PD CEN ISO/TS 20440:2023

BSI Standards Publication

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

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National foreword

This British Standard is the UK implementation of CEN ISO/TS 20440:2023. It is identical to ISO/TS 20440:2023. It supersedes PD CEN ISO/TS 20440:2016, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee IST/35, Health informatics.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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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)

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 (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)

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 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.

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Endorsement notice

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

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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.

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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.

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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.

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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.

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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.

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4.2.2.4 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.

4.2.2.5 Code-term pair: Domain

User Guidance	This field is used to identify whether a term is considered appropriate for both human and veterinary use, or whether it is considered appropriate for veterinary use only.
Data Type	Concept Descriptor <CD>
Conformance	Optional
Value Allowed	"Human and veterinary"; "Veterinary only"
Business Rule(s)	Each code-term pair may have one domain. Although veterinary medicines are outside the scope of IDMP, certain regions use a single terminology system to cover both medicines for human use and medicines for veterinary use; this optional field is therefore included in order to allow veterinary-only terms to be easily distinguished in such systems.

4.2.2.6 Code-term pair: Comment

User Guidance	This optional field contains a textual comment for the code-term pair. It is used to provide to the user additional information and guidance that would not be strictly appropriate to appear as part of the definition.
Data Type	String <ST>
Conformance	Optional
Value Allowed	Free text
Business Rule(s)	Each code-term pair may have one comment.

4.2.2.7 Code-term pair: Language code

User Guidance	This field contains the language in which the term, definition and comment are described; in this document, the working language is English. The language code used is in accordance with ISO 639-1.
Data Type	Concept Descriptor <CD>
Conformance	Mandatory
Value Allowed	ISO 639-1 code, OID reference 1.0.639.1

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Business Rule(s)	Each code-term pair shall have one language code.

4.2.2.8 Code-term pair: Region code

User Guidance	This field contains the region/country that uses this code-term pair, in the language described above; it can be used to differentiate between regional variants of that language; in this document, the default region is the United Kingdom. The region code used is in accordance with ISO 3166-1. Alpha-2 (i.e. 2-letter) codes are used. The additional code EU is also allowed to represent the European Union. It should be noted that the United Kingdom is represented in ISO 3166-1 by the 2-letter code GB, as in the examples used in this document.
Data Type	Concept Descriptor <CD>
Conformance	Mandatory
Value Allowed	ISO 3166-1 alpha-2 code, OID reference 1.0.3166.1.2.2.
Business Rule(s)	Each code-term pair shall have one region code.

4.2.2.9 Code-term pair example

An example of a code-term pair for the concept "Tablet", a pharmaceutical dose form, is shown in Table 2. Since the working language of this document is UK English, the language is English and the region is the United Kingdom.

Table 2 — Example code-term pair for pharmaceutical dose form "Tablet" in UK English

Code	**PDF-10219000-EN-GB**
Term	Tablet
Definition	Solid single-dose uncoated preparation obtained by compressing uniform volumes of particulate solids or by other means such as extrusion or moulding. Tablets include single-layer tablets resulting from a single compression of particles and multi-layer tablets consisting of concentric or parallel layers obtained by successive compressions of particles of different composition. Tablets are intended for oral use to release active substance(s) in the gastrointestinal fluids by a rate depending essentially on the intrinsic properties of the active substance(s) (conventional release).
languageCode	EN
regionCode	GB

4.2.3 Coded concept

4.2.3.1 Coded concept overview

This is the class that is used to represent the concept itself, and it is a collection of all of the code-term pairs that define the same concept for each language/region combination. The code-term pairs for a given concept can be considered as different translations of that concept; the coded concept groups those various translations under a single, unique code. In order to represent the coded concept, one of the code-term pairs is selected as the "value", while each other code-term pair is a "translation".

The use of a coded concept in another system allows for the identification of a concept without specifying a particular language and region. The code-term pair selected as the "value" may be used by default to represent the coded concept when a textual term is requested. The default code-term pair in this document is English/United Kingdom. Where a language/region combination is specified by the requesting system, the appropriate code-term pair for that combination can be used to represent the coded concept.

As described in 4.2.2.1, 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, even when the request

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originates from a different language/region combination. The maintenance organization shall provide instructions on how to request a new term, as well as how to request a revision to an existing term.

4.2.3.2 Coded concept: Code

User Guidance	This field contains a unique, machine-readable identifier for the coded concept.
Data Type	String <ST>
Conformance	Mandatory
Value Allowed	Free text
Business Rule(s)	Each coded concept shall have one code.

4.2.3.3 Coded concept: Value

User Guidance	This field contains the identifier of the code-term pair that has been chosen to represent the coded concept. In this document this code-term pair is always that of the English/United Kingdom combination.
Data Type	String <ST>
Conformance	Mandatory
Value Allowed	Code-term pair identifier
Business Rule(s)	Each coded concept shall have one value, which is considered to be its default code-term pair. Whenever a new concept is created, the code-term pair with the language/region combination that is chosen for the "value" shall always be created first, even if the request is made for a different language/region combination.

4.2.3.4 Coded concept: Translation

User Guidance	This repeatable field contains the identifier of the code-term pair that represents the concept using a language/region combination that is different from that of the code-term pair used for the above coded concept value. In this document, since the above value is always represented by English/United Kingdom, these code-term pairs will represent combinations such as English/United States, Japanese/Japan, French/France, etc.
Data Type	String <ST>
Conformance	Optional
Value Allowed	Code-term pair identifier
Business Rule(s)	Each coded concept may have zero to many translations.

4.2.3.5 Coded concept example

An example of a coded concept for the concept "Tablet" is shown in Table 3. Since the working language of this document is UK English, the value is the code-term pair that has English as the language and United Kingdom as the region (as shown in Table 2). In order to simplify the example, just two translations are associated with it here: the code-term pair that has French as the language and France as the region, and the code-term pair that has Japanese as the language and Japan as the region. As can be seen from Table 3, only the code-term pair identifiers are required, since each one represents all of the necessary information for each language/region combination, (such as for English and the United Kingdom as shown in Table 2). The overall concept of "Tablet" (i.e. including all language/region combinations) has its own identifier (code PDF-10219000 in this example).

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Table 3 — Example coded concept for pharmaceutical dose form "Tablet", linking the code-term pairs for the concept in English for the United Kingdom, French for France, and Japanese for Japan

code	**PDF-10219000**
value	PDF-10219000-EN-GB
translation	PDF-10219000-FR-FR PDF-10219000-JA-JP

4.3 Versioning

4.3.1 Versioning of the term

ISO/TR 14872 includes guidance on principles and procedures for versioning and change control.

Code-term pairs are used to populate a terminology database, and as such they can be considered as the current representation of specific concepts for specific language/region combinations. They contain the information that is considered to be the most important and relevant to the database user. However, as controlled vocabularies can evolve over time, the situation arises whereby terms in a database need to be revised, which means that code-term pairs therefore need to be revised.

In order to maintain a traceable history of a code-term pair, including any changes that are made to it, each code-term pair is associated with versioning information. This is done with the use of versions. Each time a code-term pair is created or modified, a version of that code-term pair is created.

A version acts as a record of a code-term pair at a specific point in time. It contains the elements of the code-term pair at that point in time, as well as a timestamp, an identifier of the operator that made the modification, and a description of the modification that took place. Also recorded in the version is the status of the term; any change in status of a code-term pair will evoke the creation of a new version of that code-term pair. Certain information, such as the identifier of the operator, may not be made publicly available, but is nevertheless recorded.

These additional elements of versioning information are described in more detail below.

The coded concept can be considered as the container for all of the translations (i.e. code-term pairs) for a given concept; it does not therefore require versioning information itself. The addition of a new translation (i.e. a new code-term pair) does not therefore result in the creation of a new version of the coded concept.

4.3.1.1 Versioning: Code

User Guidance	This field contains the unique, machine-readable identifier for the version of the code-term pair that is the subject of the versioning. In this document, the following format is used for the code: — XXX-12345678-LL-RR-V where — XXX-12345678-LL-RR represents the code-term pair; — V represents the version number, the length of which is not limited to a single digit.
Data Type	String <ST>
Conformance	Mandatory
Value Allowed	The code is generated automatically from the code-term pair and the version number.
Business Rule(s)	Each version shall have one code.

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4.3.1.2 Versioning: Creation date

User Guidance	This field contains the time and date upon which the concept was first created. The time stamp used is in accordance with ISO 8601.
Data Type	Timestamp <TS>
Conformance	Mandatory
Value Allowed	YYYY-MM-DD hh:mm:ss
Business Rule(s)	The creation date refers to the creation of the coded concept and the first code-term pair for the default language/region. The time standard chosen to measure the point in time (e.g. UTC, UTC+1) is used consistently throughout the database.

4.3.1.3 Versioning: Created by

User Guidance	This field contains an identification of the operator who created the concept, such as their name or identifier.
Data Type	String <ST>
Conformance	Mandatory
Value Allowed	Free text
Business Rule(s)	This information is not made publicly available to all users, but is recorded in the database and is accessible to the database administrator.

4.3.1.4 Versioning: Version date

User Guidance	If a modification has been made to a term, then a new version of that term is created, and this field contains the time and date upon which that version was created. This also applies to the creation of the first version of the code-term pair. The first version of the first code-term pair represents the creation of the coded concept itself, and therefore has particular importance, which is why it is considered appropriate always to indicate that date, even for subsequent versions and for different translations. The time stamp used is in accordance with ISO 8601.
Data Type	Timestamp <TS>
Conformance	Mandatory
Value Allowed	YYYY-MM-DD hh:mm:ss
Business Rule(s)	Each version of a code-term pair shall have one version date.

4.3.1.5 Versioning: Modification made

User Guidance	If a modification has been made to a term, then a new version of that term is created, and this field shall be used to add a description of or explanation for the modification that was made. This also applies to the creation of the first version of the code-term pair.
Data Type	String <ST>
Conformance	Mandatory
Value Allowed	Free text, although a drop-down list of common modifications may be considered appropriate in order to help harmonise the entries.
Business Rule(s)	Each version of a code-term pair shall have one entry for modification made.

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4.3.1.6 Versioning: Modification by

User Guidance	If a modification has been made to a term, then a new version of that term is created, and this field contains an identification of the operator who made the modification, such as their name or identifier. This also applies to the creation of the first version of the code-term pair. The first version of the first code-term pair represents the creation of the coded concept itself, and therefore has particular importance, which is why it is considered appropriate always to record the creator, even for subsequent versions and for different translations.
Data Type	String <ST>
Conformance	Mandatory
Value Allowed	Free text
Business Rule(s)	This information is not made publicly available to all users, but is recorded in the database and is accessible to the database administrator.

4.3.1.7 Versioning: Concept status

User Guidance	This field contains the status of the term.
Data Type	Concept descriptor <CD>
Conformance	Mandatory
Value Allowed	"Current"; "Deprecated"; "Rejected"; "Pending"
Business Rule(s)	Each version of a code-term pair has a status, which allows the history of any change in status of a term to be recorded. For example, if an existing, current term (version 1) is to be deprecated, then a new version of the code-term pair is created (version 2), with the status changed from "current" to "deprecated". It is the intention that, for any given concept, the status is the same for all of the translations; therefore, a mechanism should be implemented to ensure that the status of each code-term pair of a coded concept is changed at the same time.

4.3.1.8 Versioning: Current concept

User Guidance	If a term has been deprecated or rejected, and one or more other terms are identified as a replacement, this repeatable field contains the identifier of the replacement term.
Data Type	String <ST>
Conformance	Conditional
Value Allowed	Coded concept identifier
Business Rule(s)	This field is conditional on the status of a term being "deprecated" or "rejected", and there being a replacement term identified.

4.3.1.9 Versioning: Version number

User Guidance	This field contains an identifier for the particular version of the term being described, in the form of a whole number. When a modification to a term is made, a new version is created and identified through the version number, which increases by a value of 1 from the previous version of the term. When a term is first created this field has the value 1.
Data Type	Integer <INT>
Conformance	Mandatory
Value Allowed	Positive integer greater than zero.
Business Rule(s)	Each version shall have one version number.

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