TECHNICAL SPECIFICATION

ISO/TS 19256

First edition

Health informatics — Requirements for medicinal product dictionary systems for health care

Informatique de santé — Exigences pour les systèmes de dictionnaires de produits médicaux pour les soins de santé

PROOF/ÉPREUVE

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Foreword

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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).

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For an explanation on 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*.

Introduction

This introduction contains the following topics:

a) What is a Medicinal Product Dictionary system?

b) What are the use cases and who are the stakeholders?

c) What are the benefits for the different stakeholders?

d) What are the core functional requirements for an MPD-system for healthcare?

The main target audience is the developers and service providers of MPD-systems, and those who contract such developers and service providers.

The goal of MPD Systems is to offer various parties in healthcare a complete overview of available medicinal products in such a way the (elements of the) concepts and the descriptions and medicinal product identifiers can be used in a variety of other healthcare information systems. The principle for this Technical Specification is that the global unique IDs of IDMP (Identification of Medicinal Products) shall be maintained in any MPD-system.

Medicinal products play an important role in healthcare. There are many (thousands of) medicinal products and each medicinal product has many characteristics (attributes), both defining and non-defining. The development and use of medicinal products is highly regulated; currently the way to define information about them is guided by the ISO IDMP standards. Furthermore, many healthcare providers, institutions and enterprises are involved in the use of medicinal products. Each of these actors uses information systems in which information on medicinal products is stored and exchanged. These information systems need an MPD-system to accurately and consistently identify medication concepts in the form(s) that fulfill their use cases.

An MPD-system establishes a consistent representation of medication concepts (set of identifiers) at various levels of detail and with meaningful relationships between the concepts, in order to support parts of several processes in healthcare in which medication plays a role. This Technical Specification describes a Medicinal Product Dictionary system in that way, that the concepts, identifiers and the relationships form a kind of structure that supports the use cases; together with the description of how this structure supports the use cases and what is needed for that. The MPD-system is further described from within an architecture in which it is connected to other parts of healthcare information systems.

Cultural differences in the practice and delivery of care and national legislation require electronic MPD-systems that meet specific local, regional or national needs. Each MPD-system is designed to support a particular set of use cases, which helps to determine the functional requirements which must be met by such systems. These functional requirements will then, in turn, determine the specific collection of 'medication abstractions' which must be identified, defined and related to each other within the MPD-system. Each 'medicinal product' in the MPD-system is described in terms of a specific subset of all possible defining and non-defining information elements, which together enable it to support one or more specific use case(s). The concepts are formally defined in terms of their characteristics and relationships with other concepts according to the ISO IDMP Standards, in particular ISO 11615, ISO 11616 and ISO 11238. Relationships between each of these medicinal product entries give the MPD-system the potential to support interoperability between use cases, processes, information systems, organizations and jurisdictions.

The anticipated stakeholders of this Technical Specification include healthcare providers that have responsibilities in selecting appropriate MPD-systems, software vendors, governments, pharmaceutical companies, wholesalers, payers, drugs regulatory authorities, and patients / patients' organizations.

In general, this Technical Specification supports the following business goals:

- It provides information to MPD-system developers, to help them design MPD-systems which are better able to meet the ISO IDMP standards and the needs of multiple use cases;

- It facilitates accuracy and consistency of the use of concepts and terms according to the ISO IDMP standards in the MPD-systems;
- It increases the potential for consistency between MPD-systems around the world;
- It reduces redundancy of data collection and governance;
- It provides the foundations for future international standards, which help to enable interoperability between medication use cases, information systems, and jurisdictions involved in cross-border healthcare;
- It might reduce the cost of developing and maintaining medicinal product dictionaries systems.

The Technical Specification is partly based on the following terminologies / databases:

- The Australian Medicinal Terminology (AMT);
- NHS dictionary of medicines and devices (DM+D);
- Singapore Drug Database;
- SNOMED CT;
- Dutch G-Standaard from Z-Index (and Pharmabase from Healthbase) (NEN 7507);
- ISO/TR 22790, *Health informatics — Functional characteristics of prescriber support systems*.

Health informatics — Requirements for medicinal product dictionary systems for health care

1 Scope

This Technical Specification defines the required characteristics for any MPD-system to support use cases in healthcare.

These characteristics include the medication concepts, identifiers and relationships to form a kind of structure that supports the use cases.

In order to support the use cases, an MPD-system needs to:

- be comprehensive and exhaustive as far as possible – unless all medicinal products that are in scope are included, other systems cannot fully rely on the MPD-system to supply the necessary information, and some amount of duplicated registration of information will still be necessary;
- contain the information in a consistent and appropriate structure according to the ISO IDMP Standards (as described in this Technical Specification) and with an appropriate level of detail.

Outside the scope of this Technical Specification are:

- the functionality of health, clinical and/or pharmacy systems;
- the other kinds of content of health, clinical or pharmacy systems that are needed to support the whole process of healthcare providers, like:
  - the wide range of knowledge about medicines, which would be handled in drug knowledge databases and decision support systems,
  - the medication record,
  - the dose instructions;
- in terms of products:
  - traditional Chinese medicines,
  - medical devices, such as for medication administration [this Technical Specification focuses on administration devices that are intended for correct administration of the medicinal product only (see ISO 11615)],

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

  - veterinary medicines.

The purpose of this Technical Specification is to provide a set of functional requirements for systems handling details about medicinal products and the relationships between them for the purpose of supporting healthcare.

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 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*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
administration
act of (self-)administering a (prescribed) medicinal product to the patient, using an administration method, and via a defined route, and recording that the act has actually happened at a particular date and time

3.2
administration method
general method by which a pharmaceutical product is intended to be administered to the patient

EXAMPLE Application, inhalation, injection.

Note 1 to entry: The administration method is a general term that is used to group related pharmaceutical dose form concepts, and is not intended to describe a precise method or route of administration.

[SOURCE: ISO 11239:2012, 3.1.3]

3.3
administration device
equipment intended for correct administration of the Medicinal Product

EXAMPLE Applicator, needle, oral syringe.

Note 1 to entry: An administration device can be an integral part of an immediate container or a closure.

[SOURCE: ISO 11239:2012, 3.1.2, modified]

3.4
attribute
characteristic of an object or entity

Note 1 to entry: In the context of this Technical Specification: a specific characteristic of a data element.

[SOURCE: ISO/IEC 11179-1:2015, 3.1.1, modified]

3.5
authorized product
medicinal product that has a marketing authorization

3.6
concept
unit of knowledge created by a unique combination of characteristics

[SOURCE: ISO 1087-1:2000, 3.2.1, modified]

3.7
context
related conditions and situations that provide a useful understanding and meaning of a subject

[SOURCE: ISO /TR 17119:2005, 2.4]

3.8
data
reinterpretable representation of information in a formalized manner suitable for communication, interpretation or processing

[SOURCE: ISO/IEC 2382:2015, 2121272, modified]

3.9
dispensing
process by which an individual healthcare provider takes in a prescription, assesses that prescription, selects the prescribed medicinal product and delivers that medicinal product to the subject of care or their representative

Note 1 to entry: In most cases, but not necessarily always, the individual healthcare provider concerned will be a Pharmacist.

[SOURCE: IHE Pharmacy - Technical Framework Specification]

3.10
dispense record
record of dispensed medicinal product and dispense process

Note 1 to entry: Dispensed medicinal product includes the actual product dispensed identifiers, brand, type, form, quantity etc. Dispense process record includes details of the delivery method, date and recipient (where this is not the subject of care) and the dispenser. The ability to record a comment where assessments of prescriptions are undertaken might also be part of this record.

3.11
dispenser
healthcare professional responsible for filling / dispensing prescriptions

Note 1 to entry: The dispenser is usually a pharmacist but can be other individuals according to local jurisdiction.

[SOURCE: ISO 21549-7:—, 3.5, modified]

3.12
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 1 to entry: Pharmaceutical dose form can refer to the administered dose form or the packaged dose form, depending on the product it is describing.

[SOURCE: ISO 11616:2012, 3.1.10]

3.13
Electronic Health Record
EHR
logical representation of information regarding or relevant to the health of a subject of care

[SOURCE: ISO 18308:2011, 3.20, modified]

3.14
entity
concrete or abstract thing of interest, including associations among things

[SOURCE: ISO/IEC 2382:2015, 2120770]

3.15
identifiers
sequence of characters, capable of uniquely identifying that with which it is associated, within a specified context

[SOURCE: ISO/IEC 11179-1:2015, 3.1.3, modified]

3.16
immediate container
immediate packaging in which a manufactured item or pharmaceutical product is contained and with which it is in direct contact

EXAMPLE Ampoule, vial, prefilled syringe, bottle, blister.

Note 1 to entry: An immediate container can be fitted with or have integrated into it an administration device and/or closure.

Note 2 to entry: A pharmaceutical dose form can fulfill 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 to entry: An alternative, compatible definition of immediate container ("immediate packaging") is given in Directive 92/27/EEC.

[SOURCE: ENV 12610:1997]

3.17
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

[SOURCE: ISO 11615:2012, 3.1.28]

3.18
Investigational Medicinal Product Identifier
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 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.

[SOURCE: ISO 11615:2012, 3.1.31]

3.19
knowledge database
system in which knowledge on a specific topic is specified as set of declarative statements, hierarchical organization of such statements, and relationships between declarative statements, which serves as the underpinning of decision support systems

