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Health informatics — Identification of medicinal products (IDMP) — Implementation guidelines for ISO 11238 for data elements and structures for the unique identification and exchange of regulated information on substances

Informatique de santé — Identification des médicaments — Lignes directrices pour la mise en oeuvre ~~des~~de l'ISO 11238 relative aux éléments de données et structures pour l'identification unique et l'échange d'informations réglementées sur les substances

Contents

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 WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 215, *Health informatics*.

This third edition cancels and replaces the second edition (ISO/TS 19844:2016), which has been technically revised.

Introduction

This document provides guidelines for implementing ISO 11238. This document is developed in response to a worldwide demand for guidance on the implementation of internationally harmonized specifications for medicinal products. It is one of a group of four implementation guides for a total of five ISO standards which together provide the basis for the unique identification of medicinal products. The other standards in this group are:

— 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 11239[2], *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 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.

The business objective of this implementation guide is to provide a means for exchanging regulatory substance information. To meet the primary objectives of the regulation of medicines and pharmacovigilance, it is necessary to exchange medicinal product information in a robust and reliable manner.

For the purposes of this document, all conditions (e.g. mandatory, conditional, optional) correspond to the necessary requirements to uniquely and unambiguously identify a substance. Implementation of the ISO IDMP standards may dictate that mandatory elements for identification be tagged as conditional or optional, based on regional requirements. If a subclause is identified as ‘optional’ but is implemented in a specific region, conformance described within that subclause is applicable. The scope of this document is to identify the scientifically necessary elements for the unique identification of Substances/Specified Substances.

In this document, “% ~~(V/V)”~~{v/v}” is used in place of “% volume fraction”.

Health informatics — Identification of medicinal products (IDMP) — Implementation guidelines for ISO 11238 for data elements and structures for the unique identification and exchange of regulated information on substances

CAUTION — This document uses colour. This should be taken into consideration when printing.

1 Scope

This document is used in the implementation of ISO 11238. This document defines substances based on their scientific identity (i.e. what they are) rather than on their use or method of production.

ISO 11238 provides the conceptual framework for defining Substances and Specified Substances and for assigning unique identifiers in the context of the ISO IDMP standards. ISO 11238 describes general concepts for defining and distinguishing substances and a high-level model for the structuring of information for substances. This document provides detailed explanations of each type or grouping of substance information, an element-by-element description for implementation of ISO 11238, and examples for a variety of Substances and Specified Substances.

This third edition of the document addresses Substances Groups 1 to 3 of the Specified Substances as defined in ISO 11238 and Annexes A, B, C, D, E, F, G, H, I, J and K. It is anticipated that Specified Substances Group 4, as defined in ISO 11238, will be addressed in a subsequent edition of this document. Some information that would typically fall under Specified Substances Group 4 is covered in the Annexes of this document. This information, although not defining of either a Substance or a Specified Substance Group 1, might be essential to distinguishing substances. This document addresses the following:

— data elements necessary for defining Substances and Specified Substances Groups 1 to 3;

— the logical use of data elements as defined in ISO 11238;

— Substances and Specified Substances Groups 1 to 3 business rules for:

  — determining necessary data elements,

  — distinguishing and defining materials according to ISO 11238,

  — triggering the assignment of identifiers.

This document does not address the following:

— business processes for data management;

— implementation of a specific data information system (e.g. a relational database schema);

— normative messaging standards for substances;

— the maintenance of controlled vocabularies;

— the specific global identifier system that should be used;

— nomenclature standards for substances.

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 11240, *Health informatics — Identification of Medicinal Products — Data elements and structures for the unique identification and exchange of units of measurement*

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/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*

3 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

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

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

4 Symbols and abbreviated terms

NOTE The abbreviations are listed are either used within ISO 11238 or ISO/TS 19844 since they are regarded as inseparable documents.

4.1
ACS
American Chemical Society[1]

4.2
ASK Number
ID of a substance in German "Arzneistoffkatalog" (Pharmaceutical Substance Dictionary)

4.3
BAN
British Approved Name[127]

4.4
COL
Catalogue of Life[2]

4.5
DCF
Dénominations Communes Françaises (French approved drug name)[128]

4.6
EVcode
EudraVigilance Code (Unique Identifier) used for a substance in the Extended EudraVigilance Medicinal Product Dictionary (XEVMPD)[3]

4.7
ExPASy
SIB (Swiss Institute of Bioinformatics) Bioinformatics Resource Portal[4]

4.8
HAB
Homöopathisches Arzneibuch, Amtliche Ausgabe

4.9
HTS
high-throughput sequencing

4.10
INCI
International Nomenclature of Cosmetic Ingredients[5]

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[1] https://www.acs.org/content/acs/en.html

[2] http://www.catalogueoflife.org/

[3] http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000596.jsp

[4] https://www.expasy.org/

[5] http://www.cirs-reach.com/Cosmetic_Inventory/International_Nomenclature_of_Cosmetic_Ingredients_INCI.html

4.11
INN
International Nonproprietary Name [also consider as rINN (recommended International Nonproprietary Name) or pINN (proposed International Nonproprietary Name)][6]

4.12
iPSCs
induced pluripotent stem cells

4.13
ITIS
Integrated Taxonomic Information System[7]

4.14
JAN
Japanese Approved Name[8]

4.15
JP
Japanese Pharmacopoeia[129]

4.16
NCBI
National Center for Biotechnology Information

4.17
NDF-RT
National Drug File - Reference Terminology, produced by the U.S. Department of Veterans Affairs, Veterans Health Administration (VHA)[130]

4.18
NLT
not less than

4.19
NMT
not more than

4.20
OMG
Object Management Group[9]

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[6] http://www.who.int/medicines/services/inn/en/

[7] https://www.itis.gov/

[8] http://jpdb.nihs.go.jp/jan/index.aspx

[9] http://www.omg.org/

4.21
PBMCs
Peripheral Blood Mononuclear cells

4.22
Ph.Eur.
European Pharmacopoeia (Pharmacopée Européenne)[131]

4.23
UCUM
Unified Code for Units of Measure[10]

4.24
UML
Unified Modeling Language[11]

4.25
UNII
Unique Ingredient Identifier. Identifier of a substance in the FDA Global Substance Registration System (G-SRS)[12]

4.26
UniProt
Universal Protein Resource[13]

4.27
USAN
United States Adopted Name[14]

4.28
USP
United States Pharmacopeia [132]

4.29
WHO-ATC
World Health Organization – Anatomical Therapeutic Chemical Classification System[133]

5 General background and history

Due to the lack of a common and harmonized approach to define substances, regulators and pharmaceutical industry are faced with the inability to:

1) effectively exchange medicinal substance information in a structured and efficient way;

[10] http://unitsofmeasure.org/trac

[11] http://www.uml.org/

[12] https://www.fda.gov/forindustry/datastandards/substanceregistrationsystem-uniqueingredientidentifierunii/

[13] http://www.uniprot.org/

[14] https://www.ama-assn.org/about/united-states-adopted-names-council