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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

Informatique de santé — Identification des médicaments — Éléments de données et structures pour l'identification unique et l'échange d'informations réglementées sur les formes pharmaceutiques, les unités de présentation, les voies d'administration et les emballages

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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 document 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).

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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.

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 11239:2012), which has been technically revised.

The main changes are as follows:

— it is now specified that pharmaceutical dose form attributes can in some cases be used directly in order to describe features of a medicinal product, rather than just serving as internal attributes to classify the pharmaceutical dose form.

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.

Introduction

This document was developed in response to a worldwide demand for internationally harmonized specifications for medicinal products. It is one of a group of five International Standards, which together provide the basis for the unique identification of medicinal products; the four other International Standards are ISO 11615, ISO 11616, ISO 11238 and ISO 11240.

These International Standards on the identification of medicinal products (IDMP) can be used in the activities of medicines regulatory agencies worldwide. These include a variety of regulatory activities related to development, registration and life cycle management of medicinal products, as well as pharmacovigilance and risk management.

The International Standards on IDMP therefore can be used in the following interactions (this is not an exhaustive list):

— regulator to regulator;

— pharmaceutical company to regulator;

— sponsor of clinical trial to regulator;

— regulator to other stakeholders;

— regulator to worldwide-maintained data sources.

The necessary messaging specifications are included as an integral part of the International Standards on IDMP to secure the interactions above.

Unique identifiers produced in conformance with the International Standards on IDMP are aimed at supporting applications where it is needed to reliably identify and trace the use of medicinal products.

There are many terms in use to describe basic concepts in the regulatory, pharmaceutical and healthcare standards development domain for different purposes and in different contexts.

In the context of identification of pharmaceutical dose forms, units of presentation, routes of administration and packaging, this document describes the essential elements for the specification, translation and versioning of the specified controlled terms. Also described are recommendations concerning the mapping of terms that are already used by stakeholders to the concepts arising from the implementation of this document.

The high-level concepts described consist of:

— pharmaceutical dose form;

— unit of presentation;

— route of administration;

— packaging.

The supporting, more mechanical, components are described separately from the high-level clinical concepts. The supporting concepts consist of:

a) terms and codes;

b) translations;

c) versioning;

d) mapping.

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

1 Scope

This document specifies:

— the data elements, structures and relationships between the data elements required for the exchange of information, which uniquely and with certainty identify pharmaceutical dose forms, units of presentation, routes of administration and packaging items (containers, closures and administration devices) related to medicinal products;

— a mechanism for the association of translations of a single concept into different languages, which is an integral part of the information exchange;

— a mechanism for the versioning of the concepts in order to track their evolution;

— rules to help regional authorities to map existing regional terms to the terms created using this document, in a harmonized and meaningful way.

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 639-1, *Codes for the representation of names of languages — Part 1: Alpha-2 code*

ISO 3166-1, *Codes for the representation of names of countries and their subdivisions — Part 1: Country code*

3 Terms, definitions and abbreviated terms

3.1 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

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/

3.1.1
administrable dose form
aDF
pharmaceutical dose form (3.1.21) for administration to the patient, after any necessary *transformation* (3.1.27) of the *manufactured items* (3.1.17) and their corresponding *manufactured dose forms* (3.1.16) has been carried out

EXAMPLE Solution for injection, tablet for oral use, hard-capsule powder for inhalation.

Note 1 to entry: The administrable dose form is identical to the manufactured dose form in cases where no transformation of the manufactured item is necessary [i.e. where the manufactured item is equal to the *pharmaceutical product* (3.1.22)].

3.1.2
administration device
equipment intended to allow the *medicinal product* (3.1.18) to be administered correctly to the patient

EXAMPLE Needle, oral syringe.

Note 1 to entry: An administration device may be an integral part of an *immediate container* (3.1.13) or a *closure* (3.1.5).

[SOURCE: ENV 12610:1997, 3.1, modified — The definition has been revised, the Example has been added, the Notes to entry have been replaced.]

3.1.3
administration method
general technique by which a *pharmaceutical product* (3.1.22) is intended to be administered to the patient

EXAMPLE Application, inhalation, injection.

Note 1 to entry: The administration method is used to group related *pharmaceutical dose form* (3.1.21) concepts, and is not intended to describe a precise method or *route of administration* (3.1.25).

Note 2 to entry: In certain circumstances, the administration method may be used, alone or in combination with one or more other pharmaceutical dose form attributes, to describe a *medicinal product* (3.1.18) where a pharmaceutical dose form term cannot be used, for example as part of an adverse event report in which the precise pharmaceutical dose form is unknown but the administration method is known.

3.1.4
basic dose form
generalized version of the *pharmaceutical dose form* (3.1.21), used to group together related pharmaceutical dose forms

EXAMPLE Capsule, tablet, powder, solution.

Note 1 to entry: In certain circumstances, the basic dose form may be used, alone or in combination with one or more other pharmaceutical dose form attributes, to describe a *medicinal product* (3.1.18) where a pharmaceutical dose form term cannot be used, for example as part of an adverse event report in which the precise pharmaceutical dose form is unknown but the basic dose form is known.

3.1.5
closure
item used to close a *container* (3.1.9) for the purpose of the correct storage and (where appropriate) use of the *medicinal product* (3.1.18)

EXAMPLE Cap, child-resistant closure, screw cap.

Note 1 to entry: A closure may have an *administration device* (3.1.2) incorporated into it.

Note 2 to entry: A closure may be an integral part of an *immediate container* (3.1.13).

3.1.6
coded concept
datatype (3.1.11) that groups together a set of *code term pairs* (3.1.7) that represent a single concept but differ in language and/or geographical region

Note 1 to entry: The coded concept is used to manage translations, and is the basic datatype that is found in all of the high-level conceptual models.

3.1.7
code term pair
datatype (3.1.11) that groups together the attributes required to describe a single concept in a specified language and for a specified geographical location

3.1.8
combined pharmaceutical dose form
single term to describe two or more *manufactured items* (3.1.17) that are intended to be combined in a specific way to produce a single *pharmaceutical product* (3.1.22), and which includes information on the *manufactured dose form* (3.1.16) of each manufactured item and the *administrable dose form* (3.1.1) of the pharmaceutical product

EXAMPLE Powder and solvent for solution for injection. The *medicinal product* (3.1.18) contains two manufactured items (a powder for solution for injection and a solvent for solution for injection); the pharmaceutical product that is prepared from the two manufactured items is a solution for injection. The combined pharmaceutical dose form for the medicinal product is "powder and solvent for solution for injection" (see also Table A.7).

3.1.9
container
item of packaging that is part of a *medicinal product* (3.1.18) and is used for storage, identification and/or transport of the components of the medicinal product

EXAMPLE Ampoule, bottle, box.

Note 1 to entry: "Container" is a general concept that groups together the concepts of *immediate container* (3.1.13), *intermediate packaging* (3.1.15) and *outer packaging* (3.1.20).

3.1.10
controlled vocabulary
finite set of values that represent the only allowed values for a data item

Note 1 to entry: These values may be codes, text, or numeric.

3.1.11
datatype
set of distinct values, characterized by properties of those values, and by operations on those values

[SOURCE: ISO/IEC 11404:2007, 3.12]

3.1.12
identifier
description that is sufficient to represent an object in a given environment

[SOURCE: ENV 12610:1997, 3.13, modified — The Note to entry has been deleted.]

3.1.13
immediate container
container (3.1.9) in which a *manufactured item* (3.1.17) or *pharmaceutical product* (3.1.22) is contained and with which it is in direct contact

EXAMPLE Ampoule, vial, prefilled syringe, bottle, blister.

Note 1 to entry: An immediate container can be fitted with or have integrated into it an *administration device* (3.1.2) and/or *closure* (3.1.5).

Note 2 to entry: A *pharmaceutical dose form* (3.1.21) can fulfil the role of an immediate container, e.g. a capsule containing a powder for inhalation; the capsule in this case is not a container.

[SOURCE: ENV 12610:1997, 3.14, modified — The definition has been revised, the admitted terms have been deleted, the Example has been replaced, the Notes to entry have been replaced.]

3.1.14
intended site
general description of the area of the body at which a *pharmaceutical product* (3.1.22) is intended to be administered

EXAMPLE Auricular, ocular, oral.

Note 1 to entry: The intended site is used to group related *pharmaceutical dose form* (3.1.21) concepts, and is not intended to describe a precise site or *route of administration* (3.1.25).

Note 2 to entry: In certain circumstances, the intended site may be used, alone or in combination with one or more other pharmaceutical dose form attributes, to describe a *medicinal product* (3.1.18) where a pharmaceutical dose form term cannot be used, for example as part of an adverse event report in which the precise pharmaceutical dose form is unknown but the intended site is known.

3.1.15
intermediate packaging
container (3.1.9) between the *outer packaging* (3.1.20) and the *immediate container* (3.1.13)

EXAMPLE Box.

3.1.16
manufactured dose form
mDF
pharmaceutical dose form (3.1.21) of a *manufactured item* (3.1.17) as supplied by the manufacturer and, where applicable, before *transformation* (3.1.27) into the *pharmaceutical product* (3.1.22)

EXAMPLE Powder for solution for injection.

Note 1 to entry: The manufactured dose form is identical to the *administrable dose form* (3.1.1) in cases where no transformation of the manufactured item is necessary (i.e. where the manufactured item is equal to the pharmaceutical product).

3.1.17
manufactured item
qualitative and quantitative composition of a product as contained in the packaging of the *medicinal product* (3.1.18) as put on the market or investigational medicinal product as used in a clinical trial

Note 1 to entry: A medicinal product may contain one or more manufactured items.

Note 2 to entry: In many instances, the manufactured item is equal to the *pharmaceutical product* (3.1.22). However, there are instances where the manufactured item(s) must undergo a *transformation* (3.1.27) before being administered to the patient (as the pharmaceutical product) and the two are not equal.

3.1.18
medicinal product
pharmaceutical product (3.1.22) or combination of pharmaceutical products that can be administered to human beings or animals for treating or preventing disease, with the aim of making a medical diagnosis or to restore, correct or modify physiological functions

Note 1 to entry: A medicinal product may contain in the packaging one or more *manufactured items* (3.1.17) and one or more pharmaceutical products.

Note 2 to entry: In certain regions, a medicinal product is defined as any substance or combination of substances that can be used to make a medical diagnosis.

[SOURCE: ENV 13607:2000, 3.19, modified — The definition has been revised, The Note to entry has been replaced.]

3.1.19
medicinal product identifier
MPID
unique *identifier* (3.1.12) allocated to a *medicinal product* (3.1.18) supplementary to any existing authorisation number as ascribed by a medicines regulatory agency in a region

Note 1 to entry: This is for indexing purposes and to contribute to improving patient safety by allowing for the unique identification of medicinal products worldwide.

3.1.20
outer packaging
external *container* (3.1.9) in which a *medicinal product* (3.1.18) is supplied

EXAMPLE Box.

Note 1 to entry: The *manufactured item* (3.1.17) or *pharmaceutical product* (3.1.22) is not in direct contact with the outer packaging except where the outer packaging also serves as the *immediate container* (3.1.13).

3.1.21
pharmaceutical dose form
physical manifestation of a product that contains the active ingredient(s) and/or inactive ingredient(s) that are intended to be delivered to the patient

Note 1 to entry: "Pharmaceutical dose form" can refer to the *administrable dose form* (3.1.1) or the *manufactured dose form* (3.1.16), depending on the product that it is describing.

3.1.22
pharmaceutical product
qualitative and quantitative composition of a *medicinal product* (3.1.18) in the *pharmaceutical dose form* (3.1.21) approved for administration in line with the regulated product information

Note 1 to entry: A medicinal product may contain one or more pharmaceutical products.

Note 2 to entry: In many instances, the pharmaceutical product is equal to the *manufactured item* (3.1.17). However, there are instances where the manufactured item(s) must undergo a *transformation* (3.1.27) before being administered to the patient (as the pharmaceutical product) and the two are not equal.

3.1.23
pharmaceutical product identifier
PhPID
unique *identifier* (3.1.12) for a *pharmaceutical product* (3.1.22)

3.1.24
release characteristics
description of the modified timing by which an active ingredient is made available in the body after administration of the *pharmaceutical product* (3.1.22), in comparison with a conventional, direct release of the active ingredient

EXAMPLE Delayed, extended, none.

Note 1 to entry: In certain circumstances, the release characteristics may be used, alone or in combination with one or more other *pharmaceutical dose form* (3.1.21) attributes, to describe a *medicinal product* (3.1.18) where a pharmaceutical dose form term cannot be used, for example as part of an adverse event report in which the precise pharmaceutical dose form is unknown but the release characteristics are known.

3.1.25
route of administration
path by which the *pharmaceutical product* (3.1.22) is taken into or makes contact with the body

EXAMPLE Intravenous, ocular, oral, oromucosal.

3.1.26
state of matter
physical condition describing the molecular form of a product

EXAMPLE Gas, liquid, semi-solid, solid.

Note 1 to entry: State of matter is used to group *basic dose forms* (3.1.4) according to their physical properties.

Note 2 to entry: In certain circumstances, the state of matter may be used, alone or in combination with one or more other *pharmaceutical dose form* (3.1.21) attributes, to describe a *medicinal product* (3.1.18) where a pharmaceutical dose form term cannot be used, for example as part of an adverse event report in which the precise pharmaceutical dose form is unknown but the state of matter is known.

3.1.27
transformation
procedure that is carried out in order to convert a *manufactured item* (3.1.17) that requires such a procedure into a *pharmaceutical product* (3.1.22), i.e. from its *manufactured dose form* (3.1.16) to its *administrable dose form* (3.1.1)

EXAMPLE Dilution, dissolution, suspension.

Note 1 to entry: A transformation is not required when the manufactured item is equal to the pharmaceutical product.

Note 2 to entry: In certain circumstances, the transformation may be used, alone or in combination with one or more other *pharmaceutical dose form* (3.1.21) attributes, to describe a *medicinal product* (3.1.18) where a pharmaceutical dose form term cannot be used, for example as part of an adverse event report in which the precise pharmaceutical dose form is unknown but the transformation is known.

3.1.28
unit of measurement
real scalar quantity, defined and adopted by convention, with which any other quantity of the same kind can be compared in order to express the ratio of the two quantities as a number

Note 1 to entry: Depending on the nature of the reference scale, the unit of measurement expression may stand either for a physical unit of measurement that is related to a system of quantities (e.g. SI units) or for an arbitrarily defined unit of measurement, which might refer to a certain reference material, a standard measurement procedure, a material measure or even a combination of those.

3.1.29
unit of presentation
qualitative term describing the discrete countable entity in which a *pharmaceutical product* (3.1.22) or *manufactured item* (3.1.17) is presented, in cases where strength or quantity is expressed referring to one instance of this countable entity

EXAMPLE 1 To describe strength: actuation, spray, tablet; “contains 100 mcg per spray” (unit of presentation = spray).

EXAMPLE 2 To describe quantity: bottle, box, vial; “contains 100 ml per bottle” (unit of presentation = bottle).

Note 1 to entry: A unit of presentation can have the same name as another controlled vocabulary, such as a *basic dose form* (3.1.4) or a *container* (3.1.9), but the two concepts are not equivalent, and each has a unique *controlled vocabulary* (3.1.10) term *identifier* (3.1.12).

3.2 Abbreviated terms

HL7 Health Level Seven

IDMP Identification of medicinal products

SI International System of Units

4 Requirements

4.1 General information regarding controlled vocabularies

Controlled vocabularies can also be used independently of the International Standards on IDMP. HL7®[1)] messaging is used for communication of controlled vocabulary messages in IDMP.

Management of translations of controlled terms is described in this document so that the exchange of information related to medicinal products can be implemented on a global scale.

Management of the versioning of the controlled terms is described in this document so that the controlled vocabularies and any modifications to them can be appropriately tracked, to allow for an auditable history.

Guidelines are provided in this document to assist users to map existing terms to the controlled terms so that terms that are already in use in different regions can be associated with the controlled terms.

4.2 Requirements for use

The controlled vocabularies shall satisfy the following criteria:

— provide appropriate terms and identifiers to describe the pharmaceutical dose form for a medicinal product, as required for the generation and description of the PhPID and the MPID; this includes the provision of the pharmaceutical dose form attributes (state of matter, basic dose form, release characteristics, transformation, intended site and administration method):

— provide appropriate terms and identifiers to describe the intended route(s) of administration for a medicinal product, as required for the complete description of the medicinal product and the generation of the MPID;

— provide appropriate terms and identifiers to describe the unit of presentation for a medicinal product, as required for the complete description of the strength of certain types of medicinal product for the generation of the MPID;

— provide appropriate terms and identifiers to describe the container (which includes the immediate container, the intermediate packaging and the outer packaging), closure and administration device for a medicinal product, as required for the description of the medicinal product for the generation of the MPID.

The controlled terms and codes shall be publicly available.

5 Schema

5.1 General

This document describes the essential elements for the specification, translation and versioning of the controlled terms. Also described are recommendations concerning the mapping of terms that are already used by stakeholders to the concepts arising from the implementation of this document.

The supporting components are:

— terms and codes;

— translations;

— versioning;

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— mapping.

The high-level concepts are:

a) pharmaceutical dose form;

b) unit of presentation;

c) route of administration;

d) packaging.

The schemata employ the datatypes ST (String), CD (Concept Descriptor), TS (Point in Time) and INT (Integer) specified in ISO 21090.

An attribute showing no explicit cardinality means that the attribute shall be valued with one value (this is equivalent to [1..1]).

5.2 Conceptual models — Supporting concepts

5.2.1 General

The following conceptual models specify the elements, structures and inter-element relationships that describe the supporting concepts (terms and codes, translations, versioning, mapping) for each set of controlled terms.

5.2.2 Terms and codes

5.2.2.1 The codeTermPair datatype

The codeTermPair shall be used as the underlying class that carries the base code, the associated text string and other elements of definition, and will be used as a datatype in the creation of the codedConcept.

The attributes of the underlying class codeTermPair (see Figure 1) shall be:

a) code: a unique (machine-processable) identifier for the codeTermPair (datatype: ST).

b) term: the textual term description for the concept (datatype: ST);

c) definition: a textual definition for the concept (datatype: ST);

d) domain: an optional indicator for use where veterinary-only terms are also provided in the same database; indicates that the concept is for either “human and veterinary” or “veterinary only” use (default value is “human and veterinary”) (datatype: CD);

e) comment: an optional textual comment (datatype: ST);

f) languageCode: the language in which b) to e) are described, which shall conform to ISO 639-1 (datatype: CD);

g) regionCode: the country/region that uses this codeTermPair in this language, which shall conform to ISO 3166-1 (datatype: CD).

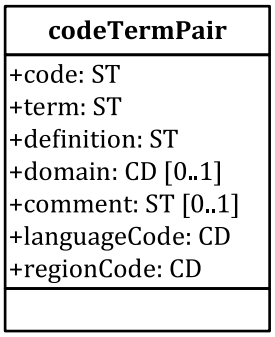

Figure 1 — Conceptual diagram for the codeTermPair datatype

5.2.2.2 The codedConcept datatype

The codedConcept associates a concept for a selected language and geographical region (e.g. in English for the UK) with zero to many translations of that same concept for different languages and/or geographical regions (e.g. in French for France, in German for Germany). The codeTermPair code for the concept for the user-selected language and region is used for the "value" element, and zero to many codeTermPair codes for that same concept for different languages and/or regions are used for the "translation" element; together these specify the codedConcept datatype.

The codedConcept (see Figure 2) shall be made up of the following attributes:

a) code: the unique (machine-processable) identifier for the codedConcept (datatype: ST);

b) value: the codeTermPair code for the concept that has the user-selected language code (e.g. English) and user-selected region code (e.g. UK) (datatype: codeTermPair);

c) translation: zero to many codeTermPair codes for the same concept with different language and/or region codes (e.g. French and France, German and Germany) (datatype: codeTermPair).

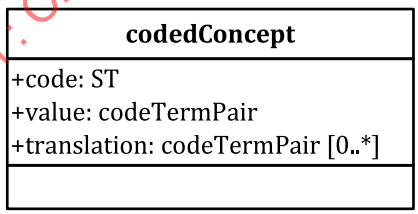

Figure 2 — Conceptual diagram for the codedConcept datatype

5.2.2.3 The versioning of a concept

Versioning provides a traceable history for each concept from the point of creation of the concept, including details of all modifications thereafter.

The versioning (see Figure 3) shall be made up of the following attributes:

a) code: the unique (machine-processable) identifier for the concept that is the subject of the versioning (datatype: ST);

b) creationDate: a time stamp indicating the date and time that the concept was created (datatype: TS);

c) createdBy: information to identify the person who created the concept (datatype: ST);

d) modificationDate: a time stamp indicating the date and time that the modification was made for the specified version (datatype: TS);

e) modificationMade: a description in free text of the modification made for the specified version (datatype: ST);

f) modifiedBy: information to identify the person who modified the concept (datatype: ST);

g) conceptStatus: the status of the concept, i.e. whether it is current, deprecated, etc. (datatype: CD);

h) currentConcept [0..*]: when a concept is deprecated, the code of the concept that replaces it; there may be more than one replacement concept for a single deprecated concept (datatype: codeTermPair/codedConcept);

i) versionNumber: a number that indicates the version of the concept (datatype: INT).

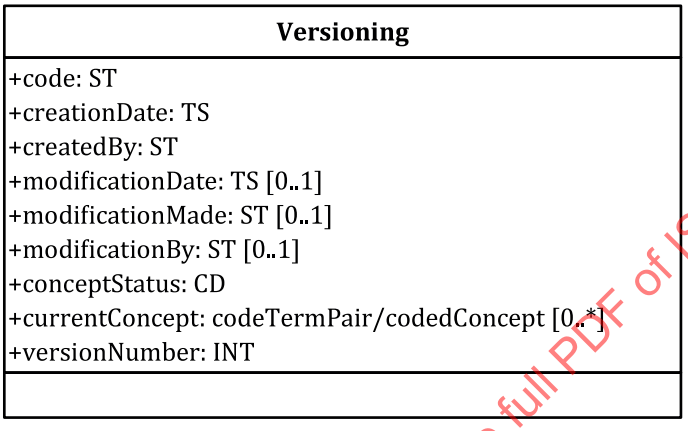

Figure 3 — Conceptual diagram for the versioning of a concept

The concepts that arise from the implementation of this document (referred to here as "standardized concepts") will not necessarily match terms that are already in use by the various stakeholders in the different countries and regions (referred to here as "regional terms"). In order that the regional terms that are already in use, in particular those specified by the appropriate medicines regulatory agencies in the different countries and regions, can be linked to the standardized concepts, it is envisaged that the appropriate stakeholders map their regional terms to these standardized concepts in their own databases and/or systems. Such a mapping exercise will help users of an existing database to identify the equivalent standardized concept for a given regional term.

A single regional term can map to zero to many standardized concepts, and zero to many regional terms can map to a single standardized concept (see Figure 4).

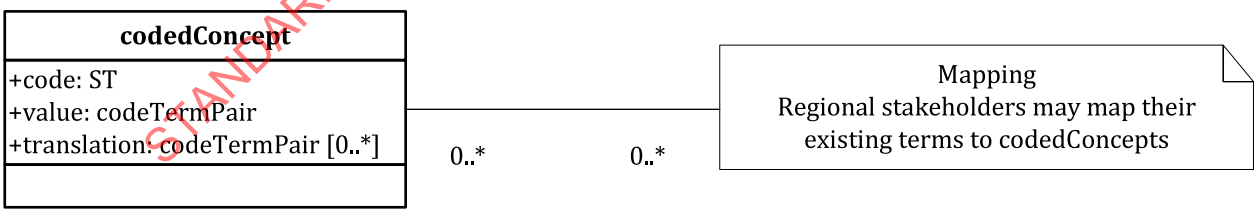

Figure 4 — Conceptual diagram indicating the target of any mapping process

This is to account for the differences in granularity that existing databases in different regions exhibit when creating and defining regional terms. For example, region A might use less-specific terms with a low level of detail, such that one of their regional terms maps to three standardized concepts, while region B might use more specific terms with a high level of detail, such that three of their regional terms map to a single standardized concept (see Table 1).

Table 1 — Theoretical examples of mapping to standardized concepts of regional terms with lower (region A) and higher (region B) levels of granularity

Region A regional term (lower granularity)	Maps to standardized concepts (one to many)
Injection	Solution for injection
	Suspension for injection
	Solution for infusion

Region B regional terms (higher granularity)	Map to standardized concept (many to one)
Granule-filled soft capsule	Soft oral capsule
Liquid-filled soft capsule	
Powder-filled soft capsule	

5.3 Conceptual models — High-level concepts

5.3.1 General

The following conceptual models specify the elements, structures and inter-element relationships that describe the high-level concepts (pharmaceutical dose form, unit of presentation, route of administration, packaging) for the controlled terms.

5.3.2 Pharmaceutical dose form

5.3.2.1 General

The following conceptual models specify the pharmaceutical dose form concept and the associated elements, structure and inter-element relationships that describe it, and the combined pharmaceutical dose form.

5.3.2.2 Pharmaceutical dose form concept

The pharmaceutical dose form is built from a set of basic dose forms, which are in turn grouped according to state of matter. Each pharmaceutical dose form is associated with attributes that describe any release characteristics, any transformation that is required to be carried out before administration, the intended site of administration, and the intended method of administration (see Figure 5). The pharmaceutical dose form concept and its attributes are described using the codedConcept datatype, thereby incorporating the translated concepts.

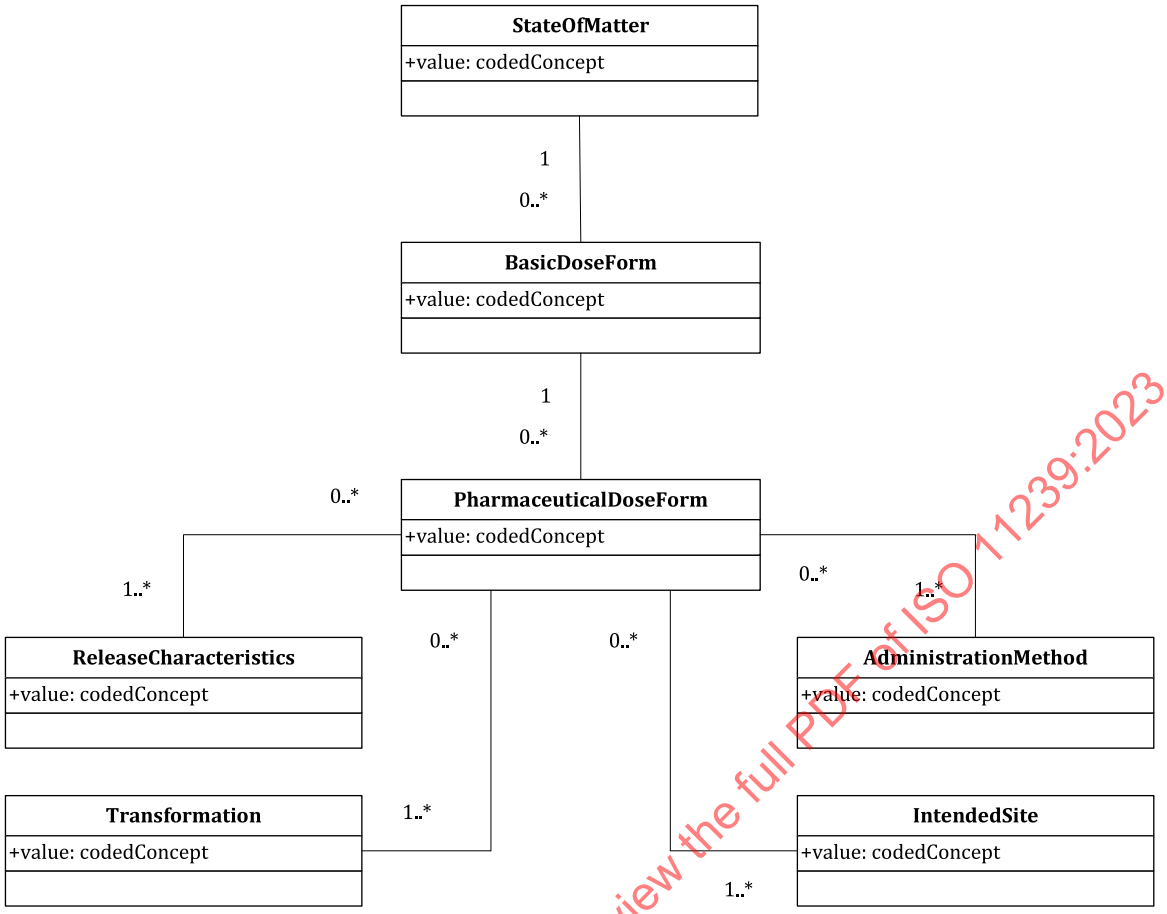

Figure 5 — Conceptual diagram for the pharmaceutical dose form class

5.3.2.3 State of matter class

The state of matter class shall be used as the high-level grouping category that classes the pharmaceutical dose form, via the basic dose form, according to its state of matter attribute. A state of matter class has zero to many basic dose forms.

EXAMPLE Solid, semi-solid, liquid, gas.

NOTE See also Table A.1 for controlled vocabulary examples, and Annex B for medicinal product examples.

In certain circumstances, the state of matter class may be used, alone or in combination with one or more other pharmaceutical dose form attributes, to describe a medicinal product where a pharmaceutical dose form term cannot be used, for example as part of an adverse event report in which the precise pharmaceutical dose form is unknown but the state of matter is known.

The state of matter class shall be described using a codedConcept.

5.3.2.4 Basic dose form class

The basic dose form class shall be used as the high-level grouping category that classes the pharmaceutical dose form according to its general type of pharmaceutical dose form. A basic dose form has zero to many pharmaceutical dose forms.

EXAMPLE Tablet, capsule, powder, solution.

NOTE See also Table A.1 for controlled vocabulary examples, and Annex B for medicinal product examples.

In certain circumstances, the basic dose form class may be used, alone or in combination with one or more other pharmaceutical dose form attributes, to describe a medicinal product where a pharmaceutical dose form term cannot be used, for example as part of an adverse event report in which the precise pharmaceutical dose form is unknown but the basic dose form is known.

The basic dose form class shall be described using a codedConcept.

5.3.2.5 Release characteristics class

The release characteristics class shall be used to describe the release characteristics of the pharmaceutical dose form. Where there are no release characteristics to be specified, the class has an appropriate null value. A release characteristic is associated with zero to many pharmaceutical dose forms.

EXAMPLE Delayed, extended, pulsatile, none.

NOTE See also Table A.2 for controlled vocabulary examples, and Annex B for medicinal product examples.

In certain circumstances, the release characteristics class may be used, alone or in combination with one or more other pharmaceutical dose form attributes, to describe a medicinal product where a pharmaceutical dose form term cannot be used, for example as part of an adverse event report in which the precise pharmaceutical dose form is unknown but the release characteristics are known.

The release characteristics class shall be described using a codedConcept.

5.3.2.6 Transformation class

The transformation class shall be used to describe the physical operation that is required in order to convert a manufactured dose form into an administrable dose form, where this is necessary. Where there is no transformation, the class has an appropriate null value. A transformation is associated with zero to many pharmaceutical dose forms.

EXAMPLE Dilution, dissolution, none.

NOTE See also Table A.3 for controlled vocabulary examples, and Annex B for medicinal product examples.

In certain circumstances, the transformation class may be used, alone or in combination with one or more other pharmaceutical dose form attributes, to describe a medicinal product where a pharmaceutical dose form term cannot be used, for example as part of an adverse event report in which the precise pharmaceutical dose form is unknown but the transformation is known.

The transformation class shall be described using a codedConcept.

5.3.2.7 Intended site class

The intended site class shall be used to describe the general body site at which the pharmaceutical dose form is intended to be administered. It is a set of high-level general terms expressly for describing the intended site, rather than a specialized vocabulary detailing precise sites of administration. It is not the same concept as route of administration. Where there is no intended site associated, the class has an appropriate null value. An intended site is associated with zero to many pharmaceutical dose forms.

EXAMPLE Auricular, ocular, oral, none.

NOTE See also Table A.4 for controlled vocabulary examples, and Annex B for medicinal product examples.

In certain circumstances, the intended site class may be used, alone or in combination with one or more other pharmaceutical dose form attributes, to describe a medicinal product where a pharmaceutical dose form term cannot be used, for example as part of an adverse event report in which the precise pharmaceutical dose form is unknown but the intended site is known.

The intended site class shall be described using a codedConcept.

5.3.2.8 Administration method class

The administration method class shall be used to describe the pharmaceutical dose form according to the general intended method by which it is to be administered to the body. It describes a set of high-level general terms expressly for describing the intended administration method for a pharmaceutical dose form, rather than a specialized vocabulary detailing precise methods of administration. Where there is no administration method associated, the class has an appropriate null value. An administration method is associated with zero to many pharmaceutical dose forms.

EXAMPLE Application, inhalation, injection, none.

NOTE See also Table A.5 for controlled vocabulary examples, and Annex B for medicinal product examples.

In certain circumstances, the administration method class may be used, alone or in combination with one or more other pharmaceutical dose form attributes, to describe a medicinal product where a pharmaceutical dose form term cannot be used, for example as part of an adverse event report in which the precise pharmaceutical dose form is unknown but the administration method is known.

The administration method class shall be described using a codedConcept.

5.3.2.9 Pharmaceutical dose form class

The pharmaceutical dose form class shall be used to describe the pharmaceutical dose form as it is used in describing medicinal products. It also describes the relationship of the pharmaceutical dose form to the attributes that are needed to specify properly the concept. It can be summarized as shown in Figure 6.

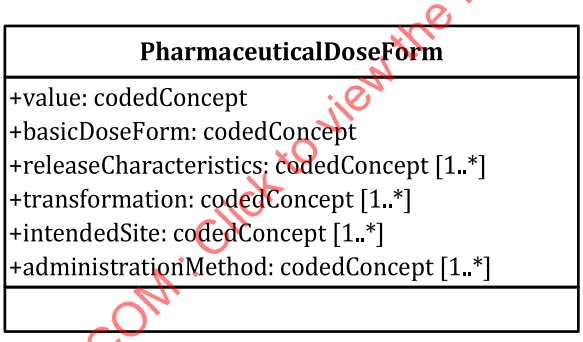

Figure 6 — Conceptual diagram summarizing the pharmaceutical dose form class

The pharmaceutical dose form class is associated with one basic dose form class, and has one to many release characteristics, one to many transformations, one to many intended sites of administration, and one to many administration methods.

EXAMPLE Tablet, powder for solution for injection, powder for concentrate for solution for injection.

NOTE See also Table A.6 for controlled vocabulary examples, and Annex B for medicinal product examples.

The pharmaceutical dose form class shall be described using a codedConcept.

5.3.2.10 Combined pharmaceutical dose form class

The combined pharmaceutical dose form class shall provide unique concepts to describe specific combinations of pharmaceutical dose forms where these are required. Two or more pharmaceutical dose form concepts combined are described using a unique coded concept (see Figure 7).

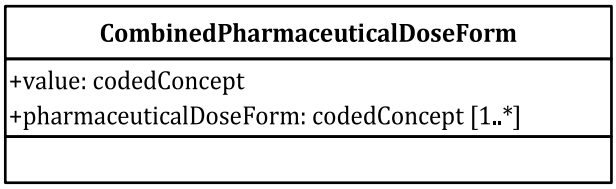

Figure 7 — Conceptual diagram for the combined pharmaceutical dose form

EXAMPLE Powder and solvent for solution for injection (see Figure 8).

NOTE See also Table A.7 for controlled vocabulary examples, and Clauses B.4 and B.5 for medicinal product examples.

In the example shown in Figure 8, a medicinal product contains in its packaging two separate manufactured items: a powder and a solvent. The powder is intended to be dissolved in the solvent in order to produce a solution, which is the pharmaceutical product that is intended to be administered to the patient by injection. The two manufactured items are described by the manufactured dose forms "powder for solution for injection" and "solvent for solution for injection" respectively. The pharmaceutical product that is formed from the manufactured items and administered to the patient is described by the administrable dose form "solution for injection". The medicinal product as a whole can be described by the combined pharmaceutical dose form "powder and solvent for solution for injection". In the conceptual diagram shown in Figure 7, "value" would be filled by the coded concept "powder and solvent for solution for injection", and "pharmaceuticalDoseForm" would be filled by the coded concepts "powder for solution for injection" and "solvent for solution for injection". The coded concept "solution for injection" may also be included as a "pharmaceuticalDoseForm", but in that case the administrable dose form should be distinguished from the manufactured dose forms, for example by labelling the concepts as "manufacturedDoseForm" and "administrableDoseForm" accordingly.

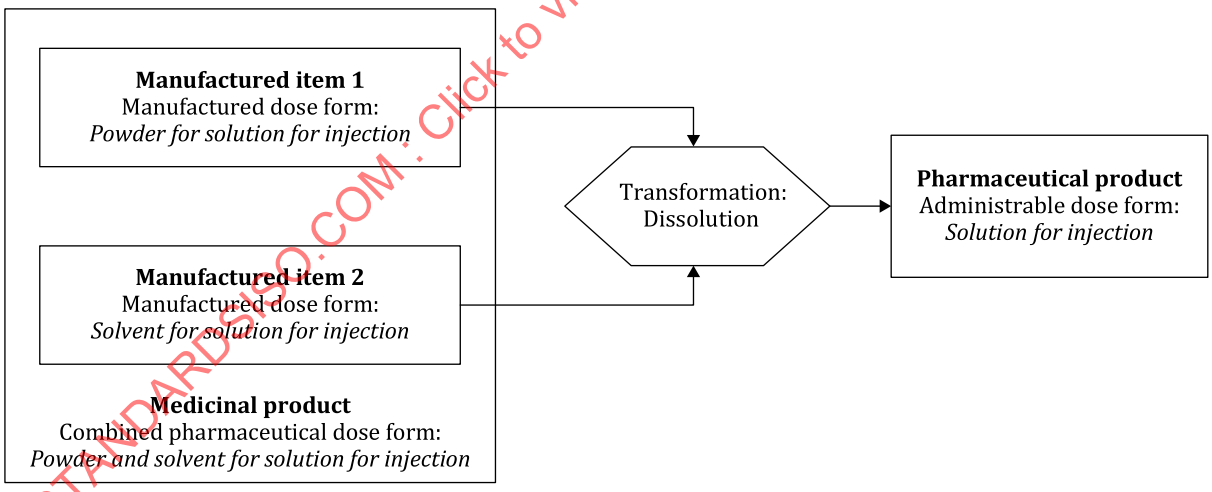

Figure 8 — Diagram illustrating the relationship between manufactured dose form, administrable dose form and combined pharmaceutical dose form for a medicinal product consisting of two manufactured items, and where a transformation is required

The combined pharmaceutical dose form class shall be described using a codedConcept.

5.3.3 Unit of presentation

5.3.3.1 General

The following conceptual model specifies the unit of presentation concept and the elements that describe it.

5.3.3.2 Unit of presentation concept

The unit of presentation (see Figure 9) is used where the strength may be described in terms of "each" in a general manner; in such a case, "each" would be replaced by "per tablet", "per actuation", "per patch", etc. It is also used where the strength or total quantity of a manufactured item or pharmaceutical product is described in terms of the packaging, such as "100 ml per bottle".

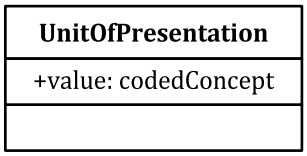

Figure 9 — Conceptual diagram for the unit of presentation class

5.3.3.3 Unit of presentation class

The unit of presentation class shall be used to specify the attributes that are needed to describe properly the unit of presentation concept.

EXAMPLE Actuation, drop, patch, tablet, bottle, tube.

NOTE See also Table A.8 for controlled vocabulary examples, and Annex B for medicinal product examples.

The unit of presentation class shall be described using a codedConcept.

5.3.4 Route of administration

5.3.4.1 General

The following conceptual model specifies the route of administration concept and the elements that describe it.

5.3.4.2 Route of administration concept

The route of administration (see Figure 10) is a concept that is used to describe the path by which the pharmaceutical product is taken into or makes contact with the body.

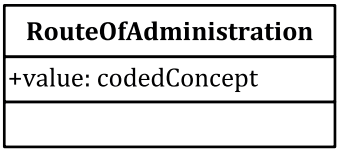

Figure 10 — Conceptual diagram for the route of administration class

5.3.4.3 Route of administration class

The route of administration class shall be used to specify the attributes that are needed to describe properly the route of administration concept.

EXAMPLE Intramuscular, intravenous, oral, subcutaneous.

NOTE See also Table A.9 for controlled vocabulary examples, and Annex B for medicinal product examples.

The route of administration class shall be described using a codedConcept.

5.3.5 Packaging

5.3.5.1 General

The following conceptual model specifies the packaging concept and the associated elements, structure and inter-element relationships that describe it.

5.3.5.2 Packaging concept

The packaging concept is a group of three concepts that describe particular elements of the medicinal product: container, closure and administration device (see Figure 11).

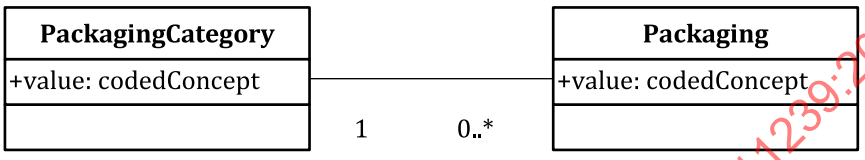

Figure 11 — Conceptual diagram for the packaging class

5.3.5.3 Packaging category class

The packaging category class shall be used as the high-level grouping category that classes the packaging concept according to the general category of packaging into which it falls, namely: container, closure and administration device. A packaging category has zero to many types of packaging.

The packaging category class shall be described using a codedConcept.

5.3.5.4 Packaging class

The packaging class shall be used to specify the attributes that are needed to describe properly the container, closure, or administration device concept. A packaging has one packaging category.

EXAMPLE 1 For the container: ampoule, blister, bottle, tube, box.

EXAMPLE 2 For the closure: cap, screw-cap, stopper.

EXAMPLE 3 For the administration device: needle, oral syringe.

NOTE See also Table A.10 for controlled vocabulary examples, and Annex B for medicinal product examples.

The packaging class shall be described using a codedConcept.

Annex A
(informative)

Examples of controlled vocabularies

A.1 Purpose of provided examples

These examples may be used for the creation of controlled vocabularies, but their presence here does not imply that they are or will be the official controlled vocabulary terms, and nor are these intended to be complete lists.

A.2 Pharmaceutical dose form

Table A.1 — State of matter and basic dose form examples

State of matter	Basic dose form
Gas	Medicinal gas
	Vapour
Liquid	Collodion
	Concentrate
	Emulsion
	Liquid
	Solution
	Suspension
Semi-solid	Cream
	Gel
	Ointment
	Paste
Solid	Capsule
	Film
	Granules
	Gum
	Implant
	Insert
	Tablet
Unclear	Unclear

Table A.2 — Release characteristics examples

Release characteristics
Delayed
Extended
Modified
None

Table A.3 — Transformation examples

Transformation
Dilution
Dissolution
Extraction
Mixing
Suspension/Dispersion
None

Table A.4 — Intended site examples

Intended site
Auricular
Cutaneous
Dental
Intrauterine
Intravesical
Nasal
Ocular
Oral
Oromucosal
Pulmonary
Rectal
Transdermal
Vaginal
None

Table A.5 — Administration method examples

Administration method
Application
Bathing
Chewing
Gargling
Infusion
Injection
Insertion
Instillation
Orodispersion
Spraying
Swallowing
None

Table A.6 — Pharmaceutical dose form examples

Pharmaceutical dose form
Capsule for oromucosal use
Chewable tablet
Concentrate for solution for cutaneous use
Cream for nasal use
Delayed-release tablet
Effervescent granules
Emulsion for injection
Extended-release tablet
Foam for cutaneous use
Granules for suspension for oral use
Hard capsule
Hard, delayed-release capsule
Hard-capsule powder for inhalation
Implant
Muco-adhesive tablet for buccal use
Ointment for auricular use
Ointment for cutaneous use
Oral powder
Orodispersible film
Powder for cutaneous use
Powder for solution for infusion
Powder for solution for injection
Powder for solution for oral use
Pressurized solution for inhalation
Pressurized suspension for inhalation
Prolonged-release eye drops
Shampoo
Soft capsule
Soft, delayed-release capsule
Soluble tablet
Solution for ear-drop use
Solution for ear-spray use
Solution for eye-drop use
Solution for infusion
Solution for injection
Solution for oral use
Spray for oromucosal use
Spray for sublingual use
Suppository
Suspension for injection
Suspension for oral use
Tablet

Table A.6 *(continued)*

Pharmaceutical dose form
Tablet for solution for gargle
Tablet for sublingual use
Tablet for vaginal use

Table A.7 — Combined pharmaceutical dose form examples

Combined pharmaceutical dose form	Components (pharmaceutical dose forms: manufactured/administrable)
Concentrate and solvent for solution for cutaneous use	Concentrate for solution for cutaneous use (mDF)
	Solvent for solution for cutaneous use (mDF)
	Solution for cutaneous use (aDF)
Powder and solvent for solution for injection	Powder for solution for injection (mDF)
	Solvent for solution for injection (mDF)
	Solution for injection (aDF)
Suspension and granules for suspension for oral use	Suspension for suspension for oral use (mDF)
	Granules for suspension for oral use (mDF)
	Suspension for oral use (aDF)

A.3 Unit of presentation

Table A.8 — Unit of presentation examples

Unit of presentation
Actuation
Bottle
Capsule
Dose
Drop
Implant
Insert
Patch
Scoop
Suppository
Tablet
Vial

A.4 Route of administration

Table A.9 — Route of administration examples

Route of administration
Auricular
Cutaneous
Dental
Gingival
Inhalational
Intestinal
Intraarterial
Intracardiac
Intracerebral
Intracervical
Intralymphatic
Intramuscular
Intraocular
Intrauterine
Intravenous
Intravesical
Laryngopharyngeal
Nasal
Ocular
Oral
Oromucosal
Rectal
Route of administration not applicable
Subcutaneous
Sublingual
Transdermal
Urethral
Vaginal

A.5 Packaging

Table A.10 — Packaging category and packaging examples

Packaging category	Packaging
Container	Ampoule
	Blister
	Bottle
	Box
	Cartridge
	Tube