ICS 35.240.80 PREDBEŽNÁ SLOVENSKÁ TECHNICKÁ NORMA December 2018

STN P	**Zdravotnícka informatika Identifikácia liekov Návod na implementáciu ISO 11616 pre dátové prvky a štruktúry na jednoznačnú identifikáciu a výmenu informácií o regulovaných farmaceutických výrobkoch (ISO/TS 20451: 2017)**	**STN P CEN ISO/TS 20451** 84 8133

Health informatics - Identification of medicinal products - Implementation guidelines for ISO 11616 data elements and structures for the unique identification and exchange of regulated pharmaceutical product information (ISO/TS 20451:2017)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 11/18

Táto predbežná STN je určená na overenie. Pripomienky zasielajte ÚNMS SR najneskôr do mája 2021.

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CEN ISO/TS 20451

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ICS 35.240.80

English Version

Health informatics - Identification of medicinal products - Implementation guidelines for ISO 11616 data elements and structures for the unique identification and exchange of regulated pharmaceutical product information (ISO/TS 20451:2017)

Informatique de santé - Identification des médicaments - Lignes directrices pour l'implémentation des éléments de données et structures ISO 11616 pour l'identification unique et l'échange d'informations réglementées sur les produits pharmaceutiques (ISO/TS 20451:2017)

Medizinische Informatik - Identifikation von Arzneimitteln - Implementierungsleitfaden für ISO 11616 Datenelemente und -strukturen zur eindeutigen Identifikation und zum Austausch von Informationen über pharmazeutische Produkte (ISO/TS 20451:2017)

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European foreword

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Endorsement notice

The text of ISO/TS 20451:2017 has been approved by CEN as CEN ISO/TS 20451:2018 without any modification.

TECHNICAL SPECIFICATION

ISO/TS 20451

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Health informatics — Identification of medicinal products — Implementation guidelines for ISO 11616 data elements and structures for the unique identification and exchange of regulated pharmaceutical product information

Informatique de santé — Identification des médicaments — Lignes directrices pour l'implémentation des éléments de données et structures ISO 11616 pour l'identification unique et l'échange d'informations réglementées sur les produits pharmaceutiques

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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 gives guidelines for implementing ISO 11616, 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 of 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.

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TECHNICAL SPECIFICATION ISO/TS 20451:2017(E)

Health informatics — Identification of medicinal products — Implementation guidelines for ISO 11616 data elements and structures for the unique identification and exchange of regulated pharmaceutical product information

1 Scope

This document defines the concepts required to associate pharmaceutical products with an appropriate set of PhPID(s) in accordance with ISO 11616.

Pharmaceutical identifiers and elements are to represent pharmaceutical products as represented in a Medicinal Product as indicated by a Medicines Regulatory Authority. The suite of ISO IDMP standards can be applied to off-label usage of Medicinal Products, but is currently outside of the scope of this document.

Reference to ISO 11238, ISO 11239, ISO 11240 and ISO 11615 and HL7 messaging standards, HL7 Reference Information Model (RIM), HL7 V3 Common Product Model (CPM) and HL7 V3 Structured Product Labelling (SPL) can be applied for pharmaceutical product information in the context of this document.

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 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/TS 19844, *Health informatics — Identification of Medicinal Products — Implementation guidelines for data elements and structures for the unique identification and exchange of regulated information on substances*

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*

ISO/TS 20443, *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*

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