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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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Contents

Page

Foreword

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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