INTERNATIONAL STANDARD

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Health informatics — Identification of medicinal products — Data elements and structures for unique identification and exchange of regulated pharmaceutical product information

Informatique de santé — Identification des médicaments — Éléments de données et structures pour l'identification unique et l'échange d'informations réglementées sur les produits pharmaceutiques

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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 11616 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 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.*

The purpose of this International Standard is to present data elements, structures and their relationships in order to uniquely identify and exchange regulated pharmaceutical product information. This International Standard provides an accurate and consistent mechanism to fully represent the relationship of Pharmaceutical Product Identifier(s) (PhPID) with the following:

— Medicinal Product Identifier(s) (MPIDs);

— Investigational Medicinal Product Identifier(s) (IMPIDs).

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 reliably exchange medicinal product information in a robust and reliable manner. The IDMP standards therefore support the following interactions:

— Regulatory Medicines Authority to Regulatory Medicines Authority;

— pharmaceutical company to Regulatory Medicines Authority;

— sponsor of a clinical trial to Regulatory Medicines Authority;

— Regulatory Medicines Authority to other stakeholders (as applicable);

— Regulatory Medicines Authority to worldwide-maintained data sources.

Unique identifiers produced in conformance with the IDMP standards are intended to support applications where it is necessary to reliably identify and trace the use of medicinal and pharmaceutical products.

Messaging specifications are included as an integral part of the IDMP standards. This is critical to describing and protecting the integrity of the interactions listed above for the submission of regulated medicinal product information in the context of unique product identification and acknowledgement of receipt (which includes the validation of transmitted information).

There are many terms in use to describe basic concepts in the regulatory and pharmaceutical 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 required 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.

This International Standard has been developed in conjunction with the Common Product Model in HL7. It is anticipated that implementation will use HL7 V3 messaging to transmit information between stakeholders.

Health informatics — Identification of medicinal products — Data elements and structures for unique identification and exchange of regulated pharmaceutical product information

1 Scope

This International Standard is intended to provide specific levels of information relevant to the identification of a medicinal product or group of medicinal products. It defines the data elements, structures and relationships between data elements that are required for the exchange of regulated information, in order to uniquely identify pharmaceutical products. This identification is to be applied throughout the product lifecycle to support pharmacovigilance, regulatory and other activities worldwide. In addition, this International Standard is essential to ensuring that pharmaceutical product information is assembled in a structured format with transmission between a diverse set of stakeholders. This ensures interoperability and compatibility for both the sender and the recipient.

This International Standard is not intended to be a scientific classification for pharmaceutical products. Rather, it is a formal association of particular data elements categorized in prescribed combinations and uniquely identified when levelling degrees of information are incomplete. This allows for medicinal products to be unequivocally identified.

References to other normative IDMP and messaging standards for pharmaceutical product information are included in Clause 2, to be applied in the context of this International Standard.

Medicinal products for veterinary use are out of scope of this International Standard.

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

ISO 11615, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal 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*

HL7 Version 3 Standard, *Common Clinical Product Model*

HL7 Version 3 Standard, *Common Product Model CMETS*

HL7 Version 3 Standard, *Regulated Product Submission*

HL7 Version 3 Standard, *Structured Product Labeling*

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 as administered to the patient, after any necessary transformation of the packaged pharmaceutical dose form has been carried out

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

3.1.2
adverse drug reaction
noxious and unintended response associated with the use of a drug in humans

NOTE 1 This can be post-approval (an adverse event that occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of diseases or for modification of physiological function) or pre-approval (an adverse event that occurs at any dose and where a causal relationship is at least a reasonable possibility).

NOTE 2 FDA 21 CFR 310.305 defines an adverse drug experience to include any adverse event, "whether or not considered to be drug-related." CDISC recognizes that current usage incorporates the concept of causality.

NOTE 3 Adapted from WHO Technical Report 498(1972); ICH E2A.

3.1.3
clinical trial
research investigation involving human subjects that is designed to answer specific questions about the safety and efficacy of a biomedical intervention (drug, treatment, device) or new ways of using a known drug, treatment, or device

[ICH E6 Glossary, Directive 2001/20/EC:2002, Version: 1-2009/04/19]

3.1.4
clinical trial registration number
registration number (identifier for tracking purposes) for a clinical trial as assigned by the Regulatory Medicines Authority

3.1.5
code value
result of applying a coding scheme to an element within a coded set

NOTE Adapted from ISO/IEC 2382-4:1999.

3.1.6
coding scheme
collection of rules that maps the elements of one set onto the elements of a second set

NOTE 1 The coding scheme applied in this International Standard refers to the following standards:

— ISO 11615, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal 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*.

NOTE 2 Adapted from ISO/IEC 2382-4:1999.

3.1.7
controlled vocabulary
finite set of values that represent the only allowed values for a data item

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

[CDISC Clinical Research Glossary V8.0, 2009]

3.1.8
TermID
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 The TermID remains constant over time, independent of the particular version of the knowledge resource.

NOTE 2 Adapted from HL7 Core Principles.

3.1.9
designation
symbolic representation of a concept

NOTE Adapted from ISO 1087-1:2000.

3.1.10
dose form
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 may refer to the administered dose form or the packaged dose form, depending on the product it is describing.

3.1.11
globally unique identifier
identifier that is different from any other such identifier in any domain namespace

3.1.12
healthcare professional
person entrusted with the direct or indirect provision of defined healthcare services to a subject of care or a population of subjects of care

EXAMPLES Qualified medical practitioner, pharmacist, nurse, social worker, radiographer, medical secretary or clerk.

[ENV 1613:1995]

3.1.13
identifier
description that is sufficient to differentiate objects in a given environment

[ENV 12610]

NOTE In the context of this International Standard, this is a list of identifying characteristics that together unambiguously identify a medicinal product, pharmaceutical product, substance, detailed substance description, excipient, route of administration, dose form and any other element that requires to be uniquely identified.

3.1.14
investigational code
sponsor code
code assigned by a regulatory authority to a sponsor's investigational new drug application prior to the initiation of a clinical trial

3.1.15
investigational medicinal product
pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including products already with a marketing authorization but used or assembled (formulated or packaged) in a way different from the authorized form, or when used for an unauthorized indication, or when used to gain further information about the authorized form

3.1.16
jurisdiction
geographical area or subject matter to which the pharmaceutical legislative authority applies

3.1.17
manufactured dose form
pharmaceutical dose form as presented in the packaging by the manufacturer, before any necessary transformation has been carried out to yield the administered dose form

EXAMPLE Powder for solution for injection.

NOTE In many instances, there is no transformation necessary and the manufactured dose form is equal to the administered dose form.

3.1.18
medical device
any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease;

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;

— investigation, replacement or modification of the anatomy or of a physiological process;

— control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

[EC Directive 2007/47 on Medical Devices]

NOTE This definition is applicable for the purposes of this and related standards alone (ISO 11238, ISO 11239, ISO 11240, ISO 11615 and this International Standard).

3.1.19
medicinal product
any substance or combination of substances, which may be administered to human beings for treating or preventing disease with the view to making a medical diagnosis or to restore, correct or modify physiological functions

[ENV 13607, ENV 12610]

NOTE 1 A medicinal product may contain 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 that may be used to make a medical diagnosis.

3.1.20
pharmaceutical product
qualitative and quantitative composition of a medicinal product in the dose form authorized for administration by a regulatory authority, 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 undergoes a transformation before being administered to the patient (as the pharmaceutical product) and the two are not equal.

3.1.21
packaged pharmaceutical product
qualitative and quantitative composition of the pharmaceutical product as contained in the package of the medicinal product

NOTE In many instances the packaged pharmaceutical medicinal product will be equal to the medicinal product. However, there are instances where, for example, the packaged pharmaceutical product(s) must be reconstituted before it can be administered to the patient (powder and solvent for solution for injection).

EXAMPLE Each vial of Fabrazyme contains a nominal value of 35 mg of agalsidase beta (packaged pharmaceutical product). After reconstitution with 7,2 ml of water for injections, each vial of Fabrazyme contains 5 mg/ml (35 mg/7 ml) of agalsidase beta (pharmaceutical product after reconstitution).

3.1.22
PHPID
pharmaceutical product identifier
globally unique identifier assigned to the pharmaceutical product(s)

3.1.23
pharmacovigilance
the process and science of monitoring the safety of medicines and taking action to reduce risks and increase benefits from medicines

NOTE 1 It is a key public health function.

EXAMPLE Pharmacovigilance includes:

— collecting and managing data on the safety of medicines;

— looking at the data to detect "signals" (any new or changing safety issue) and evaluating the data and making decisions with regard to safety issues;

— acting to protect public health (including regulatory action) and communicating with stakeholders;

— auditing, both of the outcomes of action taken and of the key processes involved.

NOTE 2 Those directly involved in pharmacovigilance include:

— patients as the users of medicines;

— doctors, pharmacists, nurses and all other healthcare professionals working with medicines and regulatory authorities responsible for monitoring the safety of medicines;

— pharmaceutical companies and companies importing or distributing medicines.

3.1.24
quantity value
value of a quantity number and unit (reference), together expressing magnitude of a quantity

NOTE 1 A quantity value expresses the magnitude of a quantity. This expression consists of a numerical value together with a unit of measurement. The unit of measurement represents a quantitative scale of reference that relates the measured (or estimated) quantity value to one or more reference quantity values. The numerical value is the result of comparing the measured quantity to this reference scale.

NOTE 2 The word "magnitude" is not defined in ISO/IEC Guide 99. However, this definition of quantity value indicates that "magnitude" is expressed as a quantity value, i.e. a quantity value is an expression of a magnitude and the same magnitude might be expressed in many quantity values.

NOTE 3 A reference can be a unit of measurement, a measurement procedure, a reference material, or a combination of such.

3.1.25
radiopharmaceutical kit
preparation to be reconstituted or combined with radionuclides in the final radiopharmaceutical, usually prior to its administration

NOTE In the context of a radiopharmaceutical kit, which is to be radio-labelled after supply by the manufacturer, the active substance/specified substance is considered to be that part of the formulation which is intended to carry or bind the radio-nuclide.

3.1.26
reference strength
substance(s) and/or specified substance(s) used as a reference to form the basis of strength of an investigational or authorized medicinal product

NOTE The reference strength refers to the strengths of the base, in case the strength of the substance is expressed as the salt or water for hydration.

3.1.27
specified substance
group of elements that describe multiple substance materials and specify further information on substances and multi-substance materials relevant to the description of medicinal products

NOTE 1 This could include grade, units of measure, physical form, constituents, manufacturer, critical manufacturing processes (i.e. extraction, synthetic, recombinant processes), specification and the analytical methods used to determine whether a substance is in compliance with a specification.

NOTE 2 There are four different groups of elements that can be used to define a given specified substance and specific relationships between each group of elements.

3.1.28
sponsor
individual, company, institution or organization which takes responsibility for the initiation, management and/or financing of a clinical trial

3.1.29
strength
quantitative composition
amount of substance or specified substance expressed quantitatively per dosage unit, per unit of mass or volume, according to the dosage form

NOTE 1 It is necessary for the quantitative composition of the substance(s)/specified substance descriptions of the finished authorized/investigational medicinal products, depending on the pharmaceutical form concerned, to specify the mass, or the number of units of biological activity, either per dosage unit or per unit of mass or volume, of each substance/specified substance.

NOTE 2 Substances/specified substance descriptions present in the form of compounds or derivatives are always designated quantitatively by their total mass and, if necessary or relevant, by the mass of active entity, or entities, of the molecule.

3.1.30
substance
matter of defined composition that has discrete existence, whose origin may be biological, mineral or chemical

NOTE 1 Substances may be either single substances or mixture substances.

NOTE 2 Single substances are always defined using a minimally sufficient set of data elements divided into five types: chemical, protein, nucleic acid, polymer and structurally diverse. Substances may be salts, solvates, free acids, free bases, or mixtures of related compounds that are either isolated or synthesized together.

NOTE 3 Pharmacopeial terminology and defining characteristics are used when available and appropriate. Defining elements are dependent on the type of substance.

NOTE 4 Discrete existence refers to the ability of a substance to exist independently of any other substance. Substances may either be well-defined entities containing definite chemical structures, synthetic (i.e. isomeric mixtures) or naturally-occurring (i.e. conjugated oestrogens) mixtures of chemicals containing definite molecular structures, or materials derived from plants, animals, microorganisms or inorganic matrices for which the chemical structure may be unknown or difficult to define.

3.1.31
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 may refer to a certain reference material, a standard measurement procedure, a material measure or even to a combination of those.

3.1.32
unit of presentation
qualitative term describing the unit in which the strength(s) of the manufactured item or pharmaceutical product is presented and described

NOTE 1 This is often used specifically at the point of delivery to the patient in cases where a quantitative unit of measurement is not applicable.

NOTE 2 A unit of presentation may have the same "display name" as in another controlled vocabulary, such as a pharmaceutical dose form, but the two concepts are not equivalent, and each has a unique controlled vocabulary term identifier.

EXAMPLE A tablet, spray or puff "contains 100 µg per spray" (unit of presentation = spray).

3.1.33
UDI
unique device identifier
unique identifier assigned to a medicinal product as defined by the International Medical Device Regulators' Forum (IMDRF)

3.1.34
(vaccine) adjuvant
component that potentiates the immune response to an antigen and/or modulates it towards the desired immune response

3.1.35
vocabulary
terminological dictionary which contains designations and definitions from one or more specific subject fields

NOTE Adapted from ISO 1087-1:2000, definition 3.7.2.

3.2 Abbreviations

3.2.1
CV
Controlled Vocabulary

3.2.2
FDA
United States Food and Drug Administration

3.2.3
EP
European Pharmacopeia

3.2.4
IMDRF
International Medical Device Regulators' Forum