IPRP
International Pharmaceutical Regulators Programme

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International Pharmaceutical Regulators Programme (IPRP)
IDMP Working Group

IDMP Frequently Asked Questions

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

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

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Global Regulatory Environment

Regulatory oversight of medicinal products in the 21st century entails both challenges and opportunities for national regulatory authorities (NRAs). Product development, manufacturing and distribution are now globalized and virtually digitized enterprises, each with their own information collection and management standards that compartmentalize information into domain-specific databases.

Globalized operations mean that any given NRA must have a "reach" outside its own jurisdiction. Digitized information translates into vast quantities of data not all of which is uniform in structure, format, and content across jurisdictions and across databases. 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.

Global medicinal product identification is needed across all regulatory information systems whether the global enterprise is clinical trial data, manufacturing data or safety / pharmacovigilance data. During the SARS CoV 2 pandemic, the need for global medicinal product identification became more apparent, in particular, due to the global deployment and pharmacovigilance associated with COVID-19 vaccines and therapies.

The standardized data elements and structures across databases 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 investigational clinical trials compared to post-market setting safety / pharmacovigilance reporting may be a challenge because of different data standards used to define and identify potentially related medicinal products. Moreover, sharing and pooling of data for global safety / pharmacovigilance analysis among NRAs is next to impossible without a standardized way to uniquely identify a suspected subject medicinal product.

Adoption of international electronic standards to uniquely identify a medicinal product can empower NRAs to collaborate more effectively through data exchanges and/or shared data mining, as well as introduce efficiencies to any individual NRA's oversight across the life cycle of an individual medicinal product.

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 information. Further, the ISO IDMP documents make it possible to standardize

The IDMP standards establish common definitions, common identifiers, and common 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 batch details, dosage form and therapeutic indications. The Medicinal Product Identifier is a regional or national code controlled by the appropriate regulatory agency. The U.S. National Drug Code (NDC) is an example of regional MPIDs.

- ISO 11616 – Pharmaceutical product information
  - The standard describes the components that can be utilized to generate pharmaceutical product identifiers that could be assigned to pharmaceutical products that have the same substance, dosage form and strength as products in other regions or countries.

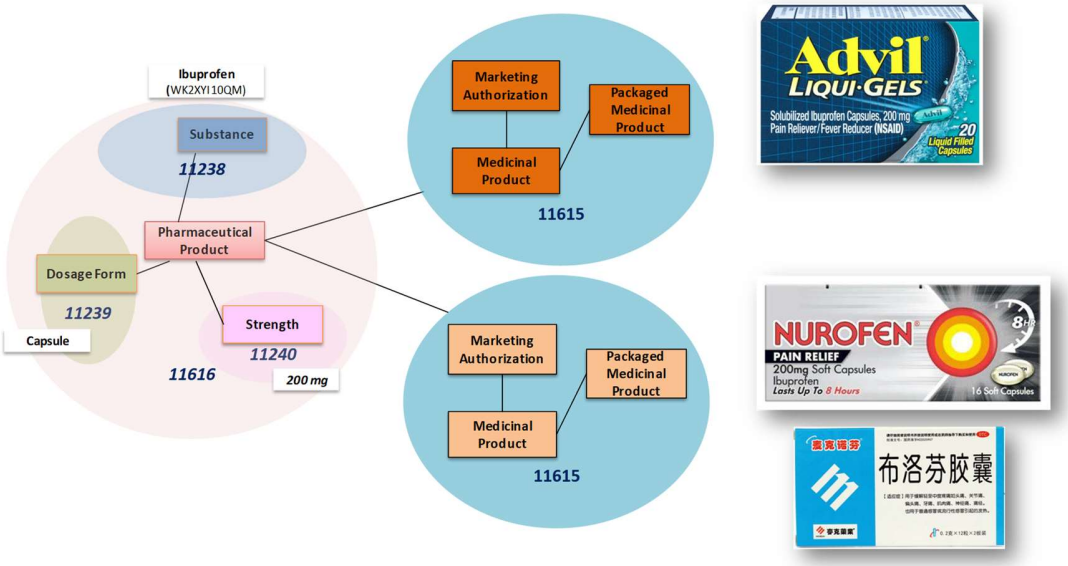
- ISO 11238 – Substance identification
  - The standard describes the data that uniquely defines substances, including active ingredients, adjuvants, and excipients, as well as specified substances from a variety of manufacturers.

- 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: IDMP Information from three regional Ibuprofen products used to generate a unique pharmaceutical product identifier (PhPID).



What are the IDMP Process Steps for Assigning Unique Global Identifiers?

Step 1: Assign Global Substance Identifier (SID)

Medicinal Products consist of substances which can be active ingredients, excipients, or packaging materials. There are two levels of ingredients: Substance 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). Specified Substances can have further attributes, such as grade or purity, manufacturing information and specifications. Once a substance has been defined, a unique global identifier can be assigned and maintained in a global system (See IDMP Adoption Considerations below).

Step 2: Assign Pharmaceutical Product Identifier (PhPID)

A substance of specific strength and a specific pharmaceutical dose form when administered to a patient via a specific route of administration forms a Pharmaceutical Product. Each Pharmaceutical Product has a set of Pharmaceutical Product IDs or PhPIDs. The PhPID is generated by an algorithm using the substance identifier (SID), the pharmaceutical dose form ID and the specific strength. Once a pharmaceutical Product has been identified, a unique global identifier can be assigned and maintained in a global system.

It's important to notice that without global identifiers for each PhPID element no unique global PhPIDs can be generated and maintained.

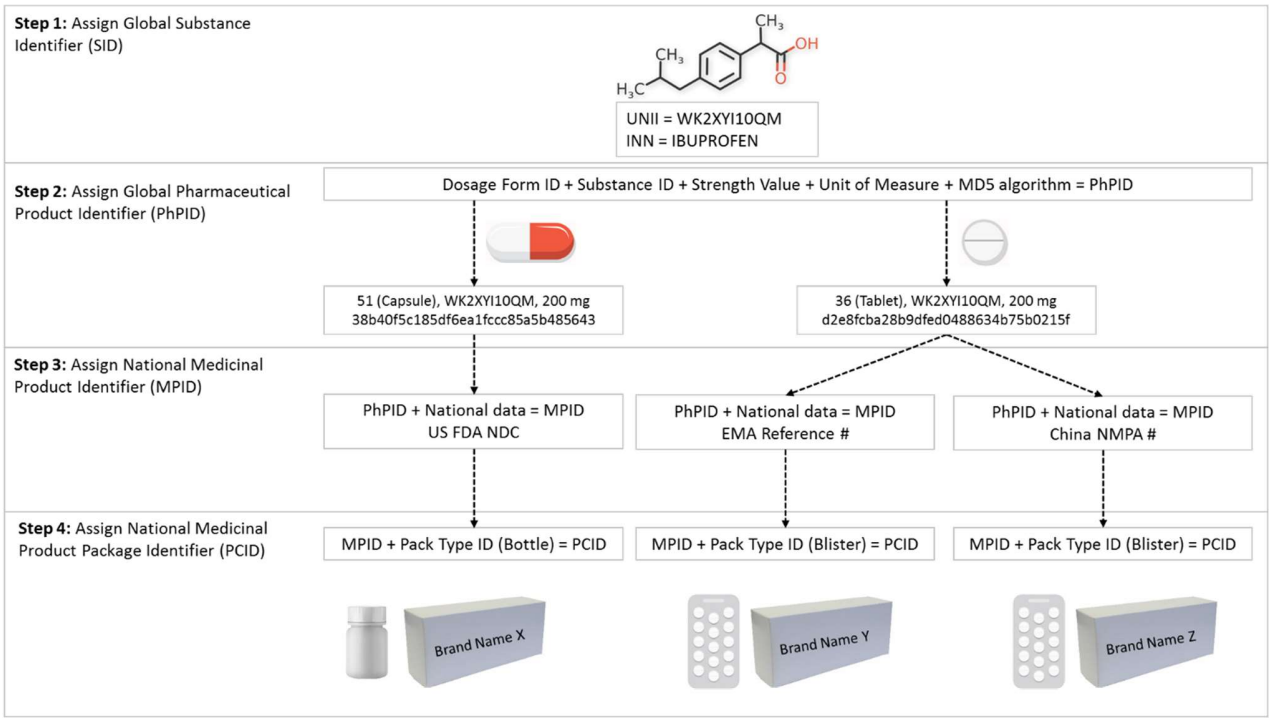
Step 3: Medicinal Product Identifier (MPID)

A unique Medicinal Product Identifier or MPID is assigned each time a marketing authorization holder receives marketing authorization for a product in a new country. 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.

Step 4: Assign Medicinal Product Package Identifier (PCID)

A unique Medicinal Product Packaged Identifier or PCID is assigned to the Medicinal Product. When the MPID changes or the packaged items (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) change another PCID is assigned. PCIDs are assigned and maintained regionally.

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



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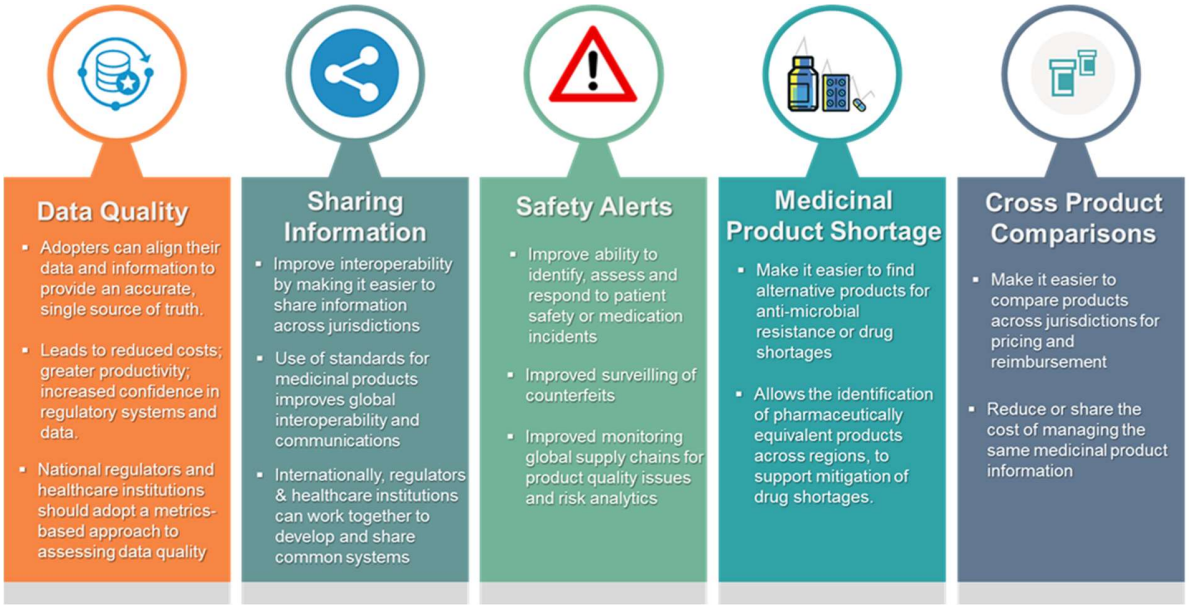
Benefits of IDMP

As noted above, medicinal product development, manufacturing and distribution are now globalized and with the rapid advancement of technology, the international community demand that we standardize medicinal product data. It is important to remember that IDMP is only a set of standards. It is not a system; it is not a software application. The benefits from the IDMP standards can only be realized when the international community comes to a consensus on their implementation.

The benefits of IDMP are focused in five key areas where improvement can be delivered: Data Quality; Sharing Information; Safety Alerts; Medicinal Product Shortage 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 alignment of data and information sources to provide an accurate, single source of truth. The global adoption and use of the standards should improve interoperability by making it easier to **share information** electronically and communicate using harmonized terminologies. Sharing information using common formats and standards 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** across jurisdiction for pricing and reimbursement.

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 implementation. The standards must include many aspects / fields / interests of regulators and industry. 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 health data systems that use product identifiers that are not explicitly IDMP compliant, adopting the IDMP standards will need to be a stepwise effort over time to achieve a fully integrated system specific to product identification. 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?

A unique global substance identifier for IDMP has not yet been established, as well an international organization to maintain the global identifiers. A global Substance ID is a critical input code for the generation of the PhPID. Work should be initiated within ISO to develop a solution to the global substance identifier issue.

At the May 2020 bi-annual meeting (virtual) of ISO Technical Committee 215 Working Group 6 it was agreed to revise ISO TS 19844: 2018 to include a new annex L on Signature / Minimum Substance Field.

EMA, FDA and WHO/UMC are working together on the EU Substance Registration System (SRS) to review and update the substance database for chemicals, proteins, and vaccines.
EMA and FDA are working together with Health Level Seven (HL7) International to incorporate the ISO IDMP standards into the Fast Healthcare Interoperability Resources (FHIR) specification for information exchange.

What are the current considerations with Medicinal Product ID?

EMA and FDA are working together with HL7 International to incorporate the ISO IDMP standards into the FHIR specification for information exchange.

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 code for the generation of the 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 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 TS 20440 document were proposed to align with the outcomes / recommendations from the final report of the pilot project conducted by FDA-UMC on use of dose form characteristics for the global PhPID use case.

What are the current considerations with Pharmaceutical Product ID?

The PhPID is generated by an algorithm using 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 implementation and use of global IDMP standards will be delayed.

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Regulators Planning to Use Global IDMP Standards

- **European Medicines Agency**
  European Medicines Agency

- **U.S. Food and Drug Administration**
  - FDA continues to focus on the challenges of the global supply chain and external sourcing of medicinal products. FDA's participation in the development, implementation and use of global IDMP standards will to ensure the safety of medications throughout the world. FDA has been using standards and terminologies similar to 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). As noted above, FDA will continue to collaborate with ISO, other organizations, as well as regulatory agencies to adopt a global solution to substance ID and dose form ID (U.S. Food and Drug Administration).

- **Swissmedic**
  - Swissmedic 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 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 take into account some specific requirements for Switzerland. In addition, Swissmedic will ensure the data sovereignty of pharmaceutical and organizational data with its own databases.
  - Swissmedic 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**
  - Health Canada's Health Products and Food Branch (HPFB) supports and is internationally engaged in the work for a global substance registry and IDMP. Under existing projects, HPFB 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. HPFB'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, HPFB fully is interested in engaging and sharing expectations, knowledge, and plans for the future implementation of these important data standards.

  - In addition, HPFB is establishing a data governance network that will support better use,

management and stewardship of HPFB'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)