SLOVENSKI STANDARD
SIST-TS CEN ISO/TS 20451:2018

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Zdravstvena informatika - Identifikacija medicinskih izdelkov - Smernice za uporabo ISO 11616 podatkovnih elementov in struktur za enotno identifikacijo in izmenjavo predpisanih informacij o farmacevtskih izdelkih (ISO/TS 20451:2017)

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 (ISO/TS 20451:2017)

Medizinische Informatik - Identifikation von Arzneimitteln - Implementierungsleitfaden für ISO 11616 Datenelemente und -strukturen zur eindeutigen Identifikation und zum Austausch von Informationen über pharmazeutische Produkte (ISO/TS 20451:2017)

Informatique de santé - Identification des médicaments - Lignes directrices pour l'implémentation des éléments de données et structures ISO 11616 pour l'identification unique et l'échange d'informations réglementées sur les produits pharmaceutiques (ISO/TS 20451:2017)

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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 (ISO/TS 20451:2017)

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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European foreword

This document (CEN ISO/TS 20451:2018) has been prepared by Technical Committee ISO/TC 215 " Health informatics " in collaboration with Technical Committee CEN/TC 251 “Health informatics” the secretariat of which is held by NEN.

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Endorsement notice

The text of ISO/TS 20451:2017 has been approved by CEN as CEN ISO/TS 20451:2018 without any modification.

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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

Informatique de santé — Identification des médicaments — Lignes directrices pour l'implémentation des éléments de données et structures ISO 11616 pour l'identification unique et l'échange d'informations réglementées sur les produits pharmaceutiques

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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 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*.

Introduction

This document gives guidelines for implementing ISO 11616, one of the five ISO IDMP standards. The five ISO Standards and four ISO Technical Specifications, when used together, provide the basis for exchanging data elements that will support the unique and unambiguous identification of Medicinal Products. The primary purpose of this document is to provide technical guidance to software implementers; short descriptions of business rationale are also included, where relevant, to provide context. Thus, this document focuses on business and technical considerations for implementation that will construct and parse well-formed, transmittable IDMP messages. Following transmission of required data elements, unique identifiers are to be produced in conformance with the standards to support applications where it is necessary to reliably identify and trace regulated biopharmaceutical products. However, this document does not include extensive information on creation or maintenance of identifier repositories. Reference is made to regional guidance/implementation guides to support practical implementation within a given region/jurisdiction. The development of an ISO technical report for identifying core principles for the maintenance of identifiers and terms for ISO IDMP is to be developed and referenced for applicable ISO IDMP standards and corresponding technical specifications.

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

1 Scope

This document defines the concepts required to associate pharmaceutical products with an appropriate set of PhPID(s) in accordance with ISO 11616.

Pharmaceutical identifiers and elements are to represent pharmaceutical products as represented in a Medicinal Product as indicated by a Medicines Regulatory Authority. The suite of ISO IDMP standards can be applied to off-label usage of Medicinal Products, but is currently outside of the scope of this document.

Reference to ISO 11238, ISO 11239, ISO 11240 and ISO 11615 and HL7 messaging standards, HL7 Reference Information Model (RIM), HL7 V3 Common Product Model (CPM) and HL7 V3 Structured Product Labelling (SPL) can be applied for pharmaceutical product information 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 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, *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*

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 http://www.iso.org/obp

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

4 Conformance

— *Mandatory*: Defining elements *necessary* for the unique identification of Medicinal Products per the ISO IDMP standards/technical specifications.

— *Conditional*: Conditional applies to the "*within category*" data elements, as applicable, when there are alternative data sources for a given data element(s) to identify a medicinal/pharmaceutical product. Regional implementation of the ISO IDMP standards/technical specifications may elevate the conditional conformance categories to "*mandatory*" per regional requirements.

— *Optional*: When listed at the category level (e.g. specified substance), optional corresponds to ISO categories or data elements that are not absolutely necessary for the *unique* identification of medicinal/pharmaceutical products according to the ISO IDMP standards/technical specifications. Regional implementation of the ISO IDMP standards/technical specifications may elevate the optional conformance categories to "*mandatory*" or "*conditional*" per regional requirements.

5 Concepts required for the unique identification of pharmaceutical products

5.1 General considerations for elements required for the unique identification of pharmaceutical products

This clause, along with Annex A and Annex B, describes the elements and messaging required to uniquely identify and characterise a pharmaceutical product. It provides the requirements to support pharmaceutical product identification. Examples are given in Annex C.

Pharmaceutical product identification (PhPID) shall be based on the following subset of elements that describe the pharmaceutical product (see Figure 1):

a) active substance(s)/specified substance(s);

NOTE The substance(s) within the ingredient role "active" and "adjuvant" are utilised to define the PhPID.

b) strength(s), strength units (units of measurement and/or unit of presentation);

c) reference strength(s) includes reference substance(s) (i.e. active moiety and its corresponding strength);

d) administrable dose form;

e) medical device, when it is a component of a Medicinal Product.

5.2 Principles required for the unique identification of a pharmaceutical product

The following principles for the unique identification of a pharmaceutical product shall apply:

a) a Medicinal Product may relate to one or more pharmaceutical products as part of a treatment regime [e.g. a kit, which might be a combination pack containing vaginal tablets (500 mg) and an external vaginal cream (10 %)];

b) the characterisation of the pharmaceutical product(s) based on the active substance(s)/specified substance(s), the (reference) strength thereof, the administrable dose form(s), and the medical device (e.g. a scaffolding for cell-based products) being part of the Medicinal Product (e.g. drug/device combination);

c) the description of the pharmaceutical product(s) in the pharmaceutical dose form approved for administration, where applicable, after reconstitution and as authorised in accordance with the regulated product information;

d) the association of the regulated (investigational) Medicinal Product and the pharmaceutical product(s) using the PhPID(s).

6 Identifying characteristics for the identification of pharmaceutical products

6.1 Pharmaceutical product identification strata and levels

PhPID sets shall be represented within two strata (active substance stratum and specified substance stratum), both of which contain four PhPID identification levels, for each pharmaceutical product contained in a Medicinal Product.

PhPID sets shall be generated using the substance standard (see ISO 11238 and ISO/TS 19844), the strength and administrable dose form section (see ISO 11239 and ISO/TS 20440) and the unit(s) of measurement standard (see ISO 11240) as illustrated below.

Reference strength shall be repeated in both PhPID strata. The reference strength shall be derived from the active moiety/moieties of an active substance(s) depending on the specific product characteristics.

All the PhPID strata can be described at four different levels from 1 to 4 as shown in Table 1.

Table 1 — Four levels of PhPID

PhPID active substance stratum	PhPID_SUB_L1 → substance(s) PhPID_SUB_L2 → substance(s) + strength + reference strength PhPID_SUB_L3 → substance(s) + administrable dose form PhPID_SUB_L4 → substance(s) + strength + reference strength + administrable dose form
PhPID specified substance stratum	PhPID_SpSUB_L1 → specified substance(s) PhPID_SpSUB_L2 → specified substance(s) + strength + reference strength PhPID_SpSUB_L3 → specified substance(s) + administrable dose form PhPID_SpSUB_L4 → specified substance(s) + strength + reference strength + administrable dose form

A pharmaceutical product may refer to a drug that is associated with a medical device. In this instance, the device term and term ID (i.e. unique device identifier) shall be displayed with the active substance(s) and specified substance(s) terms for the product at all applicable PhPID levels. This association shall be made by directly associating the assigned PhPIDs to a Medicinal Product and its corresponding MPID/PCID as outlined in ISO 11615 and ISO/TS 20443.

Strength is not applicable to a device.

A region may further refine the requirements in relation to specification of the medical device as part of this document at implementation so that this information is to be specified only if required.

A pharmaceutical product may refer to a drug that is associated with an adjuvant (e.g. vaccine). In this instance, the adjuvant term and term ID shall be displayed with the active substance(s) and specified substance(s) terms for the product at all applicable PhPID levels. This association shall be made by