TECHNICAL SPECIFICATION

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CEN ISO/TS 20443

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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)

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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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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Endorsement notice

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

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Foreword

ISO (the International Organization for Standardisation) 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 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 the following URL: www.iso.org/iso/foreword.html.

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

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.

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).

HL7 Version 3 Standard, Common Clinical Product Model

HL7 Version 3 Standard, Common Product Model CMETs

HL7 Version 3 Standard, Regulated Product Submission

HL7 Version 3 Standard, Structured Product Labeling

3 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at http://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

4 Message exchange

4.1 General

HL7 messaging standards are widely implemented globally. The HL7 V3 messaging standard deals with a static model of healthcare information as viewed within the scope of HL7 standards development activities. ISO recognises HL7 as an accredited partner organisation for mutually issuing standards. The first mutually published standard was ISO/HL7 21731:2006.

HL7 V3 was developed to address the complex requirements of health information technology. The HL7 Reference Information Model (RIM) is the cornerstone of V3 and the essential model from which all HL7 messages are derived. The RIM defines data content needed in a specific context and provides an explicit representation of the semantic and lexical connections that exist between the information carried in the elements of a message. V3 seeks to develop specifications that facilitate interoperability between systems. The HL7 model-driven methodology is used to develop consensus-based standards for healthcare system interoperability and information exchange. HL7 V3 messages are based on an XML encoding syntax.

The ISO IDMP standards were designed to specify the necessary data elements and associated standards to be used for unique identifiers. These were developed as an integral part of the IDMP consensus requirements and are consistent with the HL7 Common Product Model (CPM). The IDMP data elements represent a subset of those in the CPM. The normative use of HL7 standards will facilitate the integration of IDMP into the broader healthcare community.

4.2 Message exchange format

In the context of this document, the normative message exchange format to be utilised as reference in transactions is HL7 Structured Product Labeling (SPL). SPL is a standard message exchange format based on Clinical Document Architecture (CDA) and the HL7 Reference Information Model (RIM). Various solutions for creating SPL files exist and range from basic software tools to comprehensive information management systems. SPL instances (code snippets) are provided throughout to illustrate the representation of an IDMP concept within the HL7 SPL message exchange format. Technical conformance criteria for SPL messages will not be addressed in this document and shall be left to regional guidance/implementation per their respective requirements. A reference to the most up to date HL7 CPM and SPL reference as a resource for IDMP implementation is accessible on the HL7 website[1]).