IPRP
International Pharmaceutical Regulators Programme

15 October 2024
V6.0

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

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 presents both challenges and opportunities for regulatory authorities (RAs). The development, manufacturing, and distribution of these products are increasingly globalized and digitized, leading to the creation of diverse information systems with varying standards that often isolate data into specific domains.
This digitization results in vast amounts of regulatory data that differ in structure, semantics, format, and content across different jurisdictions and IT systems. These inconsistencies pose significant challenges but also present opportunities for improved oversight through the adoption of standardized data elements and structures that can uniquely identify medicinal products.

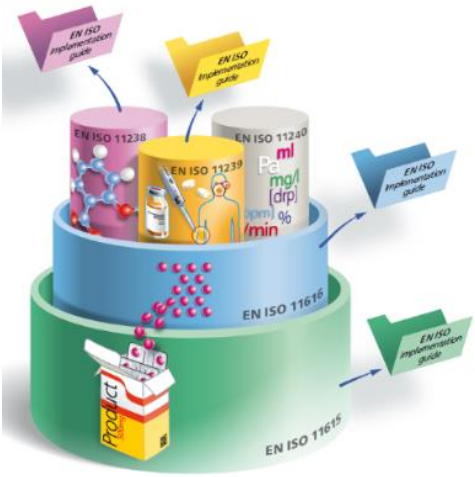
To effectively identify medicinal products across regions and integrate data within regulatory and industry systems, harmonized approaches are essential. This need spans the entire product lifecycle, from development to manufacturing, authorization, marketing, and safety monitoring (pharmacovigilance).

Currently, the lack of standardized data structures across IT systems and jurisdictions hampers the ability to analyze pooled data or compare data from different databases. For example, analyzing a safety event from clinical trials in the context of post-market pharmacovigilance reports becomes more complex due to differing data standards used to define and identify related medicinal products.

Adopting international standards to harmonize data structures and uniquely identify medicinal products will empower RAs to collaborate more effectively, enabling smoother electronic data exchanges and more comprehensive shared data analyses.

The ISO IDMP standards play a crucial role in facilitating the accurate and consistent identification and exchange of medicinal product information. These standards support regulatory and pharmacovigilance activities, help mitigate drug shortages, and enhance cross-border healthcare. Implementing IDMP standards globally will significantly improve data interoperability among regulatory and healthcare communities, ensuring clear and 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), 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.

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 similar products in European Union, Japan, and Brazil, because they all share the same PhPID level 4 information (i.e., substance, dose form attributes, and strength).

In Figure 2, the relationship between substance identification, pharmaceutical product identification, packaged product identification and medicinal product Identification is shown.

[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]

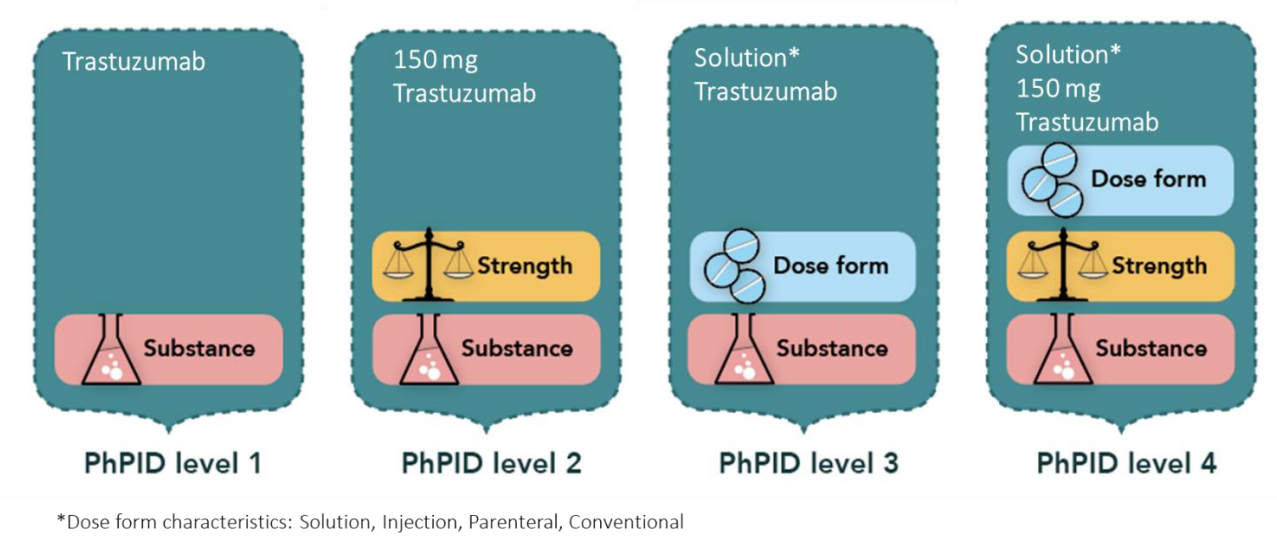
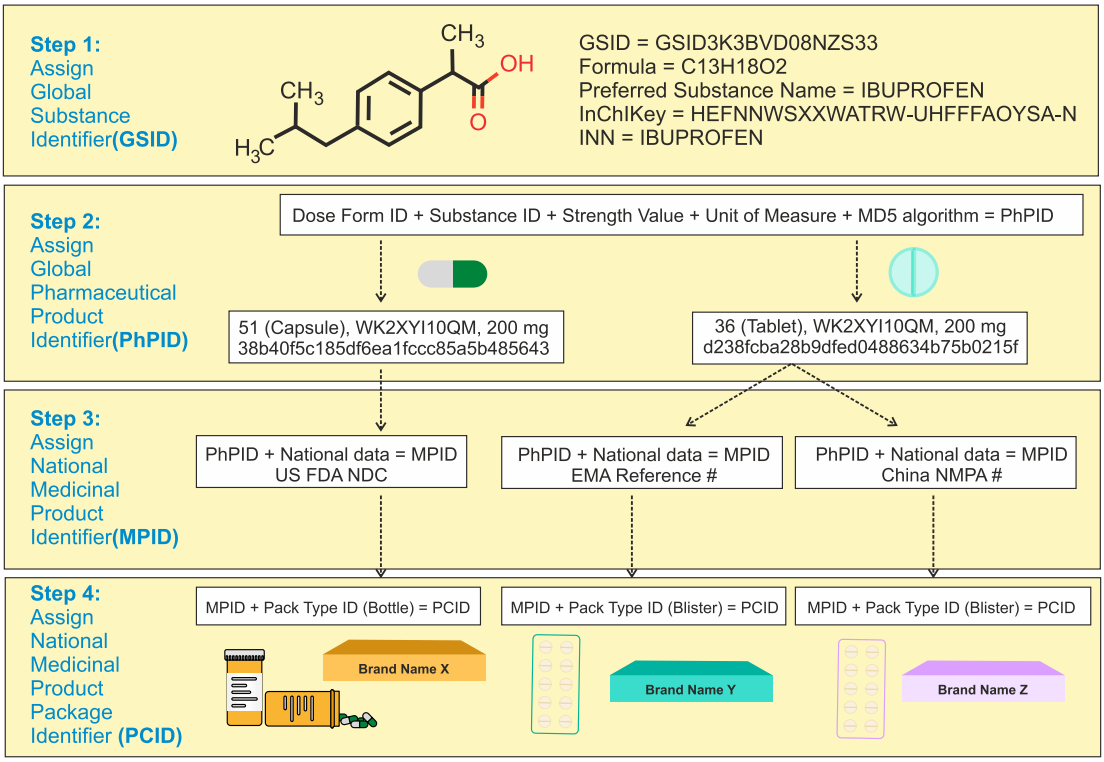


Figure 2: Global and National Identifiers (high level approach)



4. Benefits of IDMP

The implementation of the Identification of Medicinal Products (IDMP) standards offers numerous benefits across various aspects of healthcare, particularly in the areas of safety and

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

pharmacovigilance, medicinal product shortage management, cross-border healthcare, and interoperability (See Figure 3).

4.1 Safety & Pharmacovigilance

The IDMP standards enhance the safety and efficacy of medicinal products by providing a unified framework for identifying and tracking products throughout their lifecycle. By standardizing data elements and structures, IDMP enables more accurate reporting and analysis of adverse events, facilitating quicker identification of potential safety issues. This uniformity allows regulatory authorities to detect, assess, and prevent adverse effects more effectively, improving patient safety across the globe. Additionally, the consistent identification of medicinal products enables more reliable post-market surveillance, contributing to the overall robustness of pharmacovigilance systems.

4.2 Medicinal Product Shortage Management

IDMP plays a crucial role in mitigating medicinal product shortages by enabling better tracking and management of supply chains. The standardized identification of products allows for faster recognition of substitute or alternative products, which can be critical during shortages. By linking products with similar compositions across different jurisdictions, IDMP supports the identification of potential replacements, ensuring that patients continue to receive essential medications even when the original product is unavailable. This capability is particularly important during emergencies or supply chain disruptions, where rapid response is essential to avoid interruptions in patient care.

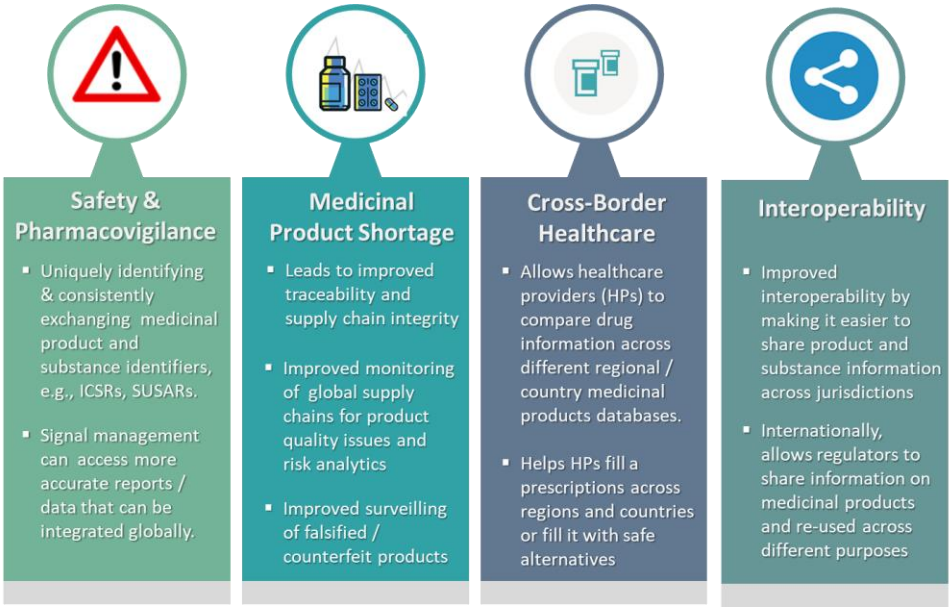
4.3 Cross-Border Healthcare

In the increasingly interconnected world of healthcare, the ability to deliver consistent care across borders is vital. IDMP facilitates cross-border healthcare by ensuring that medicinal products are identified consistently and unambiguously, regardless of the country of origin. This standardization enables healthcare providers in different regions to understand which products are being used, reducing the risk of errors in prescribing or dispensing medications. For patients receiving treatment in multiple countries, IDMP ensures that their medication history is accurately communicated, supporting continuity of care and improving health outcomes.

4.4 Interoperability

The IDMP standards are key to achieving semantic interoperability across different healthcare systems and regulatory frameworks. That is, a common language for identifying medicinal products across diverse IT systems that seamlessly and unambiguously enables efficient data exchange and integration. This form of interoperability supports a wide range of applications, from electronic health records to regulatory submissions, ensuring that the transfer of information about medicinal products between applications is accessible, accurate, and up to date across all platforms regardless of the inherent differences. As healthcare systems continue to adopt digital solutions, the role of IDMP in facilitating semantic interoperability becomes increasingly important, ultimately contributing to more coordinated and effective healthcare delivery.

Figure 3: Regulatory Benefits of IDMP



5. Implementation of IDMP Standards

The current level of detail in the IDMP standards and their technical specifications is insufficient to support uniform global implementation. To achieve global acceptance, the standards must account for various aspects, including regulatory, industry, and regional practices.

Due to the need for broader acceptance, some areas of the standards lack specificity. Efforts are ongoing within the ISO TC 215 Working Group 6 and other organizations to address these challenges. Below is a summary of the current status of various ISO IDMP standards.

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

For organizations with existing medicinal product data systems that do not explicitly comply with IDMP, a stepwise approach to adoption is necessary. Unlike starting from scratch, implementing IDMP in these systems requires an initial assessment of current systems and standards. This assessment forms the basis for building an effective implementation plan.

5.2 What are the current considerations with Substance ID?

ISO 11238 and ISO TS 19844 outline the attributes required to define or distinguish materials at either the Substance or Specified Substance level. Regulatory authorities and industry partners are working together to harmonize and share common substance data and identifiers as part of their IDMP implementation efforts. ISO TR 14872 offers a general framework and service delivery model to support the implementation and ongoing maintenance of IDMP terminologies. Establishing a global Substance ID is crucial for

generating a global PhPID. Ongoing work with various stakeholders, including EMA/EU SPOR, the UNICOM project, FDA GSRS, and the Global IDMP Working Group (GIDWG), aims to define a global substance identifier.

5.3 IDMP FHIR Exchange Standard?

EMA and FDA, United States are collaborating with Health Level Seven (HL7) International to incorporate ISO IDMP standards into the Fast Healthcare Interoperability Resources (FHIR) specification. This integration will facilitate the exchange of medicinal product information.

5.4 What are the current considerations with Medicinal Product ID?

The implementation of the Medicinal Product ID (MPID) at the regional level, along with specific regional considerations, is detailed in the EU Implementation Guide (current public version 2.1.1[7]).

5.5 What is the Global IDMP Working Group?

The GIDWG was established to lead global projects for implementing IDMP standards. The GIDWG deliverables are detailed business rules necessary for real-world implementations. Founding members include the European Medicines Agency (EMA), the U.S. Food and Drug Administration (FDA), and the World Health Organization's Uppsala Monitoring Center (WHO/UMC). Other members include regulatory authorities from Brazil (ANVISA), Canada, Saudi Arabia, Switzerland, El Salvador, and IFPMA.

The GIDWG was formed following the IDMP Workshop hosted by the WHO in September 2019. The workshop participants recommended projects focused on creating and maintaining global substance identifiers and PhPIDs to support the global implementation of IDMP standards. The GIDWG has completed five international pilot projects on Substance Identifier, Dose Form Identifier, Strength, FHIR IDMP Exchange Standard, and the Operating Model for Global Maintenance of Identifiers. In 2024, the GIDWG will report on end-to-end testing of these 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 relied on a centrally controlled terminology that regions could use for communication. The technical specification, TS 20440:2016, guided ISO 11239 adopters to use or map to this central vocabulary. However, no agreement currently exists on a central vocabulary for pharmaceutical dose forms, leading to inaccuracies in mapping between regional terminologies.

In October 2020, a proposal was made at the ISO TC 215 WG6 meeting to use a centrally maintained set of high-level dose form characteristics for global IDMP and PhPID generation. The dose forms used for PhPID generation are now expressed according to three centralized

[7] For the most recent version of the EU IG see: https://www.ema.europa.eu/en/human-regulatory-overview/research-development/data-medicines-iso-idmp-standards-overview/substance-product-organisation-referential-spor-master-data/substance-product-data-management-services#eu-idmp-implementation-guide-12045

EDQM dose form characteristics: release characteristics, intended site, and administration method. Basic administrable dose form was also included to describe the form administered to a patient.

The GIDWG conducted several pilot projects, confirming that the subset of centralized dose form characteristics, as described in ISO 11239 and TS 20440, could be used to generate the global PhPID and resolve mapping issues between different dose form terminologies. The GIDWG recommended updates to the dose form standard, which are reflected in the latest version of ISO 11239:2023. Additionally, revisions of the substance and PhPID standards are underway by ISO TC 215 WG6.

5.7 What are the current considerations with Pharmaceutical Product ID?

The Pharmaceutical Product Identifier (PhPID) was initially introduced for pharmacovigilance but has broader applications, such as linking products with similar compositions across jurisdictions and identifying substitute products during drug shortages. Although a unique global substance identifier and the central dose form characteristics are not officially recognized, the IPRP IDMP Working Group and GIDWG support their 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 were in partnership in the UNICOM project which had 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. The Agency has 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, 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