IPRP
International Pharmaceutical Regulators Programme

9 April 2024
v5.0

International Pharmaceutical Regulators Programme (IPRP) Identification of Medicinal Products (IDMP) Working Group (WG)

IDMP Frequently Asked Questions

This document is intended to be "living" document which will be amended as needed.

Disclaimer
This document reflects the views of subject matter experts participating in the IPRP IDMP WG and should not be construed to represent the official views of any given regulatory authority participating in the IPRP.

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1. Global Regulatory Environment

Regulatory oversight of medicinal products entails both challenges and opportunities for regulatory authorities (RAs). Product development, manufacturing and distribution are often globalized and digitized enterprises, each with their own information collection and management standards that compartmentalize information into domain-specific databases.

Digitized information translates into vast quantities of medicinal products and regulatory data not all of which is uniform in structure, semantics, format, and content across jurisdictions and across IT systems. These challenges can be transformed into opportunities for enhanced oversight with the use of data standards; in particular, standardized data elements and structures that would uniquely identify individual medicinal products.

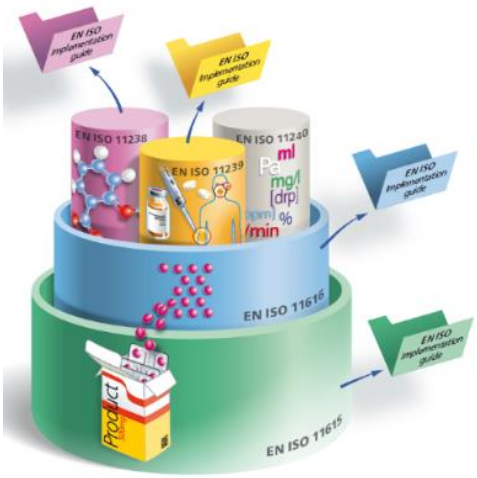
Harmonised approaches are needed to identify medicinal products across regions and regulatory and industry information systems. This need arises over the full lifecycle from clinical trials, manufacturing, authorisation, marketing, and safety / pharmacovigilance.

The standardized data structures and elements across IT systems and across jurisdictions, as currently used, do not exist, impeding the analysis of pooled data or the comparative analysis of data contained in separate databases. For example, an analysis of a safety event in clinical trials compared to post-market setting pharmacovigilance reporting is more complex because of different data representation/standards used to define and identify potentially related medicinal products.

Adoption of international standards to support harmonised data structures and to uniquely identify medicinal products can empower RAs to collaborate more effectively through electronic data exchanges and/or shared data analysis.

The ISO IDMP standards facilitate the identification and exchange of medicinal product information in an accurate and consistent manner to support regulatory and pharmacovigilance activities, drug shortage mitigation, and cross border healthcare. Implementation of the IDMP standards on a global level would improve interoperability across regulatory and healthcare communities, ensuring unambiguous communication.

2. What is IDMP?



Identification of Medicinal Products (IDMP) is a set of five standards developed by the International Organization for Standardization (ISO). Together, these five standards, along with their respective technical specifications, will make it possible to uniquely identify medicinal products and to standardize the electronic exchange of medicinal product data.

The IDMP standards establish common definitions, rules, identifiers, and data structures. In the "wedding cake" diagram[1] the bottom layer, ISO 11615, is known as the unique medicinal product identification. This standard encompasses product name (authorized by regulatory agency product (substance, dosage form, route), clinical particulars (e.g., indications, contraindications), pharmaceutical e of administration), medicinal product packaging, marketing authorization (e.g., authorization number, application information), and manufacturer/establishment.

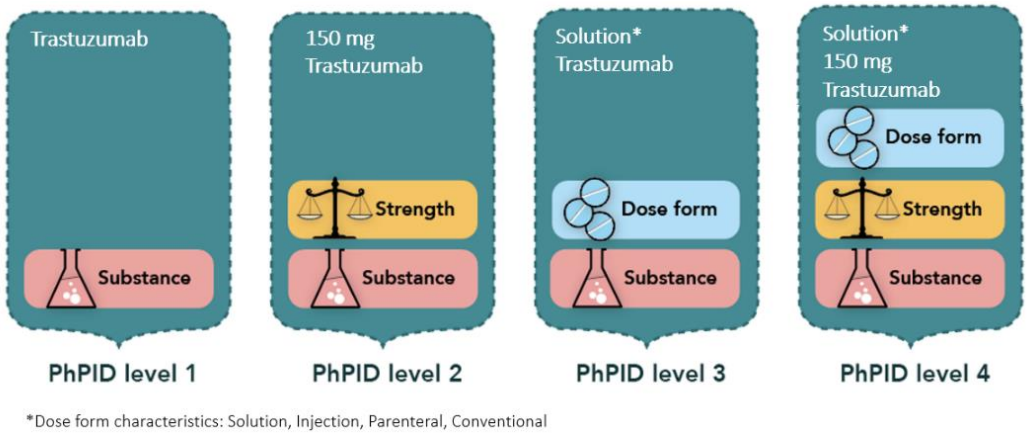
The next layer up is ISO 11616[2], which describes the pharmaceutical product identification standard. Pharmaceutical products are identified by the Pharmaceutical Product Identifiers (PhPID). The PhPIDs are generated based on the combination of substance (ISO 11238[3]), strength (ISO 11240[4]), and dose form attributes (basic dose form, administration method, intended site, and release characteristics) (ISO 11239[5]).

3. How Does PhPID Work?

In Figure 1, the PhPID for trastuzumab can be classified at four levels of granularity. Level 1 is generated using the substance ID only. Level 2 is substance and strength. Level 3 is substance and dose form. Level 4, the most precise level, includes substance, strength, and dose form information.

[1] https://isotc215-wg6.team/wp-content/uploads/2018/07/IDMP-flyer_final_light.pdf
[2] https://www.iso.org/obp/ui/en/#iso:std:iso:11616:ed-2:v1:en
[3] https://www.iso.org/obp/ui/en/#iso:std:iso:11238:ed-2:v1:en
[4] https://www.iso.org/obp/ui/en/#iso:std:iso:11240:ed-1:v1:en:e
[5] https://www.iso.org/obp/ui/en/#iso:std:iso:11239:ed-2:v1:en

Figure 1: Levels of Granularity for the PhPID[6]

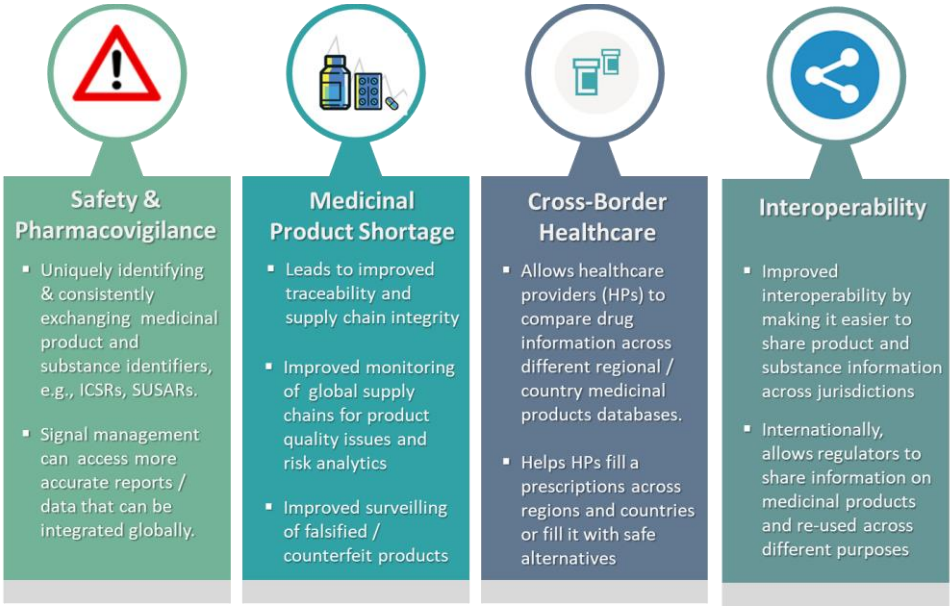


PhPID connects medicinal products within a region / country, and across regions. In the example trastuzumab 150 mg solution for injection marketed in the United States can be linked to the same products in European Union, Japan, and Brazil, because they all share the same PhPID level 4 information (i.e., substance, dose form characteristics, and strength).

4. Benefits of IDMP

Figure 2 below provides an overview of the key regulatory benefits of the implementation and use of the ISO IDMP standards.

Figure 2: Regulatory Benefits of IDMP



[6] https://who-umc.org/idmp/gidwg-working-group/

5. Implementation of IDMP Standards

The level of detail of the standards and their technical specifications is not sufficient to support a uniform global implementation. The standards must include several aspects / fields/ interests of regulators and industry and regional practices.

Therefore, they lack specificity in some areas to increase the global acceptance of the general concept, including things that everybody can agree on. There are efforts underway to address these challenges within the ISO TC 215 Working Group 6 community and other organizations. In the section below, we provide a brief status on some of the ISO IDMP standards.

5.1 What have been the approaches to adopting IDMP in the context of existing systems and standards?

In contrast to building a new system where none currently exists, it is recognized that for parties with existing medicinal product data systems that are not explicitly IDMP compliant, adopting the IDMP standards will need to be a stepwise effort to achieve the benefits. A first step learned from parties who have faced this challenge is that an initial assessment of current systems and standards is necessary to build an implementation plan.

5.2 What are the current considerations with Substance ID?

According to ISO 11238 and ISO TS 19844, to define or distinguish materials either at a Substance or Specified Substance level, a number of attributes need to be taken into consideration.

Regulatory authorities, along with industry are collaborating to harmonize and share common substance data and identifiers as part of their IDMP implementation projects. ISO TR 14872 provides a general framework of core principles and a general service delivery model for supporting implementation and ongoing maintenance of IDMP terminologies. A global Substance ID is a critical input criterion amongst other criteria for the generation of a global PhPID. Work is ongoing within a wider stakeholders' community to define the global substance identifier (e.g., EMA/EU SPOR, UNICOM project, FDA GSRS, and the Global IDMP Working Group (GIDWG)).

5.3 IDMP FHIR Exchange Standard?

EMA and FDA, United States are working together with Health Level Seven (HL7) International to incorporate the ISO IDMP standards into the Fast Healthcare Interoperability Resources (FHIR) specification to allow information exchange.

5.4 What are the current considerations with Medicinal Product ID?

An example on how the MPID can be implemented at a regional level together with some regional considerations is presented in the EU Implementation guide (current public version 2.1.1., Implementation Guide).

5.5 What is the Global IDMP Working Group?

GIDWG is a group established to conduct projects that lead to the implementation of the IDMP standards for global use (GIDWG). The founding members are European Medicines Agency (EMA), Food and Drug Administration (FDA, United States) and the World Health Organization Collaboration Center for International Drug Monitoring / Uppsala Monitoring Center (WHO/UMC). Other members include ANVISA, Brazil; Health Canada, Canada; SFDA, Saudi Arabia; Swissmedic, Switzerland and IFPMA.

The GIDWG was established as a follow-up to the IDMP Workshop hosted by the World Health Organization on 11-12 September 2019 in Geneva. The Workshop participants recommended projects focused on the creation and maintenance of global substance identifiers and PhPIDs that would lead to the global implementation of the IDMP standards and further outreach and collaboration with stakeholders.

The GIDWG completed five international pilot projects focused on: Substance Identifier, Dose Form Identifier, Strength, FHIR IDMP Exchange Standard and Operating Model for Global Maintenance of Identifiers. In 2024, GIDWG will report on end-to-end testing of the standards, including the specification of business rules for global implementation.

5.6 What are the current considerations with Dose Form?

The original ISO 11239:2012 standard was based on the use of central controlled terminology that regions could use to communicate with each other. The technical specification, TS 20440:2016 guide for ISO 11239, expected adopters to use a central controlled vocabulary or to map to it. However, currently, there is no agreement on a central vocabulary for pharmaceutical dose forms. The various levels of granularity across regional terminologies results in low accuracy when performing one-to-one mapping to a central controlled terminology.

In October 2020 a proposal was made at the International Standards Organization TC 215 WG6 meeting to use a centrally maintained set of dose form characteristics that are associated with the dose form term and code, for use in global IDMP, and in the generation of a global PhPID. The dose forms used for the PhPID generation are expressed according to three of the centralized EDQM dose form characteristics (and their codes): release characteristics, intended site, and administration method. Basic administrable dose form was included to describe the dose form (with or without transformation) that is administered to a patient.

The GIDWG conducted several pilot projects and the results confirmed that the subset of centralized dose form characteristics, as described in ISO 11239 and TS 20440, can be used as input in the generation of the global PhPID and will solve the issues with mapping between different dose form terminologies. The GIDWG provided recommendations to ISO WG 6 for updates to the doe form standard and those recommendations are reflected in the latest version of the ISO 11239:2023 standard. Further, recommendations to revise the substance, and PhPID standards are under active systematic review by the ISO TC 215 WG 6.

5.7 What are the current considerations with Pharmaceutical Product ID?

Although initially introduced and used for safety reasons related to pharmacovigilance the pharmaceutical product identifier (PhPID) can support wider use cases, for example to associate products of similar composition in different jurisdictions and identification of substitute products during a drug shortage. A unique global substance identifier and the use of a central set of dose form characteristics as input to a global PhPID have not been officially recognized at this time but the IPRP IDMP Working Group and the GIDWG support the international adoption.

6. Regulators Planning to Use Global IDMP Standards

6.1 European Medicines Agency (EMA)

The ISO IDMP standards are mandated by the EU legislation (*e.g.*, Regulation (EU) No 520/2012, Regulation (EU) 2022/123, etc.). EMA has been implementing the ISO IDMP standards in a phased programme based on the four domains of master data management in the pharmaceutical regulatory processes, that is, substances (SMS), products (PMS), organisations (OMS) and referentials (RMS) / aka SPOR and uses the HL7 FHIR standard for the exchange and publication of data concerning medicinal products for humans and veterinary use.

The RMS provides controlled terminologies and value sets to support the attributes of medicinal products (ISO 11615) and substances (ISO 11238) such as lists of pharmaceutical dose forms, units of presentation, routes of administration and packaging (ISO 11239), units of measurement (ISO 11240), etc. The OMS provides a single source of validated organisation data comprising organisation name and location address for organisations such as marketing authorisation holders, sponsors, regulatory authorities, and manufacturers that can be used as a reference to support EU regulatory activities and business processes. PMS will be used as a trusted source by the whole EMRN (European Medicines Regulatory Network consisting of EMA, NCAs (National Competent Authorities), and European Commission (EC) and it will replace public product data register in the European legacy systems. SMS services will be enhanced by the EU-SRS and FDA GSRS systems (they are currently supporting incremental implementation of ISO 11238 and ISO/TS 19844).

EMA, in partnership with FDA, United States, WHO, Member States, regulatory, industry and other stakeholders will continue the collaboration within ISO, HL7 and ICH on maintaining and further develop the IDMP standards, specifications and reports on the unique identification of medicinal products and substances, as well as implement and further develop the underlying HL7 FHIR messaging infrastructure for both human and vet domains. The Agency will continue to collaborate with the GIDWG and participate in global pilots/use cases to support use of standards for global implementation.

Eleven EU Member States are in partnership in the UNICOM project which has the objective to foster the IDMP implementation across Europe.

6.2 FDA, United States

FDA, United States continues to focus on the challenges of the global supply chain and external sourcing of medicinal products. FDA, United States' participation in the development, implementation, and use of global IDMP standards will ensure the safety of medications throughout the world. FDA, United States has been using standards and terminologies like the concepts presented in the IDMP standards. We have assessed internal operations and systems and determined that many of the terminologies and standards currently used in regulatory submissions across the medical product development lifecycle are compatible with the data concepts in Medicinal Product Identification (U.S. National Drug Code), Substance Identification (Unique Ingredient Identifier) and Units of Measure (Unified Code for Units of Measure).

FDA, United States will continue to collaborate with ISO, as well as other regulatory agencies, In March 2023, the FDA, United States issued guidance on Identification of Medicinal Products – Implementation and Use which recommends establishing a framework for the global implementation of the ISO IDMP standards and the maintenance of global identifiers.

FDA, United States intends for the framework to ensure that global identifiers are accessible to stakeholders for global pharmacovigilance, supply chain integrity, and reliable exchange of product information.

6.3 Swissmedic, Switzerland

Swissmedic, Switzerland is currently evaluating targets and priorities for the implementation of IDMP in connection with the replacement of internal platform systems. As far as implementation is concerned, Swissmedic, Switzerland will align as much as possible to the EU requirements and the EU timetable, applying a "fast follower strategy". However, the implementation will also have to consider some specific requirements for Switzerland. In addition, Swissmedic, Switzerland will ensure the data sovereignty of pharmaceutical and organizational data with its own databases.

Swissmedic, Switzerland is interested in sharing expectations, knowledge, and plans for the future implementation of IDMP. The first meeting with a group of experts from industry took place in Q2 2019.

6.4 Health Canada, Canada

Health Canada, Canada supports and is internationally engaged in the work for a global substance registry and IDMP. In 2023, Health Canada, Canada joined the Global IDMP working group to pursue projects leading to the establishment of IDMP standards and to help ensure better implementation of these data standards into Canadian systems and data policies. Additionally, Health Canada, Canada is working on accurately mapping existing pharmaceutical and biologic substances to UNII global identifiers and EDQM terminology. It has also undertaken other projects to accommodate the IDMP data model for health products including the replacement of legacy IT systems with those that support international

standards. Health Canada, Canada's earlier work used to support e-prescribing in Canada helped to establish the baseline and readiness of Canada's healthcare systems to adopt these data standards. Similar to other national regulatory authorities, Health Canada, Canada is fully interested in engaging and sharing expectations, knowledge, and plans for the future implementation of these important data standards.

In addition, Health Canada, Canada has established a data governance network to support better use, management and stewardship of Health Canada, Canada's data overall, including the eventual adoption of IDMP.

7. Additional Information on IDMP

- See the following links for more information.
  - International Organization for Standardization
  - Health Level 7 International
  - Implementation of Regulatory Information Submission Standards Forum (IRISS)
  - Global IDMP Working Group