Medicines Agency (EMA) is in the process of implementing the standards developed by the International Organization for Standardization (ISO) for the Identification of Medicinal Products (IDMP). The European Union (EU) Member States, marketing authorisation holders (MAHs) and EMA are required to make use of the ISO IDMP standards to support the exchange of medicinal product information in standardised manner.

EMA is implementing the standards in a phased programme based on the four domains of master data in pharmaceutical regulatory processes: Substance, Product, Organisation and Referential (SPOR) master data.

Scope of this document

This document has been developed with the goal of facilitating the maintenance and accessibility to data on medicinal products for human use in the EU. This document provides an overview of:

- on-boarding of users to SPOR data services;
- the registration requirements to be fulfilled in order to submit medicinal product information to PMS;
- access management to the information held in PMS;
- training requirements to submit and maintain product information in PMS.

Scope of PMS

The scope of PMS is to have harmonised data and definitions to uniquely identify a medicinal product based on regulated information (e.g. marketing authorisation, packaging and medicinal information).

The key benefits of having standardised data are:

- more efficient regulatory action and decision-making, thanks to improved data integrity and reliability;
- better quality of data and simplification of data management practices. Data will be reviewed, assessed and approved as part of the new data operating model;
- regulatory requirements can be met more effectively by reducing data silos and improving interoperability across EU systems;

- operational savings and efficiencies can be achieved, as pharmaceutical companies only need to supply regulatory data once. This data will be re-used across different procedures and regulators. These operational benefits should have a positive impact on public health and safety.

On-boarding of users to SPOR data services

User registrations requirements for PMS follows the user registration model described at SPOR programme and initiated for Referentials Management Service (RMS) and Organisation Management Service (OMS). The 'On-boarding of users to Substance, Product, Organisation and Referentials (SPOR) data services' document must be considered the reference guidance, as this document includes the type of user roles available for SPOR, permission matrix listing access to functionalities in accordance to its roles, information and requirements for registration. Therefore, users must read this chapter in conjunction with the 'On-boarding of users to Substance, Product, Organisation and Referentials (SPOR) data services' document.

Registration requirements

To begin medicinal product submission in PMS, the MAH organisation must be registered with the Organisation Management Service (OMS). The 'OMS web user manual' describing how to register an organisation in OMS can be found on the OMS portal, in section 'Help'.

To manage MAH data within OMS and product data in PMS, an industry user must be registered in the EMA Account Management portal (IAM) and affiliated to a specific organisation with the required **user role(s)**, as described in the 'On-boarding of users to Substance, Product, Organisation and Referential (SPOR) data services' document.

The first step involves the registration of a 'Super User' in IAM. Once approved by EMA, the 'Super User' will have permissions to approve or revoke any other users affiliated to the same organisation. This will include industry 'Users' and industry 'Qualified Users'. Having the role of a 'Qualified user' is necessary to create or edit medicinal product data. It is recommended that each organisation should have at least two 'Super Users' registered in IAM.

Multiple user roles can be assigned to one person; e.g. a person affiliated to organisation X can have the role of a 'Super User', as well as a 'Qualified User' or a 'User'.

The 'SPOR User Registration Manual' provides a comprehensive step-by-step guidance which describes all existing SPOR user roles and authorisation process flow. In addition, it provides detailed instructions on how to register and manage SPOR roles. The 'SPOR User Registration Manual' will be updated in due course to account for PMS specificities.

Access to data

Access to PMS data will be provided through the SPOR application programming interface (API) or Web UI and will be based on the **user roles** available for each stakeholder group as described in the 'On-boarding of users to Substance, Product, Organisation and Referentials (SPOR) data services' document.

The stakeholders are grouped as follows:

- competent authorities: The European Commission (EC), national competent authorities (NCAs) and the EMA responsible for regulating medicinal products;
- industry: marketing authorisation holders/product owners and applicants, including relevant external service providers, and medicines developers;
- general public: persons or organisations, other than the competent authorities and industry referred to above.

API specifications are available in the 'Substance, Product, Organisation, Referentials (SPOR): API specifications' document and in Chapter 6: Technical specifications of the Product Management Service (PMS) - Implementation of International Organization for Standardization (ISO) standards for the Identification of Medicinal Products (IDMP) in Europe document.

Web UI access will be described in the 'SPOR User Registration Manual'.

Access is defined based on the stakeholder's interests and needs as well as the requirement to comply with General Data Protection Regulation (GDPR) i.e., Regulation (EU) 2016/679 and the EU Data Protection Regulation (DPR), i.e. Regulation (EU) 2018/1725. The protection of personal data is a fundamental right of EU citizens. In addition, the principles applied to delete commercially confidential information on the disclosure of EMA regulatory documents are also applied to determine access to information. Therefore, due to the often-detailed nature of some of the information, not all data elements can be disclosed.

Product data in PMS will be classified as follows:

- public: medicinal product data not considered commercially sensitive [e.g. medicinal product data available in the Summary of medicinal Product Characteristics (SmPC);];
- restricted: medicinal product data that is considered commercially sensitive or contains personal information (e.g. other information not available in the SmPC).

Information on PMS Access policy will be included in 'Chapter 5: Data access and exports' of the EU IDMP Implementation Guide, which is currently under development.

Training

To ensure that the product information submitted to PMS is in accordance with the guidance and processes described in 'Chapter 2: Data elements for the electronic submission of information on medicinal products for human use' and 'Chapter 3: Process for the electronic submission of information on medicinal products for human use' of the EU ISO IDMP Implementation Guide, the EMA will develop an online training course comprising of series of presentations, videos and step-by-step guides. Access to this training will be free of charge. Additional information on the location of the training materials as well as on the aspects of the knowledge evaluation will be made available in future updates of this chapter.

Once the training course is completed, participants will be invited to perform a knowledge evaluation test. Following a successful completion of this test a 'training confirmation' will be issued by the EMA.

The training will be mandatory for 'Qualified users'; 'training confirmation' will be required from at least one 'Qualified User' as part of the registration process before data submission can begin.

It will be the responsibility of the 'Super Users' to check that a 'training confirmation' is provided at the time of registration of all 'Qualified Users' before they approve their requests for access to SPOR on behalf of the organisation they are affiliated with. This measure is of utmost importance to ensure data quality assurance.

Qualified users who have been non-active for more than 6 months are advised to repeat the training course before initiating the process of medicinal product data submission.

Figure 1: Registration process overview to Access PMS via API and UI (once available)