IPRP
International Pharmaceutical Regulators Programme

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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 over time.

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Disclaimer

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Global Regulatory Environment

Regulatory oversight of medicinal products in the 21st century 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 product 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 persist and identify medicinal products across regions, regulatory and industry information systems. This need arises over the fill lifecyde from clinical trials, manufacturing, authorisation, marketing, safety / pharmacovigilance. during the recent pandemic.

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 global 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 of a medicinal product can empower RAs to collaborate more effectively through electronic data exchanges and/or shared data analysis, as well as introduce efficiencies to any individual RA's oversight across the life cycle of medicinal products.

Background on IDMP

What is IDMP?

Identification of Medicinal Products (IDMP) is a set of five standards developed by the International Organization for Standardization (ISO) (www.iso.org). 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. All of which are outlined below:

- ISO 11615 – Medicinal product information
  - The standard describes the data used for market authorization of the medicinal product. Generally, it is much of the information submitted to the regulator, e.g., product name, manufacturer, packaged product details, dosage form and therapeutic indications. Multiple Medicinal Product Identifiers are codes controlled by responsible regulatory agencies. The European Medicinal Product identifier and the U.S. National Drug Code (NDC) will be examples of regional identifiers. ISO 11615 introduces a worldwide identification number

- ISO 11616 – Pharmaceutical product information
  - The standard describes this element and components that can be utilized to generate pharmaceutical product identifiers. These will identify pharmaceutical products that have the same criteria (like substance, dosage form and strength). With this a link to products in other regions or countries can be found. See Figure 1

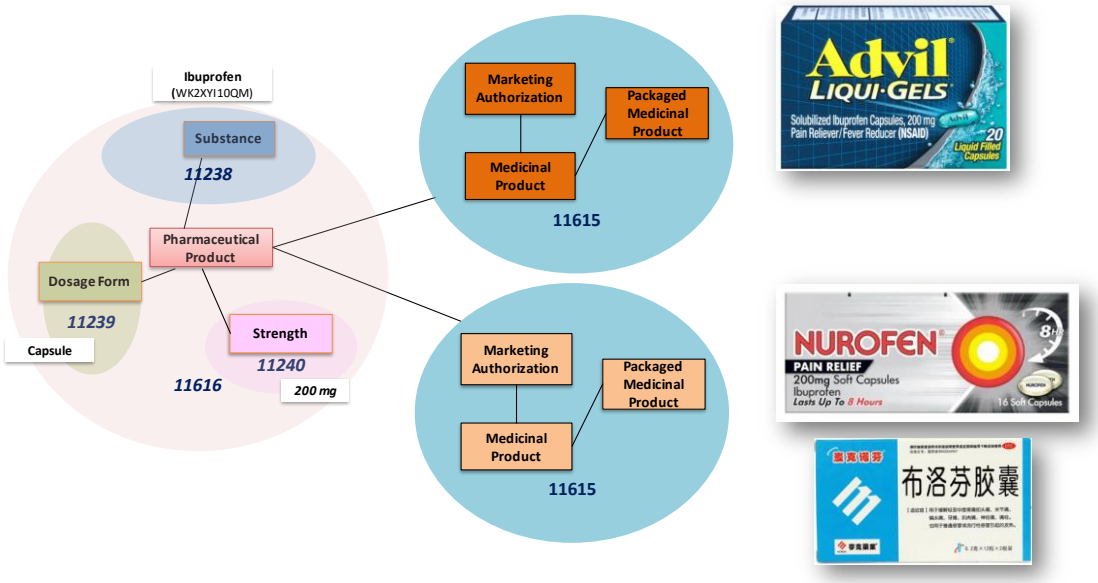
- ISO 11238 – Substance identification
  - The standard describes the data that uniquely defines substances, including active ingredients, adjuvants and excipients.

- ISO 11239 – Pharmaceutical dose forms, units of presentation, routes of administration and packaging
  - The standard describes the controlled terminologies to use to characterize pharmaceutical dosage form, routes of administration, units of presentation and packaging.

- ISO 11240 – Units of Measurement
  - The standard describes the standardized units of measurement to use to define the strength of a medicinal product.

The relationships between the standards are depicted in Figure 1 and demonstrate how three regional pharmaceutical products composed of ibuprofen in 200 mg capsules use standardized data to generate a unique pharmaceutical product identifier (PhPID).

Figure 1: ISO IDMP Information from three regional "Ibuprofen2 products used to generate a unique pharmaceutical product identifier (PhPID).



Unique Substance Identification (SID)

ISO IDMP defines two levels of substance details :

- Substance or/and
- Specified Substance which are further defined by several attributes, including whether the substance is a chemical, protein, nucleic acid, polymer or structurally diverse (e.g., tissue, gene, blood, herbal, homeopathic, plasma-derived, allergen, vaccines). Specified Substances can have further attributes, such as grade or purity, manufacturing information and specifications.

Multiple substance materials such as simethicone, aluminum lakes and flavors, herbal extracts, juices, oils and tinctures and polymorphic forms of materials, single component substances that differ in physical form, etc. are Specified Substances (see ISO/TS 19844 for more details).

Once a substance has been defined according to the ISO 11238 and ISO/TS 19844, unique regional and even global identifier can be assigned and maintained via regional or even global processes. (See Section IDMP Adoption Considerations below).

Unique Pharmaceutical Product Identification (PhPID)

Each Pharmaceutical Product has a set of Pharmaceutical Product IDs (PhPIDs).

PhPIDs are generated according to ISO 11616 by an algorithm based on controlled terminologies (e.g., using the substance identifier (SID), administrable dose form ID and

strength details).

Medicinal Product Identification (MPID)

A unique Medicinal Product Identifier or MPID according to ISO 11615 is assigned each time a marketing authorization holder receives marketing authorization for a product. It may also change during the lifecycle of medicinal products (e.g., if information about the authorized product changes, then a new MPID is assigned (see the ISO 11615 standard for more detail). MPIDs are assigned and maintained regionally.

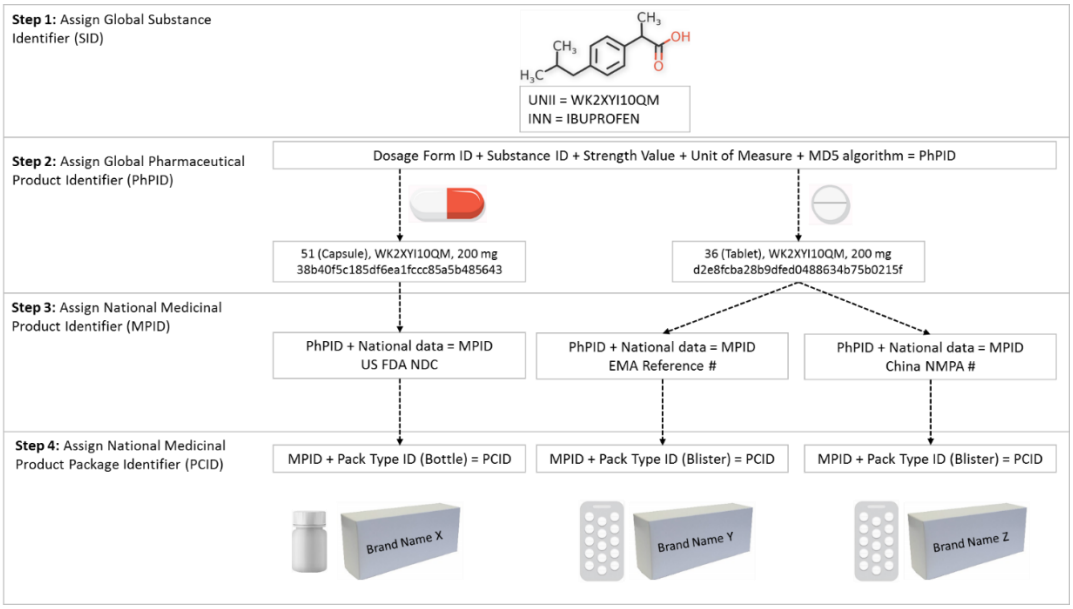
Medicinal Product Package Identification (PCID)

Several unique Medicinal Product Packaged Identifiers or PCID are assigned to a Medicinal Product depending on the number of different packages (e.g., different pack sizes) of the product.

The PCID will be updated on changes of packaged items information (i.e., type, quantity, materials and alternate materials) or package components (i.e., type, materials, alternate materials) or manufactured items (i.e., dose form, unit of presentation, quantity).

The PCID is also following changes of the MPID and will be updated if the MPID changes. PCIDs are assigned and maintained regionally.

Figure 2: Relationship Between Substance Identification, Pharmaceutical Product Identification, Packaged Product Identification and Medicinal Product Identification



Benefits of IDMP

As noted above, medicinal product development, manufacturing and distribution are now globalized and with the rapid advancement of technology, the international community demands that we standardize medicinal product data. It is important to remember that IDMP is a set of standards. It is not a system; it is not a software application. It's also not defining the code systems to be used to describe medicinal product information.

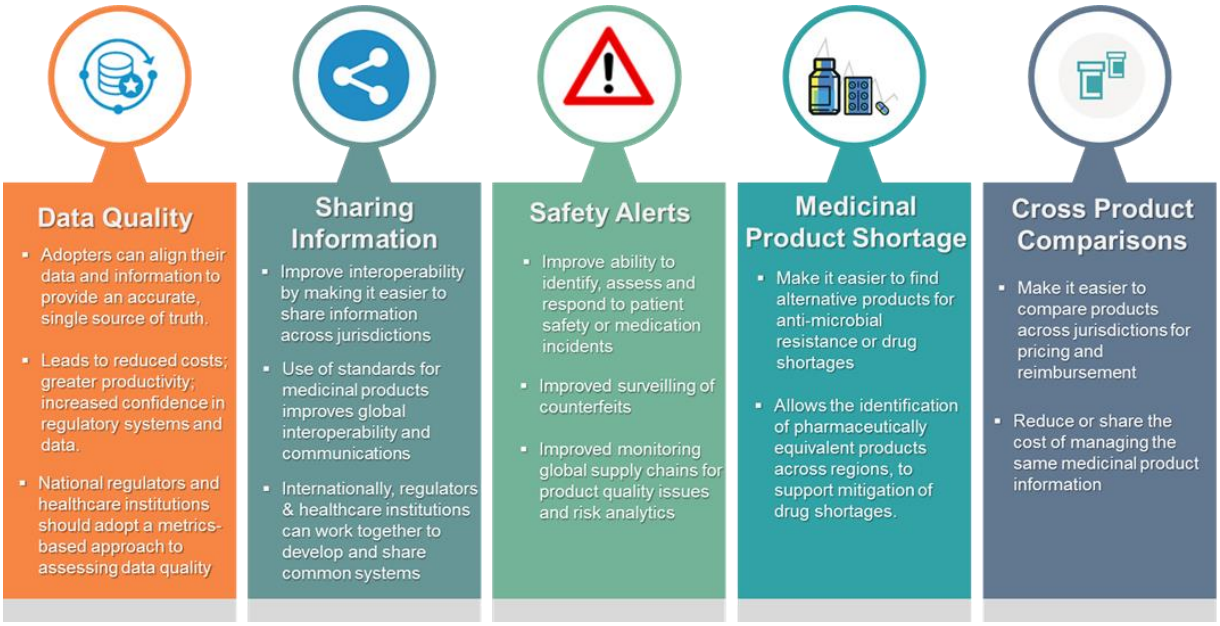
They can be implemented either regionally, globally, or both. The global benefits can only be realized when the international community comes to a consensus on their implementation (like usage of code systems and/or mapping between code systems that are in place in different regions, often legally driven).

The benefits of IDMP are focused in five key areas where improvement can be delivered:

- Data Quality due to a common definition how to structure and understand information, also to enforce the usage of controlled terminology
- Sharing Information across partners IDMP does not define an exchange mechanism, but it describes the data elements that are shared
- Safety Alerts; easier identification of impacts
- Medicinal Product Shortage, Quality defects and Cross Product Comparisons.

These major benefits of global IDMP implementation are presented in more detail in Figure 3. The implementation of IDMP standards impacts overall **data quality** throughout the medicinal product development value chain by giving guidance on data structure and terminologies. The regional and even global adoption and use of the standards should improve interoperability by making it easier to **share information** electronically. Sharing information using common formats, terminologies and rules should improve the ability to identify, assess and respond to patient **safety or medication alerts** and to identify pharmaceutically equivalent products across regions, to support the **mitigation of medicinal product shortages**. Lastly, the adoption and use of IDMP standards should make it easier to **compare products** within and across jurisdictions for pricing and reimbursement, as well as cross-border healthcare.

Figure 3: Major Benefits of IDMP



Global 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 key IDMP standards.

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 and/or health data systems that use product representation that are not explicitly IDMP compliant, adopting the IDMP standards will need to be a stepwise effort over time to achieve the benefits of IDMP. 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.

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 should be taken into consideration. See sections 5.1 and 5.2 of the ISO/TS 19844 for more details.

Regulatory authorities are intensively 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 criteria 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)).

How are IDMP and FHIR aligned?

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.

What are the current considerations with Medicinal Product ID?

As an example, on how the MPID can be implemented at regional level together with some regional considerations with Medicinal Product ID we may see at the EU Implementation guide (current public version 2.1.1), available at the following URL: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/product-management-services-pms-implementation-international-organization-standardization-iso_en-0.pdf.

What are the current considerations with Dose Form?

A unique global dose form identifier for IDMP has not yet been established. A global dose form ID is a critical input criteria for the generation of the global PhPID.

Recently, it has been clarified that the ISO 11239 standard and TS 20440 for dose form do not specify that a region must map its terms to a central terminology.

At the May 2020 bi-annual meeting (virtual) of ISO Technical Committee (TC) 215 Working Group 6 it was agreed to revise ISO 11239: 2012 and ISO TS 20440: 2016 to address the issues. Target date for a revised publication is 24 months.

At the January 2021 ISO TC 215 Working Group 6 meeting a pilot project between FDA, United States and WHO/UMC was agreed upon to evaluate the use of dose form characteristics to describe dose forms and develop a code string that could be used for the generation of the global PhPID.

At the September 2021 ISO TC 215 Working Group 6 meeting changes to the ISO/TS 20440 document were proposed to align with the outcomes / recommendations from the final report of the pilot project conducted by FDA, United States and WHO/UMC on use of dose form characteristics for the global PhPID use case. Following the recommendations report EMA, FDA, United States and WHO/UMC established the Global IDMP Working Group (GIDWG) (see below).

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 also support wider use cases, for example to associate products of similar composition in different jurisdictions. The PhPID is automatically generated by an algorithm using criteria like the substance identifier (SID), the pharmaceutical dose form ID and the specific strength.

As noted above, a global unique substance identifier and a global dosage form characteristics set have not been established. Until such time that these major issues are resolved, the global implementation and use of IDMP standards will be delayed.

What is the Global IDMP Working Group?

GIDWG is work group established to conduct projects that lead to the implementation of the IDMP standards for global use (https://who-umc.org/idmp/). 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).

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.

Currently, there are five international pilot projects in progress focused on: Substance Identifier, Dose Form Identifier, Strength, FHIR IDMP Exchange Standard and Operating Model for Global Maintenance of Identifiers.

Regulators Planning to Use Global IDMP Standards

- **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 support 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.
- 11 EU Member States are in partnership in the UNICOM project which has the objective to foster the IDMP implementation across Europe.

- **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 to 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, and the Global IDMP Working Group to 1. evaluate the use of dose form characteristic codes as an alternative in the generation of global PhPID; 2.

update ISO 11239 (and TS 20440) and any other relevant documents; and 3. evaluate solutions for a global substance identifier. (FDA, United States).

- **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. A first meeting with a group of experts from industry has taken place in Q2 2019.

- **Health Canada, Canada**
  - Health Canada, Canada supports and is internationally engaged in the work for a global substance registry and IDMP. Under existing projects, Health Canada, Canada is working on accurately mapping existing pharmaceutical and biologic substances to UNII global identifiers. 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.

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