GIDWG
Global IDMP Identifiers

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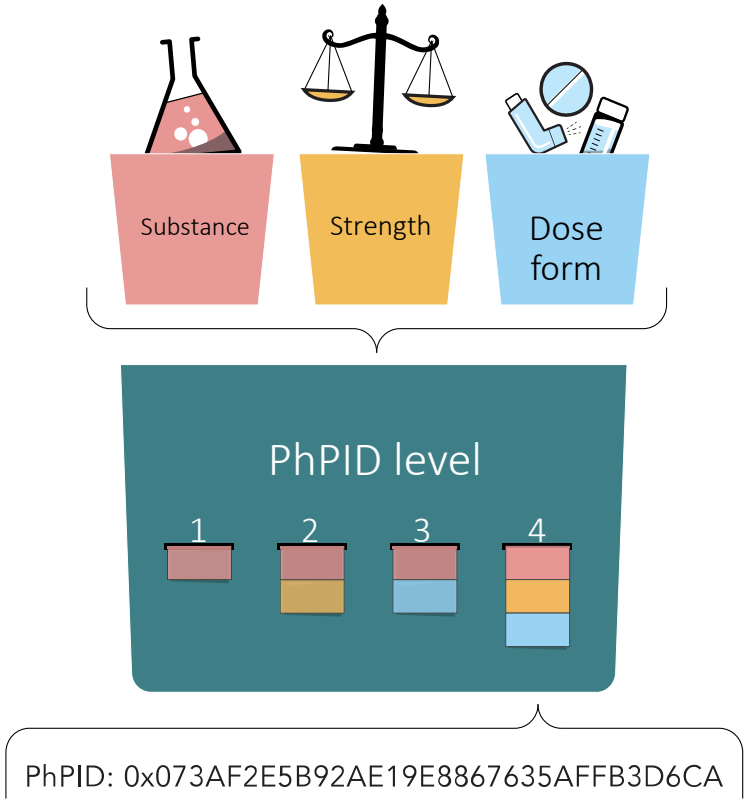
Agenda

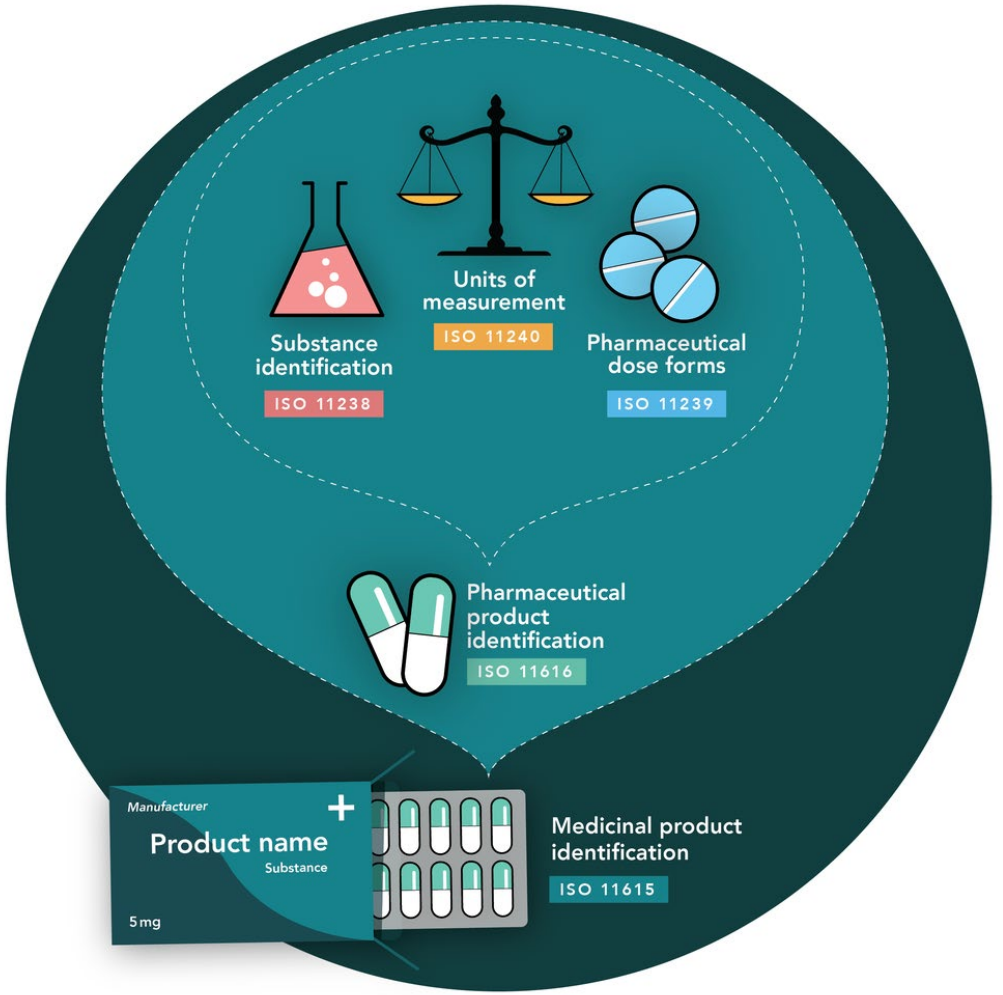
- Global IDMP identifiers in the GIDWG End-to-end
  - PhPID
  - GSID
  - Strength
  - Dose Form
- Outcomes of the GIDWG end-to-end

Global IDMP Working Group

Pharmaceutical product ID

PhPID





ISO IDMP suits of standards
ISO 11615, 11616, 11238, 11239 and 11240

E2E: Data Validation Working Process

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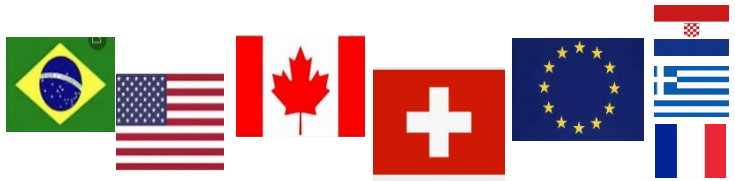
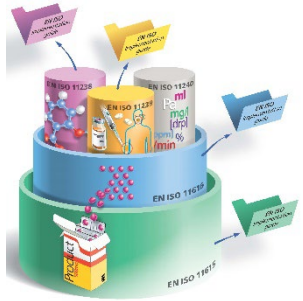
Countries:



Medicinal product data

Selected data set

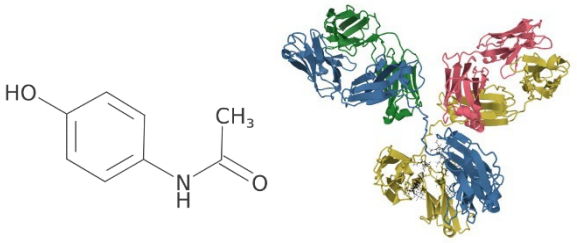


Substance

Strength

Dose form

PhPID



Administration method

Intended site

Basic dose form

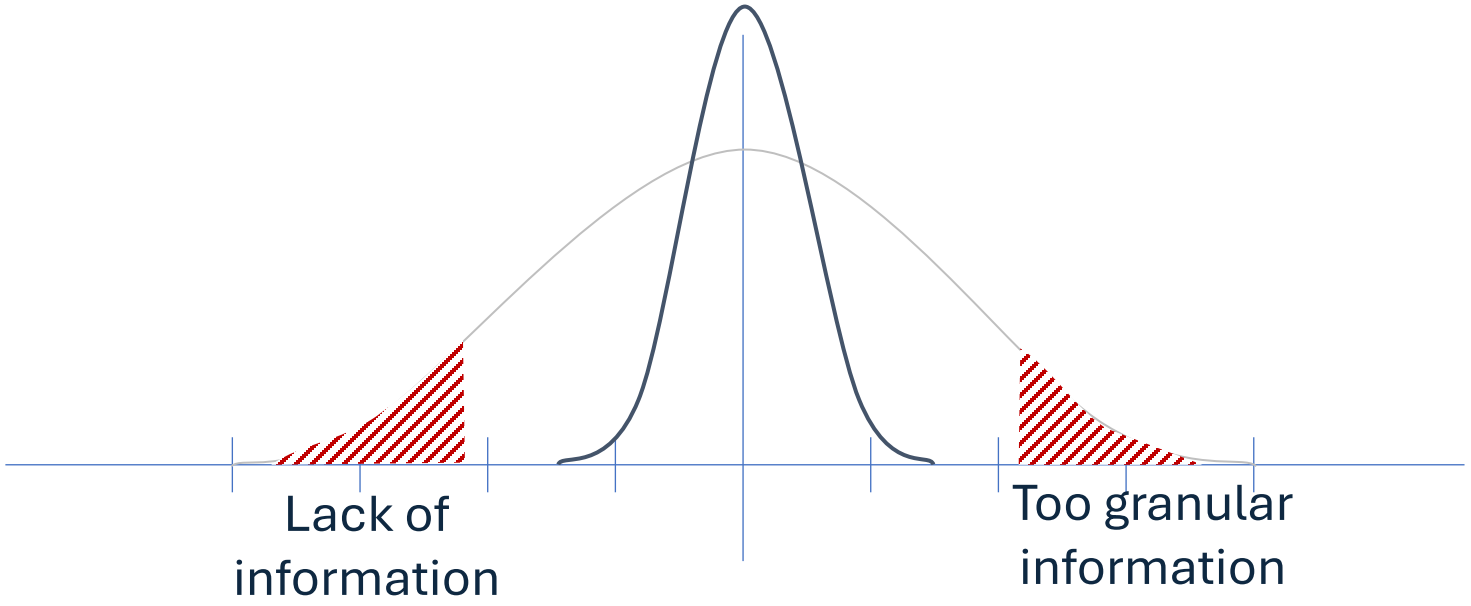
Release characteristics

Pattern	Type of product
A	
B	
C	

0x073AF2E5B92AE19E8B67635AFFB3D6CA

Harmonization

Medicinal product information when assigning global identifiers.



Consultation with experts

Finding

The extent of medicinal product information harmonization was evaluated across three use-cases:

1. Pharmacovigilance
2. Drug shortage
3. Cross-border healthcare

Recommendation

Ensure involvement of SMEs with competence within the different use-cases for global PhPID.

Five-regions verification

Finding

Analyzing substances and products across five key regions to understand how specific substances or products are described globally.

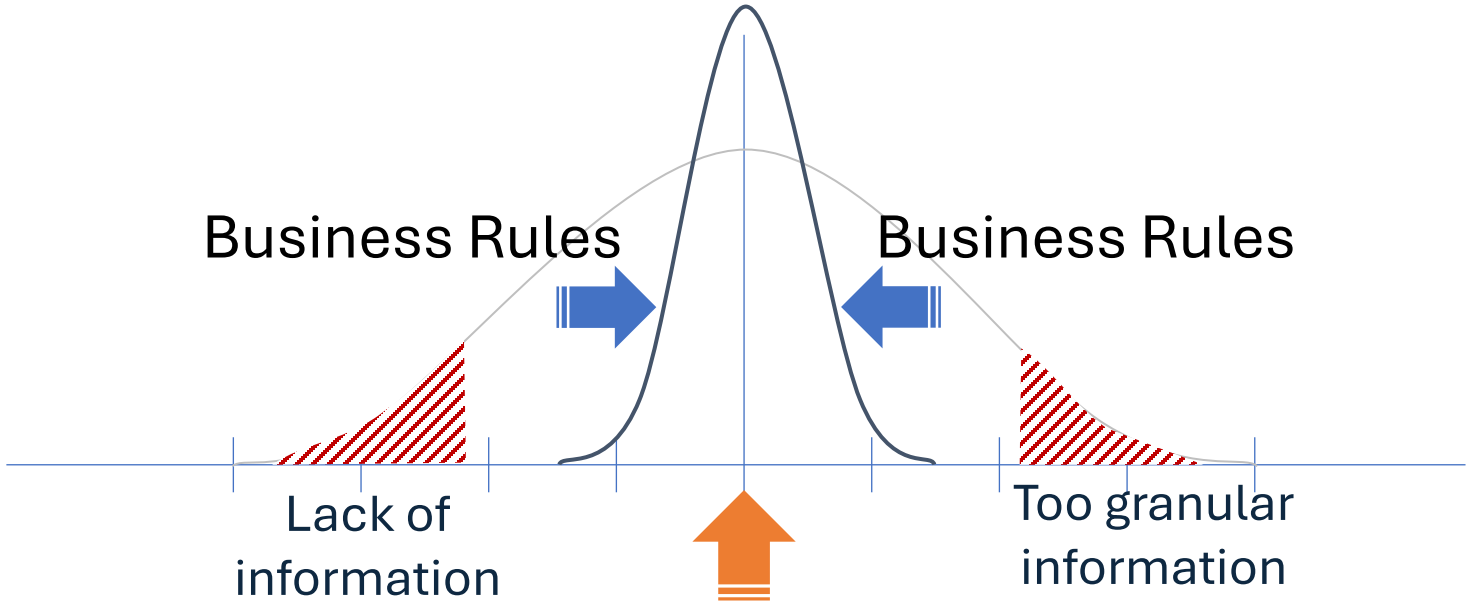
Recommendation

Pro: Valuable method when validating additional products with the same substance variant and pharmaceutical form.

Con: time consuming, should only be applied when relevant.

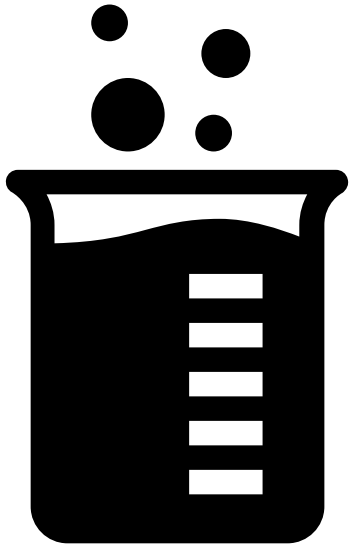
Harmonization

Reduce variations on medicinal product information when assigning global identifiers.



Five Region Verification

Global substances



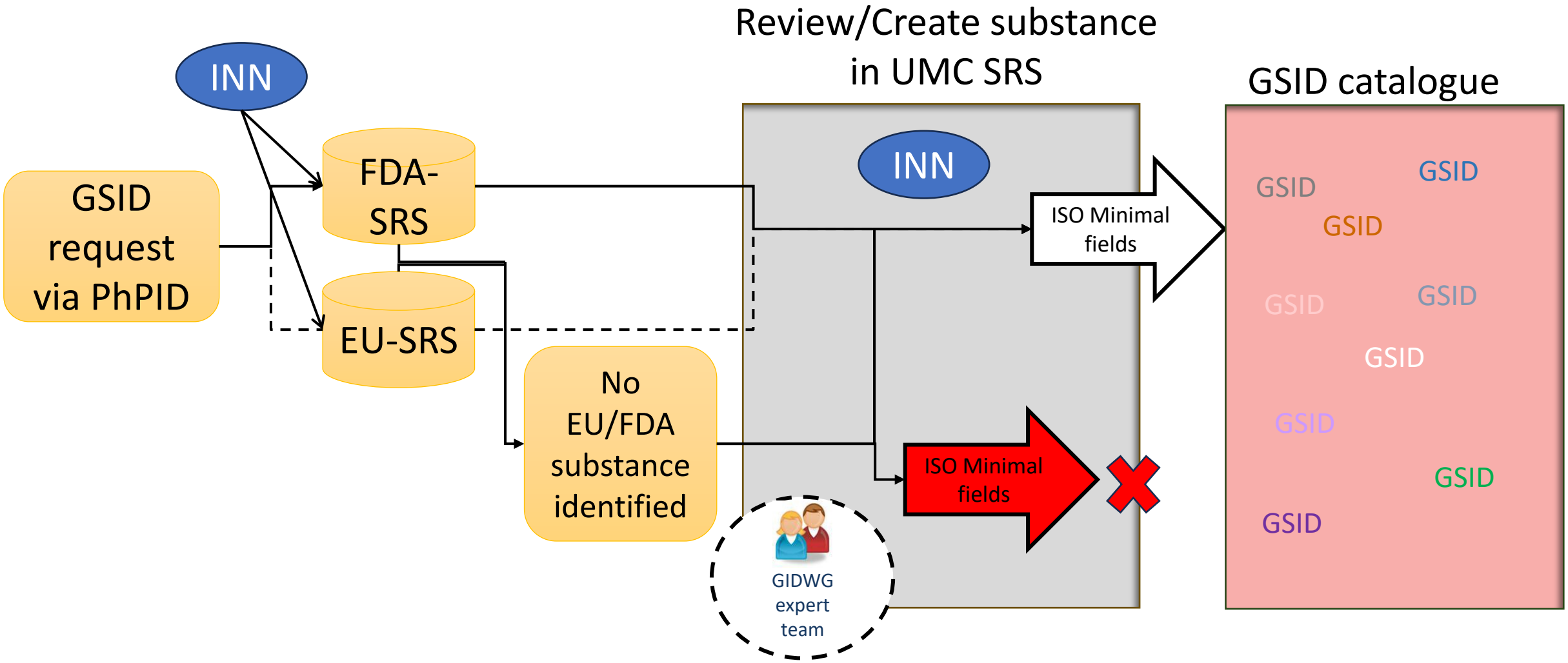
Several different naming (including definition) organisations

- INN
- USAN
- Ph. Eur.
- JAN

Alignment to ISO IDMP standards 11238 and TS 19844

- For the majority of substances there are no issues
- Business Rules
- Case by case mitigation

GSID assignment



Selection of GSID for PhPID Hydrates

Finding

Comparable products are often described differently when it comes to hydrates, therefore, hydrates were excluded to ensure aggregation of comparable products to the same PhPID.

Decision

After the end-to-end and considering the use cases, the recommendation is to continue to use the corresponding anhydrous substance.

Global Strength Definitions

No common approach to strength and unit

- Different unit expression
  - IU, %, mg/mL, or mg/g
- Different precision of strength
  - 18 mg vs 18.06 mg
- Concentration strength vs presentation strength for liquids
  - 500 mg or 500 mg/ml

Mitigation

- Business Rules
- Patterns
- Conversion tables
- UCUM units

Strength Unit Conversion

Finding

The absence of a globally approved unit conversion framework presents challenges in handling unit conversions (e.g., mg to IU).

Strength Unit Conversion

Some examples of Unit Conversions During End-to-End Testing			
Substance	**From unit**	**To PhPID unit**	**Conversion factor (Source)**
Alteplase	IU	mg	10 mg = 5.8 MIU (SPCs)
Lenograstim	IU	mcg	150 mcg = 19.2 MIU (Martindale)
Somatropin	IU/units	mg	3 units = 1 mg (Martindale)

Strength Unit Conversion

Finding

The absence of a globally approved unit conversion framework presents challenges in handling unit conversions (e.g., mg to IU).

Recommendation

To minimize the number of unit conversions, a five-region verification has been performed to identify the most common unit which is used for PhPID generation.

Dose Form Attributes

No centralized/common terminology for Dose Form

- Different granularity
  - Capsule vs Soft or Hard Capsule
  - Tablet, Coated Tablet, Film coated Tablet
- Regulators approve different terms
  - Pellet vs granule

Mitigation

- Dose Form Attributes
- Business Rules

Dose Form Attributes

ISO 11239:2023

Basic dose form Administrable

Administration method

Transformation

Intended site

Global dose form attributes

Basic dose form Manufactured

Release characteristics

Dose Form Attributes Release characteristics (RCA)

Finding

The dose form are differently labeled, for example “delayed release tablet” in one country and a “modified-release tablet” in another.

Information about how the active substance is released is not always available in SPCs.

Terms such as ´controlled release´ and ´modified release´ indicate some special form of release, but not exactly which RCA.

Dose form attributes
Release characteristics (RCA)

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Example of advanced formulations of Mesalazine

Formulations	Proprietary names	Mode of delivery	Site of drug release	Corresponding RCA for PhPID
pH dependent	Asacol®; Mesren®	Eudragit-S coating (dissolves at pH ≥ 7)	Terminal ileum, colon	**Delayed**
	Salofalk®; Mesasal®; Claversal®	Eudragit-L coating (dissolves at pH ≥ 6)	Mid ileum to colon	**Delayed**
	Salofalk Granules®	Eudragit-L coating and matrix core	Mid ileum to colon	Delayed + Prolonged → **Prolonged**
Time dependent	Pentasa®, Pentasa® granules	Microspheres encapsulated within an ethycellulose semi-permeable membrane	Duodenum to colon	**Prolonged**
MMX	Lialda®; Mezavant XL®; Mezavant®	Enteric coating (dissolves at pH ≥ 7). MMX of lipophilic and hydrophilic excipients	Terminal ileum and entire colon	Delayed + Prolonged → **Prolonged**

Table source: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4635154/

Dose form attributes Release characteristics (RCA)

Finding

The dose form are differently labeled, for example “delayed release tablet” in one country and a “modified-release tablet” in another.

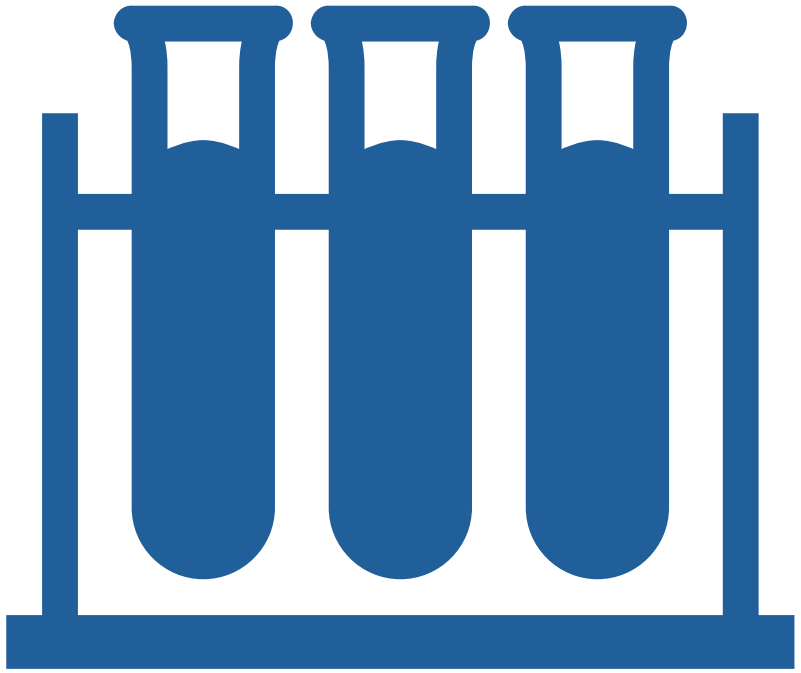
Information about how the active substance is released is not always available in SPCs.

Terms such as ´controlled release´ and ´modified release´ indicate some special form of release, but not exactly which RCA.

Recommendation

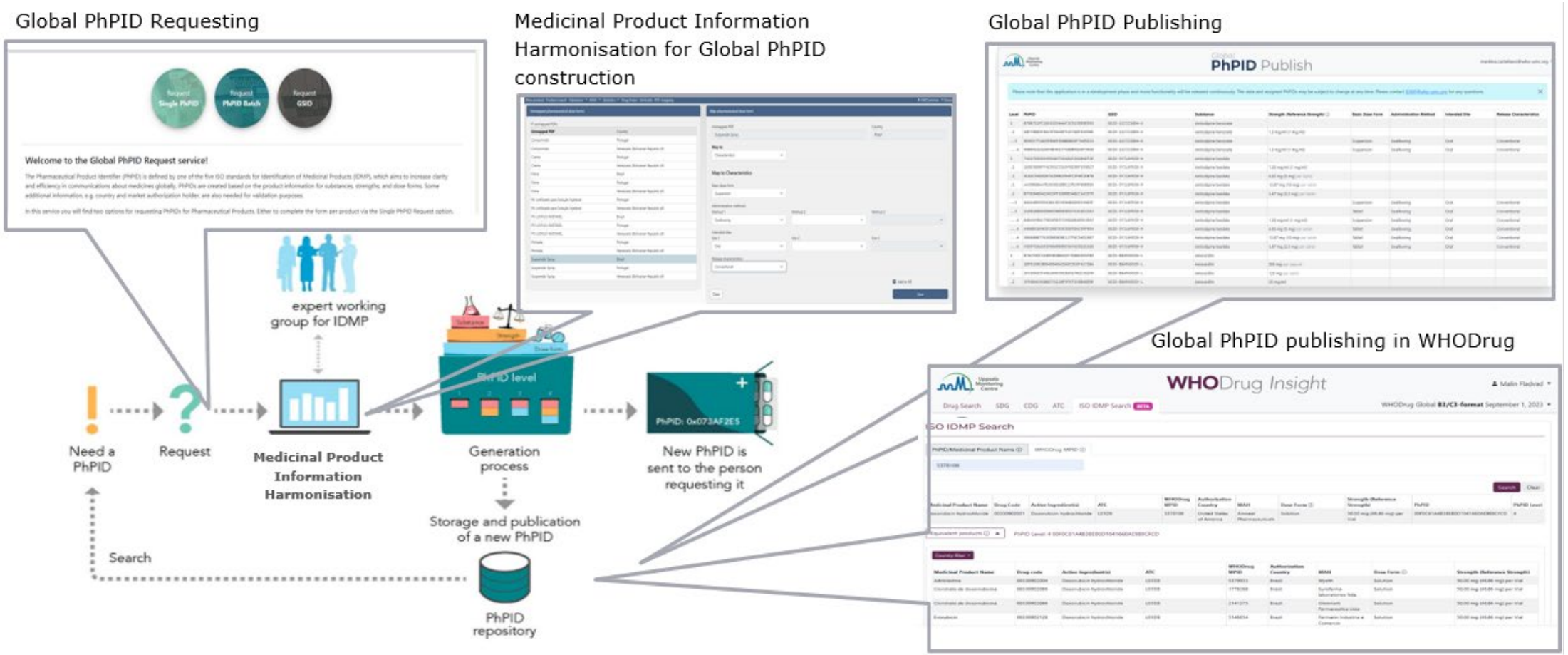
Only one RCA is used for one PhPID.

Formulations combining different release characteristics will be assigned one RCA.

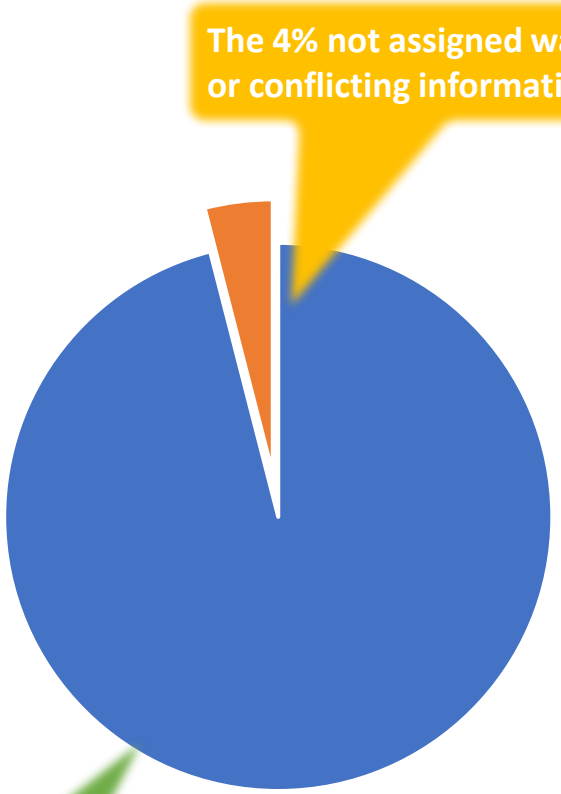


Outcome of the End-to- End

Operating model for Global PhPID



GSID and PhIPD assignment in end-to-end



The 4% not assigned was due to lack of or conflicting information

96% of the substances where successfully assigned a GSID

10% of Medicinal Products are part of E2E Findings and are under evaluation

90% of Medicinal Products have PhPID assigned

Business rules for PhPID generation

Business rules for PhPID construction

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Public Version 1.0

1 May 2024

The flow chart in Figure 10 illustrates strength pattern assignment for different parenteral preparations:

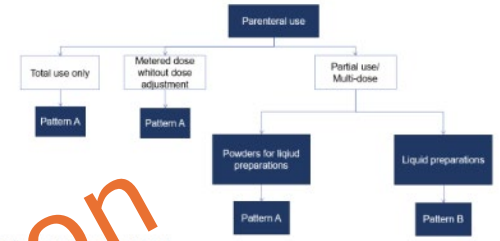


Figure 10. Illustrates strength pattern assignment

2. When the ManDF is different from the AdmDF, the BDF is manually changed from the ManBDF to the AdmBDF (examples in Table 10). For a product example of how dose forms can differ between regions as well change from ManBDF to AdmBDF, see Table 11.

Table 10. Examples of business rules for PDFs with different AdmDF and ManDF

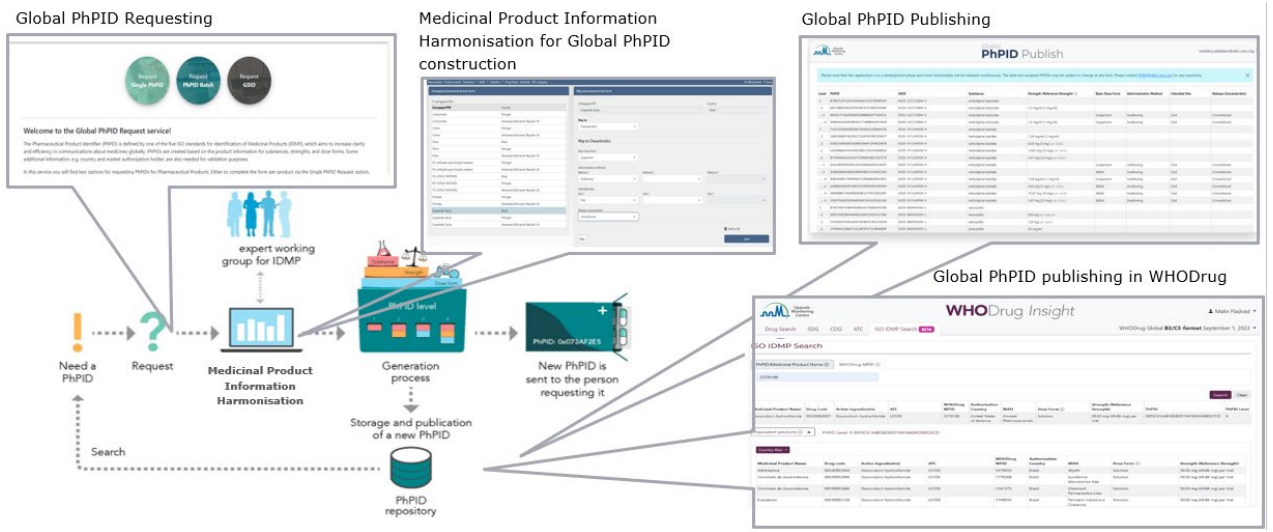
Medicinal product name	ManDF	AdmDF	ManBDF	AdmBDF	Harmonised AdmBDF for PhPID
Hyaluronidase	Powder for solution for infusion	Solution for infusion	Powder	Solution	Solution
Deferasirox®	Dispersible tablet	Oral suspension	Tablet	Suspension	Suspension For tablets that are always dispersed before being taken, the BDF will be 'Suspension'
Lamictal® (Lamotrigine)	Chewable/ dispersible tablet	Chewable tablet Oral suspension	Tablet	Tablet Suspension	Tablet For tablets that can be swallowed and taken as a solution/suspension, the BDF will be 'Tablet'
Berocca®	Effervescent (soluble) tablet	Oral solution	Tablet	Solution	Solution

Table 11. Examples of business rules for PDFs with different AdmDF and ManDF, and same product expressed differently in different regions

Medicinal product name	Country	ManDF	AdmDF	ManBDF	AdmBDF	Harmonised AdmBDF for PhPID
Zithromax® (azithromycin)	UK	Powder for oral suspension	Oral suspension	Powder	Suspension	Suspension
	Korea	Dry syrup	Syrup	Powder	Syrup	
	USA	For oral suspension	Oral suspension	Powder	Suspension	

Published later this year on https://gidwg.org/

Technical readiness



SYSTEM TESTING: ALL FUNCTIONAL, INTEGRATION, USER ACCEPTANCE, AND REGRESSION TESTING HAVE BEEN COMPLETED.

BACKUP AND RECOVERY: BACKUP AND DISASTER RECOVERY PROCESSES ARE IN PLACE.

INFRASTRUCTURE: HARDWARE, NETWORKING, AND OTHER INFRASTRUCTURE COMPONENTS ARE CORRECTLY CONFIGURED.

SECURITY AND MONITORING: SECURITY ASSESSMENTS, AND TESTING COMPLETED. MONITORING IN PLACE

CONFIGURATION MANAGEMENT: ALL SYSTEM CONFIGURATIONS ARE DOCUMENTED AND VERSION-CONTROLLED.

INTEGRATION READINESS: INTERFACES WITH THIRD-PARTY SYSTEMS, APIS, AND OTHER OPTIONS ARE STILL UNDER DEVELOPMENT.

Operational Readiness

User Training and documentation

Help Desk/Customer Support

SLA Agreements

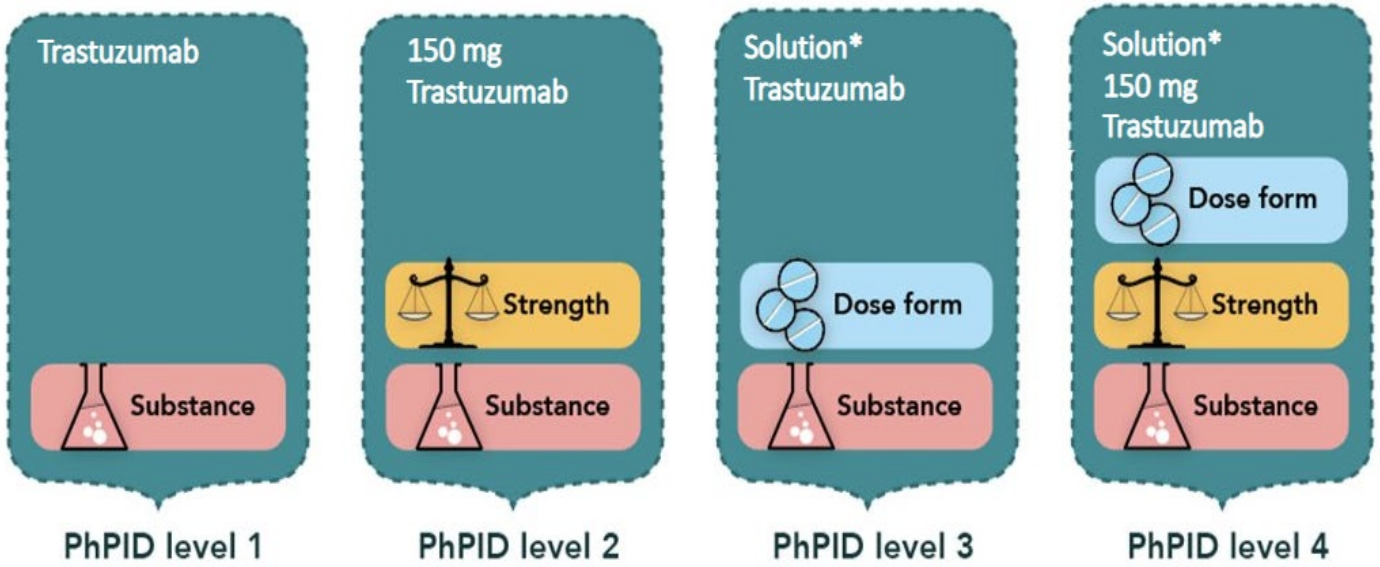
Change Management

Communication Plan

Process readiness

Global PhPID linked to Medicinal product dictionaries

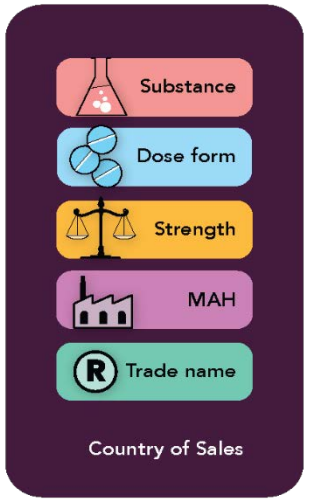
Pharmaceutical products



*Dose form characteristics: Solution, Injection, Parenteral, Conventional

Medicinal products

National IDs: MPID



WHODrug

Stable Local IDs

(MPID, local dose form, local strength expression, units)

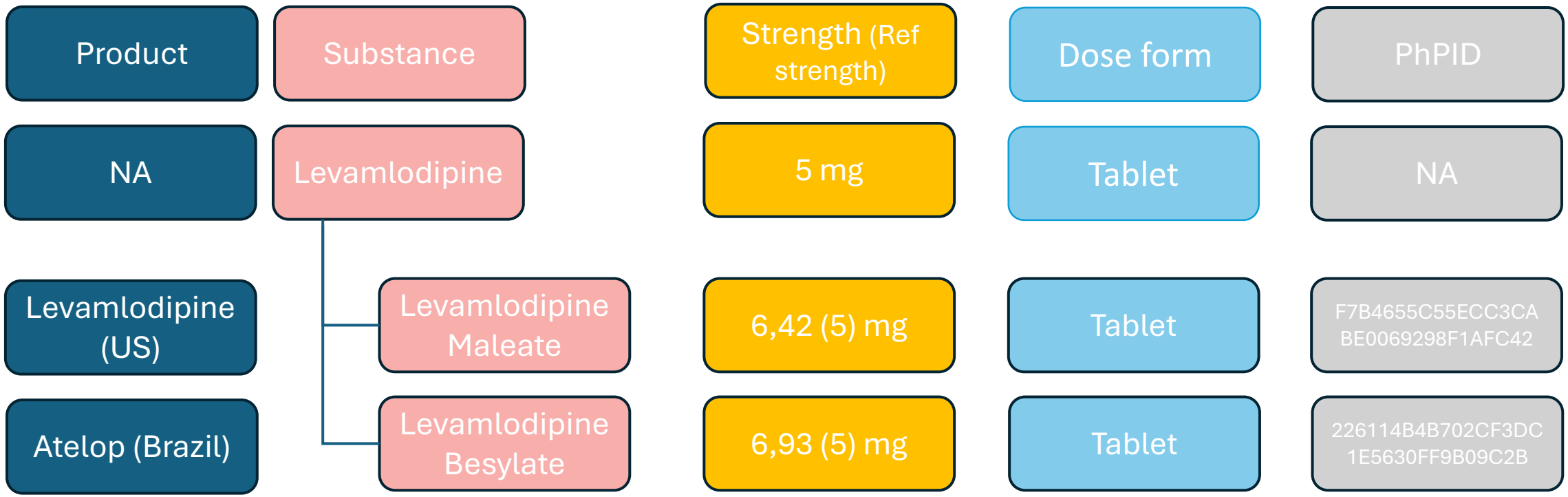
Finding

End-to-end testing identified the need to collect and provide local IDs with global PhPID to facilitate interpretation of the data

Recommendation

Stable local IDs would be recommended to be included in the request both through API and PhPID Request Tool

Overarching PhPID



Overarching PhPID

Finding

There is a need to group related chemical substances, such as bases and their corresponding salts, to improve aggregation and search functionalities

Recommendation

Development of an overarching PhPID

Recommendations for non-normative amendments to ISO 11616/TS 20451

Key message Global Identifiers

The assignment of Global Identifiers and selection for PhPID are based on the ISO IDMP suite of standards and GIDWG business rules.

All of the work with the GIDWG end-to-end has provided confidence of the establishment of the global PhPID framework.

Thank you!