16 January 2026
EMA/8954/2024
Information Management

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

Chapter 5: Data access to medicinal products for human use

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

Table of contents

Glossary

API Application Programming Interface

C Create

CI Confidential Information

D Delete

EC European Commission

EMA European Medicines Agency

EU DPR European Data Protection Regulation

EU European Union

GDPR General Data Protection Regulation

GPI General Public Information

IDMP Identification of Medicinal Products

IG Implementation Guide

ISO International Organisation for Standardisation

N No

PD Personal Data[1]

PII Personal Identifiable Information

PLM Product Management Lifecycle

PMS Product Management Service

R Read

SIAMED European Medicines Agency's product information and application tracking system

U Update

UI User Interface

WHO The World Health Organization

Y Yes

[1] Personal Data shall mean any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person; (Article 3(1) of Regulation (EU) 2018/1725).

Executive Summary

The European Medicines Agency (hereafter referred to as "the Agency"), Member States' competent authorities and the European Commission collectively comprise the European Union (EU) medicinal regulatory network. The network's responsibilities are the protection and promotion of public and animal health and the environment through the evaluation and supervision of medicines.

In line with the above, Articles 25 and 26 of Commission Implementing Regulation (EU) No 520/2012[2] mandates the use of International Organisation for Standardisation (ISO) Identification of Medicinal Products (IDMP) standards to support the submission and exchange of product data in PMS.

The above-mentioned electronic submission and maintenance product information for human use by the marketing authorisation holders is regulate in the Article 57(2) of Regulation (EC) No 726/2004.[3]

In the light of the above, the Agency has developed the EU IG Chapter 5 defining rules to access data applicable to medicinal product for human use authorised in the European Union.

This document defines the levels of stakeholder access to product data reported to Product Management Service (PMS). Product data are accessible throughout the Product User Interface (UI) and PMS-SPOR Application Programming Interface (API) whilst fully respecting the need to protect personal data as defined by the EU DPR[4] and the GDPR[5].

Commission Implementing Regulation (EU) No 520/2012 mandates that the Agency establishes and, in collaboration with the Member States, maintains, a Product Management Service database on human medicinal products (PMS), containing information on human medicinal products authorised within the European Union falling within the scope of Article 57(2) of Regulation (EC) No 726/2004 legal obligations. For further reference on medicinal products not falling in the scope of Article 57(2) of Regulation (EC) No 726/2004 legal obligations, please refer to section "Medicinal products in scope" available in the PMS EU IG Chapter 2.

This database shall also be used to contain further information such as product data related to the marketing status of authorised packaged medicinal products, information on the availability for each human medicinal product including the risk of shortage of supply of medicinal products[6], data on medical device used in combination with the medicinal products[7] and information on certified manufacturer and related manufacturing activities. PMS is currently designed to contain authorised product data updated as a result of the regulatory procedures (e.g., variations, initial marketing authorisation etc) requiring assessment as well as updated product data not requiring assessment for authorised human medicinal products. Articles 25 and 26 of Commission Implementing Regulation (EU) No 520/2012 Mandates Member States (MSs), marketing authorisation holders (MAHs) and the European Medicines Agency (EMA) to use the internationally agreed format and ISO IDMP standards for the exchange and communication of information on medicinal products.

[2] Commission Implementing Regulation (EU) No 520/2012 of 19 June 2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council.
[3] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency.
[4] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC.
[5] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation.
[6] Article 13 of Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices.
[7] Medical devices Regulation (EU) 2017/745, and in vitro diagnostic medical devices Regulation (EU) 2017/746.

Commission Implementing Regulation (EU) No 520/2012 laying down the necessary measures and practical arrangements for the product database on human medicinal products details the specifications to implement in order to fulfil the requirements of the mentioned Regulation.

In this context, it is mandated that detailed rules to access data be drawn up and applied by the Agency, in collaboration with the national competent authorities and the European Commission, and in consultation with marketing authorisation holders. EU IG Chapter 5 should enable actors to perform their obligations as provided for in Commission Implementing Regulation (EU) No 520/2012, while protecting confidential information and personal data. This guidance should therefore provide different levels of access to the Product Data processes.

1. Scope of this guidance

This guidance defines the overall principles for providing access to human medicinal product information held in Product Management Service (PMS), considering that the interest in and the use of the data may vary between stakeholders.

The chapter has been drafted with the aim of providing transparency and visibility of information on human medicinal products while protecting confidential information as defined by the Agency on the basis of the Regulation (EC) No 1049/2001. Requirements to protect personal data based on Regulation (EU) 2016/679 and Regulation (EU) 2018/1725[8] are reflected in the EU IG Chapter 5 accordingly.

'Human medicinal products' in this guidance include:

- authorised human medicinal products that fall under the scope of Article 57(2) of Regulation (EC) No 726/2004, as amended by Regulation (EU) 1235/2010 and Regulation (EU) 1027/2012;
- authorised and registered medicinal products falling out of scope of Article 57(2) of Regulation (EC) No 726/2004 legal obligations that may be submitted on a voluntary basis in line with the requirements and business processes as described in Chapter 2 of the PMS EU IDMP Implementation Guide. The above-mentioned products refer to:
    - investigational medicinal products;
    - products for which the marketing authorisation is not valid;
    - traditional use registration for herbal medicinal products (Article 16a(1) of Directive 2001/83/EC[9]);
    - simplified registration for homeopathic medicinal products (Article 14 of Directive 2001/83/EC);
    - medicinal products within the scope of Article 5 of Directive 2001/83/EC i.e., 'Named patient use' falling under Article 5(1) and 'EU Distribution Procedure' under Article 5(2);
    - parallel distribution/parallel import of medicinal products (Article 76(3) and (4) of Directive 2001/83/EC);
    - medicinal products authorised outside the European Economic Area (EEA) or following a non-EU procedure;

[8] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents.
[9] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

- extemporaneous Medicinal products (e.g., medicinal products prepared in a pharmacy based on a medical prescription such as pharmacy preparations);
- intermediate products intended for subsequent processing by an authorised manufacturer.

Article 57(1)(I) of Regulation (EC) No 726/2004 states, in relation to the level of product access, that:

1. the Agency shall create a database on medicinal products, to be accessible to the general public, and ensuring that it is updated, and managed independently of pharmaceutical companies; the database shall facilitate the search for information already authorised for package leaflets; it shall include a section on medicinal products authorised for the treatment of children; the information provided to the public shall be worded in an appropriate and comprehensible manner.

The description of individual scenarios and human medicinal products are further outlined in Annex A.

2. Guidance statement

The following aspects are addressed in this guidance:

- Objectives of the guidance.
- Characteristics of the guidance.
- Date of coming into effect of the guidance.

3. Objectives

EU Implementation Guide Chapter 5 has been developed with the goal of facilitating the maintenance of and accessibility to information on human medicinal products in the EU, within the overall aim of promoting and protecting animal and public health and the environment.

Furthermore, this chapter aims to meet the EU principles of transparency and openness while ensuring compliance with EU personal data protection legislation. The following objectives should be met, by providing proactive access to product information on human medicinal products:

1. Increasing availability of and access to public information on human medicinal products authorised;
2. Supporting the functioning of the internal EU market for human medicinal products;
3. Improving transparency of human medicinal products used in the EU;
4. Strengthening the decision making for the European Commission, national competent authorities and marketing authorisation holders by providing access to data analytics and reports;
5. Simplifying the regulatory environment and reducing the administrative burden by giving marketing authorisation holders and competent authorities access to the functionalities of PMS.

4. Characteristics of the guidance

Product Management Service (PMS) Database

The PMS comprises a range of functions required for the administration and quality management of information related to authorised human medicinal products as defined in ISO IDMP 11615 and 11616 and its secure electronic transmission. Additionally, the Product Database offers a specific mechanism for handling changes to the authorised data which occurs when these are based on regulatory or non-regulatory procedures, and which does or does not require assessment.

Different levels of access to PMS database must be defined and implemented to ensure that the different stakeholders interacting with the PMS can access the information necessary to fulfil their responsibilities as outlined in Regulation (EC) No 726/2004, as amended by Regulation (EU) 1235/2010 and Regulation (EU) 1027/2012 or enjoy their right to access information.

4.1. Access to PMS database

Access to PMS product data to the related documents is provided through the PMS-SPOR Application Programming Interface (API) and PMS Product User Interface (UI) hosted in the Product Lifecycle Management (PLM) portal.

Access is based on the PMS user roles available for each stakeholder group as described in the 'On-boarding of users to SPOR data services' document. This document is subject to periodic review.

4.1.1. Stakeholder groups

The stakeholders being granted access to PMS data can be grouped as follows:

- Stakeholders with interest in accessing authorised product data for regulatory purposes. This stakeholder group is reserved to organisations who requires to fulfil their legal responsibilities (i.e. marketing authorisation holders users) and whose role is to fulfil their responsibilities to protect public and animal health and the environment (i.e. national competent authority users, the Agency and the European Commission).
- Stakeholders with interest in accessing public product data for specific cases falling outside the regulatory scope. This stakeholder group is reserved for the general public (patients, consumers, including health care professional and academia, WHO).

Note: Access to authorised product data required by any other organisation not falling in the above stakeholder groups is defined on a case-by-case basis and in relation to the specific declared interest.

4.1.2. PMS General principles

Authorised human medicinal products are recorded in the PMS as derived from the current legal obligations placed on marketing authorisation holders as outlined in the Directive 2001/83/EC and Article 57(2) of Regulation (EC) No 726/2004, as amended by Regulation (EU) 1235/2010 and Regulation (EU) 1027/2012. The submission and maintenance of information on medicinal products for human use authorised in the European Union is required by provisions laid down in the above-mentioned legislation.

PMS gives the widest possible access to Human medicinal product data and to the related documents while protecting certain public and private interests, such as personal data and confidential information as defined by the Agency on the basis of Regulation (EC) No 1049/2001.

The implemented PMS data elements for human medicinal product data stored in the PMS are defined in the Articles 25 and 26 of Commission Implementing Regulation (EU) No 520/2012 mandating the use of ISO IDMP standards ('the Implementing Regulation') and further detailed in the EU IDMP Implementation Guide on human medicines product data in the Product Management Service database ('the PMS EU ISO IDMP Implementation Guide'). Additional ISO IDMP data elements can be further implemented in subsequent iterations of PMS.

In accordance with the above mentioned Articles of Commission Implementing Regulation (EU) No 520/2012, the use of the internationally agreed format and of ISO IDMP standards is required for the

exchange and communication of information on medicinal products by Member States, marketing authorisation holders and the European Medicines Agency (EMA).

Making product information in PMS available to the various stakeholders will:

- Increase access to information on medicinal products authorised for human use in the EU and EEA;
- Simplify the regulatory environment since data will be reviewed, assessed and approved as part of the new data operating model;
- Make regulatory action and decision-making more efficient thanks to improved data quality, integrity and reliability;
- Support meeting regulatory requirements more effectively by reducing data silos and improving interoperability across EU systems;
- Achieve operational savings and efficiencies as pharmaceutical companies need to supply regulatory data only once, which will be re-used across different procedures and regulators.

4.1.3. Personal Data Protection

The protection of personal data is a fundamental right of all European. The Agency, competent authorities and marketing authorisation holders are all responsible for ensuring integrity and confidentiality of human medicinal product data and protecting personal data by implementing appropriate technical and organisational measures to protect information and personal data processed against unauthorised or unlawful access, disclosure, dissemination, alteration, or destruction or accidental loss in accordance with the applicable law on personal data protection.

For the Agency, the provisions set out in Regulation (EU) 2018/1725 apply (EU DPR); for competent authorities and marketing authorisation holders, the rules set out in Regulation (EU) No 679/2016 (GDPR) apply.

The processing of personal data by the EMA is subject to the Data Protection Notice publicly available on the EMA webpage: Data protection and privacy | European Medicines Agency (europa.eu);

4.1.4. PMS Access Levels

Access is defined based on the stakeholder's interests and needs as well as the requirements of the EU DPR and GDPR. The access is further defined at different levels considering that due to the nature of the information not all data elements can be disclosed to avoid identification of data subjects or dissemination of confidential information.

Annex A to EU IG Chapter 5 lists all PMS human medicinal product data elements as laid down in the Implementing Regulation and outlines which can be accessed by the different stakeholder groups, based on the access levels described in Table 1.

Table 1. Description of access levels

Access Level	Stakeholder	Description
Level 1	General public Patient and Consumers Health Care Professionals Academia	Public subset of all authorised and registered human medicinal product.

Access Level	Stakeholder	Description
Level 2	Marketing Authorisation Holders Contractors, vendors and other external service providers working for the above companies on the PMS subject	Full access to both public and restricted subsets of their own authorised human medicinal product to fulfil their legal responsibilities for their own products. This level has sub-levels of access: • Level 2a providing full access to confidential information (CI) and Personal Identifiable Information (PII); • Level 2b providing access to General Public Information (GPI) and to confidential Information (CI) only, where applicable. Access to some confidential information (CI) and Protection of Personal Identifiable Information (PII) is not granted. For further information please refer to Annex A to Chapter 5.
Level 3	Competent authorities[10] Agency Contractors and external service providers working for the above authorities on the PMS subject European Commission	Full access to both public and restricted subsets of all human medicinal product data elements without restrictions.

PMS data are classified as follow:

- Confidential Information (CI) i.e. Manufacturer data
- Personal Identifiable Information (PII) ie. QPPV ID
- General Public Information (GPI) i.e. Medicinal product full name, Marketing authorisation number, Marketing authorisation holder.

4.1.5. Detailed description of access to human medicinal product data held in PMS, by PMS Access Level

The below sections provide detailed information on the level of accessibility of human medicinal product data held in PMS.

Access to authorised and registered product data required by any other organisation not falling in the stakeholder groups as reported in section 4.1.1. Stakeholder groups is defined on a case-by-case basis and in relation to the specific declared interest.

[10] Subject to clarification between EU Member State Competent Authorities. Further updates will be release in subsequent versions of this Chapter.

4.1.5.1. PMS Access Level 1

4.1.5.1.1. Human medicinal products in PMS

In accordance with Article 57(1)(I) of Regulation (EC) No 726/2004, the general public (including patients, consumers, health care professionals and academia, WHO) shall have access to public subset of data of authorised human medicinal product in PMS, without the possibility to change the information therein, as regards the list of the human medicinal products, the summary of product characteristics and, package leaflets.

Access Level 1 is reserved to any stakeholder with interest in accessing public product data for specific cases falling outside the regulatory scope.

Table 2. Access to PMS data by Level 1

Stakeholder	Access Level	Access Type
• General public • Patient and Consumers • Health Care Professionals • Academia • Internal Health Organisations	PMS Level 1: Subset of data elements for all human medicinal products reported to PMS (for details refer to Annex A)	Not required/controlled

4.1.5.1.2. Personal data protection requirements

Data access and provision is based on a defined human medicinal product data set (Level 1) in compliance with the Regulation.

4.1.5.2. PMS Access Level 2

4.1.5.2.1. Human medicinal products in PMS

In accordance with the Regulation, the organisations falling under the stakeholder group with interest in accessing authorised and registered product data for regulatory purposes shall have full access to public (Level 1) and restricted subsets of information reported in PMS.

Access Level 2 is reserved to allow users to fulfil their legal obligation and responsibilities for their own products (i.e. Marketing Authorisation Holders).

Table 3. Access to PMS data by Level 2

Stakeholder	Access Level	Access Type
• Marketing Authorisation Holders • Contractors, vendors and other external service providers working for the above companies on the PMS subject	PMS Level 2: Subset of data elements for human medicinal products owned by the relevant MAH and reported to PMS (for details refer to Annex A) classified as public and restricted with restriction as follow: • Level 2a providing full access to confidential information (CI) and	Authorised Personnel only

Stakeholder	Access Level	Access Type
	Personal Identifiable Information (PII); • Level 2b providing access to General Public Information (GPI) and to confidential information (CI) only, where applicable. Access to some confidential information (CI) and Personal Identifiable Information (PII) is not granted. For further information please refer to Annex A to Chapter 5.	

4.1.5.2.2. Personal data protection requirements

Data access and provision is based on a defined human medicinal product data set (Level 2) in compliance with the Regulation.

4.1.5.3. PMS Access Level 3

4.1.5.3.1. Human medicinal product in PMS

In accordance with the Regulation, the organisations falling under the stakeholder group with interest in accessing authorised product data for regulatory purposes shall have full access to both public and restricted subsets of all human medicinal product data elements without restrictions.

Access Level 3 is reserved to allow users to fulfil their responsibilities to protect public and animal health and the environment (i.e. national competent authority users, the Agency and the European Commission).

Table 4. Access to PMS data by Level 3

Stakeholder[11]	Access Level	Access Type
• National Competent authorities • Agency • Contractors and external service providers working for the above authorities on the PMS subject • European Commission	PMS Level 3: All data elements for human medicinal products reported to PMS (for details refer to Annex A) classified as public and restricted with no restriction	Authorised personnel only

[11] EU bodies and agencies having a clear role in the authorisation and supervision of medicinal product lifecycle.

4.1.5.3.2. Personal data protection requirements

Data access and provision is based on a defined human medicinal product data set (Level 3) in compliance with the Regulation.

Note: This guidance will be subject to revision and further releases based on the PMS progresses and deliverables.

Annex A – Product data elements accessible by stakeholder group

RCUD = Read, Create, Update, Delete

Y/N = Yes, No