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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 It supersedes PD CEN ISO/TS 20440:2016, which is withdrawn.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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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)

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.

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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.

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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

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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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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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TECHNICAL SPECIFICATION **ISO/TS 20440:2023(E)**

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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