SLOVENSKI STANDARD
oSIST prEN ISO 11239:2022

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Zdravstvena informatika - Identifikacija medicinskih izdelkov - Elementi in zgradba podatkov za enotno identifikacijo in izmenjavo predpisanih informacij na obrazcih o farmacevtskih odmerkih, predstavitvenih enotah, administrativnih poteh in pakiranju (ISO/DIS 11239:2022)

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/DIS 11239:2022)

Medizinische Informatik - Identifikation von Arzneimitteln - Datenelemente und -strukturen zur Identifikation von pharmazeutischen Darreichungsformen, pharmazeutischen Konventionseinheiten, Anwendungsarten und Verpackungen (ISO/DIS 11239:2022)

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 (ISO/DIS 11239:2022)

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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 des doses 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 documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 215, Health informatics.

This second edition cancels and replaces the first edition (ISO 11239:2012), which has been technically revised.

The main change is as follows:

— it is now specified that pharmaceutical dose form attributes may 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 harmonised specifications for medicinal products. It is one of a group of five documents, 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 documents 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 documents 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 documents to secure the interactions above.

Unique identifiers produced in conformance with the IDMP documents 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 document are to be applied for the concepts which are required in order to uniquely identify, characterise and exchange regulated medicinal products and associated information.

The terms and definitions adopted in this document 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 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 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.

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 allow regional authorities to map existing regional terms to the terms created using this document, in a harmonised and meaningful way.

In addition, to support the successful application of this document, references to documents 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
aDF
administrable dose form
pharmaceutical dose form for administration to the patient, after any necessary transformation of the manufactured dose form 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).

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

EXAMPLE Needle, oral syringe.

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

Note 2 to entry: 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

EXAMPLE Application, inhalation, injection.

Note 1 to entry: 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.

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 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
generalised version of the pharmaceutical dose form, 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 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 for the purpose of the correct storage and (where appropriate) use of the product

EXAMPLE Cap, child-resistant closure, screw cap.

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

Note 2 to entry: 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 1 to entry: 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

EXAMPLE Ampoule, bottle, box.

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

Note 2 to entry: 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 to entry: It remains constant over time, independent of the particular version of the knowledge resource.

Note 2 to entry: 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

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 and/or closure.

Note 2 to entry: 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 to entry: An alternative, compatible definition of immediate container (“immediate packaging”) is given in Directive 92/27/EEC.

Note 4 to entry: Adapted from ENV 12610:1997.

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

EXAMPLE Auricular, ocular, oral.

Note 1 to entry: 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.

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 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.

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

EXAMPLE Box.

3.1.15
mDF
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 1 to entry: 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 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. 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 to entry: 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

[SOURCE: ENV 13607:2000; ENV 12610:1997]

Note 1 to entry: A medicinal product may consist of one or more manufactured items and one or more pharmaceutical products.

Note 2 to entry: 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 authorisation number as ascribed by a medicines regulatory agency in a jurisdiction

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.

