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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 7

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Summary of changes

Following the publication of version 5 in October 2024, the following information has been removed:

- 3.2.1. Registration to PMS Application Programming Interface (API): the Note for NCAs included at the bottom of the paragraph has been removed

- 3.2.1.1. Temporary arrangements for NCA section has been removed

1. 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.

1.1. 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.

1.2. 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.

2. 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 shall 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 shall read this chapter in conjunction with the 'On-boarding of users to Substance, Product, Organisation and Referentials (SPOR) data services' document.

3. PMS Registration requirements

PMS authorised product data can be accessible via the following available tools:

- **PMS Application Programming Interface (API)** machine-to-machine connection

- **PMS Product User Interface (PUI)** hosted in Product Lifecycle Management (PLM) Portal

Depending on the tool the user intends to use, the user is required to follow the below registration process steps:

- Step 1: Common registration step: Request of the first Administrator user role for the same organisation

    - Step 2: Dedicated registration step based on the application intended to be used: all other users of the same organisation

In case the user shall also request other SPOR-related roles such as RMS and OMS, the 'SPOR User Registration Manual' provides a comprehensive step-by-step guidance which describes all existing SPOR RMS and OMS user roles and authorisation process flow. In addition, it provides detailed instructions on how to register and manage SPOR RMS and OMS roles.

3.1. Step 1: Request of the first Administrator user role for the same organisation

The process below described applies to both Industry and national competent authorities (NCAs) users.

To access PMS either from API or from PUI the first requirement is having an Administration role for the organisation the user intends to access products.

In order to start this process the user has to confirm the registration of the relevant organisation in Organisation Management Service (OMS).

User can check whether the relevant organisation is in OMS by searching using 'Request Access for Organizations' at EMA account management. In case the user's organisation is not in OMS, the user can request a new organisation. The 'OMS web user manual' describes how to register an organisation in OMS and can be found on the OMS portal, in section Document.

Once the Organisation is registered and the ORG-ID has been assigned, the second step for the user is to be registered in the EMA Account Management portal (IAM). The user must be 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 and in the PMS Product UI Registration Guide to access PUI.

The first role to be requested for the Organisation is the registration of the first 'Administrator' user in IAM. For Industry this role is equal to '**IRIS / PLM Industry Admin**' and for NCA it is equal to '**IRIS / PLM NCA Admin**'. The first Administrator role is always approved by IRIS / PLM EMA Admin user.

The role IRIS / PLM Industry Admin and IRIS / PLM NCA Admin refers to the previously named IRIS / eAF Industry Admin and IRIS / eAF Competent Authority Admin respectively. Users having this role granted prior the date of PMS go live (31 May 2024) will see their role name updated in their IAM account management platform and do not need to request it again.

To request the Admin role the user shall complete the [Letter of affiliation](). The letter of affiliation is a proof of authority that a 'User Administrator' of an organisation must submit to approve and revoke access for users of the same organisation.

The first request for a 'User Administrator' for each organisation is always evaluated and granted by EMA. For the role request to be approved, the letter of affiliation must be attached, duly filled in and signed.

Once the first Administrator user is approved, this user has the permissions to approve or revoke any other users affiliated to the same organisation such as other 'Administrator' user(s), regular 'Read/Users' and 'Read/Qualified Users'. Please note that this role does not grant direct access to PMS.

It is recommended that each organisation has at least two 'Administrator' users registered in IAM.

Please note that the administrator roles are shared with the PLM Portal, thus including eAF, ePI and the IRIS Portal. If user's organisation has worked with eAF, ePI and/or IRIS, he/she probably already has a user in the organisation with this role. Users should check within their IAM account before requesting it.

3.2. Step 2: Access based on the application intended to be accessed: all other users of the same organisation

The steps described in these sections apply when the first Administrator user has been approved by EMA, thus any subsequent request of user role for the same organisation can be approved or revoked by the Administrator user.

Similarly to the first step, in order to access the potential PMS PUI user is required to perform the following steps:

a. Ensure to have an active EMA user account — user can log in to user's EMA account or create an account at [EMA account management]()

b. Ensure the organisation the user is working for is listed in EMA's Organisation Management Service (OMS) — if the user has previously submitted applications, the relevant organisation is probably listed in OMS.
    Users can check whether user organisation is in OMS by searching using '[Request Access for Organisations]()' at [EMA account management]().
    In case the user's organisation is not in OMS, user can [request a new organisation]().

c. The third step is reported below and is based on the type of application the user intends to access.

3.2.1. Registration to PMS Application Programming Interface (API)

In this section is reported a step-by-step description of the **PMS API Registration Process** to follow when registering for PMS API access in the Production environment.

To access PMS API the user shall request the administrator user role (ie. **IRIS / PLM Industry Admin**' in case of Industry user and **IRIS / PLM NCA Admin**' in case of NCA user). This can be achieved upon completion of the step 1 if the user requesting access to PMS API is the first Administrator user of the Organisation or by completion of step 2.

This last step **applies to any other Administrator users not being the first user approved by EMA**. Once steps 2 a and b have been completed, the user can request the relevant administrator role in his/her EMA account management account. This role will be approved by the existing Administrator role of the same organisation.

In both cases, after the Administrator user request is approved the user can request access to PMS API through the menu item under drop down menu available to the left side.

User should expand the 'Manage Access' section and select the 'Request API Access' as depicted below:
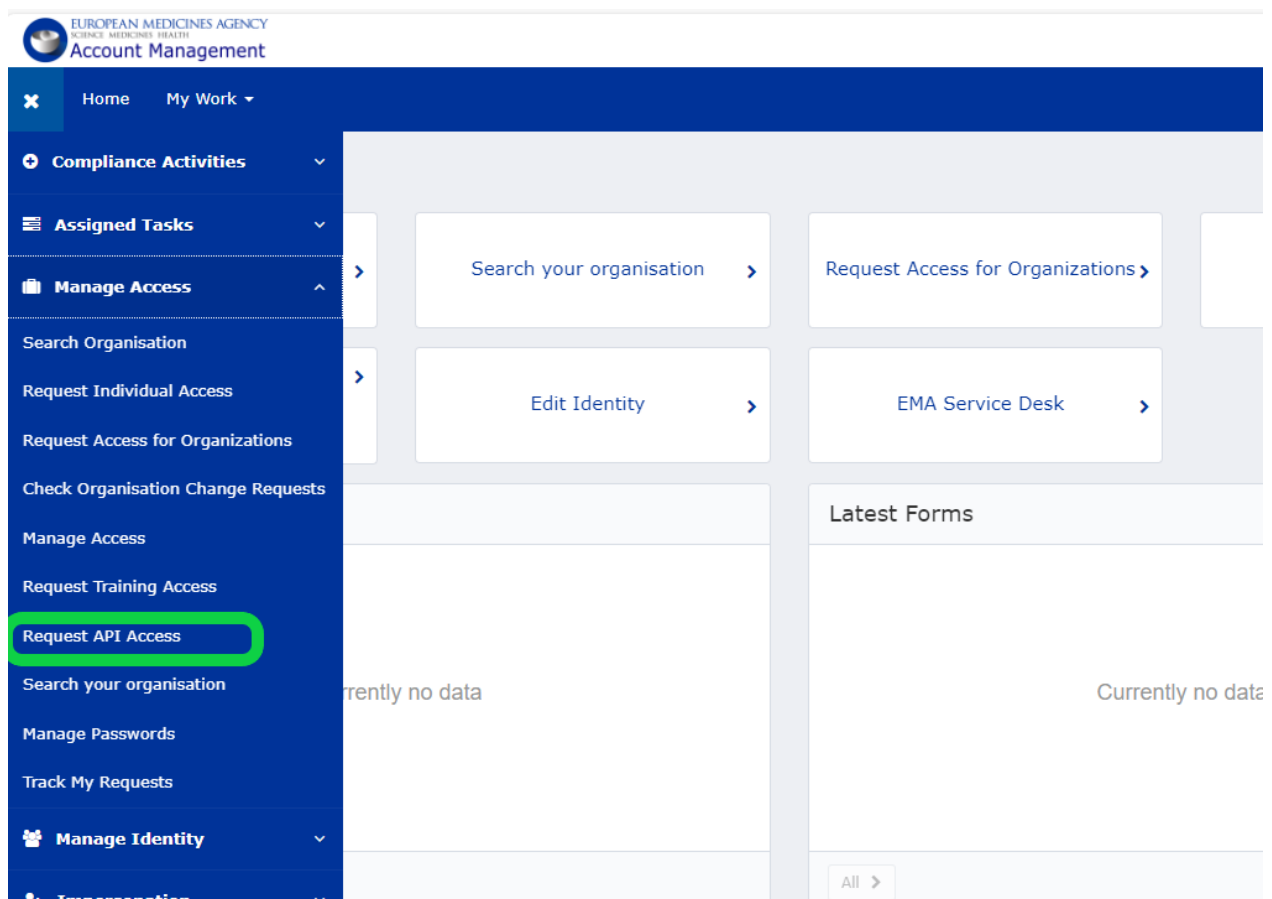

Figure 1: How to request PMS API access in IAM.

The first step is to agree to the EMA API General Terms and Conditions of Use as below reported.

Figure 2: Agreement to the EMA API Terms and Conditions

After having agreed to the EMA API Terms and conditions the user shall select/provide the following information:

- **PMS application**

- **Organisation** (ORG-ID) the Administrator user is registered for.

- An **e-mail address** the Administrator use can access. The API Client Credentials will be generated by this request and sent to the e-mail address indicated.

- select the **IRIS PLM role** (this role is equal to PMS Industry API role in case of industry; PMS NCA API role in case of NCA). **Note**: The naming in the "Select your Application" at the moment cannot be changed due to technical limitation. User shall select this type of application to be allowed to request the PMS API role in the last field of the form as displayed in the picture below.

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Figure 3: Request the API access; provision of user details.

Once the above steps have been completed the request is automatically approved by the system. The user will receive and email containing the following information necessary to access PMS API:

- Client ID

- Client Secret

- OAuth2 Token Endpoint

- Scope

Users shall take into consideration the following aspects:

- The protocol supported is OAuth2 Client Credentials flow.

- Registered users upon accessing PMS API can connect their internal system and access products data based on the need.

- The API Client Credentials are generated only upon request by the Administrator users. If multiple (not-administrator) users from the same Organisation wish to access PMS API should either:

    o   use the same set of credentials Or

    o   should set up the access into their internal system to meet their needs.

- EU IG Chapter 5 and Annex A provides clarification on the level of accessibility per stakeholder group and PMS data element. The principles outlined in this chapter can therefore be used to set up different level of accessibility in the NCA/Industry system (i.e. in case of consultancy companies working on their behalf).

Application Registration	
Object ID	8e379c2a-1385-409a-a22c-a467c79e643a
Client ID	e1e68a03-6b1f-47d1-a158-
Display Name	spor-apim-s2s-client

Application Secret	
Key ID	39ece8a8-7c7a-41a0-b63c-3220410926ff
Display Name	spor-apim-s2s-client-54
Expiration Date	10/20/2025 12:16:13
Secret	pKZ8C

OAuth 2.0 - Client Code Grant Flow

OAuth 2.0 token endpoint (v2)	GET https://login.microsoftonline.com/4efbf65c-4a81-4f2d-835a-e8630de67663/oauth2/v2.0/token
Scope	api://euemanp.

Figure 4: Example of contents included in the email generated by the system upon completion of the registration in IAM.

3.2.2. Registration to PMS Product User Interface (PUI)

To request the PUI user access role(s) to be assigned to the user's EMA account, users can access to the PMS Product UI - Registration Guide available in the Product Lifecycle Management (PLM) Portal. This guide aims to provides deep information on the type of PMS PUI user roles established, how to request access to PMS PUI portal and manage authorised products data in line with the EU IG Chapter 5 and Annex A.

When requesting access, users should take into consideration the following aspects:

- PMS PUI roles are assigned to single users and are granted at organisation level – not at PMS PUI level.

- **Multiple user roles** can be assigned to the **same user** of the **same organisation** (e.g. a user affiliated to organisation ABC can have the role of Administrator user, as well as a 'Read/Qualified User' **or** a 'Read/User'.)

- In case the Administrator user requests the Read/User or Read/Qualified User role, the request will be **automatically approved in its EMA account management account**.

- PMS PUI Users **shall not request two PUI roles (ie. PUI Read/User and PUI Read/Qualified user role**s) **for the same Organisation** as this will result in the higher privileges of the qualified user role bypassing the user role ones. Users with double role for the same organisation will access commercially sensitive information. For further information on the Access levels and accessibility based on each PMS data elements please read EU IG Chapter 5 and Annex A.

- For the **same organisation**, PMS PUI Users shall request their role taking into consideration the following **criteria**:

    o Shall the PLM user aim to request or is already granted the **eAF Contributor** role, only the **PUI Read/User role** (with lower privileges) shall be requested as these roles result in lower privileges.

    o Shall the PLM user aim to request or is already granted either the **eAF Coordinator** or **Manager** roles, only the **PUI Read/qualified user role** shall be requested as these roles result in higher privileges.

    o PLM Users **shall not request mixed eAF/PMS PUI roles for the same organisation** as this will result in the higher privileges bypassing the lower ones. However, PLM User can have different roles across different organisations.

    o The PUI NCA Qualified User role is not available. NCA can request the regular PUI NCA User to access the full PMS product data set available.

The figure below provides and overview on the PMS registration process.

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Figure 1: Overview on the PMS registration process

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4. Access to data

Access to PMS data is provided through the SPOR application programming interface (API) and Product User Interface. It is 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 as well as in the PMS PUI registration guide and in the EU IG Chapter 5 and Annex A to Chapter 5 describing the PMS Access Levels.

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.

The current API version is V3, only the HTTPS protocol is supported, and the authentication mechanism follows the OAuth2 Client Credentials standard. The current supported FHIR version is 4.4.0 (R5 Preview 2).

API Property	Value
Base Path	https://spor.azure-api.net/pms/api/v3
Protocol	HTTPS
Authentication	OAuth2 Client Credentials flow
FHIR Version	4.4.0 (R5 Preview 2)

The table below describes which endpoints are currently in scope.

API Endpoint	Name
EP301	Search Product
EP303	Get Product
EP304	Get Product Full
EP306	Get Product Version
EP307	Get Product Versions

Web UI access is described in the PMS PUI registration guide available on the PLM portal.

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. For further information on how data are classified please refer to EU IG Chapter 5 and Annex A to Chapter 5.

5. 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 will be made available in future updates of this chapter.

At the time of the PMS go live foreseen in Q2 2024, users will have read-only privileges in PMS. The enabling of the write privileges will be released for specific set of PMS data elements at later stage in Q4 2024.

Even though training is not mandatory to access, read and write the specific set of PMS data attributes authorised products data in PMS, users are strongly recommended to start familiarising with the released below video recording made available on EMA website before starting electronically handling and submitting authorised product data in PMS.

Product Management Services (PMS) deep-dive webinar | European Medicines Agency (europa.eu)

Product Management Service (PMS) Info-Day | European Medicines Agency (europa.eu)

This measure is of utmost importance to ensure data quality assurance.

In due course the Agency may consider to reserve the right of training confirmation in case of full data provision and enrichment of products data. Any change to the current process will be communicated in due time.

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.