INTERNATIONAL STANDARD

**ISO 11239**

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

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.

# 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.