SLOVENSKI STANDARD
SIST-TS CEN ISO/TS 20440:2023

01-julij-2023

Nadomešča:
SIST-TS CEN ISO/TS 20440:2016

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 20440:2023)

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 20440:2023)

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, Verabreichungswegen und Verpackungen (ISO/TS 20440:2023)

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 20440:2023)

Ta slovenski standard je istoveten z: **CEN ISO/TS 20440:2023**

ICS:

35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology

SIST-TS CEN ISO/TS 20440:2023 **en,fr,de**

TECHNICAL SPECIFICATION

SPÉCIFICATION TECHNIQUE

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CEN ISO/TS 20440

April 2023

ICS 35.240.80

Supersedes CEN ISO/TS 20440:2016

English Version

Health informatics - Identification of medicinal products - Implementation guidelines 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 20440:2023)

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This Technical Specification (CEN/TS) was approved by CEN on 10 March 2023 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
COMITÉ EUROPÉEN DE NORMALISATION
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European foreword

This document (CEN ISO/TS 20440:2023) 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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes CEN ISO/TS 20440:2016.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this Technical Specification: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO/TS 20440:2023 has been approved by CEN as CEN ISO/TS 20440:2023 without any modification.

TECHNICAL SPECIFICATION

ISO/TS 20440

Second edition
2023-03

Health informatics — Identification of medicinal products — Implementation guidelines 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 œuvre 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).

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 of 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 215, *Health informatics,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 251, *Health informatics,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO/TS 20440:2016), which has been technically revised.

The main changes are as follows:

— addition of a recommendation to label administrable dose forms as such, to distinguish them from those pharmaceutical dose forms that are only manufactured dose forms;

— a section has been added describing how pharmaceutical dose form attributes can be used directly, rather than simply serving to classify the pharmaceutical dose form;

— several examples have been updated to reflect terms and definitions that are in use.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at http://www.iso.org/members.html.

Introduction

The terminologies described in ISO 11239 and in this document 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 document is to describe how these controlled vocabularies are constructed and illustrate their use for ISO 11239 implementation.

A number of the codes, terms and definitions used as examples in this document are taken from the Standard Terms database of the European Directorate for the Quality of Medicines & HealthCare, Council of Europe (EDQM), specifically those for UK English (EN-GB). The EDQM Standard Terms database is not static and its content changes over time, so the examples provided in this document might not remain current; furthermore, examples provided in language/region combinations other than UK English are not necessarily taken from the EDQM Standard Terms database.

The EDQM Standard Terms database is an example of an implementation of ISO 11239, but reference to it in this document does not imply that it is the standardized terminology to use for IDMP implementation.

Health informatics — Identification of medicinal products — Implementation guidelines 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 document 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 document, 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 document is intended for use by:

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

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

— owners of databases who want to map their own terms to a standardized list of controlled vocabularies;

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

This document does not specify a particular terminology for the implementation of ISO 11239.

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 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*

3 Terms and definitions

No terms and definitions are listed in this document.

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

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

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

4 Organization of controlled terms

4.1 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 5 describes the different types of terminologies and sub-vocabularies that use these data types, and any relevant relationships between them.

Each field in Clause 4 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.

4.2 Code-term pair and coded concept

4.2.1 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.

4.2.2 Code-term pair

4.2.2.1 Code-term pair overview

This is the underlying class for each term, and it 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 must be used.

When a new concept is required, a new coded concept shall 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 organization shall provide instructions on how to request a new term or a revision to an existing term.

4.2.2.2 Code-term pair: Code

User Guidance	This field contains a unique, machine-readable identifier for the code-term pair. In this document, 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 document 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

4.2.2.3 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.