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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 sur les médicaments contrôlés

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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 on 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 the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 215, *Health informatics*.

This second edition cancels and replaces the first edition (ISO 11615:2012), which has been technically revised.

Introduction

This document was developed in response to a worldwide demand for internationally harmonised specifications for Medicinal Products. It is part of a set of five ISO Standards and four ISO Technical Specifications which together provide the basis for the unique Identification of Medicinal Products (IDMP).

These sets of standards and technical specifications comprise:

— ISO 11615

— ISO/TS 20443;

— ISO 11616;

— ISO/TS 20451;

— ISO 11238;

— ISO/TS 19844;

— ISO 11239;

— ISO/TS 20440;

— ISO 11240.

These standards and technical specifications for the identification of Medicinal Products (IDMP) support the activities of medicines regulatory agencies worldwide by region. 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:

— 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.

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 document are to be applied for the concepts which are required 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.

This document has been developed in conjunction with the Common Product Model (CPM) and Structured Product Labelling (SPL) in HL7.

In the context of exchange of regulatory information, the purpose of this document 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 document in order to support successful 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 document 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, characterise and uniquely identify regulated Medicinal Products for human use during their entire life cycle, i.e. from development to authorisation, post-marketing and renewal or withdrawal from the market, where applicable.

Furthermore, to support successful information exchange in relation to the unique identification and characterisation of Medicinal Products, the use of other normative IDMP messaging standards is included, which are to be applied in the context of this document.

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 3166-1:2013, *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 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 11616, *Health informatics — Identification of Medicinal Products — Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information*

ISO/TS 19844, *Health informatics — Identification of Medicinal Products — Implementation guidelines for data elements and structures for the unique identification and exchange of regulated information on substances*

ISO/TS 20440, *Health informatics — Identification of Medicinal Products — Implementation guide for ISO 11239 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/TS 20443, *Health informatics — Identification of Medicinal Products — Implementation guide for ISO 11615 data elements and structures for the unique identification and exchange of regulated Medicinal Product information*

ISO/TS 20451, *Health informatics — Identification of Medicinal Products — Implementation guide for ISO 11616 data elements and structures for the unique identification and exchange of regulated pharmaceutical product information*

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

HL7 Version 3 Standard, Structured Product Labelling

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 terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at http://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1.1
adjuvant
component that potentiates the immune response to an antigen and/or modulates it towards the desired immune response

3.1.2
administrable dose form
pharmaceutical dose form for administration to the patient, after any necessary transformation of the *manufactured items* (3.1.37) and their corresponding *manufactured dose forms* (3.1.36) has been carried out

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).

Note 2 to entry: Administered dose form and pharmaceutical administrable dose form are synonyms of administrable dose form.

3.1.3
administration device
equipment intended for correct administration of the *Medicinal Product* (3.1.50)

Note 1 to entry: An administration device may be an integral part of an *immediate container* (3.1.27) or a closure.

[SOURCE: ENV 12610:1997]

3.1.4
allergen
material (3.1.47) of concern used as *ingredient* (3.1.28) or in a device capable of stimulating a type-I hypersensitivity or allergic reaction in atopic individuals

3.1.5
authorisation date
date when the authorisation was granted by a *Medicines Regulatory Agency* (3.1.56) following a specific regulatory activity

3.1.6
authorisation procedure
formal procedure applied by a *Medicines Regulatory Agency* (3.1.56) to grant a *marketing authorisation* (3.1.40), to amend an existing one, to extend its duration or to revoke it

Note 1 to entry: The terms authorisation procedure and *marketing authorisation procedure* (3.1.43) are synonymous.

3.1.7
authorisation status
phase of the *marketing authorisation* (3.1.40) during its life cycle

Note 1 to entry: The status indicates a particular moment in its life cycle.

3.1.8
batch
specific quantity of a drug or other *material* (3.1.47) that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture

3.1.9
batch number
identifier (3.1.26) assigned to a specific *batch* (3.1.8) of a *Medicinal Product* (3.1.50) or item resulting from a manufacturing process at a specific point of time

3.1.10
characteristic
abstraction of a property of an object

3.1.11
clinical trial
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)* (3.1.31), 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 1 to entry: The terms clinical trial and clinical study are synonymous.

3.1.12
clinical trial authorisation
approval given by a *Medicines Regulatory Agency* (3.1.56) to conduct a *clinical trial* (3.1.11) in a *region* (3.1.73)

3.1.13
class
set of objects that share the same specifications of features, constraints, and semantics

3.1.14
combined pharmaceutical dose form
two or more *manufactured items* (3.1.37) 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* (3.1.36) of each manufactured item and the *administrable dose form* (3.1.2) of the pharmaceutical product

3.1.15
common name
official non-proprietary or generic name recommended by the World Health Organisation (WHO), or, if one does not exist, a non-proprietary name recommended by the *region* (3.1.73) within which the name is used

Note 1 to entry: Generic name and international non-proprietary name are synonymous of common name.

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

3.1.16
container
item of packaging that is part of a *Medicinal Product* (3.1.50) and is used for storage, identification and/or transport of the components of the Medicinal Product

3.1.17
contraindication
situations where the *Medicinal Product* (3.1.50) shall not be given for safety reasons

3.1.18
controlled vocabulary
finite set of values that represent the only allowed values for a data item

Note 1 to entry: The allowed values can be codes, text or numeric.

[SOURCE: CDISC Clinical Research Glossary V10.0, 2016]

3.1.19
datatype
set of distinct values, characterised by properties of those values, and by operations on those values

[SOURCE: ISO 11404:2007, 3.12]

3.1.20
device listing number
number assigned by a *Medicines Regulatory Agency* (3.1.56) during registration and/or listing to all devices in commercial distribution, regardless of pre-market authorisation requirements, per regional registration and listing requirements

3.1.21
device model number
identifier (3.1.26) assigned by a medical device *manufacturer* (3.1.38) to a particular design or version of a *medical device* (3.1.49)

3.1.22
distributor
organisation in possession of a license covering the procuring, holding, supplying or exporting of *Medicinal Products* (3.1.50), apart from supplying Medicinal Products to the public

Note 1 to entry: This is applicable to “wholesale distribution of Medicinal Products”.

3.1.23
dose
specified quantity of a medicine, to be taken at one time or at stated intervals

3.1.24
dose form
physical manifestation of a *Medicinal Product* (3.1.50) that contains the active *ingredient(s)* (3.1.28) and/or inactive ingredient(s) that are intended to be delivered to the patient

Note 1 to entry: Dose form, dosage form and pharmaceutical dose form are synonymous. “Pharmaceutical dose form” can refer to the *administrable dose form* (3.1.2) or the *manufactured dose form* (3.1.36).

3.1.25
Global Trade Item Number
GTIN
GS1 unique *identifier* (3.1.26) of items that are traded [e.g. pharmaceuticals, *medical devices* (3.1.49)] in the supply chain

Note 1 to entry: A GTIN is used to identify any item upon which there is a need to retrieve predefined 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.

3.1.26
identifier
description that is sufficient to represent an object in a given environment

Note 1 to entry: In the context of this document, this is a list of identifying *characteristics* (3.1.10) that together unambiguously identify a *Medicinal Product* (3.1.50), pharmaceutical product, *substance* (3.1.80), *specified substance* (3.1.77), *route of administration* (3.1.76), pharmaceutical dose form or any other element which requires to be uniquely identified.

[SOURCE: ENV 12610:1997]

3.1.27
immediate container
packaging in which a *manufactured item* (3.1.37) or pharmaceutical product is contained and with which it is in direct contact

Note 1 to entry: An immediate container can be fitted with or have integrated into it an *administration device* (3.1.3) and/or closure. 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* (3.1.16). An alternative, compatible definition of immediate container ("immediate packaging") is given in Directive 92/27/EEC.

[SOURCE: ENV 12610:1997]

3.1.28
ingredient
material (3.1.47) used in the preparation of a medicinal/pharmaceutical product

Note 1 to entry: The ingredient is part of a *Medicinal Product* (3.1.50), either alone or in combination with other ingredients. The ingredient is also a component of a pharmaceutical product. Ingredient is equal to a *substance* (3.1.80) with the indication of the specific role it is playing in the product.

3.1.29
intermediate packaging
container (3.1.16) between the *outer packaging* (3.1.57) and the *immediate container* (3.1.27)

3.1.30
invented name
proprietary name for a *Medicinal Product* (3.1.50) as authorised by a *Medicines Regulatory Agency* (3.1.56) in a *region* (3.1.73)

Note 1 to entry: The term invented name is synonymous with trade name and with brand name for a Medicinal Product.

3.1.31
Investigational Medicinal Product
pharmaceutical product or combination of pharmaceutical products or placebo(s) being tested or used as a reference in a *clinical trial* (3.1.11), including products already with a *marketing authorisation* (3.1.40) but used or assembled (packaged) in a way different from the authorised form, used for an unauthorised indication, or used to gain further information about the authorised form

3.1.32
Investigational Medicinal Product Identifier
unique *identifier* (3.1.26) allocated to an *Investigational Medicinal Product* (3.1.31) supplementary to any existing identifier as ascribed by a *Medicines Regulatory Agency* (3.1.56) in a *region* (3.1.73)/*jurisdiction* (3.1.34) or a sponsor of a *clinical trial* (3.1.11)

Note 1 to entry: This is an alphanumeric text field.

Note 2 to entry: This is for indexing purposes and to contribute to improving patient safety by allowing for the unique identification of *Medicinal Products* (3.1.50) worldwide.

3.1.33
Investigational Medicinal Product Package Identifier
unique *identifier* (3.1.26) allocated to an Investigational Packaged Medicinal Product at package level supplementary to any existing identifier as ascribed by a *Medicines Regulatory Agency* (3.1.56) in a *region* (3.1.73)/*jurisdiction* (3.1.34) or a sponsor of a *clinical trial* (3.1.11)

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* (3.1.50) worldwide.

3.1.34
jurisdiction
geographical area within a country/*region* (3.1.73) or subject matter to which the *Medicines Regulatory Agency* (3.1.56) applies

3.1.35
legal status of supply
regional/jurisdictional rule as to whether a *Medicinal Product* (3.1.50) is subject to a medical prescription before it may be supplied to a patient or consumer

3.1.36
manufactured dose form
pharmaceutical dose form of a *manufactured item* (3.1.37) as manufactured and, where applicable, before transformation into the pharmaceutical product

Note 1 to entry: The manufactured dose form is identical to the *administrable dose form* (3.1.2) in cases where no transformation of the manufactured item is necessary (i.e. where the manufactured item is equal to the pharmaceutical product).

3.1.37
manufactured item
qualitative (3.1.70) and *quantitative composition* (3.1.71) of a product as contained in the packaging of the *Medicinal Product* (3.1.50) as put on the market or *Investigational Medicinal Product* (3.1.31) as used in a *clinical trial* (3.1.11)

Note 1 to entry: A *Medicinal Product* (3.1.50) may contain one or more manufactured items. 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.

3.1.38
manufacturer
organisation that holds the authorisation for the manufacturing process

Note 1 to entry: Establishment is a synonym of manufacturer.

3.1.39
manufacturing authorisation
authorisation provided by a *Medicines Regulatory Agency* (3.1.56) to manufacture *Medicinal Products* (3.1.50) within a *region* (3.1.73)

Note 1 to entry: Such authorisation may be required for both total and partial manufacture and for the various processes of dividing up, packaging or presentation. However, such authorisation 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 authorised in a region to carry out such processes.

3.1.40
marketing authorisation
authorisation issued from a *Medicines Regulatory Agency* (3.1.56) that allows a *Medicinal Product* (3.1.50) to be placed on the market

3.1.41
marketing authorisation holder
organisation that holds the authorisation for marketing a *Medicinal Product* (3.1.50) in a *region* (3.1.73)

3.1.42
marketing authorisation number
identifier (3.1.26) assigned by a *Medicines Regulatory Agency* (3.1.56) to a *Medicinal Product* (3.1.50)

3.1.43
marketing authorisation procedure
formal procedure applied by a *Medicines Regulatory Agency* (3.1.56) to grant a *marketing authorisation* (3.1.40), amend an existing one, extend its duration or to withdraw it

Note 1 to entry: Marketing authorisation procedure and *authorisation procedure* (3.1.6) are synonymous.

3.1.44
marketing start date
date when the authorised Medicinal Product is marketed in a *region* (3.1.73)

Note 1 to entry: The date of actual marketing of a *Medicinal Product* (3.1.50) is always after a *marketing authorisation* (3.1.40) has been granted by a *Medicines Regulatory Agency* (3.1.56).

3.1.45
marketing stop date
date when the marketing of the authorised Medicinal Product is stopped in a *region* (3.1.73)

3.1.46
marketing status
when a *Medicinal Product* (3.1.50) is actually put on the market or is no longer available in a country or *jurisdiction* (3.1.34)

3.1.47
material
substance (3.1.80) or *specified substance* (3.1.77) of which a certain packaging or device is made

Note 1 to entry: This applies to a Medicinal Product package item [*container* (3.1.16)], package (component) and device.

3.1.48
measurement point
physical location on an *administration device* (3.1.3) where the quantity of the medication being delivered is measured