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 2.0

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Summary of changes

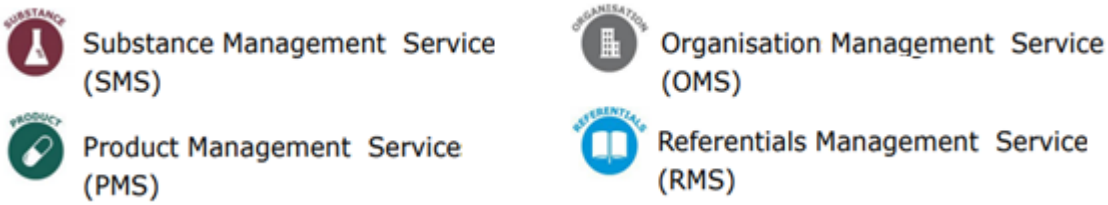
Following the publication of version 1 in February 2020, the content of sections 2. Chapters and 3. Considerations was amended to include information relevant to the publication of version 2.0 of the EU Implementation Guide (IG) documents. Information relevant to the publication of version 1 of the documents was removed from this section.

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.

In order 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 2.0 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 v2.0** release).

Chapter 1 – Registration requirements: Guidance on how to get access to SPOR (Substances, Products, Organisations and Referential Management Services). (Updated in **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 v2.0** release. This chapter may be subject to minor updates in v2.1 and 2.2 releases).

Chapter 3 – Process for the electronic submission of medicinal products information: Guidance on the processes driving the submission of medicinal product information. (New chapter created and included in **EU IG v2.0** release. This chapter may be updated to contain additional significant clarifications in v2.1 and 2.2 releases).

Chapter 4 – Data quality assurance: (scheduled for **EU IG v3** release).

Chapter 5 – Data access/export: (scheduled for **EU IG v3** release).

Chapter 6 – Technical specifications: Technical specifications for the API, contains description of principles, security, resources, calls, end-points**.** (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).

Chapter 8 – Practical examples: A comprehensive list of practical examples to support the user in correctly populating the PMS data elements. (New chapter created and included in **EU IG v2.0 release.** This chapter may be subject to minor updates in v2.1 and 2.2 releases).

Chapter 9 - Process for submitting existing data on medicinal products authorised for human use: (scheduled for **EU IG v3** release)

Note: The chapters which are not included in the EU IG version 2.0 publication are scheduled to be released with version 3 of the EU IG (EU IG v3). Any of the above-mentioned outstanding chapters may be deprioritised and removed during the development of EU IG v3.

3. Considerations

3.1. About the EU IG

EMA published version one of the EU IDMP Implementation Guide ('EU IG v1') in February 2020. It provided early information to stakeholders on the specification, data elements and associated business rules in preparation for implementation of ISO IDMP standards in the EU.

The EU IDMP Implementation Guide version two ('EU IG v2.0'), describes the high level principles of the target operating model for the submission and maintenance of medicinal product data in the EU, provides further guidance on how to populate the PMS data elements, and will be the basis for medicinal product data exchange in the EU.

The EU IG v2.0 is the basis for the European medicines regulatory network to prepare for the PMS implementation and primarily supports the **implementation of PMS Step 1**. The information provided in the EU IG v2.0 are deemed necessary to prepare the Network for the data submission of medicinal products authorized under the centralised authorisation procedure (CAP) via PMS.

Subsequent versions of the EU IG v3 are planned to support the **implementation of PMS Step 2** and to reflect the latest agreements and details available.

3.2. About version two

The EU IG v2 primarily supports the implementation of PMS Step 1 and therefore is required to prepare the data submission of medicinal products authorized under the centralised authorisation procedure via PMS.

EU IG v2.0 provides clarifications on the concepts of the target operating model of PMS, process for submission, exchange or validation of medicinal product information.

It contains detailed guidance on the registration requirements, as well as information on product data access, and provides further clarification on the data elements to use for the electronic submission of information on medicinal products for human use and the applicable business rules.

It also provides practical examples aimed to support the SPOR users to correctly structure the product data when the direct application of IDMP data model may need additional guidance.

The information provided in the EU IG v2.0 are also deemed necessary to prepare the Network for the data submission of medicinal products authorised in the EU.

The EU IG V2.0 can be 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 subsequent versions to the EU IDMP Implementation Guide v2.0 ('EU IG v2.1' and 'EU IG v2.2') will be released during 2021 to reflect the latest agreements and details available and enhance the quality of the EU IG v2.

Although the data fields and specification presented in EU IG v2.0 are expected to be stable, some business rules may be subject to minor modifications as part of publication of the subsequent release of the EU IG v2.1 and v2.2 (i.e. minor modifications may occur in EU IG Chapter 2 and 8).

While overall no substantial changes are expected to the submission process defined it is expected that further details will be added particularly with regards to data migration and enrichment of data (i.e. updates are expected for EU IG Chapter 3).

Additional EU IG Chapters will be developed and published as part of the EU IG v3, to support the European medicines regulatory network to prepare for the second step of the 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.

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

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