IDMP NEWSLETTER

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Volume 1 | May 5, 2023

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Identification of Medicinal Products (IDMP)

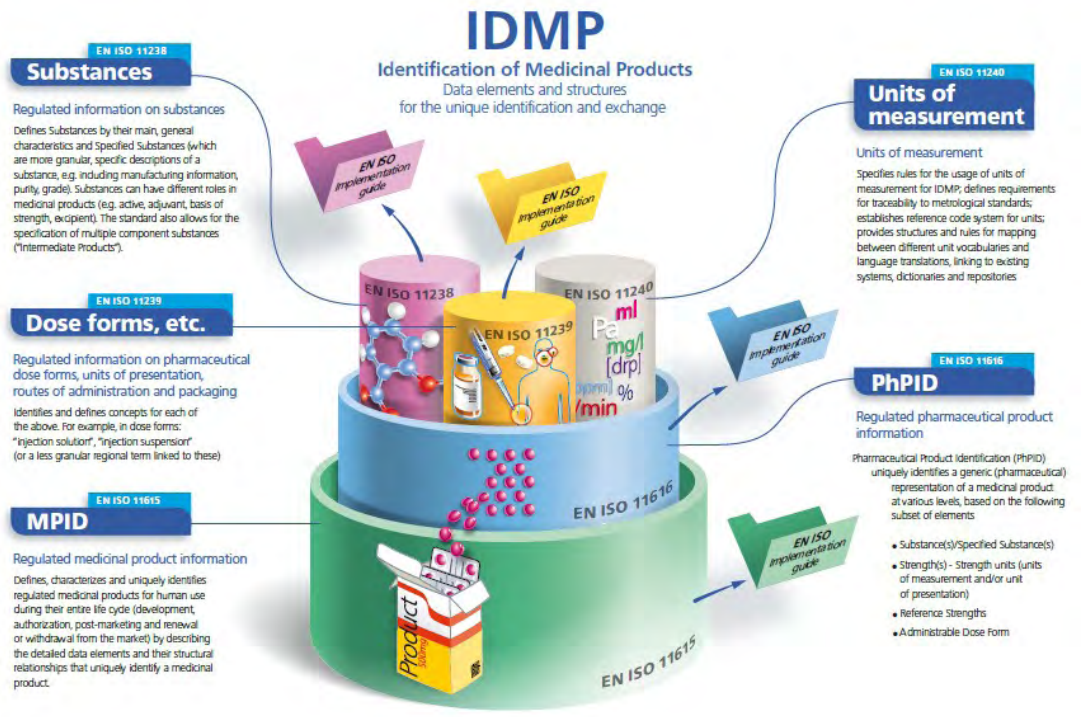
Identification of Medicinal Products (IDMP) is a collection of five International Organization for Standardization (ISO) standards developed to uniquely identify medicinal products for human use in the context of pharmacovigilance and patient safety through out the world.

Over the next few years, Regulatory Health Authorities (HAs) are planning to implement the IDMP standards to enhance patient safety. The forerunner in this marathon is the European Medicines Agency (EMA), which is using the Substances, Products, Organization, and Referential (SPOR) methodology for the implementation of the standards.

ISO IDMP covers the entire medicinal product lifecycle, including products in development, investigational products, products under evaluation, and authorized products.

Though ISO IDMP standards relate only to human medicinal products, SPOR applies to both human and veterinary domains.

In a nutshell, pharma companies marketing their products in Europe have regulatory implications that require them to submit product information in a prescribed format on an ongoing basis.



What is SPOR?

SPOR is the acronym for Sustances, Products, Organization, and Referential.

The EMA is implementing the standards in a phased program based on the four domains of master data in pharmaceutical Regulatory processes, which is the SPOR master data.

SPOR data services will act as the vehicle for implementation of ISO IDMP standards in the Regulatory and health sectors.

Is IDMP a Bane or a Boon?

Considerable effort is required from the Pharmaceutical Industry to establish IDMP-compliant data; and the compliance provides incredible opportunities to streamline internal processes and build synergy within an organization.

Unveiling the DADI Project

DADI, the Buzzword in the IDMP Space in the Recent Past...

The Digital Application Dataset Integration (DADI) project was initially announced in March 2021 to improve data interoperability. The DADI project builds upon the Common European Single Submission Portal (CESSP). Seven National Competent Authorities (NCAs) are collaborating regarding the setting up of the DADI project.

The core aim of the DADI project is to introduce new technology for forms, which is a key step in optimizing submissions handling processes and enabling the full use of Product Management Service(s) (PMS) master data.

The DADI project is expected to replace the current PDF file-based electronic application forms (eAFs) with a new eAF web-based portal. The initial release of which (web-based portal) is intened to cover variations forms for human medicinal products. The new eAF portal is expected to reduce the administrative effort that is currently necessary. The European Medicines Agency (EMA) has published the DADI implementation roadmap in August 2021.

DADI Web-based forms timeline

- 1st release on 04 NOV 2023: Variation for CAPs is online.
- 2nd release Q2/23 2023: CAPs + NAPs and start of transition phase.
- 3rd release Q1 2024: CAPs/NAPs in structured format.
- 4th release TBD: MAA form
- 5th release TBD: Renewal form

The web form sources the product data from the Product Management System (PMS). In the new form, applicants can select reference products and additional products that are relevant to the associated variation. The first release of the Variation Appliction Forms is successfully online since November 4, 2022. This version only covers variations of CAPs. The new form will not alter any of the existing submission processes of the EMA.

PLM, the new name for DADI...

The DADI name will gradually be phased out, and the new PLM portal will, in due course, host all eAFs.

The UNICOM project also supported the DADI's development with no contractual obligations with the EMA; UNICOM is specifically targeted to ensure the availability of pan-European ISO IDMP-compliant forms and IDMP implementation in national agencies.

We, the IDMP team @Freyr constantly update our knowledge on current trends and developments with regard to the implementation of the ISO IDMP standards across the globe by participating in webinars conducted by eminent institutions like the European Medicines Agency (EMA), IRISS and UNICOM.

IRISS is a non-profit organization which provides companies with a forum to stay current on Regulatory happenings.

The new eAF web forms for human variations will become mandatory for CAPs and NAPs in September 2023 as the six (06)-month transition period ends for companies.

What's Happening in the EU?

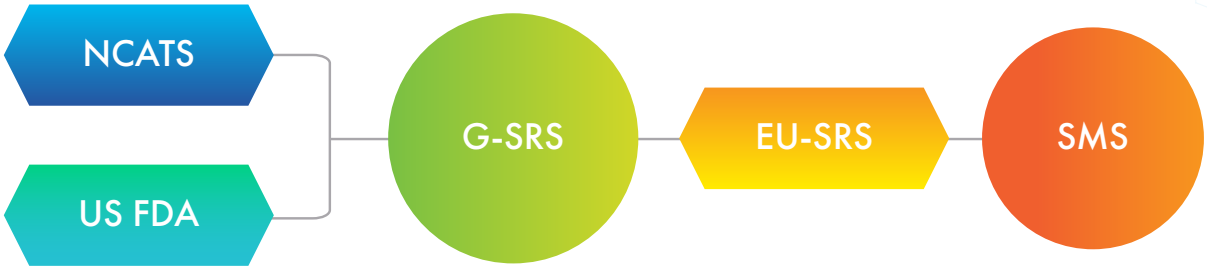
The EU Substance Registration System (EU-SRS) is Live Now...

A team of experts from the European medicines Regulatory network, national medicines authorities from the European Union (EU) member-states, and support from experts of the United States Food and Drug Administration (US FDA) and the US National Centre for Advaning Translational Sciences (NCATS), are executing a project to implement a European Substance Registration System (EU-SRS).

The EU-SRS provides scientifically sound descriptions of substances used in medicinal products in the EU by applying Regulatory standards for the identification of medicinal substances in accordance with the ISO IDMP standards. This is a core component in the identification of medicinal products.

The EU-SRS is making use of the Global Substance Registration System (GSRS) developed by the USFDA and NCATS.

The EU-SRS is live from January 25, 2023. It is hosted and maintained by the European Medicines Agency (EMA). Maintenance of data, guidelines, and standards for the EU-SRS is done by the Heads of Medicines Agencies (HMAs) Substance Validation Group (SVG).



Key substance information such as substance ID will be fed into Substance Management System (SMS)

The UNICOM (upscaling the global univocal identification of medicines) is yet another project that has been represented by nine-teen (19) coun-tries, including twenty-six (26) national Drug and eHealth Agencies help-ing to ensure that any medi-cine and what it contains can be accurately identified any-where in the world.

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About Freyr

Freyr is the largest, global, Regulatory solutions and services company that offers end-to-end Regulatory solutions to life sciences industries. The services include Regulatory affairs, pharmacovigilance, clinical research, quality management, and technology solutions such as Regulatory information management systems and Regulatory data integration. Freyr's expertise in Regulatory affairs makes it a trusted partner for life sciences companies seeking to navigate the complex Regulatory landscape.

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