



Technical  
Specification

**ISO/TS 20451**

**Health informatics — Identification  
of medicinal products —  
Implementation for ISO 11616 data  
elements and structures for the  
unique identification and exchange  
of regulated pharmaceutical  
product information**

*Informatique de santé — Identification des médicaments —  
Implémentation des éléments de données et structures ISO  
11616 pour l'identification unique et l'échange d'informations  
réglementées sur les produits pharmaceutiques*

**Second edition  
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## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at [www.iso.org/patents](http://www.iso.org/patents). ISO shall not be held responsible for identifying any or all such patent rights.

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 215, *Health informatics*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 251, *Health informatics*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO/TS 20451:2017 [\[1\]](#)), which has been technically revised.

The main changes are as follows:

- alignment with the changes done in the first revision of ISO 11616 [\[2\]](#);
- addition of the concept for global PhPID (gPhPID).

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at [www.iso.org/members.html](http://www.iso.org/members.html).

## Introduction

This document provides guidelines and requirements for implementing ISO 11616 [2], one of the five ISO standards on the identification of medicinal products (IDMP)<sup>1)</sup>. The five ISO standards on IDMP and the corresponding four ISO Technical Specifications, when used together, provide the basis for exchanging data elements that will support the unique and unambiguous identification of medicinal products. The primary purpose of this document is to provide technical guidance to software implementers; short descriptions of business rationale are also included, where relevant, to provide context. Thus, this document focuses on business and technical considerations for implementation that will construct and parse well-formed, transmittable IDMP messages. Following transmission of required data elements, unique identifiers are to be produced in conformance with the standards to support applications where it is necessary to reliably identify and trace regulated biopharmaceutical products. However, this document does not include extensive information on creation or maintenance of identifier repositories. Reference is made to either regional guidance or implementation guides to support practical implementation within either a region or a jurisdiction. ISO/TR 14872 [7] describes the general core principles and proposed service delivery model for supporting implementation and ongoing maintenance of IDMP terminologies.

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1) ISO 11615 [3], ISO 11616 [2], ISO 11238 [4], ISO 11239 [5], ISO 11240 [6].

# Health informatics — Identification of medicinal products — Implementation for ISO 11616 data elements and structures for the unique identification and exchange of regulated pharmaceutical product information

## 1 Scope

This document provides requirements and recommendations related to the concepts required to associate pharmaceutical products or groups of pharmaceutical products with an appropriate set of PhPID(s) in accordance with ISO 11616 [2].

Pharmaceutical product identifiers and the related elements are intended to represent pharmaceutical products as defined within a medicinal product by a medicines regulatory authority. While the ISO standards on IDMP can be applied to off-label usage of medicinal products, such applications are currently outside of the scope of this document.

Reference to ISO 11238 [4], ISO 11239 [5], ISO 11240 [6], ISO 11615 [3], HL7 V3 messaging standards (HL7 Reference Information Model (RIM) [8], HL7 Common Product Model (CPM) [9] and HL7 V3 Structured Product Labelling (SPL) [10], and HL7 FHIR [11] can be applied for pharmaceutical product information in the context of this document.

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 11238, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on substances*

ISO 11239, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging*

ISO 11240, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of units of measurement*

ISO 11615, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information*

ISO 11616, *Health informatics — Identification of medicinal products — Data elements and structures for unique identification and exchange of regulated pharmaceutical product information*

ISO/TS 19844, *Health informatics — Identification of medicinal products (IDMP) — Implementation guidelines for ISO 11238 for data elements and structures for the unique identification and exchange of regulated information on substances*

ISO/TS 20440, *Health informatics — Identification of medicinal products — Implementation guidelines for ISO 11239 data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging*

ISO/TS 20443, *Health informatics — Identification of medicinal products — Implementation guidelines for ISO 11615 data elements and structures for the unique identification and exchange of regulated medicinal product information*

ISO 21090, *Health informatics — Harmonized data types for information interchange*

## 3 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

## 4 Conformance

- **Mandatory:** Defining elements necessary for the unique identification of Medicinal Products per the ISO IDMP standards and technical specifications.
- **Conditional:** Applies to the “within category” data elements, as applicable, when there are alternative data sources for a given data element(s) to identify medicinal and pharmaceutical products. Regional implementation of the ISO IDMP standards and technical specifications may elevate the conditional conformance categories to “mandatory” per regional requirements.
- **Optional:** When listed at the category level (e.g. specified substance), optional corresponds to ISO categories or data elements that are not absolutely necessary for the unique identification of medicinal or pharmaceutical products according to the ISO IDMP standards and technical specifications. Regional implementation of the ISO IDMP standards and technical specifications may elevate the optional conformance categories to “mandatory” or “conditional” per regional requirements.

## 5 Concepts required for the unique identification of pharmaceutical products

### 5.1 General considerations for elements required for the unique identification of pharmaceutical products

[Clause 5](#), along with [Annex A](#) and [Annex B](#), describes the elements and messaging required to uniquely identify and characterize a pharmaceutical product. It provides the requirements to support pharmaceutical product identification. Examples are given in [Annex C](#).

The information modelling in this document uses the Unified Modelling Language (UML)<sup>2)</sup>, which is maintained by OMG (Object Management Group)<sup>3)</sup>.

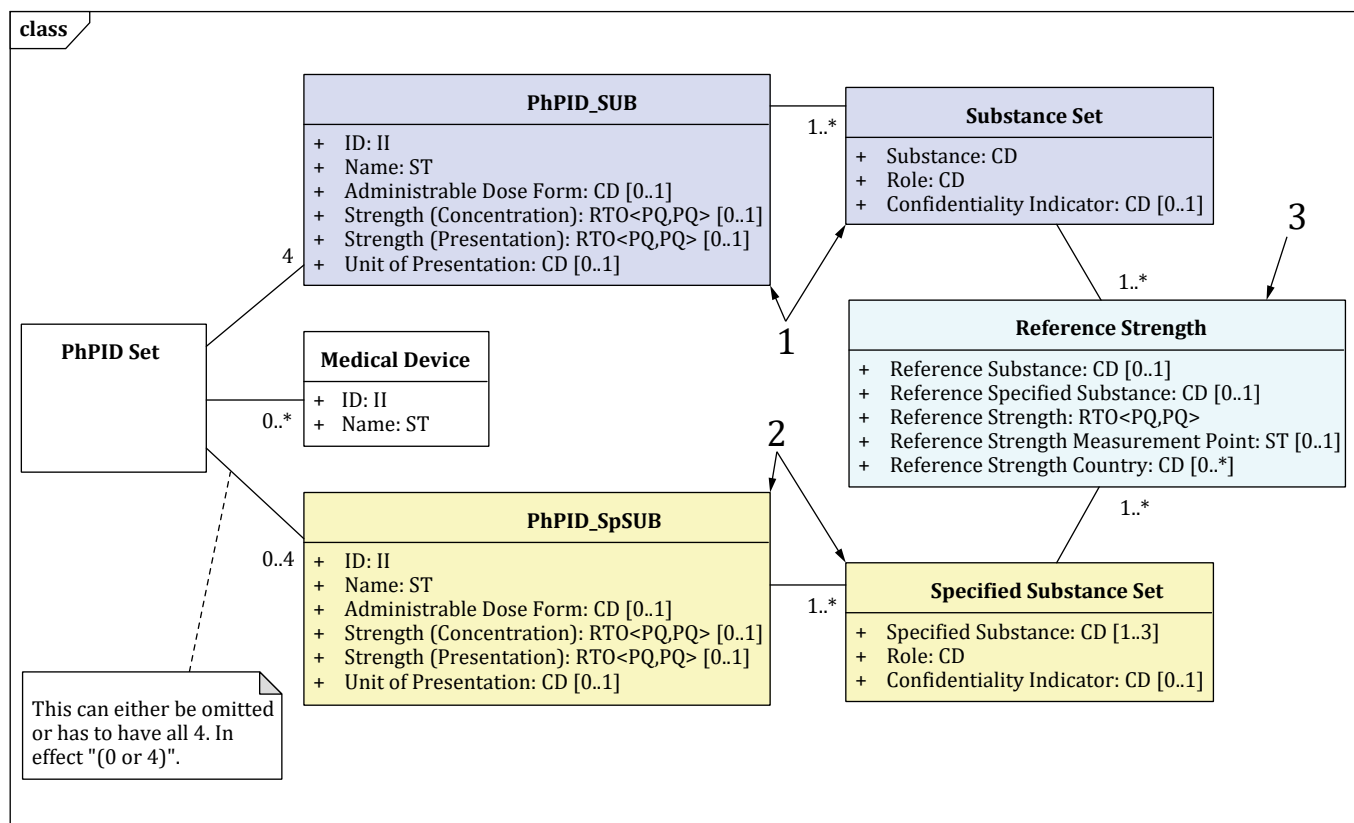
[Figure 1](#) shows the pharmaceutical product identification (PhPID) detailed model.

Pharmaceutical product identification (PhPID) shall be based on the following subset of elements that describe the pharmaceutical product.

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2) <https://www.uml.org/>

3) <https://www.omg.org/about/omg-standards-introduction.htm>



**Key**

- 1 substance stratum
- 2 specified substance stratum
- 3 strengths

**Figure 1 — Pharmaceutical product identification (PhPID) detailed model**

a) active substance(s) or specified substance(s);

NOTE The substance(s) within the ingredient role “active” and “adjuvant” are utilised to define PhPID.

- b) strength(s), strength units (units of measurement or unit of presentation, or both);
- c) reference strength(s) includes reference substance(s) (i.e. active moiety and its corresponding strength);
- d) administrable dose form;
- e) medical device, when it is a component of a Medicinal Product.

**5.2 Principles required for the unique identification of a pharmaceutical product**

The following principles for the unique identification of a pharmaceutical product shall apply:

- a) a medicinal product may relate to one or more pharmaceutical products as part of a treatment regime [e.g. a kit, which might be a combination pack containing vaginal tablets (500 mg) and an external vaginal cream (10 %)];
- b) the characterization of the pharmaceutical product(s) based on the active substance(s) or specified substance(s), the (reference) strength thereof, the administrable dose form(s), and the medical device (e.g. a scaffolding for cell-based products) being part of the Medicinal Product (e.g. drug-device combination);

- c) the description of the pharmaceutical product(s) in the pharmaceutical dose form approved for administration, where applicable, after reconstitution and as authorized in accordance with the regulated product information;
- d) the association of the regulated (investigational) medicinal product and the pharmaceutical product(s) using the PhPID(s).

## 6 Identifying characteristics for the identification of pharmaceutical products

### 6.1 Pharmaceutical product identification strata and levels

As per ISO 11616, PhPID sets shall be represented within two strata (active substance stratum and specified substance stratum), both of which contain four PhPID identification levels, for each pharmaceutical product contained in a Medicinal Product.

PhPID sets shall be generated using the substance part according to ISO 11238 and ISO/TS 19844, the strength and administrable dose form part as per ISO 11239 and ISO/TS 20440, and the unit(s) of measurement part as per ISO 11240, and as illustrated in [Table 1](#).

Reference strength shall be repeated in both PhPID strata. The reference strength shall be derived from the active moiety/moieties of an active substance(s) depending on the specific product characteristics.

All the PhPID strata can be described at four different levels from 1 to 4 as shown in [Table 1](#).

**Table 1 — Four levels of PhPID**

<b>PhPID active substance stratum</b>	PhPID_SUB_L1 → substance(s) PhPID_SUB_L2 → substance(s) + strength + reference strength PhPID_SUB_L3 → substance(s) + administrable dose form PhPID_SUB_L4 → substance(s) + strength + reference strength + administrable dose form
<b>PhPID specified substance stratum</b>	PhPID_SpSUB_L1 → specified substance(s) PhPID_SpSUB_L2 → specified substance(s) + strength + reference strength PhPID_SpSUB_L3 → specified substance(s) + administrable dose form PhPID_SpSUB_L4 → specified substance(s) + strength + reference strength + administrable dose form

A pharmaceutical product may refer to a drug that is associated with a medical device. In this instance, the device term and term ID (i.e. unique device identifier) shall be displayed with the active substance(s) and specified substance(s) terms for the product at all applicable PhPID levels. This association shall be made by directly associating the assigned PhPIDs to a Medicinal Product and its corresponding MPID-PCID as outlined in ISO 11615 and ISO/TS 20443.

Strength is not applicable to a device.

A region may further refine the requirements in relation to specification of the medical device as part of this document at implementation so that this information is to be specified only if required.

A pharmaceutical product may refer to a drug that is associated with an adjuvant (e.g. vaccine). In this instance, the adjuvant term and term ID shall be displayed as s separate active substance(s) or specified substance(s) terms for the product at all applicable PhPID levels. This association shall be made by directly associating the assigned PhPIDs to a medicinal product and its corresponding MPID and PCID as outlined in ISO 11615 and ISO/TS 20443.

Strength shall indicate quantity, unit of measurement and/or unit of presentation.

Administrable dose form is derived from the pharmaceutical product.

Placebos shall be captured as active substances when utilised as a comparator. Regional implementation guides will provide more information as some regional regulation defines what is considered a placebo or active substance.

NOTE The classification of a placebo as an “active substance” in this context is for data management purposes only and does not imply pharmacological activity.

## 6.2 PhPID specified substance

As described in ISO 11238 [4], specified substance(s) shall capture detailed characteristics of single substances or the composition of material that contains multiple substances or multiple physical forms.

The elements necessary to define specified substances shall be divided into four groups of elements to facilitate implementation. These groups are described as follows.

- Specified Substance Group 1. These elements shall be used to describe material that contains multiple substances, solvents used in the preparation of herbal or allergenic extracts, specific marker or signature substances present in plant or animal derived materials, the physical form of a substance, when relevant, and any properties essential to the description of the material.

The element groups used to define a Specified Substance Group 1 shall include constituents, physical form and property.

NOTE 1 This grouping of elements allows for the definitions of many materials in commerce that are used in the formulation of Medicinal Products.

- Specified Substance Group 2. These elements shall be used to capture the manufacturer of either a substance or Specified Substance Group 1 along with minimal manufacturing information.

The minimal manufacturing information shall include the overall production method type (i.e. synthetic, extractive, recombinant), production system type (i.e. cell line, plant or animal tissue) and production system (specific cell line).

NOTE 2 Group 2 elements allows the tracking of the substance to the manufacturer. They also allow the distinguishing of synthetic peptides from recombinant peptides and the capture of the product cell line.

- Specified Substance Group 3. These elements shall capture the grade of the material along with the source that defines the given grade.

Group 3 elements shall be used to distinguish specific pharmacopoeia grades and technical grades of material.

The grade for each pharmacopoeia shall be a separate substance if a pharmacopoeia monograph related to a substance is not harmonized.

NOTE 3 For most active pharmaceutical substances, generally recognised pharmacopoeias are USP, Ph., Eur. or JP. For herbal substances, the grades would be standardised, quantified and unstandardised.

- Specified Substance Group 4. These elements shall contain the most detailed information on a substance. This information shall include critical manufacturing processes, specifications (e.g. impurities and related substance limits would be captured using constituents), unitage, reference material and analytical methods used for potency determination.

NOTE 4 The specific information described for Specified Substance Group 4 is often submitted in regulatory submissions in an unstructured manner that is difficult to capture and organize. The fields developed here will attempt to organize and structure the data in a manner that will facilitate its use in both review and compliance activities. It is anticipated that the suite of ISO IDMP standards will extend into more granular regulatory content as adoption increases by stakeholders and the standards extend deeper into additional regulatory and clinical use cases over time.

### 6.3 Pharmaceutical product specified substance identification (PhPID SpSub)

The PhPIDs for specified substance(s) shall be generated from three of the four groups (Specified Substance Groups 1, Specified Substance Group 2, Specified Substance Group 3) described in ISO 11238 and ISO/TS 19844.

Specified Substance Groups 1, 2, and 3 contain necessary data elements for more detailed pharmaceutical product identification which supports the scope and purpose of this document.

Specified Substance Groups 1, 2, and 3, as assigned to an active substance(s), shall be utilised within this document for pharmaceutical product identification with corresponding PhPIDs attributed as applicable.

Specified Substance Group 4 is a more comprehensive level of substance identification that is not necessary for the purposes of pharmaceutical product identification and shall not be utilised for PhPID generation.

Specified substance information shall be represented with the active substance(s) elements within a pharmaceutical product and within a Specified Substance Group 1, as applicable.

Groups 2 and 3 shall be associated directly with the active substance(s) of a pharmaceutical product and to a Specified Substance Group 1 as applicable.

ISO/TS 19844 [12] addresses the assignment and association of specified substance groups for defined product classes. See ISO 11238 [4] and ISO/TS 19844 [12] for detailed information related to substance and specified substance elements and identification.

A region may further refine the requirements in relation to specification of specified substances as part of this document at implementation such that this information is to be specified only if required.

### 6.4 Cardinality

The relationships within the elements of a pharmaceutical product shall respect the following cardinality:

- a PhPID has one administrable dose form (cardinality relationship: 1..1);

NOTE 1 gPhPID utilizes the four dose form attributes.

- a PhPID may have zero to one unit of presentation (cardinality relationship: 0..1);

NOTE 2 This is often used specifically at the point of delivery to the patient in cases where a quantitative unit of measurement is not applicable.

- a PhPID has one or more active substances (cardinality relationship: 1..\*);

- a PhPID has one or more active specified substances (cardinality relationship: 1..\*);

- a PhPID has one strength (cardinality relationship: 1..1) based on one to many active substances or specified substances (cardinality relationship: 1..\*);

NOTE 3 The same quantitative value for strength can be expressed in multiple units according to regional implementation (e.g. mg/g, % w/w).

For liquid preparations, the strength (presentation) and strength (concentration) shall both be represented.

A separate PhPID shall be generated to represent the strength concentration, i.e. per unit volume as applicable. This shall be known as the product code concept as it represents a calculation of the strength presentation of a liquid preparation (i.e. total volume per container) as authorized by a medicines regulatory agency.

- a PhPID has one to many reference strengths (i.e. active moieties with a corresponding strength) (cardinality relationship: 1..\*) as it relates to the strength of one to many active substances/specified substances (cardinality relationship: 1..\*).

NOTE 4 For gPhPID, the strength of the active ingredient is expressed by means of presentation strength or concentration strength, or both, depending on product type as specified in the business rules for gPhPID.

## 6.5 Representation of strength concentration

For liquid preparations, strength shall be represented by both the total volume of the container as authorized by a medicines regulatory authority using strength (presentation) and strength concentration per unit volume (e.g. 1 ml) using strength (concentration). For PhPID generation and assignment, the strength shall be expressed per total volume per container (MPID and PCID) with the corresponding strength concentration per unit volume represented in every instance of PhPID Levels 2 and 4. Both representations shall be considered mandatory elements when illustrating the strength of a pharmaceutical product.

The labelled volume should be used rather than the manufactured volume, as it reflects the quantity intended for patient use and aligns with regulatory and pharmacopoeia standards.

The strength concentration per unit volume shall be calculated from the strength per total volume of the container and presented at all PhPID levels where strength is represented in accordance with the product authorization by a medicines regulatory agency.

See [Annex D](#) for examples of representation of strength.

## 6.6 Pharmaceutical product identifier (PhPID)

The PhPID is a unique identifier assigned at the level of the pharmaceutical product and utilises the identifying characteristics as outlined in [6.7](#). For products that need to be obtained after any necessary transformation in accordance with the authorization by a medicines regulatory authority before they can be administered, the PhPID shall refer to the characteristics of the product after reconstitution.

NOTE For more detailed information regarding the specific data elements classifying a particular substance(s) and specified substance(s), see ISO 11238 [\[4\]](#) and ISO/TS 19844 [\[12\]](#). The details of these elements are defining attributes for pharmaceutical product identification and assignment of PhPIDs.

## 6.7 PhPID identity

The PhPID identity can be created using the requirements specified in ISO/IEC 15459-3 [\[13\]](#), using a qualifier followed by a string and a check character.

### — Qualifier

The first five characters are called the qualifier and will always be the text “PHPID”.

### — String

The middle twelve characters are a string built up of random digits and letters using the following requirements:

- There are 32 valid characters: 0 1 2 3 4 5 6 7 8 9 A B C D E F G H J K L M N P R S T U V X Y Z.
- Maximum three sequential letters.
- Maximum three sequential digits.
- First position shall always be a digit of 1 to 9.
- Last position shall be a digit (0 to 9) if the two previous are letters.

### — Check character

The last character is a check character built on the “Luhn mod N algorithm” used to detect errors in the string.

[Table 2](#) shows an example of a PhPID identity combining the qualifier, a string, and a check character.

**Table 2 — Example of a PhPID identity combining the qualifier, a string and a check character**

Identity		
Qualifier	String	Check character
PhPID	6NT3YNT5L8BL	7

The human readable PhPID nomenclature shall be represented by the non-proprietary name (e.g. INN, USAN) of the pharmaceutical product, active substance(s), pharmaceutical dose form, strength, and reference strength. In addition, the adjuvant and device name can be described as part of the PhPID nomenclature as applicable.

NOTE For examples of PhPID for products containing adjuvant(s) and device(s), refer to regional implementation guides.

## 7 Ingredient, substance and strength

### 7.1 General considerations

[Clause 7](#) describes the ingredients of the pharmaceutical product through its representations as the manufactured item(s) as indicated within a jurisdiction (see ISO 11615 [\[3\]](#)) and the pharmaceutical product(s).

The ingredients class and associated active substance, specified substance, strength and reference strength classes are used in the further description of manufactured item as indicated within a jurisdiction (see ISO 11615 [\[3\]](#)) and pharmaceutical product class, as shown in [Figure 2](#).

Any active substance(s) or specified substance(s) shall have its strength specified in accordance with the pharmaceutical product information as applicable. Additionally, strength can be further specified by description of reference strength. This shall be specified where applicable in accordance with the pharmaceutical product information.

EXAMPLE Paracetamol 600 mg can be represented as 0,6 g in one jurisdiction and 600 mg in another jurisdiction, but will be assigned identical PhPID sets as the strengths are identical but with different representations.

When described, reference strength shall specify the active substance and specified substance that it references.

Pharmaceutical products and their ingredients as well as the device and adjuvant ingredients of interest are represented within the UML model in the manner shown in [Figure 2](#).

Each device shall be uniquely identified using the regionally defined nomenclature.

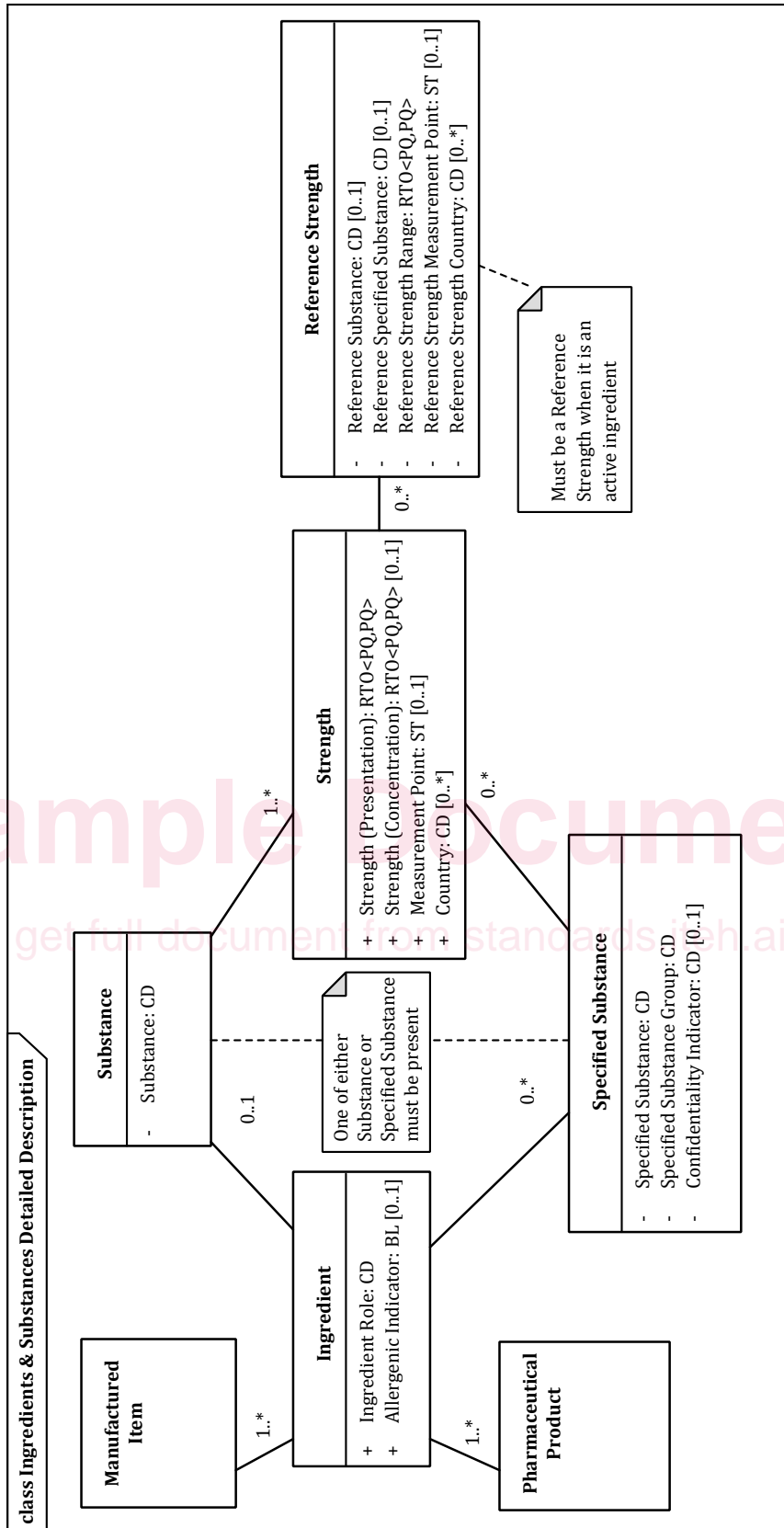


Figure 2 — Ingredients, substance and strength section detailed description diagram

Information messaging exchange relating to ingredient, substance and strength can be in accordance with [Annex A](#).