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. However, 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 electronic data exchange.

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) are examples 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.

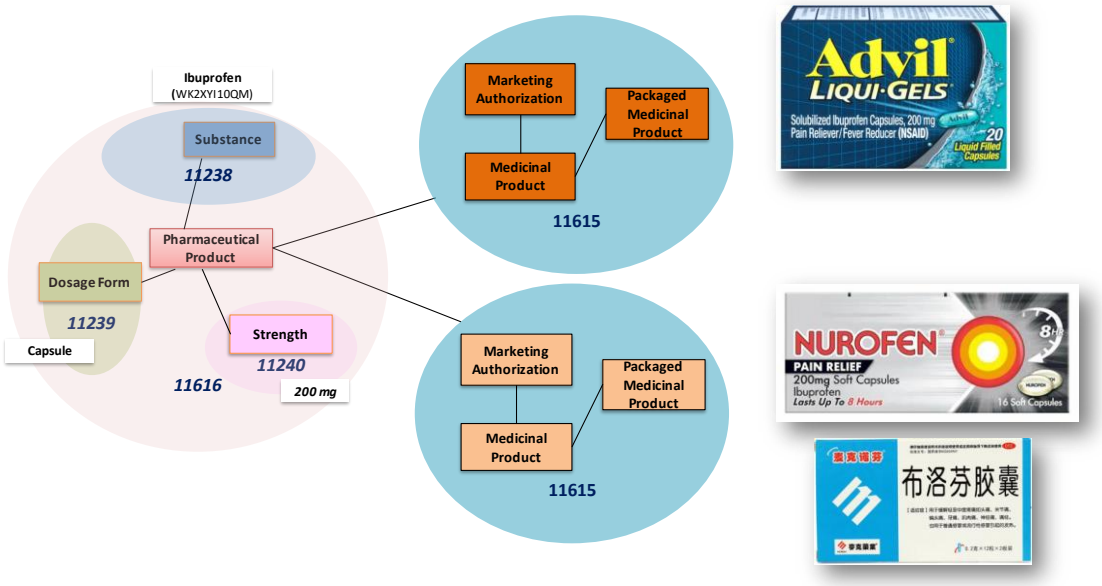
- ISO 11238 – Substance identification
  - The standard describes the data that uniquely defines substances, including active ingredients, adjuvants and excipients, as well as specified substances from a variety of manufacturers.

- 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 a number of 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.

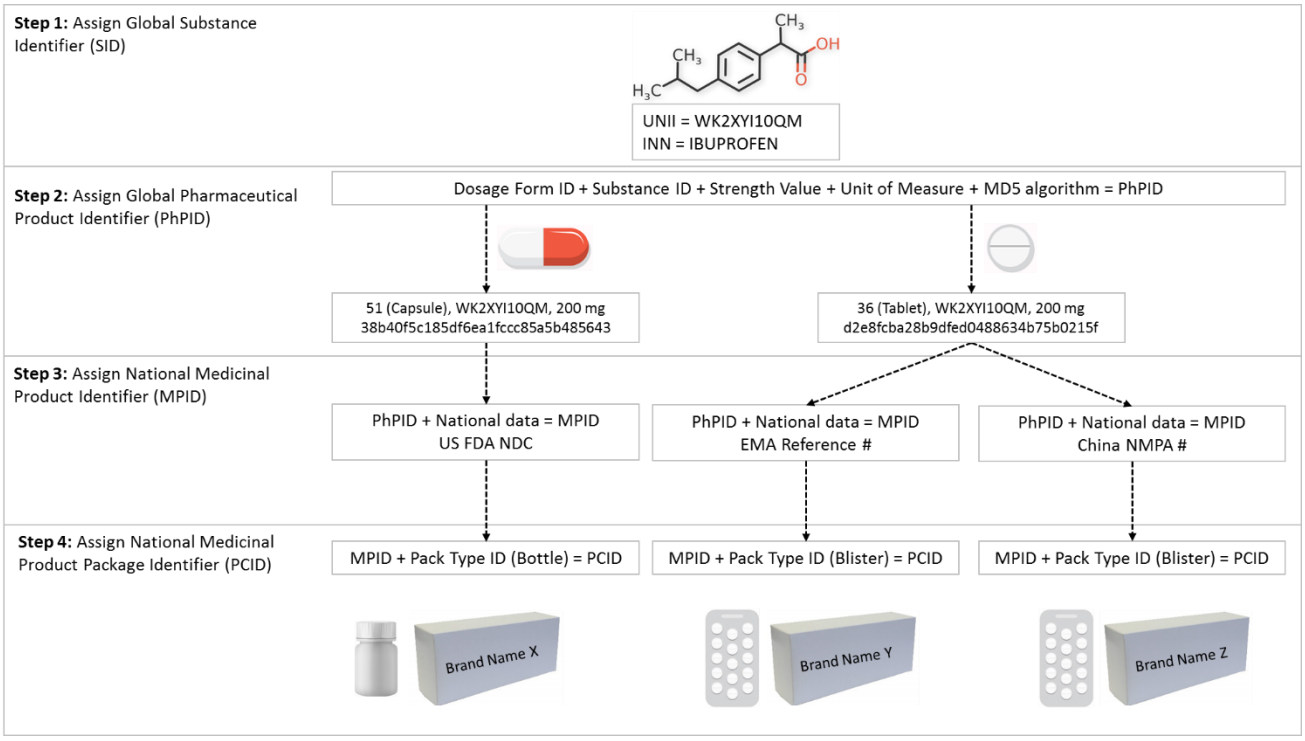
Step 3: Medicinal Product Identifier (MPID)

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

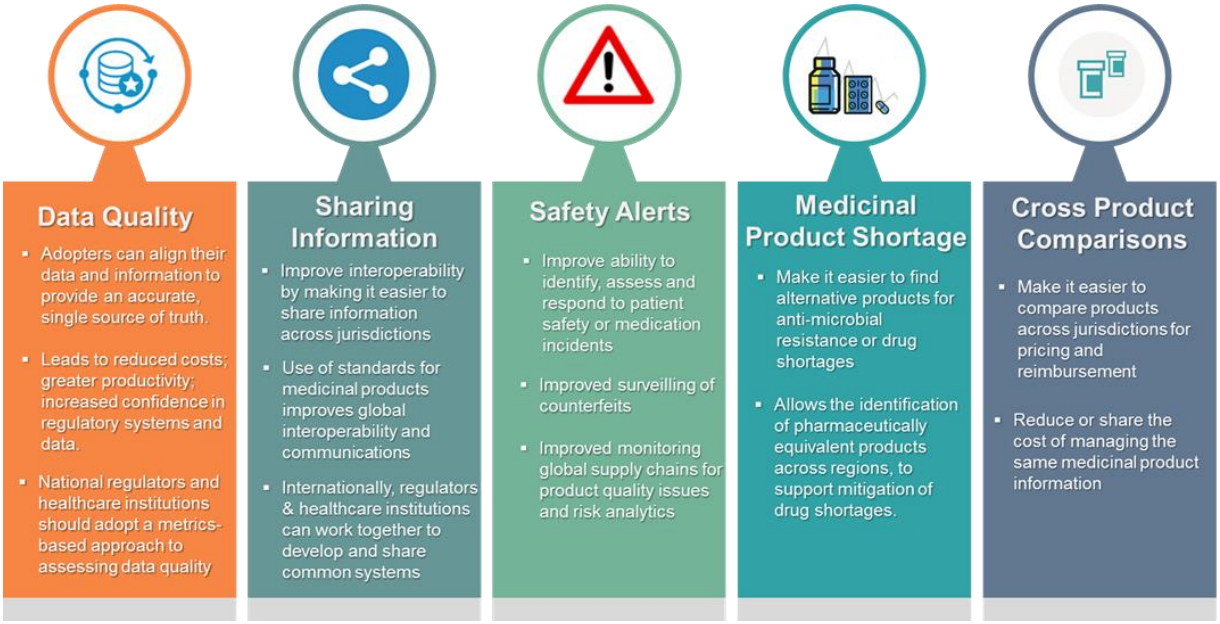


Benefits of IDMP

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



IDMP Adoption Considerations

What are the current considerations with Substance ID?

- 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.
    - HL7 International is an organization focused on standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services.
- A unique global substance identifier for IDMP has not yet been established, as well an international organization to maintain the global identifiers. For example, U.S. FDA uses the unique ingredient identifier or UNII for substance identification. However, this standard has not been adopted globally. Work should be initiated to collaborate on a global substance identifier.
    - At the May 2020 bi-annual meeting (virtual) of ISO Technical Committee 215 Work Group 6 it was agreed to revise ISO TS 19844:2018 to include a new annex L on Signature / Minimum Substance Field.
- EMA and FDA are working together on the EU Substance Registration System (SRS).

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 Dosage Form?

- According to the ISO 11239 standard regional terminologies should map to the central terminology. However, a central dosage form terminology has not been identified and this has posed issues for some regions.
- At the May 2020 bi-annual meeting (virtual) of ISO Technical Committee 215 Work Group 6 it was agreed to revise ISO 11239:2012 and ISO TS 20440:2016 to address the issues related to the generation of an international PhPID. Target date for a revised publication is 24 months.

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 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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Are Regulators Planning to Use Global IDMP?

- See the following links for more information.
    - U.S. Food and Drug Administration
    - European Medicines Agency

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)