



BSI Standards Publication

**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)**

National foreword

This Published Document is the UK implementation of CEN ISO/TS 20440:2016.

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 secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

© The British Standards Institution 2016.

Published by BSI Standards Limited 2016

ISBN 978 0 580 91041 8

ICS 35.240.80

Compliance with a British Standard cannot confer immunity from legal obligations.

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 31 July 2016.

Amendments/corrigenda issued since publication

Date	Text affected
------	---------------

TECHNICAL SPECIFICATION
SPÉCIFICATION TECHNIQUE
TECHNISCHE SPEZIFIKATION

CEN ISO/TS 20440

June 2016

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.

CEN members are required to announce the existence of this CEN/TS in the same way as for an EN and to make the CEN/TS available promptly at national level in an appropriate form. It is permissible to keep conflicting national standards in force (in parallel to the CEN/TS) until the final decision about the possible conversion of the CEN/TS into an EN is reached.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents	Page
European foreword.....	3

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.

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

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO/TS 20440:2016 has been approved by CEN as CEN ISO/TS 20440:2016 without any modification.

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Organisation of controlled terms	1
2.1 General	1
2.2 Code-term pair and coded concept	2
2.2.1 General	2
2.2.2 Code-term pair	2
2.2.3 Coded concept	5
2.3 Versioning	6
2.3.1 Versioning of the term	6
2.3.2 Versioning of the terminology	9
3 Terminologies	9
3.1 General	9
3.2 Pharmaceutical dose form	10
3.2.1 Pharmaceutical dose form overview	10
3.2.2 Pharmaceutical dose form schema	10
3.2.3 Pharmaceutical dose form example: Prolonged-release tablet	16
3.3 Combined pharmaceutical form	21
3.3.1 Combined pharmaceutical dose form overview	21
3.3.2 Combined pharmaceutical dose form schema	22
3.3.3 Combined pharmaceutical dose form example: Powder and solvent for solution for injection	23
3.3.4 Other authorised combinations of terms — Combined terms and combination packs	25
3.4 Unit of presentation	26
3.4.1 Unit of presentation overview	26
3.4.2 Unit of presentation schema	27
3.4.3 Unit of presentation example: Tablet	27
3.5 Route of administration	28
3.5.1 Route of administration overview	28
3.5.2 Route of administration schema	29
3.5.3 Route of administration example: Intravenous use	29
3.6 Packaging	30
3.6.1 Packaging overview	30
3.6.2 Packaging schema	30
3.6.3 Packaging example: Ampoule (Packaging category: Container)	31
3.6.4 Packaging example: Screw cap (Packaging category: Closure)	33
3.6.5 Packaging example: Oral syringe (Packaging category: Administration device)	34
3.6.6 Packaging concept summaries	36
4 Mapping of regional terms	36
4.1 Differences in granularity between regional terminologies	36
4.2 Organisation of regional terms in the database	38
4.2.1 General	38
4.2.2 Addition of regional terms to the database	38
4.2.3 Mapping regional terms to central coded concepts	41
4.2.4 Versioning of mapped regional terms	41
4.2.5 Mapped regional term example: Extended-release caplet	41
Bibliography	43

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 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;