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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)

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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.

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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.

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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.

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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.

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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;