INTERNATIONAL STANDARD

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Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal 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 médicaments

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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 International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 11615 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*.

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 consistent manner. The IDMP standards therefore support, at a minimum, the following interactions:

— regulator to regulator;

— pharmaceutical company to regulator;

— sponsor of clinical trial to regulator;

— regulator to other stakeholder;

— 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 given in this International Standard are to be applied for the concepts which are 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.

In the context of exchange of regulatory information, the purpose of this International Standard is twofold:

— to specify data elements, structures and relationships between the data elements which are required to uniquely and with certainty identify Medicinal Products for human use;

— to specify definitions of terms for all data elements required to uniquely and with certainty identify Medicinal Products for human use.

In addition, reference to the use of other normative IDMP and messaging standards for Medicinal Product information is included in this International Standard in order to support successful related information exchange.

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

1 Scope

This International Standard establishes definitions and concepts and describes data elements and their structural relationships, which are required for the unique identification and the detailed description of Medicinal Products.

Taken together, the standards listed in the introduction define, characterize and uniquely identify regulated Medicinal Products for human use during their entire life cycle, i.e. from development to authorization, post-marketing and renewal or withdrawal from the market, where applicable.

Furthermore, to support successful information exchange in relation to the unique identification and characterization of Medicinal Products, the use of other normative IDMP messaging standards is included, which are to be applied in the context 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 639-2, *Codes for the representation of names of languages — Part 2: Alpha-3 code*

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

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

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*

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

ISO/IEC 5218, *Information technology — Codes for the representation of human sexes*

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 Applicator, oral syringe.

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

[ENV 12610:1997]

3.1.3
allergens
materials of concern
ingredients in a device capable of stimulating a type-I hypersensitivity or allergic reaction in atopic individuals

EXAMPLE Latex.

3.1.4
authorization date
date when the authorization was granted by a Medicines Regulatory Agency for a specific activity

EXAMPLE The date of the marketing authorization, which allows the Marketing Authorization Holder to put a Medicinal Product on the market.

3.1.5
authorization procedure
marketing authorization procedure
formal procedure applied by a Medicines Regulatory Agency to grant a marketing authorization, to amend an existing one, to extend its duration or to revoke it

EXAMPLE Revocation of a marketing authorization due to an unfavourable benefit/risk balance of the medicine.

NOTE The terms authorization procedure and marketing authorization procedure are synonymous.

3.1.6
authorization status
actual state of the marketing authorization

EXAMPLES Active, suspended, expired, revoked.

3.1.7
batch
specific manufacturing release of a Medicinal Product or item by the manufacturer

3.1.8
batch number
identifier assigned to a specific batch of a Medicinal Product or item resulting from a manufacturing process at a specific point of time

3.1.9
characteristic
abstraction of a property of an object

3.1.10
clinical trial
clinical study
any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an Investigational Medicinal Product(s), and/or to study absorption, distribution, metabolism and excretion of Investigational Medicinal Product(s) with the object of ascertaining its safety and/or efficacy

NOTE The terms clinical trial and clinical study are synonymous.

3.1.11
clinical trial authorization
authorization granted by a Medicines Regulatory Agency to conduct a clinical trial in a jurisdiction

3.1.12
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 that 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”.

3.1.13
common name
generic name

international nonproprietary name recommended by the World Health Organization (WHO), or, if one does not exist, a nonproprietary name recommended by the jurisdiction within which the name is used

[WHO 46th Consultation on International Nonproprietary Names (INNs) for Pharmaceutical Substances]

3.1.14
concept
unit of knowledge constructed through combining characteristics expressed in words

3.1.15
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

3.1.16
controlled vocabulary
finite set of values that represent the only allowed values for a data item

NOTE The allowed values can be codes, text or numeric.

[CDISC Clinical Research Glossary V8.0, 2009]

3.1.17
datatype
set of distinct values, characterized by properties of those values, and by operations on those values

[ISO 11404:2007, definition 3.12]

3.1.18
distributor
organization in possession of a licence covering the procuring, holding, supplying or exporting of Medicinal Products, apart from supplying Medicinal Products to the public

NOTE This is applicable to “wholesale distribution of Medicinal Products”.

3.1.19
dose
specified quantity of a medicine, to be taken at one time or at stated intervals

3.1.20
dose form
dosage form
pharmaceutical dose form
physical manifestation of a Medicinal Product that contains the active ingredient(s) and/or inactive ingredient(s) that are intended to be delivered to the patient

NOTE 1 Dose form, dosage form and pharmaceutical dose form are synonymous.

NOTE 2 "Pharmaceutical dose form" can refer to the administered dose form or the manufactured dose form.

3.1.21
Global Trade Identification Number
GTIN
GS1 unique identifier of items that are traded (e.g. pharmaceuticals, medical devices) in the supply chain

NOTE A GTIN is used to identify any item upon which there is a need to retrieve pre-defined information and that may be priced, ordered or invoiced at any point in any supply chain. GTINs may be 8, 12, 13 or 14 digits in length.

3.1.22
identifier
ID
description that is sufficient to represent an object in a given environment

NOTE 1 In the context of this International Standard, this is a list of identifying characteristics that together unambiguously identify a Medicinal Product, pharmaceutical product, substance, specified substance, route of administration, pharmaceutical dose form or any other element which requires to be uniquely identified.

NOTE 2 Adapted from ENV 12610:1997.

3.1.23
immediate container
immediate packaging
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.

3.1.24
ingredient
material used in the preparation of a medicinal/pharmaceutical product

NOTE The ingredient is part of a Medicinal Product, either alone or in combination with one or more ingredients. The ingredient is also a component of a pharmaceutical product. Ingredient is equal to the detailed description of a substance, a substance playing the role of an ingredient in a product.

3.1.25
international non-proprietary name
INN
official non-proprietary or generic name given to a pharmaceutical substance, as designated by the World Health Organization

3.1.26
intermediate packaging
container between the outer packaging and the immediate container

3.1.27
invented name
name for an innovative Medicinal Product as authorized by a Medicines Regulatory Agency in a jurisdiction

NOTE Synonym to “trade name” of a Medicinal Product.

3.1.28
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, used for an unauthorized indication, or used to gain further information about the authorized form

3.1.29
(Investigational) Medicinal Product Batch Identifier
(I)BAID_1
unique identifier allocated to a specific batch of an (Investigational) Medicinal Product, which appears on the outer packaging of the (Investigational) Medicinal Product

NOTE 1 It is constructed by using the batch number assigned by the manufacturer and the expiration date.

NOTE 2 This is for indexing purposes and to contribute to improving patient safety by allowing for the unique identification of an (Investigational) Medicinal Product at the package level.

3.1.30
(Investigational) Medicinal Product Batch Identifier
(I)BAID_2
unique identifier allocated to a specific batch of an (Investigational) Medicinal Product, which appears on the immediate packaging, where this is not the outer packaging

NOTE 1 It is constructed by using the batch number assigned by the manufacturer and the expiration date.

NOTE 2 This is for indexing purposes and to contribute to improving patient safety by allowing for the unique identification of an (Investigational) Medicinal Product based at the level of the immediate container.

3.1.31
Investigational Medicinal Product Identifier
IMPID
unique identifier allocated to an Investigational Medicinal Product supplementary to any existing identifier as ascribed by a Medicines Regulatory Agency in a jurisdiction or a sponsor of a clinical trial

NOTE This is for indexing purposes and to contribute to improving patient safety by allowing for the unique Identification of Medicinal Products worldwide.

3.1.32
Investigational Medicinal Product Package Identifier
IPCID
unique identifier allocated to an Investigational Medicinal Product at package level supplementary to any existing identifier as ascribed by a Medicines Regulatory Agency in a jurisdiction or a sponsor of a clinical trial

NOTE This is for indexing purposes and to contribute to improving patient safety by allowing for the unique Identification of Medicinal Products worldwide.

3.1.33
jurisdiction
geographical area or subject matter to which the Medicines Regulatory Agency applies

3.1.34
legal status of supply
jurisdictional rule as to whether a Medicinal Product is subject to a medical prescription before it may be supplied to a patient or consumer

3.1.35
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).

3.1.36
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) 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.

3.1.37
manufacturing authorization
manufacture of the Medicinal Products within a jurisdiction subject to the holding of an authorization

NOTE Such authorization may be required for both total and partial manufacture and for the various processes of dividing up, packaging or presentation. However, such authorization may not be required for preparation, dividing up, changes in packaging or presentation where these processes are carried out, solely for retail supply, by pharmacists in dispensing pharmacies or by persons legally authorized in a jurisdiction to carry out such processes.

3.1.38
manufacturing authorization date
date when the manufacturing authorization was granted

3.1.39
manufacturing authorization holder
organization that holds the authorization for the manufacturing process

3.1.40
marketing authorization
authorization issued from a Medicines Regulatory Agency that a Medicinal Product may be placed on the market

3.1.41
Marketing Authorization Holder
organization that holds the authorization for marketing a Medicinal Product in a jurisdiction

3.1.42
marketing authorization number
identifier assigned by a Medicines Regulatory Agency to a Medicinal Product

3.1.43
marketing authorization procedure
authorization procedure
formal procedure applied by a Medicines Regulatory Agency to grant a marketing authorization, amend an existing one, extend its duration or to withdraw it

NOTE Marketing authorisation procedure and authorisation procedure are synonymous.

3.1.44
marketing start date
date when the authorized Medicinal Product is marketed in a jurisdiction

NOTE The date of actual marketing of a Medicinal Product is always after a marketing authorization has been granted by a Medicines Regulatory Agency.

3.1.45
marketing stop date
date when the marketing of the authorized Medicinal Product is stopped in a jurisdiction

3.1.46
material
substance or specified substance of which a certain component is made

NOTE This applies to a Medicinal Product package item (container), package (component) and device.

3.1.47
measurement point
physical location on an administration device where the quantity of the medication being delivered is measured

3.1.48
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 on Medical Devices 2007/47]

3.1.49
Medicinal Product
any substance or combination of substances that 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

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 which may be used to make a medical diagnosis.