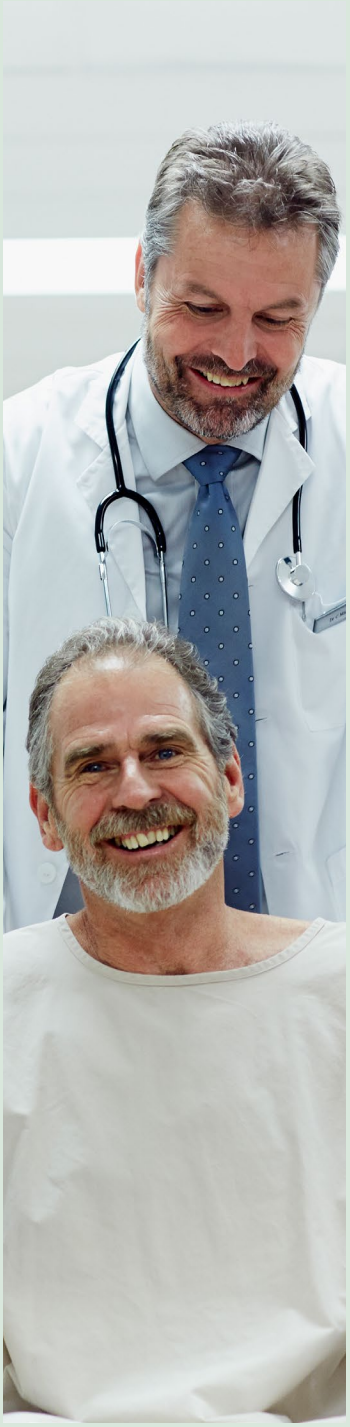
WHITE PAPER



IDMP IN EUROPE – THE JOURNEY SO FAR

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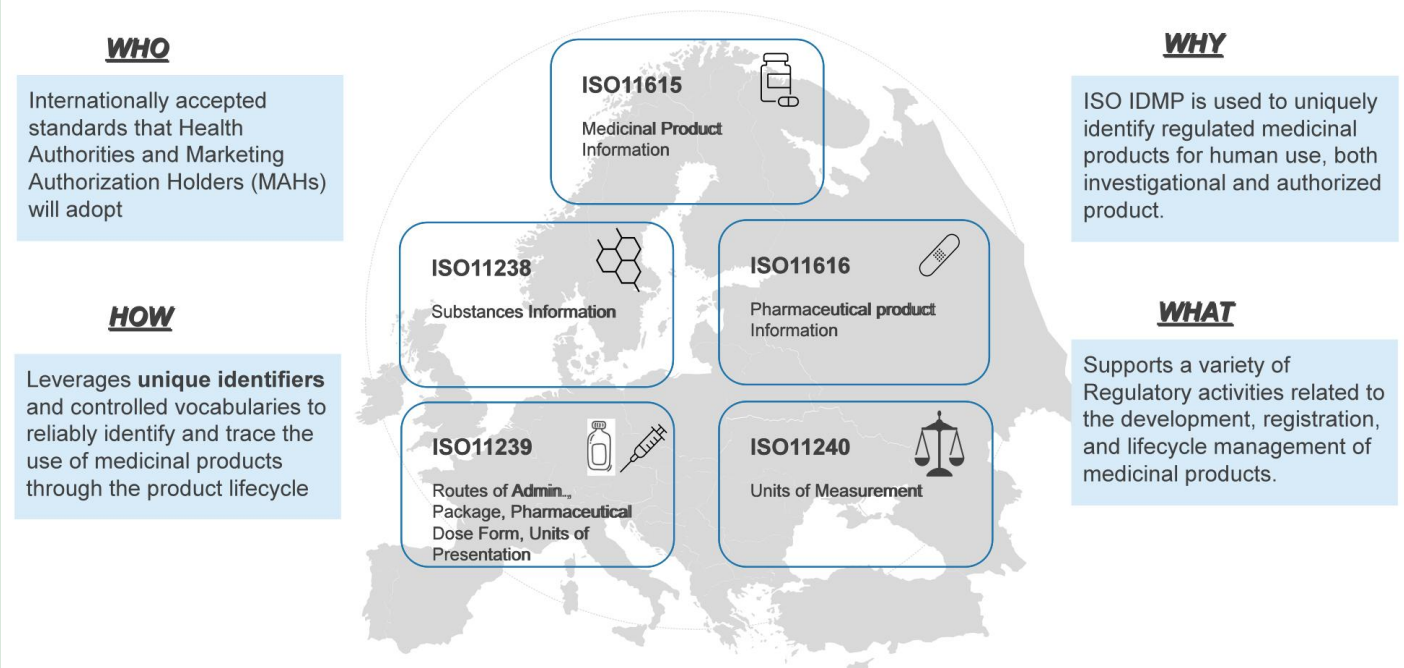
European Medicines Agency (EMA) is implementing ISO IDMP standards in the form of SPOR (Substances, Products, Organisations, Referential) master data management to support regulatory activities in the European Economic Area or EEA (EEA - includes EU countries plus Iceland, Liechtenstein, and Norway).

This whitepaper provides you with high-level information on ISO IDMP compliance covering regulatory background, data model benefits, milestones, and the challenges in implementing IDMP from the pharmaceutical industry perspective.

IDMP Regulatory Background

What is IDMP?

IDMP stands for "Identification of Medicinal Products", and it was initiated by ISO in 2012 with the aim to improve patient safety. To achieve this, ISO released five standards to support the exchange and harmonization of medicinal products information, globally. However, these standards were not prescriptive enough to cover the process to implement the IDMP data model.

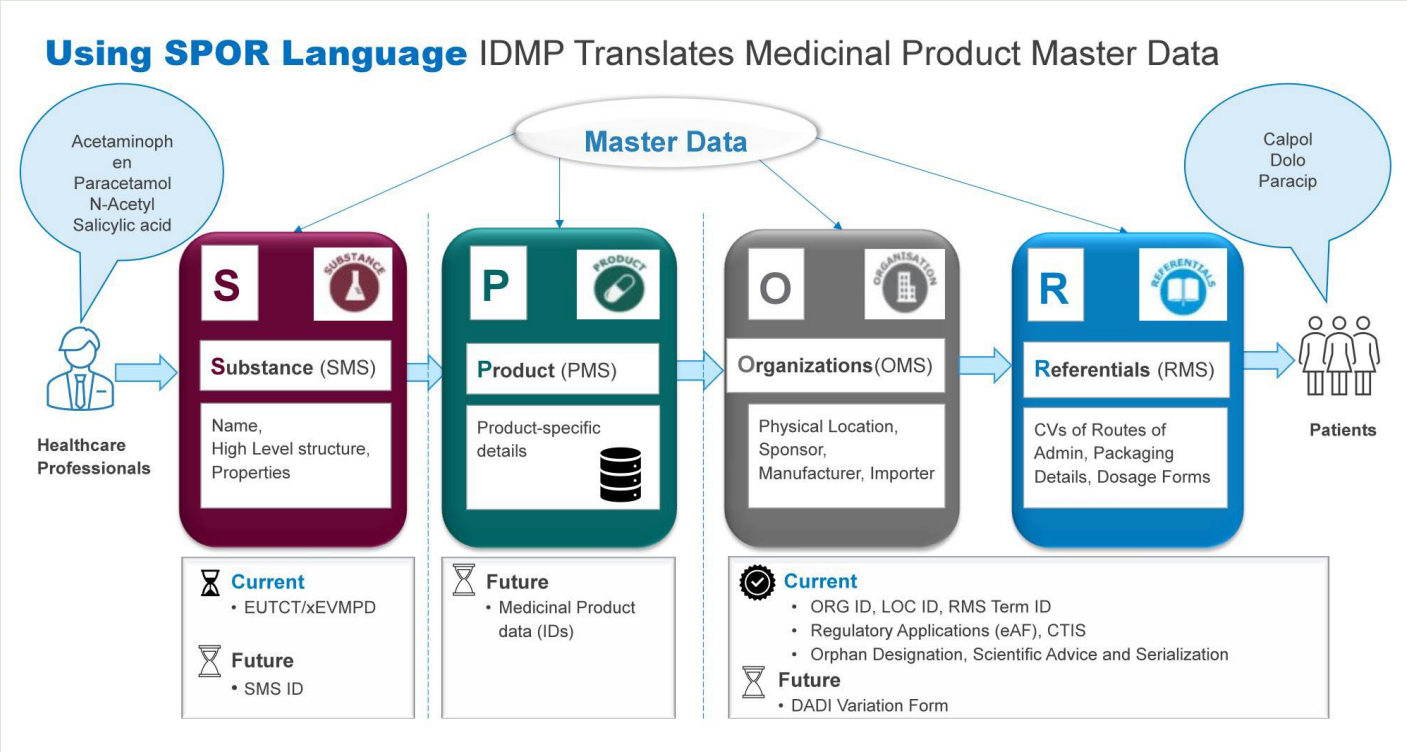


Source: EMA IDMP website

In the European context, EMA already has xEVMPD (eXtended EudraVigilance Medicinal Product Dictionary, also called Article 57 database) in place to collect, code, and report the Authorized Medicinal Products (AMPs) information in an XML-based submission (known as xEVPRM – eXtended EudraVigilance Product Report Message). In short, xEVMPD contains ~57 data elements of all the AMP information in the European Economic Area. To register a medicinal product in the xEVMPD database, Marketing Authorization Holders (MAHs) need to submit new license information in a standardized and structured format within 15 calendar days and their updates within 30 calendar days to xEVMPD (~Article 57 Database). Upon receipt of AMP (Authorised Medicinal Product) information, xEVMPD provides a unique identifier known as Product EV (EudraVigilance) Code for the submitted xEVMPD record in an acknowledgement file. This Product EV Code will be used for marketing authorisation license maintenance like variations, renewal, withdrawal, etc.

After implementing xEVMPD in 2012, EMA recognized that it was a stop-gap measure as it only contained marketed product information, but not granular information related to pharmaceutical products, packaging details, marketing authorization details, clinical particulars, manufacturing sites, etc. Hence, EMA decided to implement the ISO IDMP data model as SPOR (Substances, Products, Organizations, Referential master data) to standardize and facilitate the exchange of medicinal product information robustly and consistently within EEA.

Besides, the scope of xEVMPD was limited to human medicines whereas IDMP scope includes human and veterinary medicines.



Source: EMA SPOR portal

EMA is delivering SPOR master data management services in a phased manner as follows:

- Substance Management Service (SMS) – provides harmonized data and definitions to uniquely identify the ingredients and materials that constitute a medicinal product.
- Product Management Service (PMS) – provides harmonized data and definitions to uniquely identify a medicinal product based on regulated information (e.g., marketing authorisation, packaging, medicinal product information including clinical particulars).
- Organisation Management Service (OMS) – provides organizational data such as organisations name, location, and address details, for Marketing Authorisation Holders (MAHs), sponsors, regulatory authorities, and manufacturers.
- Referentials Management Service (RMS) – provides code list libraries i.e., controlled vocabularies to describe attributes of products (e.g., pharmaceutical dosage forms, units of measurement, and routes of administration).

As part of SPOR implementation, OMS and RMS have already gone live in 2017 and are currently being used in Electronic Application Forms (eAFs) for submitting Marketing Authorization applications to EMA and National Competent Authorities (NCA). On the other side, EMA is iteratively implementing PMS and SMS. The first iteration covers a few sections of the ISO IDMP data model, and the future iterations will cover the remaining sections in the EU.

SMS was enabled in 2019 through EMA Service Desk for users requesting the registration of new substances or for updating an existing substance term. Thus, EMA is managing the substance data. In Future iterations, SMS will be synchronized with the European Substance Reference System (EU-SRS) database and then it will be publicly available.

The first iteration of the PMS includes ~160 data elements of the Authorised Medicinal Product data model of the ISO IDMP standards. During the first iteration, the new ISO IDMP compatible data submission format (HL7 FHIR message) replaces the current XML-based xEVMPD submissions. Future PMS iterations will implement the remaining Authorised Medicinal product data elements and the investigational medicinal product part of the ISO IDMP standards.

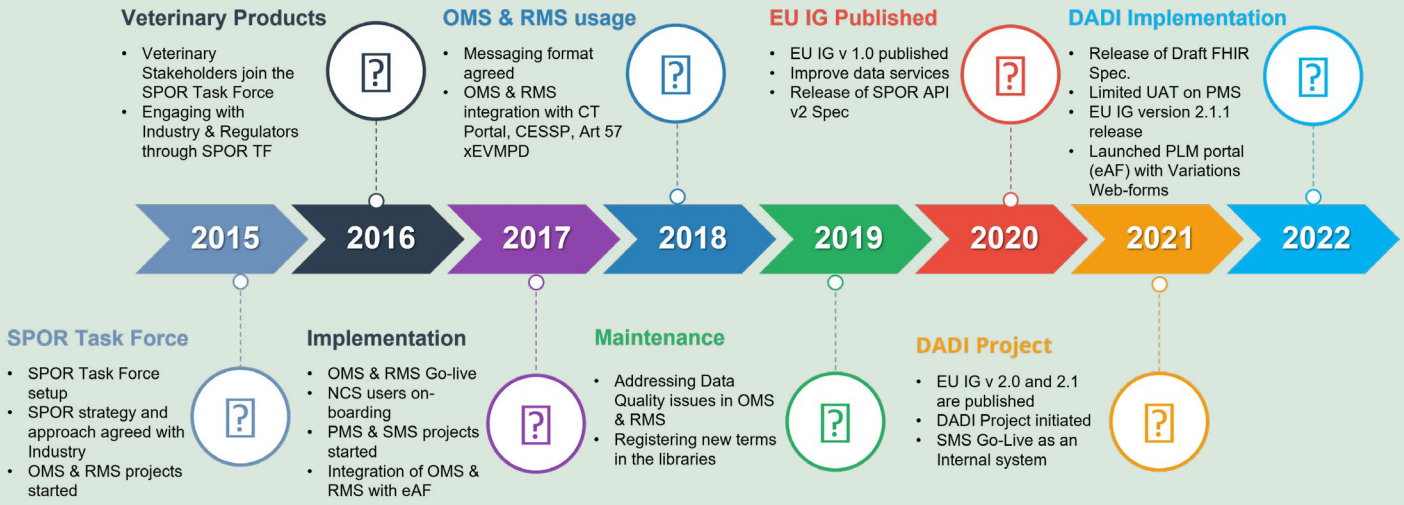
The users who have registered for the respective MAHs on the SPOR portal can request changes or additions to the master data held by EMA.

IDMP Benefits

ISO IDMP data model implementation provides multiple benefits to patients, healthcare providers, health authorities as well as the pharmaceutical industry.

- For patients and healthcare providers, ISO IDMP offers rapid and precise identifiers and key information on medicinal products.
- For health authorities, ISO IDMP improves data exchange on medicinal products through regulatory submissions or inspections and increases safety case reporting and signal detection. In addition, ISO IDMP ensures faster detection of Falsified Medicines (FMD/Serialization).
- For the pharmaceutical industry, ISO IDMP tracks medicinal product data through the entire product lifecycle. It will enable them to go "digital" in handling product information in processes or systems and in exchanging information with partners and HAs (Health Authorities).

EMA IDMP (SPOR) Milestones



Source: EMA SPOR portal

Industry Challenges in Implementing IDMP

- Requirements for IDMP submissions are dynamic (with every release of the EU Implementation Guide (IG) version, new attributes get added).
- Unclear IDMP terminology definition (controlled vocabularies are continuously evolving and not finalized).
- A delay in IDMP implementation by the pharmaceutical company will attract more unstructured data.

The Road Ahead: Latest updates from EMA on IDMP, DADI (Digital Application Dataset Integration), and xEVMPD

EMA IDMP Implementation

- EMA released the updated chapters of the EU IDMP implementation guide on 27th July 2022. As part of the new release, chapter 2 version 2.1.1 (Data Elements for the electronic submission of information on medicinal products for human use), Chapter 8 version 3 (Practical examples) and Annex 1 (Complete representation), and Chapter 7 version 2 (xEVMPD to PMS migration guide) were updated.
- However, some business rules may be subject to minor modifications in future releases of EU IG.

DADI Implementation

- Launched in November 2022, the Digital Application Dataset Integration (DADI) project replaced the current PDF-based electronic application forms for variations with new web-based forms in an updated portal i.e., PLM-eAF portal.
- Aligned with the ISO IDMP standard, DADI will be the first use of structured PMS.
- For CAPs (Centrally Authorised products) products, the web-based DADI variations form is available from November 2022.
  - Until September 2023, users can use the old eAF i.e., PDF form, or the new web-based DADI form
  - From October 2023, MAHs must use the web-based DADI form.
- For other procedures (National, Mutual Recognition & Decentralized Procedures) the existing interactive PDF forms are in use.

xEVMPD submissions

- xEVMPD data to be considered as a building block for the IDMP data set. Hence, xEVMPD data accuracy is key to securing the DADI implementation process.
- Migration of xEVMPD and SIAMED data will be crucial for DADI implementation.
- We can see the stepwise implementation of structured data fields in the overall process, but MAHs need to be prepared.
- xEVMPD submissions are still required following the current process. All medicinal products and all packages fall under the xEVMPD scope and should be compliant with Art 57 requirements.
- Applicants do not need to do extra work if they are already xEVMPD compliant.
- Some new medicinal products and packages not yet in xEVMPD scope may be required - all products need to be registered in xEVMPD even those out of scope for Art 57.

List of Abbreviations

- IDMP - Identification of Medicinal Products
- EU - European Union
- EEA - European Economic Area
- EMA - European Medicines Agency
- IG - Implementation Guide
- HA - Health Authority
- MAHs - Marketing Authorization Holders
- DADI - Digital Application Dataset Integration
- PLM – Product Lifecycle Management
- eAFs - electronic Applications Forms
- SPOR - Management Services for Substances, Products, Organisations, and Referential Terms
- SMS - Substance Management Service
- PMS - Product Management Service
- OMS - Organisation Management Service
- RMS - Referentials Management Service
- XML - Extensible Markup Language
- xEVPRM - eXtended EudraVigilance Product Report Message
- EU-SRS - European Substance Reference System
- HL7 - Health Level 7 standards organization
- FHIR - Fast Healthcare Interoperability Resources
- NCA - National Competent Authority
- FMD - Falsified Medicines Directive
- xEVMPD - Extended EudraVigilance Medicinal Product Dictionary
- AMP - Authorised Medicinal Product
- CAPs - Centrally Authorized Products
- SIAMED is a Spanish acronym that stands for Sistema de Información Automatizada sobre Medicamentos => Automated Drug Information System

Above mentioned futuristic dates are subject to change as per EMA's decision, hence please refer to EMA Website for the accurate futuristic release timelines.

About the Author

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Rajendra is a consultant with Infosys Consulting and has 10+ years of experience in Regulatory Operations, xEVMPD, IDMP & RIMS System Implementation and Data Management, Functional testing (OQ & PQ Testing) and Computer System Validation.

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