SIST

SLOVENSKI STANDARD
SIST-TS CEN ISO/TS 20440:2016

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Zdravstvena informatika - Identifikacija medicinskih izdelkov - Vodilo za uporabo ISO 11239 podatkovnih elementov in struktur za enotno identifikacijo in izmenjavo predpisanih informacij o farmacevtskih odmerkih, predstavitvenih enotah, administrativnih poteh in pakiranju (ISO/TS 20440:2016)

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 20440:2016)

Medizinische Informatik - Identifikation von Arzneimitteln - Anwendungsleitfaden für ISO 11239 Struktur und kontrollierte Vokabularien zur Identifikation von pharmazeutischen Darreichungsformen, pharmazeutischen Konventionseinheiten, Anwendungsarten und Verpackungen (ISO/TS 20440:2016)

Informatique de santé - Identification des produits médicaux - Guide de mise en oeuvre des éléments de données et structures pour l'identification unique et l'échange d'informations réglementées sur les formes des doses pharmaceutiques, les unités de présentation, les voies d'administration et les emballages de l'ISO 11239 (ISO/TS 20440:2016)

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TECHNICAL SPECIFICATION

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CEN ISO/TS 20440

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ICS 35.240.80

English Version

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 20440:2016)

Informatique de santé - Identification des produits médicaux - Guide de mise en oeuvre des éléments de données et structures pour l'identification unique et l'échange d'informations réglementées sur les formes des doses pharmaceutiques, les unités de présentation, les voies d'administration et les emballages de l'ISO 11239 (ISO/TS 20440:2016)

Medizinische Informatik - Identifikation von Arzneimitteln - Implementierungsleitfaden für ISO 11239 Datenelemente und Strukturen zur eindeutigen Identifikation und zum Austausch von vorgeschriebenen Informationen über pharmazeutische Darreichungsformen, pharmazeutische Konventionseinheiten, Anwendungsarten und Verpackungen (ISO/TS 20440:2016)

This Technical Specification (CEN/TS) was approved by CEN on 29 May 2016 for provisional application.

The period of validity of this CEN/TS is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the CEN/TS can be converted into a European Standard.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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European foreword

This document (CEN ISO/TS 20440:2016) 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 20440:2016 has been approved by CEN as CEN ISO/TS 20440:2016 without any modification.

TECHNICAL SPECIFICATION

ISO/TS 20440

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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

Informatique de santé — Identification des produits médicaux — Guide de mise en oeuvre des éléments de données et structures pour l'identification unique et l'échange d'informations réglementées sur les formes des doses pharmaceutiques, les unités de présentation, les voies d'administration et les emballages de l'ISO 11239

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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).

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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

The terminologies described in EN/ISO 11239:2012 (hereafter referred to as ISO 11239) and in this Technical Specification are essential for the implementation of the IDMP standards as a whole.

Each region traditionally uses its own sets of terminologies to describe the concepts covered in ISO 11239 within their regions; these terminologies are not harmonised with those of the other regions. Therefore, harmonised controlled terminologies need to be provided to ensure that all regions can refer to a given concept in the same manner. The purpose of this Technical Specification is to describe how these controlled vocabularies are constructed and illustrate their use for ISO 11239 implementation.

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

1 Scope

This Technical Specification describes 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.

Based on the principles outlined in this Technical Specification, harmonised controlled terminologies will be developed according to an agreed maintenance process, allowing users to consult the terminologies and locate the appropriate terms for the concepts that they wish to describe. Provisions to allow for the mapping of existing regional terminologies to the harmonised controlled terminologies will also be developed in order to facilitate the identification of the appropriate terms. The codes provided for the terms can then be used in the relevant fields in the PhPID, PCID and MPID in order to identify those concepts.

This Technical Specification is intended for use by:

— any organisation that might be responsible for developing and maintaining such controlled vocabularies;

— any regional authorities or software vendors who wish to use the controlled vocabularies in their own systems and need to understand how they are created;

— owners of databases who wish to map their own terms to a central list of controlled vocabularies;

— other users who wish to understand the hierarchy of the controlled vocabularies in order to help identify the most appropriate term to describe a particular concept.

The terminology to be applied in the context of this Technical Specification and set out in ISO 11239 is under development. All codes, terms and definitions used as examples in this Technical Specification are provided for illustration purposes only, and are not intended to represent the final terminology.

2 Organisation of controlled terms

2.1 General

This Clause describes how each controlled term is built, describing the data types used to convey the information and the versioning requirements for tracking their creation and evolution. Clause 3 describes the different types of terminologies and sub-vocabularies that use these data types, and any relevant relationships between them.

Each field in Clause 2 is described under a separate subclause, consisting of the title of the field and a table containing the following:

— “User Guidance”, a description of the field;

— “Data Type”, a description of the data type;

— “Conformance”, a description of whether the field is mandatory, optional, or conditional;

— “Value Allowed”, indicating the possible values for the field;

— “Business Rules”, providing technical guidance for the field.

2.2 Code-term pair and coded concept

2.2.1 General

The code-term pair and the coded concept are the data types that are used to represent the information that is required to describe each term in each terminology or sub-vocabulary, in each language/region combination.

2.2.2 Code-term pair

2.2.2.1 Code-term pair overview

This is the underlying class for each term, and is used to describe and define a term in a specific language and for a specific region. It contains the core attributes for each concept, including the identifier, the textual representation of the term (i.e. the controlled term itself), the definition, an optional domain to indicate whether a term is restricted to veterinary use, an optional textual comment, and the language and region codes.

Each controlled term or sub-term has a unique code-term pair for each language/region combination. This combination of language and region allows for regional variants of a specific language to be catered for; for example, where the spelling of a term or definition differs between UK English and US English, it is possible to reflect this difference. Where terms and definitions already exist for a particular language for a particular region, and the same language is used in a second region, it is a regional implementation issue to decide whether terms and definitions need to be provided for the second region, or whether the terms and definitions of the first region shall be used.

When a new concept is required, a new coded concept must be created, and at least one code-term pair is required in order to hold the data to describe the concept. The language/region combination chosen to represent the “value” shall always be created first to represent the concept, even when the request originates from a different language/region combination. The maintenance organisation shall provide instructions on how to request a new term or a revision to an existing term.

2.2.2.2 Code-term pair: Code

User Guidance	This field contains a unique, machine-readable identifier for the code-term pair. In this Technical Specification, the following format is used for the code: — XXX-12345678-LL-RR where — XXX represents the class of term (see Table 1); — 12345678 represents a unique 8-digit number; for sub-vocabularies, a 4-digit number is used; — LL represents the language code; — RR represents the region/country code.
Data Type	String <ST>
Conformance	Mandatory
Value Allowed	Free text
Business Rule(s)	Each code-term pair shall have one code.

The codes used in this Technical Specification to represent the various classes of term in the examples that follow are shown in Table 1.

Table 1 — Codes used to represent the class of term

Code	Class
SOM	State of matter
BDF	Basic dose form
RCA	Release characteristics
TRA	Transformation
ISI	Intended site
AME	Administration method
PDF	Pharmaceutical dose form
CDF	Combined pharmaceutical dose form
UOP	Unit of presentation
ROA	Route of administration
PCA	Packaging category
CON	Container
CLO	Closure
DEV	Administration device
MAP	Mapped term

2.2.2.3 Code-term pair: Term

User Guidance	This field contains the textual term description for the code-term pair.
Data Type	String <ST>
Conformance	Mandatory
Value Allowed	Free text
Business Rule(s)	Each code-term pair shall have one term.

2.2.2.4 Code-term pair: Definition

User Guidance	This field contains the textual definition for the code-term pair. The definition is as comprehensive as possible, in order to guide the user to the most appropriate term to describe a given concept. For example, it should be detailed enough to distinguish between similar pharmaceutical dose forms, and may exceptionally make direct reference to related terms in order to exclude them, although such references may be considered more appropriate in the Comments section instead.
Data Type	String <ST>
Conformance	Mandatory for the default code-term pair; optional for the translation code-term pairs
Value Allowed	Free text
Business Rule(s)	Each code-term pair may have one definition. For each coded concept, the default code-term pair (e.g. EN-GB) shall have one definition. If a code-term pair for a given language/region combination does not have a definition provided, the definition in the code-term pair for the default language/region combination is adopted.