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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 Standardisation) 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 organisations, 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 standardisation.

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 11616:2012), 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.

The purpose of this document is to present data elements, structures and their relationships in order to uniquely identify and exchange regulated pharmaceutical product information. This document 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);

— Package Component Identifier(s) (PCIDs);

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

— Investigational Package Component Identifier(s) (IPCIDs).

These standards and technical specifications for the identification of Medicinal Products 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. 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).

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

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

1 Scope

This document 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 document is essential to ensure that pharmaceutical product information is assembled in a structured format with transmission between a diverse set of stakeholders for both regulatory and clinical (e.g. e-prescribing, clinical decision support) purposes. This ensures interoperability and compatibility for both the sender and the recipient.

This document is not intended to be a scientific classification for pharmaceutical products. Rather, it is a formal association of particular data elements categorised in prescribed combinations and uniquely identified when levelling degrees of information are incomplete. This allows for Medicinal Products to be unequivocally identified on a global level.

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 document.

Medicinal products for veterinary use are out of scope 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 3166-1, *Codes for the representation of names of countries and their subdivisions — Part 1: Country codes*

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 11615:2017, *Health informatics — Identification of Medicinal Products — Data elements and structures for the unique identification and exchange of regulated Medicinal 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 guidelines 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 guidelines for ISO 11616 data elements and structures for the unique identification and exchange of regulated pharmaceutical product information*

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 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 standardisation 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* (3.1.7) for administration to the patient, after any necessary transformation of the *manufactured items* (3.1.17) and their corresponding *manufactured dose forms* (3.1.16) 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* (3.1.24)].

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

3.1.3
clinical trial
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)* (3.1.12), 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.

3.1.4
controlled vocabulary
finite set of values that represent the only allowed values for a data item

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

[SOURCE: CDISC Clinical Research Glossary V10, 2016, modified — "These values may be codes, text, or numeric" has been set as note to entry.]

3.1.5
controlled vocabulary term identifier
concept *identifier* (3.1.10) intended to be used as the preferred unique identifier for that concept in that code system and which is published by the author of a code system

Note 1 to entry: The TermID remains constant over time, independent of the particular version of the knowledge resource.

Note 2 to entry: This definition is adapted from HL7 Core Principles.

Note 3 to entry: TermID is a synonym of controlled vocabulary term identifier.

3.1.6
designation
symbolic representation of a concept

3.1.7
dose form

physical manifestation of a *Medicinal Product* (3.1.19) that contains the active ingredient(s) 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.

Note 2 to entry: "Pharmaceutical dose form" can refer to the *administrable dose form* (3.1.2) or the *manufactured dose form* (3.1.16). The terms pharmaceutical dose and dosage form are synonymous.

3.1.8
globally unique identifier
identifier (3.1.10) that is different from any other such identifier in any domain namespace

3.1.9
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

[SOURCE: ENV 1613:1995, 3.13, modified — "who is" has been removed and "subject or population of subjects" has been replaced by "subject of care or a population of subjects of care".]

3.1.10
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 that together unambiguously identify a *Medicinal Product* (3.1.19), *pharmaceutical product* (3.1.24), *substance* (3.1.35), *specified substance* (3.1.32), pharmaceutical *dose form* (3.1.7) or any other element which requires to be uniquely identified.

[SOURCE: ENV 12610:1998]

3.1.11
investigational code
code assigned by a m*edicines regulatory agency* (3.1.22) to a *sponsor's* (3.1.33) investigational new drug application prior to the initiation of a *clinical trial* (3.1.3)

Note 1 to entry: Sponsor code is a synonym of investigational code.

3.1.12
investigational Medicinal Product
any *pharmaceutical product* (3.1.24) or combination of pharmaceutical products or placebo(s) being tested or used as a reference in a *clinical trial* (3.1.3), including products already with a marketing authorisation 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

3.1.13
investigational Medicinal Product identifier
unique *identifier* (3.1.10) allocated to an *investigational Medicinal Product* (3.1.12) supplementary to any existing identifier as ascribed by a *medicines regulatory agency* (3.1.22) in a *region* (3.1.31)/*jurisdiction* (3.1.15) or a *sponsor* (3.1.33) of a *clinical trial* (3.1.3)

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* (3.1.19) worldwide.

3.1.14
investigational Medicinal Product package identifier
unique *identifier* (3.1.10) allocated to an Investigational *packaged Medicinal Product* (3.1.23) at package level supplementary to any existing identifier as ascribed by a *medicines regulatory agency* (3.1.22) in a *region* (3.1.31)/*jurisdiction* (3.1.15) or a *sponsor* (3.1.33) of a *clinical trial* (3.1.3)

Note 1 to entry: This is for indexing purposes and to contribute to improving patient safety by allowing for the unique identification of Medicinal Products worldwide.

3.1.15
jurisdiction
geographical area within a country/*region* (3.1.31) or subject matter to which the *medicines regulatory agency* (3.1.22) applies

3.1.16
manufactured dose form
pharmaceutical *dose form* (3.1.7) of a *manufactured item* (3.1.17) as manufactured and, where applicable, before transformation into the *pharmaceutical product* (3.1.24)

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).

3.1.17
manufactured item
qualitative and *quantitative composition* (3.1.27) of a product as contained in the packaging of the *Medicinal Product* (3.1.19) as put on the market or *investigational Medicinal Product* (3.1.12) as used in a *clinical trial* (3.1.3)

Note 1 to entry: A Medicinal Product may contain one or more manufactured items. In many instances, the manufactured item is equal to the *pharmaceutical product* (3.1.24). 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.

3.1.18
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.

Note 1 to entry: This definition is applicable for the purposes of this and related standards alone (ISO 11238, ISO 11239, ISO 11240, ISO 11615 and this document).

[SOURCE: EC Directive 2007/47 on Medical Devices]

3.1.19
Medicinal Product
any *pharmaceutical product* (3.1.24) or combination of pharmaceutical products that may be administered to human beings (or animals) for treating or preventing disease, with the aim/purpose of making a medical diagnosis or to restore, correct or modify physiological functions

Note 1 to entry: A Medicinal Product may contain in the packaging one or more *manufactured items* (3.1.17) and one or more pharmaceutical products. In certain *regions* (3.1.31), a Medicinal Product may also be defined as any *substance* (3.1.35) or combination of substances which may be used to make a medical diagnosis. The provisions in this document apply to proprietary Medicinal Products for human use intended to be placed on the market and to industrially manufactured Medicinal Products, the marketing of which has been authorised by a *medicines regulatory agency* (3.1.22). However, the provisions do not apply to: i) Medicinal Products prepared according to prescription (e.g. prepared in a pharmacy from a prescription intended for a specific patient), ii) Medicinal Products prepared in accordance with an official formula (e.g. prepared in a pharmacy in accordance with the instructions in a pharmacopoeia and intended to be given direct to the patient by the pharmacy), iii) Medicinal Products intended for research and development trials, and iv) intermediate products intended for subsequent processing by an authorised manufacturer.

3.1.20
Medicinal Product identifier
unique *identifier* (3.1.10) allocated to a *Medicinal Product* (3.1.19) supplementary to any existing authorisation number as ascribed by a *medicines regulatory agency* (3.1.22) in a *region* (3.1.31)

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

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

3.1.21
Medicinal Product package identifier
unique *identifier* (3.1.10) allocated to a *packaged Medicinal Product* (3.1.23) supplementary to any existing authorisation number as ascribed by a *medicines regulatory agency* (3.1.22) in a *region* (3.1.31)

Note 1 to entry: This is for indexing purposes and to contribute to improving patient safety by allowing for the unique identification of Medicinal Products worldwide.

3.1.22
medicines regulatory agency
institutional body that, according to the legal system under which it has been established, is responsible for the granting of marketing authorisations, *clinical trial* (3.1.3) authorisations and manufacturing authorisations for *Medicinal Products* (3.1.19)

Note 1 to entry: In certain *regions* (3.1.31), the role of the institutional body which according to the legal system grants the marketing authorisation of Medicinal Products may be complemented by an additional institutional body responsible for the evaluation and supervision of Medicinal Products. For example, in the EU, the European Commission is the institutional body that grants the marketing authorisation of Medicinal Products and the European Medicines Agency is the body responsible for the evaluation and supervision of Medicinal Products.

3.1.23
packaged Medicinal Product
Medicinal Product (3.1.19) in a container being part of a package, representing the entirety that has been packaged for sale or supply