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BSI Standards Publication

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

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National foreword

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The UK participation in its preparation was entrusted to Technical Committee IST/35, Health informatics.

A list of organizations represented on this committee can be obtained on request to its secretary.

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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 (ISO 11239:2012)

Informatique de santé - Identification des médicaments - Éléments de données et structures pour l'identification unique et l'échange d'informations réglementées sur les formes des doses pharmaceutiques, les unités de présentation, les voies d'administration et les emballages (ISO 11239:2012)

Medizinische Informatik - Identifikation von Arzneimitteln - Struktur und kontrollierte Vokabularien zur Identifikation von pharmazeutischen Darreichungsformen, pharmazeutischen Konventionseinheiten, Anwendungsarten und Verpackungen (ISO 11239:2012)

This European Standard was approved by CEN on 24 May 2012.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This document (EN ISO 11239:2012) has been prepared by Technical Committee ISO/TC 215 "Health informatics" in collaboration with Technical Committee CEN/TC 251 “Health informatics” the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2013, and conflicting national standards shall be withdrawn at the latest by May 2013.

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Endorsement notice

The text of ISO 11239:2012 has been approved by CEN as a EN ISO 11239:2012 without any modification.

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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.

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ISO 11239 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

Introduction

This International Standard was developed in response to a worldwide demand for internationally harmonized specifications for medicinal products. It is one of a group of five standards which together provide the basis for the unique identification of medicinal products. The group of standards comprises:

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 the unique identification and exchange of regulated pharmaceutical product information*;

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*.

These standards for the identification of medicinal products (IDMP) support the activities of medicines regulatory agencies worldwide by jurisdiction. 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.

To meet the primary objectives of the regulation of medicines and pharmacovigilance it is necessary to exchange medicinal product information in a robust and reliable manner. The IDMP standards therefore support 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 IDMP standards to secure the interactions above.

Unique identifiers produced in conformance with the IDMP standards are aimed at supporting applications where it is necessary 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. The terms and definitions described in this International Standard are to be applied for the concepts which are required in order to uniquely identify, characterize and exchange regulated medicinal products and associated information.

The terms and definitions adopted in this International Standard are intended to facilitate the interpretation and application of legal and regulatory requirements but they are without prejudice to any legally binding document. In case of doubt or potential conflict, the terms and definitions contained in legally binding documents prevail.

In the context of identification of pharmaceutical dose forms, units of presentation, routes of administration and packaging, this International Standard 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 International Standard.

The high-level concepts defined 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.

INTERNATIONAL STANDARD ISO 11239:2012(E)

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 International Standard 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 allow regional authorities to map existing regional terms to the terms created using this International Standard, in a harmonized and meaningful way.

In addition, to support the successful application of this International Standard, references to standards concerned with identification of medicinal products (IDMP) and messaging for medicinal product information are provided as required.

2 Normative references

The following referenced documents are indispensable for the application 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 (all parts), *Codes for the representation of names of languages*

ISO 3166 (all parts), *Codes for the representation of names of countries and their subdivisions*

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

3 Terms, definitions and abbreviations

3.1 Terms and definitions

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

3.1.1
administrable dose form
pharmaceutical dose form for administration to the patient, after any necessary transformation of the manufactured dose form has been carried out

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

NOTE 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).

3.1.2
administration device
equipment intended for correct administration of the medicinal product

EXAMPLES Needle, oral syringe.

NOTE 1 An administration device may be an integral part of an immediate container or a closure.

NOTE 2 Adapted from ENV 12610:1997.

3.1.3
administration method
general method by which a pharmaceutical product is intended to be administered to the patient

EXAMPLES Application, inhalation, injection.

NOTE The administration method is a general term that is used to group related pharmaceutical dose form concepts, and is not intended to describe a precise method or route of administration.

3.1.4
basic dose form
generalised version of the pharmaceutical dose form, used to group together related pharmaceutical dose forms

EXAMPLES Capsule, tablet, powder, solution.

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

EXAMPLES Cap, child-resistant closure, screw cap.

NOTE 1 A closure may have an administration device incorporated into it.

NOTE 2 A closure may be an integral part of an immediate container.

3.1.6
coded concept
data type that groups together a set of code term pairs that represent a single concept but differ in language and/or geographical region

NOTE The coded concept is used to manage translations, and is the basic data type that is found in all of the high-level conceptual models.

3.1.7
code term pair
data type 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 that are intended to be combined in a specific way to produce a single pharmaceutical product, and which includes information on the manufactured dose form of each manufactured item and the administrable dose form of the pharmaceutical product

EXAMPLE Powder and solvent for solution for injection. The medicinal product 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 Annex A, Table A.7).

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

EXAMPLES Ampoule, bottle, box.

NOTE "Container" is a general concept that groups together the concepts of immediate container, intermediate packaging and outer packaging.

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

NOTE 1 These values may be codes, text, or numeric.

NOTE 2 Adapted from CDISC Clinical Research Glossary V8.0, 2009.

3.1.11
controlled vocabulary term identifier
concept identifier intended to be used as the preferred unique identifier for that concept in that code system and which is published by the author of a code system

NOTE 1 It remains constant over time, independent of the particular version of the knowledge resource.

NOTE 2 Adapted from HL7 Core Principles.

3.1.12
immediate container
immediate packaging in which a manufactured item or pharmaceutical product is contained and with which it is in direct contact

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

NOTE 1 An immediate container can be fitted with or have integrated into it an administration device and/or closure.

NOTE 2 A pharmaceutical dose form 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.

NOTE 3 An alternative, compatible definition of immediate container ("immediate packaging") is given in Directive 92/27/EEC.

NOTE 4 Adapted from ENV 12610:1997.

3.1.13
intended site
general body site at which a pharmaceutical product is intended to be administered

EXAMPLES Auricular, ocular, oral.

NOTE The intended site is a general term that is used to group related pharmaceutical dose form concepts, and is not intended to describe a precise site or route of administration.

3.1.14
intermediate packaging
level of packaging between the outer packaging and the immediate container

EXAMPLE Box.

3.1.15
manufactured dose form
pharmaceutical dose form of a manufactured item as manufactured and, where applicable, before transformation into the pharmaceutical product

EXAMPLE Powder for solution for injection.

NOTE The manufactured dose form is identical to the administrable 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).

3.1.16
manufactured item
qualitative and quantitative composition of a product as contained in the packaging of the medicinal product

NOTE 1 A medicinal product may contain one or more manufactured items.

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

NOTE 3 The manufactured item is not in direct contact with the outer packaging except where the outer packaging also serves as the immediate container.

3.1.17
medicinal product
any substance or combination of substances, which may be administered to human beings or animals for treating or preventing disease, with the view to making a medical diagnosis or to restore, correct or modify physiological functions

[ENV 13607:2000; ENV 12610:1997]

NOTE 1 A medicinal product may consist of one or more manufactured items and one or more pharmaceutical products.

NOTE 2 In certain jurisdictions, a medicinal product may also be defined as any substance or combination of substances which may be used to make a medical diagnosis.

3.1.18
MPID
medicinal product identifier
unique identifier allocated to a medicinal product supplementary to any existing authorization number as ascribed by a medicines regulatory agency in a jurisdiction

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

3.1.19
outer packaging
external container in which a medicinal product is supplied

EXAMPLE Box.

NOTE 1 The manufactured item or pharmaceutical product is not in direct contact with the outer packaging except where the outer packaging also serves as the immediate container.

NOTE 2 An alternative, compatible definition of outer packaging is given in Directive 92/27/EEC: “packaging into which is placed the immediate packaging”.

3.1.20
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 “Pharmaceutical dose form” can refer to the administrable dose form or the manufactured dose form, depending on the product that it is describing.

3.1.21
pharmaceutical product
qualitative and quantitative composition of a medicinal product in the dose form authorized for administration by a medicines regulatory agency and as represented with any corresponding regulated product information

NOTE 1 A medicinal product may contain one or more pharmaceutical products.

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

3.1.22
PhPID
pharmaceutical product identifier
unique identifier assigned to the pharmaceutical product(s)

3.1.23
release characteristics
description of the modified timing by which an active ingredient is made available in the body after administration of the pharmaceutical product, in comparison with a conventional, direct release of the active ingredient

EXAMPLES Delayed, extended, none.

3.1.24
route of administration
path by which the pharmaceutical product is taken into or makes contact with the body

EXAMPLES Intravenous, oral, ocular, oromucosal.

3.1.25
state of matter
physical condition describing the molecular form of a product

EXAMPLES Gas, liquid, semi-solid, solid.

NOTE State of matter is used to group basic dose forms according to their physical properties.

3.1.26
transformation
procedure that is carried out in order to convert a manufactured item that requires such a procedure into a pharmaceutical product, i.e. from its manufactured dose form to its administrable dose form

EXAMPLES Dilution, dissolution, suspension.

NOTE A transformation is not required when the manufactured item is equal to the pharmaceutical product.

3.1.27
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 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 to a combination of those.

3.1.28
unit of presentation
qualitative term describing the discrete countable entity in which a pharmaceutical product or manufactured item is presented, in cases where strength or quantity is expressed referring to one instance of this countable entity

EXAMPLE 1 To describe strength: puff, 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 A unit of presentation can have the same name as another controlled vocabulary, such as a basic dose form or a container, but the two concepts are not equivalent, and each has a unique controlled vocabulary term identifier.

3.2 Abbreviations

The following abbreviations are used in this International Standard.

3.2.1
CDISC
Clinical Data Interchange Standards Consortium

3.2.2
CTS
Combined Terminology Services

3.2.3
HL7
Health Level Seven

3.2.4
IDMP
Identification of medicinal products

3.2.5
MPID
medicinal product identifier

3.2.6
PhPID
pharmaceutical product identifier

3.2.6
SI
International System of Units

4 Requirements

4.1 General requirements for controlled vocabularies

This International Standard forms part of a set of standards for the identification of medicinal products (IDMP). It provides specifications to support the creation of a set of controlled vocabularies that are essential for the implementation of the set of standards as a whole, in particular:

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

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

However, controlled vocabularies can also be used independently of the IDMP set of standards. Health Level Seven (HL7) Common Terminology Services (CTS) Version 2 messaging is used for communication of controlled vocabulary messages in the IDMP.

Management of translations of controlled terms is described in this International Standard 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 International Standard 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 International Standard 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 within the IDMP set of standards

In order that the controlled vocabularies provided for in this International Standard are suitable for their purpose as integral parts of the IDMP set of standards, they 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;

— 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 and the expectation is that their use will be royalty free.

5 Schema

5.1 General

This International Standard 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 International Standard.

The supporting components are:

— terms and codes;

— translations;

— versioning;

— mapping.

The high-level concepts are:

a) pharmaceutical dose form;

b) unit of presentation;

c) route of administration;

d) packaging.

The schemata employ the data types ST (String), CD (Concept Descriptor), TS (Point in Time) and INT (Integer) defined 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 define 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

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 data type in the creation of the codedConcept.

The attributes of the underlying class codeTermPair are:

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

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

c) definition: a textual definition for the concept (data type: 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”) (data type: CD);

e) comment: an optional textual comment (data type: ST);

f) languageCode: the language in which b) to e) are described, in accordance with ISO 639 (data type: CD);

g) regionCode: the country/region that uses this codeTermPair in this language, in accordance with ISO 3166 (data type: CD).

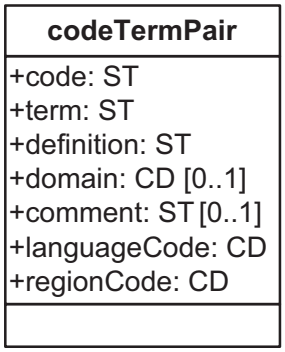

Figure 1 — Conceptual diagram for the codeTermPair data type

5.2.3 Translations

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 define the codedConcept data type.

The codedConcept is made up of the following attributes:

a) code: the unique (machine-processable) identifier for the codedConcept (data type: 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) (data type: 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) (data type: codeTermPair).

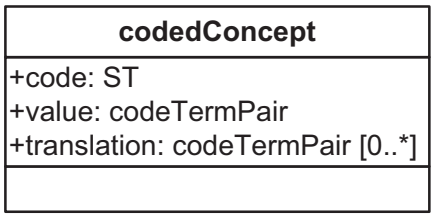

Figure 2 — Conceptual diagram for the codedConcept data type

5.2.4 Versioning

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

The versioning 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 (data type: ST);

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

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

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

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

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

g) conceptStatus: the status of the concept, i.e. whether it is current, deprecated, etc. (data type: 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 (data type: codeTermPair/codedConcept);

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

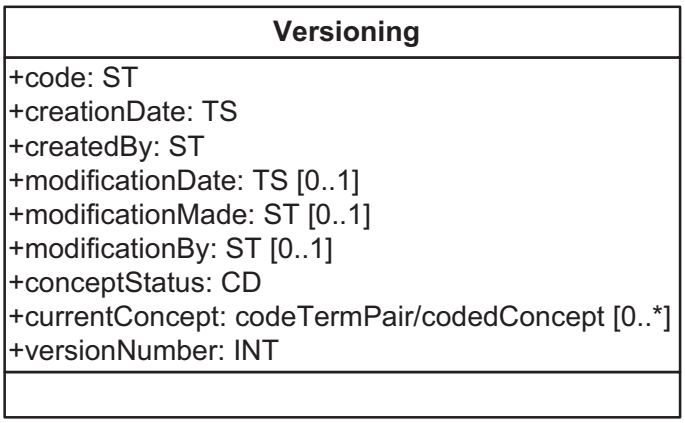

Figure 3 — Conceptual diagram for the versioning of a concept

5.2.5 Mapping

The concepts that arise from the implementation of this International Standard (referred to here as “central 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 defined by the appropriate medicines regulatory agencies in the different countries and regions, can be linked to the central concepts, it is envisaged that the appropriate stakeholders map their regional terms to these central concepts in their own databases and/or systems. Such a mapping exercise will help users of an existing database to identify the equivalent central concept for a given regional term.

A single regional term can map to zero to many central concepts, and zero to many regional terms can map to a single central concept.

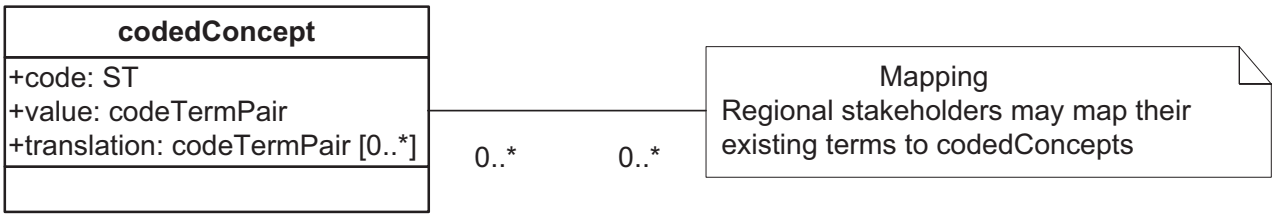

Figure 4 — Conceptual diagram indicating the target of any mapping process

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 central 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 central concept (see Table 1).

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

Region A regional term (lower granularity)	Maps to central concepts (one to many)	Region B regional terms (higher granularity)	Map to central concept (many to one)
Injection	Solution for injection	Granule-filled soft capsule	Soft oral capsule
	Suspension for injection	Liquid-filled soft capsule	
	Solution for infusion	Powder-filled soft capsule	

5.3 Conceptual models — High-level concepts

5.3.1 General

The following conceptual models define 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 define 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. The pharmaceutical dose form concept and its attributes are described using the codedConcept datatype, thereby incorporating the translated concepts.

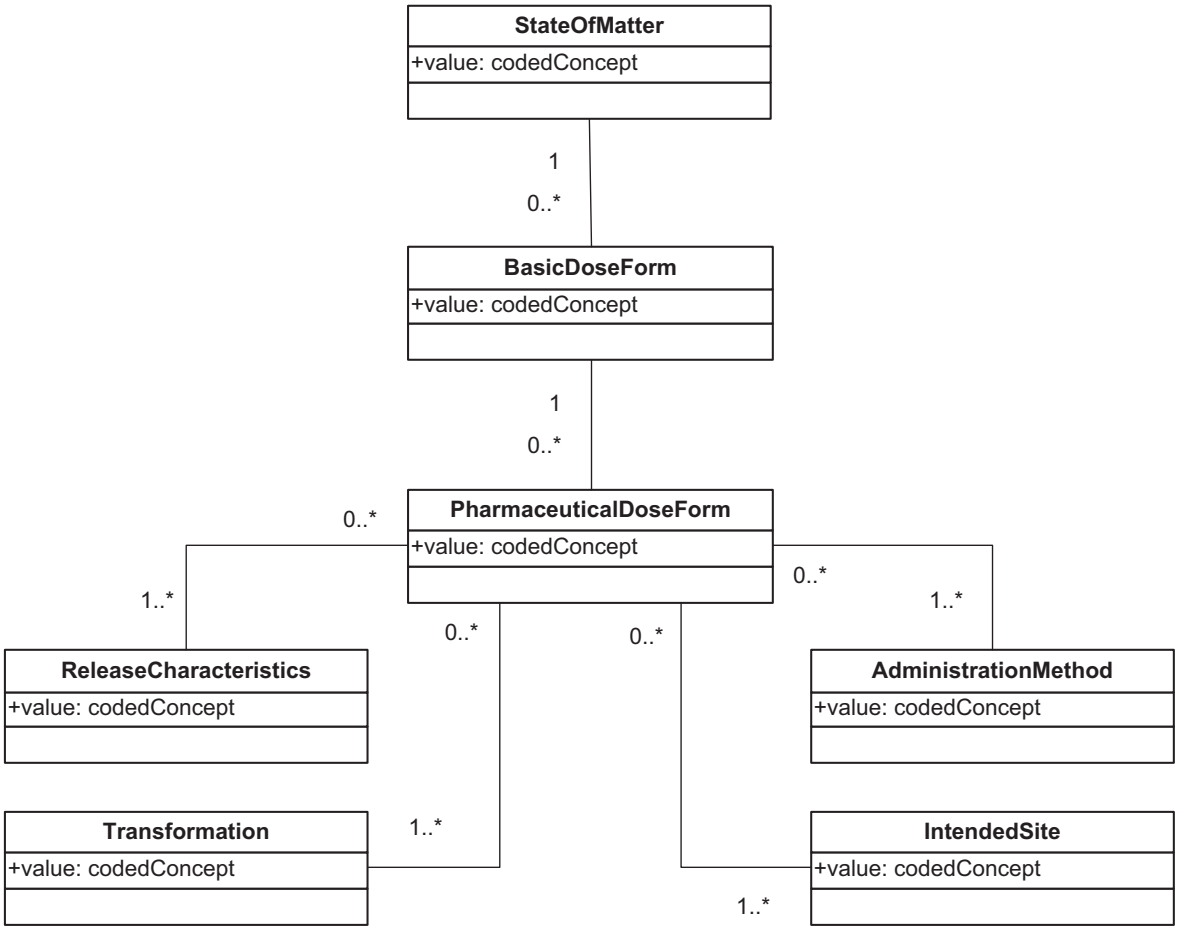

Figure 5 — Conceptual diagram for the pharmaceutical dose form class

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.

EXAMPLES Solid, semi-solid, liquid, gas. See also Annex A (Table A.1) for controlled vocabulary examples, and Annex B for medicinal product examples.

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.

EXAMPLES Tablet, capsule, powder, solution. See also Annex A (Table A.1) for controlled vocabulary examples, and Annex B for medicinal product examples.

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.

EXAMPLES Delayed, extended, pulsatile, none. See also Annex A (Table A.2) for controlled vocabulary examples, and Annex B for medicinal product examples.

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.

EXAMPLES Dilution, dissolution, none. See also Annex A (Table A.3) for controlled vocabulary examples, and Annex B for medicinal product examples.

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.

EXAMPLES Auricular, ocular, oral, none. See also Annex A (Table A.4) for controlled vocabulary examples, and Annex B for medicinal product examples.

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.

EXAMPLES Application, inhalation, injection, none. See also Annex A (Table A.5) for controlled vocabulary examples, and Annex B for medicinal product examples.

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 define properly the concept. It can be summarized as follows:

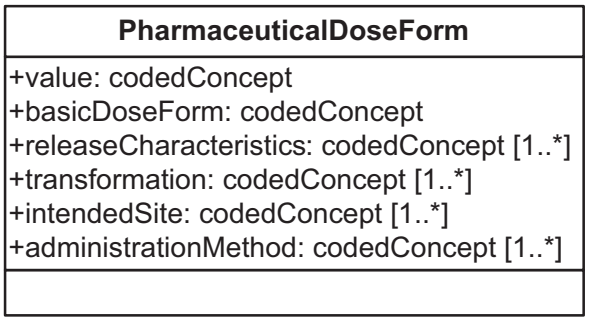

Figure 6 — Conceptual diagram summarizing the pharmaceutical dose form class

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.

EXAMPLES Tablet, powder for solution for injection, powder for concentrate for solution for injection. See also Annex A (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.

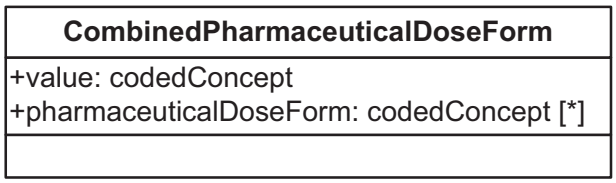

Figure 7 — Conceptual diagram for the combined pharmaceutical dose form

EXAMPLES Powder and solvent for solution for injection (see Figure 8). See also Annex A (Table A.7) for controlled vocabulary examples, and Annex B (B.1.3 and B.1.4) 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”.

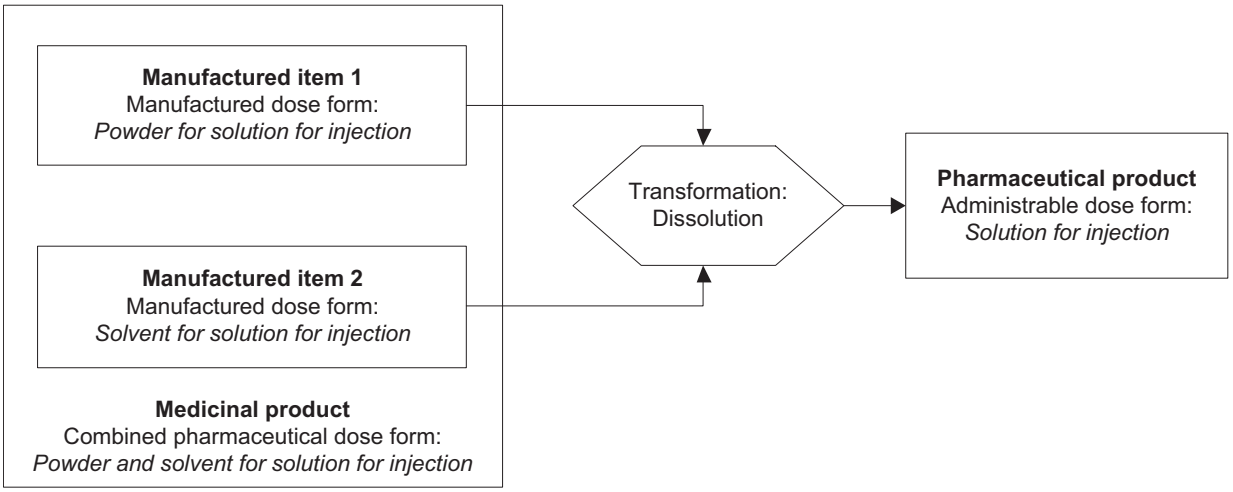

Figure 8 — Diagram illustrating the relationship between manufactured dose form, administrable dose form and combined pharmaceutical dose form for a medicinal product consisting of two manufactured items, and where a transformation is required

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 defines the unit of presentation concept and the elements that describe it.

5.3.3.2 Unit of presentation concept

The unit of presentation is a concept that is used in describing the qualitative unit in which the strength or quantity of the manufactured item or pharmaceutical product are presented and described, in cases where a quantitative unit of measurement is not applicable. It 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 puff”, “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”.

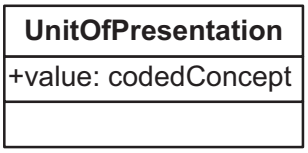

Figure 9 — Conceptual diagram for the unit of presentation class

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.

EXAMPLES Actuation, drop, patch, tablet, bottle, tube. See also Annex A (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 defines the route of administration concept and the elements that describe it.

5.3.4.2 Route of administration concept

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

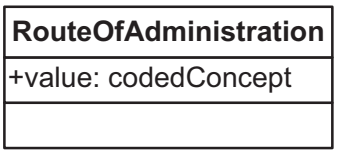

Figure 10 — Conceptual diagram for the route of administration class

5.3.4.3 Route of administration class

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

EXAMPLES Intramuscular, intravenous, oral, subcutaneous. See also Annex A (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 defines 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.

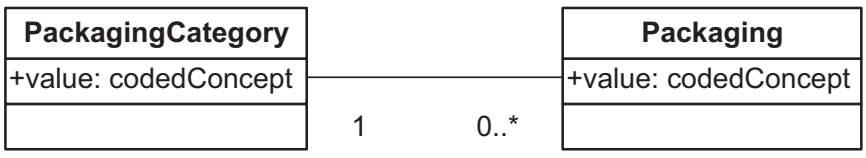

Figure 11 — Conceptual diagram for the packaging class

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 define properly the container, closure, or administration device concept. A packaging has one packaging category.

EXAMPLE 1 For the container: ampoule, blister, bottle, tube, box, carton. See also Annex A (Table A.10) for controlled vocabulary examples, and Annex B for medicinal product examples.

EXAMPLE 2 For the closure: cap, screw-cap, stopper. See also Annex A (Table A.10) for controlled vocabulary examples, and Annex B for medicinal product examples.

EXAMPLE 3 For the administration device: needle, oral syringe. See also Annex A (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

A.1.1 General

Examples of controlled vocabulary terms are given in this annex for illustrative purposes only. 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.1.2 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
Pulsatile
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
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
Pressurised solution for inhalation
Pressurised suspension for inhalation
Prolonged-release eye drops
Shampoo
Soft capsule

Table A.6 *(continued)*

Pharmaceutical dose form
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
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)
Concentrate and solvent for solution for cutaneous use	Concentrate for solution for cutaneous use
	Solvent for solution for cutaneous use
Powder and solvent for solution for injection	Powder for solution for injection
	Solvent for solution for injection
Suspension and granules for suspension for oral use	Suspension for suspension for oral use
	Granules for suspension for oral use

A.1.3 Unit of presentation

Table A.8 — Unit of presentation examples

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

A.1.4 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

Table A.9 *(continued)*

Route of administration
Urethral
Vaginal

A.1.5 Packaging

Table A.10 — Packaging category and packaging examples

Packaging category	Packaging
Container	Ampoule
	Blister
	Bottle
	Box
	Cartridge
	Tube
Closure	Cap
	Child-resistant closure
	Screw cap
Administration device	Applicator
	Brush
	Cup
	Injection needle
	Injection syringe
	Measuring spoon
	Oral syringe

Annex B
(informative)

Examples of controlled vocabularies to describe medicinal products

B.1 Purpose of provided examples

Examples of medicinal products, for which certain properties are described using controlled vocabularies, are given in this annex for illustrative purposes only, to demonstrate how such controlled vocabulary terms can be created for use in defining PhPIDs and MPIDs.

B.1.1 LITHDRUG

Pharmaceutical dose form: Manufactured = Administrable: **extended-release tablet**

State of matter: solid

Basic dose form: tablet

Release characteristics: extended

Transformation: none

Administration method: swallowing

Intended site: oral

Unit of presentation: tablet

Route of administration: oral

Packaging:

Container: Immediate container: **bottle**

Outer packaging: **box**

Closure: screw cap

Administration device: none

B.1.2 INHALDRUG

Pharmaceutical dose form: Manufactured = Administrable: **suspension for aerosol inhalation**

State of matter: liquid

Basic dose form: suspension

Release characteristics: none

Transformation: none

Administration method: inhalation

Intended site: pulmonary

Unit of presentation: actuation

Route of administration: inhalational

Packaging:

Container: Immediate container: **pressurised canister**

Intermediate packaging: **pouch**

Outer packaging: **box**

Closure: none

Administration device: actuator

B.1.3 ANTIHEMODRUG

Combined pharmaceutical dose form: powder and solvent for solution for injection

Component pharmaceutical dose form item 1: powder for solution for injection

Component pharmaceutical dose form item 2: solvent for solution for injection

Pharmaceutical dose form: Administrable: **solution for injectio**n

State of matter: liquid

Basic dose form: solution

Release characteristics: none

Transformation: none

Administration method: injection

Intended site: parenteral

Item 1: **Pharmaceutical dose form:** Manufactured: **powder for solution for injection**

State of matter: solid

Basic dose form: powder

Release characteristics: none

Transformation: dissolution

Administration method: injection

Intended site: parenteral

Pharmaceutical dose form: Administrable: **solution for injection**

Unit of presentation: vial

Route of administration: intravenous

Packaging:

Container: Immediate container: **vial**

Outer packaging: **box**

Closure: cap, stopper

Administration device: none

Item 2: **Pharmaceutical dose form:** Manufactured: **solvent for solution for injection**

State of matter: liquid

Basic dose form: solvent

Release characteristics: none

Transformation: dissolution

Administration method: injection

Intended site: parenteral

Pharmaceutical dose form: Administrable: **solution for injection**

Unit of presentation: vial

Route of administration: intravenous

Packaging:

Container: Immediate container: **vial**

Outer packaging: **box**

Closure: cap, stopper

Administration device: none

B.1.4 INFLUENZAVAC

Combined pharmaceutical dose form: suspension and emulsion for emulsion for injection

Component pharmaceutical dose form item 1: suspension for emulsion for injection

Component pharmaceutical dose form item 2: emulsion for emulsion for injection

Pharmaceutical dose form: Administrable: **emulsion for injection**

State of matter: liquid

Basic dose form: emulsion

Release characteristics: none

Transformation: none

Administration method: injection

Intended site: parenteral

Item 1: **Pharmaceutical dose form:** Manufactured: **suspension for emulsion for injection**

State of matter: liquid

Basic dose form: suspension

Release characteristics: none

Transformation: mixing

Administration method: injection

Intended site: parenteral

Pharmaceutical dose form: Administrable: **emulsion for injection**

Unit of presentation: vial

Route of administration: intramuscular

Packaging:

Container: Immediate container: **vial**

Outer packaging: **box**

Closure: stopper

Administration device: none

Item 2: **Pharmaceutical dose form:** Manufactured: **emulsion for emulsion for injection**

State of matter: liquid

Basic dose form: emulsion

Release characteristics: none

Transformation: mixing

Administration method: injection

Intended site: parenteral

Pharmaceutical dose form: Administrable: **emulsion for injection**

Unit of presentation: vial

Route of administration: intramuscular

Packaging:

Container: Immediate container: **vial**

Outer packaging: **box**

Closure: stopper

Administration device: none

B.1.5 COMBIDRUG

Item 1: **Pharmaceutical dose form:** Manufactured = Administrable: **vaginal tablet**

State of matter: solid

Basic dose form: vaginal tablet

Release characteristics: none

Transformation: none

Administration method: insertion

Intended site: vaginal

Unit of presentation: tablet

Route of administration: vaginal

Packaging:

Container: Immediate container: **blister**

Outer packaging: **box**

Closure: none

Administration device: applicator

Item 2: **Pharmaceutical dose form:** Manufactured = Administrable: **cream**

State of matter: semi-solid

Basic dose form: cream

Release characteristics: none

Transformation: none

Administration method: application

Intended site: cutaneous

Unit of presentation: none

Route of administration: cutaneous

Packaging:

Container: Immediate container: **tube**

Outer packaging: **box**

Closure: stopper, screw cap

Administration device: none

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