PD CEN ISO/TS 20443:2018

BSI Standards Publication

Health informatics – Identification of medicinal products – Implementation guidelines for ISO 11615 data elements and structures for the unique identification and exchange of regulated medicinal product information (ISO/TS 20443:2017)

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National foreword

This Published Document is the UK implementation of CEN ISO/TS 20443:2018. It is identical to ISO/TS 20443:2017.

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.

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Published by BSI Standards Limited 2018

ISBN 978 0 580 91310 5

ICS 35.240.80

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This Published Document was published under the authority of the Standards Policy and Strategy Committee on 31 May 2018.

Amendments/corrigenda issued since publication

Date	Text affected

TECHNICAL SPECIFICATION

SPÉCIFICATION TECHNIQUE

TECHNISCHE SPEZIFIKATION

CEN ISO/TS 20443

May 2018

ICS 35.240.80

English Version

Health informatics - Identification of medicinal products - Implementation guidelines for ISO 11615 data elements and structures for the unique identification and exchange of regulated medicinal product information (ISO/TS 20443:2017)

Informatique de santé - Identification des médicaments - Lignes directrices pour l'implémentation des éléments de données et structures ISO 11615 pour l'identification unique et l'échange d'informations réglementées sur les médicaments (ISO/TS 20443:2017)

Medizinische Informatik - Identifikation von Arzneimitteln - Datenelemente und -strukturen zur Identifikation von Arzneimitteln für den Austausch von behördlich genehmigten Arzneimittelinformationen (ISO/TS 20443:2017)

This Technical Specification (CEN/TS) was approved by CEN on 13 May 2018 for provisional application.

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Ref. No. CEN ISO/TS 20443:2018 E

European foreword

This document (CEN ISO/TS 20443:2018) 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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The text of ISO/TS 20443:2017 has been approved by CEN as CEN ISO/TS 20443:2018 without any modification.

Contents

Page

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Foreword

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This document was prepared by Technical Committee ISO/TC 215, *Health informatics*.

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Introduction

This document is a guide for implementing ISO 11615, one of the five ISO IDMP standards. The five ISO standards and four ISO Technical Specifications, when used together, provide the basis for exchanging data elements that will support the unique and unambiguous identification of Medicinal Products. The primary purpose for this document is to provide technical guidance to software implementers. Short descriptions of business rationale are also included, where relevant, to provide context. Thus, this document focuses on business and technical considerations for implementation that will construct and parse well-formed, transmittable IDMP messages. Following transmission of required data elements, unique identifiers are to be produced in conformance with the standards to support applications where it is necessary to reliably identify and trace regulated biopharmaceutical products. However, this document does not include extensive information on creation or maintenance of identifier repositories. Reference is made to regional guidance/implementation guides to support practical implementation within a given region/jurisdiction. The development of an ISO technical report for identifying core principles for the maintenance of identifiers and terms for ISO IDMP is to be developed and referenced for applicable ISO IDMP standards and corresponding technical specifications.

Purpose

To meet the primary objectives of the regulation of medicines (pharmacovigilance) it is necessary to reliably exchange Medicinal Product information in a robust and consistent manner. The data elements and message specifications described in this document support, at a minimum, the following interactions within the following scope:

— regulator to regulator;

— biopharmaceutical company to regulator;

— sponsor of clinical trials to regulator;

— regulator to other stakeholders;

— regulator to worldwide-maintained data sources.

Unique identifiers produced in conformance with this document are aimed at supporting applications where it is necessary to reliably identify and trace the use of Medicinal Products.

In the context of exchange of regulatory information, the purpose of this document is twofold:

— to specify data elements, structures and relationships between the data elements which are required to uniquely identify Medicinal Products for human use;

— to specify definitions of terms for all data elements required to uniquely identify Medicinal Products for human use.

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TECHNICAL SPECIFICATION **ISO/TS 20443:2017(E)**

Health informatics — Identification of medicinal products — Implementation guidelines for ISO 11615 data elements and structures for the unique identification and exchange of regulated medicinal product information

1 Scope

This document defines concepts and describes data elements and their structural relationships, which are required for the unique identification and the detailed description of Medicinal Products.

Taken together, all ISO IDMP standards (ISO 11615, ISO 11616, ISO 11238, ISO 11239 and ISO 11240) define, characterise, and uniquely identify regulated Medicinal Products for human use from approval, to post-marketing and renewal or withdrawal from the market, where applicable.

Furthermore, to support successful information exchange in relation to the unique identification and characterisation of Medicinal Products, the normative use of HL7 common product model (CPM) and structured product labeling (SPL) messaging is described. References to the use of other relevant standards for Medicinal Product information are included in this document to support successful information exchange.

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 3166-1, *Codes for the representation of names of countries and their subdivisions — Part 1: Country codes*

ISO/IEC 5218, *Information technology — Codes for the representation of human sexes*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

ISO 11238, *Health informatics — Identification of Medicinal Products — Data elements and structures for the unique identification and exchange of regulated information on substances*

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*

ISO 11240, *Health informatics — Identification of Medicinal Products — Data elements and structures for the unique identification and exchange of units of measurement*

ISO 11615, *Health informatics — Identification of Medicinal Products — Data elements and structures for the unique identification and exchange of regulated Medicinal Product information*

ISO 11616, *Health informatics — Identification of Medicinal Products — Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information*

ISO/TS 20440, *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*

HL7 Reference Information Model (RIM).

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