EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Information Management

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

Introduction – EU Implementation Guide

Version 2.1.1.

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Summary of changes

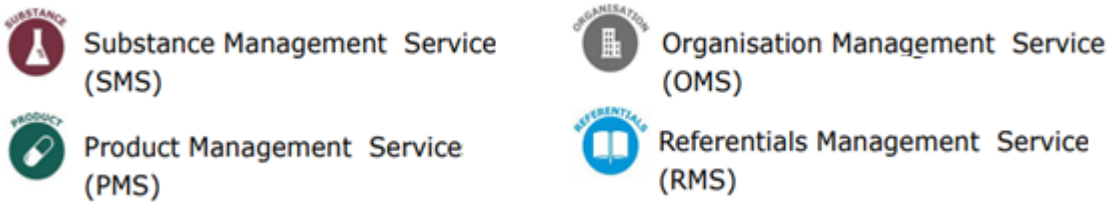
Following the publication of version 2.1 in June 2021, the content of sections *2. Chapters* and *3. Considerations* was amended to include information relevant to the publication of version 2.1.1. of the EU Implementation Guide (IG) documents to support the new web-based forms. Information relevant to the publication of version 1 of the documents was removed, while the information related to the publication of versions 2.0 and 2.1 was maintained.

1. Introduction

The International Organisation for Standardisation (ISO) Identification of Medicinal Products (IDMP) standards specify the use of standardised definitions for the identification and description of medicinal products for human use. The purpose of these standards is to facilitate the reliable exchange of medicinal product information in a robust and consistent manner, by providing a common product 'language' for stakeholders to use in their interactions.

The use of ISO IDMP standards is required in accordance with Articles 25 and 26 of Commission Implementing Regulation (EU) No 520/2012. These provisions mandate member states (MSs), marketing authorisation holders (MAHs) and the European Medicines Agency (EMA) to use ISO IDMP standards for the exchange and communication of information on medicinal products.

To pursue the implementation of the ISO IDMP standards, EMA has established services to support the management of master data including:



These services are together referred to as 'SPOR' throughout this guidance (Substance, Product, Organisation and Referentials Management Services).

Within the context of Product Management Service (PMS), implementation of the ISO IDMP standards is governed by the following specifications:

- ISO IDMP Implementation Guides (Technical Specifications): define the technical details on how to implement the standards, such as specific fields, their formats, and business rules describing their use;
- HL7 messaging specifications: define the messages that will be used to exchange IDMP information, which are based on HL7 (Health Level Seven) standards;
- EU Implementation Guide (EU IG): provides guidance on the interpretation of data fields specifically for the EU regulatory environment as well as guidance on the processes for submitting and updating data.

The EU IG has been prepared by the European Medicines Agency (EMA) upon consultation with different stakeholders (representatives of marketing authorisation holders and sponsors, national competent authorities, industry associations, international public organisations and software vendors) through the SPOR Task Force (SPOR TF) and the EU Telematics governance.

2. Chapters

The EU IG Version 2.1.1. is composed of the following chapters available on the 'Substances and products data management services' webpage:

Introduction – EU Implementation Guide: Introduction and Scope of the EU IG for implementation of ISO IDMP. (Updated in **EU IG v2.1.1.** release).

Chapter 1 – Registration requirements: Guidance on how to get access to SPOR (Substances, Products, Organisations and Referential Management Services). (Unchanged since **EU IG v2.0** release).

Chapter 2 – Data elements for the electronic submission of information on medicinal products for human use: Guidance on which medicinal product information (data fields and business rules) shall be submitted. (Updated in **EU IG v2.1.1.** release).

Chapter 3 – Process for the electronic submission of medicinal products information: Guidance on the processes driving the submission of medicinal product information. (This chapter was updated in EU IG v2.1 release. EMA will update Chapter 3 in due course to capture the impact of the new web-based forms in the data submission process).

Chapter 4 – Data quality assurance: (Scheduled for subsequent release of EU IG).

Chapter 5 – Data access/export: (Scheduled for subsequent release of EU IG).

Chapter 6 – Technical specifications: Technical specifications for the API, contains description of principles, security, resources, calls, endpoints**.** (Unchanged since **EU IG v1** release).

Chapter 7 – XEVMPD - PMS Migration guide: migration rules between the extended EudraVigilance Medicinal Product Dictionary (xEVMPD) and Products Management Services (PMS) including backwards compatibility rules. (Unchanged since **EU IG v1** release).

Annex I to EU IG Chapter 7 – Migration rules between SIAMED and PMS for Centrally Authorised Products (Published in EU IG v2.1.1. release).

Chapter 8 – Practical examples: A comprehensive list of practical examples to support the user in correctly populating the PMS data elements. (Updated in **EU IG v2.1.1.** release).

Annex I to EU IG Chapter 8 – Complete representation (Updated in **EU IG v2.1.1.** release).

Chapter 9 - Process for submitting existing data on medicinal products authorised for human use: (Scheduled for subsequent release of EU IG)

3. Considerations

3.1. About the EU IG

The **EU IDMP Implementation Guide (EU IG)** for the submission of data on medicinal products defines the implementation requirements of the **ISO IDMP standards** and will be the **basis for submission and exchange of medicinal product data in the EU**.

EMA published version one of the EU IDMP Implementation Guide (**'EU IG v1'**) in February 2020. It provided early information to help stakeholders plan and prepare their implementation of ISO IDMP standards in the EU.

EMA published version two of the EU IDMP Implementation Guide ('EU IG v2.0') in February 2021.

A minor release of the EU IDMP Implementation Guide ('EU IG v2.1') was published during 2021 to reflect the latest agreements and details available and prioritise improvements on data related aspects.

Subsequent versions of the **EU IG** will reflect the latest agreements and details available to support the full **implementation of PMS**.

3.2. About version two (v2.x)

The **EU IG v2** and additional minor releases (EU IG v2.1.1.) primarily support the **implementation of PMS** and the data submission of medicinal products authorized in the European Union by providing guidance on:

- user registration requirements as well as information on product data access;
- the **data elements** and the applicable **business rules** as well as practical examples (when the direct application of IDMP may be complex);
- the envisaged Target Operating Model and the **process** for submission, exchange and validation/assessment of medicinal product information.

The information provided in the EU IG v2.0 enables the European medicines regulatory Network to prepare for the submission of data on all medicinal products for human use authorised in the EU. It offers the basis for practical preparation activities such as performing Proof of Concept on the end-to-end process (generation and submission of FHIR messages, validation, interaction with eCTD) and test use cases (SmPC vs M3 data, placebo, use of IDs, ePI, DADI). For these PoCs a partnership between all stakeholders (Industry, Vendors, Regulators and NCAs) is crucial.

A phased release plan has been agreed with the Network and EMA is releasing several versions to the EU IDMP Implementation Guide to reflect the latest agreements, details available and enhance quality.

To minimise impacts to implementation, the **EU IG v2.1** and its sub-version (EU IG **v2.1.1.)** prioritises improvements on data related aspects to provide stakeholders clear visibility of data elements, business rules, data transformation and required data collection whereas EU IG v2.2 will focus mostly on process clarifications for the electronic submission of authorised medicinal product data in PMS.

The **current EU IG v2.1.1.** provides further details on the data elements introduced to support the new web-based forms, updated business rules and FHIR paths for those data elements, updated details on the applicable RMS lists, as well as further examples and clarifications. These updates are reflected in EU IG Chapter 2 and 8.

Although the data fields and specification presented in EU IG v2.1.1. are expected to be stable, some business rules may be subject to minor modifications in future releases of the EU IG (i.e., minor modifications may occur in subsequent releases of EU IG Chapter 2 and 8).

In relation to Chapter 3, this chapter was updated in EU IG v2.1 release. This chapter is expected to be updated in due course to capture the impact of the new web-based forms in the data submission process

Additional EU IG Chapters will be developed and published as part of the subsequent versions of EU IG to support the European medicines regulatory network and to prepare for the full PMS implementation.

The specification of the SPOR API, as reflected in Chapter 6: Technical specifications is subject to development and testing. As with any software, it may evolve over time and will be subject to change control.

In relation to Chapter 7, this has unchanged since EU IG v1 release. However, Annex I to EU IG Chapter 7 is temporarily published in EU IG v2.1.1. release to specify the migration rules between SIAMED and PMS for Centrally Authorised Products. This Annex is developed to support the initial release of the new web-based forms. Further updates to Chapter 7 are expected to be published before the next release of the web-based variation forms. Both, the EU IDMP Implementation guide and the SPOR API, can be expected to evolve with understanding of business processes and requirements and application of technological improvements, although no significant changes are expected.

4. User access & confidentiality

Data access and permission for using different functionalities of the SPOR system (view, edit, nullify, extract) is granted in accordance with a SPOR user access policy described in section 5.1 of the 'SPOR User Registration Manual'. This user access policy describes different roles and permissions for each stakeholder group, i.e., marketing authorisation holders, pharmaceutical industry, national competent authorities and EMA. Additional information can be found in Chapter 1: Registration requirements and in the 'On-boarding of users to Substance, Product, Organisation and Referential (SPOR) data services' document.

It is planned that a subset of the information contained in the SPOR database will be made available for public access once a PMS user interface (or other relevant user interface with data feeds from the PMS system) is developed. The aim is to allow the general public to retrieve information about authorised medicinal products in the European Union/European Economic Area. As a general rule, such public access will only include information (attributes) that is already available to the public through other sources (for example SmPC, EPARs or information in public databases).

Additional information on the specific attributes with restricted or open access will be made available in future versions of the EU IG.

5. References

Where possible, the EU IG and more specifically the data fields and associated business rules present in Chapter 2 –Data elements for the electronic submission of information on medicinal products for human use are based on the implementation or adaptation of the ISO IDMP standards into the European Medicinal Products regulatory framework. In the scenario where the information in ISO standards and the EU IG differs, the information or business rules mandated in the EU IG should be taken as the main reference. Overall, SPOR uses as reference the standards listed below:

- ISO 11238, Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on substances
- ISO 11615, Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information
- ISO 11616, Health informatics — Identification of medicinal products — Data elements and structures for unique identification and exchange of regulated pharmaceutical product information
- ISO 11239, Health informatics - Identification of medicinal products - Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging
- ISO 11240, Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of units of measurement
- ISO/TS 19844, Health informatics — Identification of medicinal products — Implementation guidelines for data elements and structures for the unique identification and exchange of regulated information on substances
- ISO/TS 20440, Health informatics — Identification of medicinal products — Implementation guide for ISO 11239 data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging
- ISO/TS 20443, Health informatics — Identification of Medicinal Products — Implementation guide for ISO 11615 data elements and structures for the unique identification and exchange of regulated Medicinal Product information
- ISO/TS 20451, Health informatics — Identification of Medicinal Products — Implementation guide for ISO 11616 data elements and structures for the unique identification and exchange of regulated pharmaceutical product information