ICS 35.240.80 SLOVENSKÁ TECHNICKÁ NORMA Jún 2018

STN	**Zdravotnícka informatika Identifikácia liekov Dátové prvky a štruktúry na jednoznačnú identifikáciu a výmenu regulovaných informácií o lieku (ISO 11615: 2017)**	**STN EN ISO 11615** 84 8113

Health informatics - Identification of medicinal products - Data elements and structures for the unique identification and exchange of regulated medicinal product information (ISO 11615:2017)

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. 05/18

Obsahuje: EN ISO 11615:2017, ISO 11615:2017

Oznámením tejto normy sa ruší
STN EN ISO 11615 (84 8113) z apríla 2013

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11615

December 2017

ICS 35.240.80

Supersedes EN ISO 11615:2012

English Version

Health informatics - Identification of medicinal products - Data elements and structures for the unique identification and exchange of regulated medicinal product information (ISO 11615:2017)

Informatique de santé - Identification des médicaments - Éléments de données et structures pour l'identification unique et l'échange d'informations sur les médicaments contrôlés (ISO 11615:2017)

Medizinische Informatik - Identifikation von Arzneimitteln - Datenelemente und -strukturen zur Identifikation von Arzneimitteln für den Austausch von behördlich genehmigten Arzneimittelinformationen (ISO 11615:2017)

This European Standard was approved by CEN on 17 November 2017.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN ISO 11615:2017 E

EN ISO 11615:2017 (E)

Contents

Page

European foreword

This document (EN ISO 11615:2017) 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.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2018, and conflicting national standards shall be withdrawn at the latest by June 2018.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 11615:2012.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 11615:2017 has been approved by CEN as EN ISO 11615:2017 without any modification.

INTERNATIONAL STANDARD

ISO 11615

Second edition
2017-10

Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information

Informatique de santé — Identification des médicaments — Éléments de données et structures pour l'identification unique et l'échange d'informations sur les médicaments contrôlés

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Contents

Page

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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*.

This second edition cancels and replaces the first edition (ISO 11615:2012), which has been technically revised.

Introduction

This document was developed in response to a worldwide demand for internationally harmonised specifications for Medicinal Products. It is part of a set of five ISO Standards and four ISO Technical Specifications which together provide the basis for the unique Identification of Medicinal Products (IDMP).

These sets of standards and technical specifications comprise:

— ISO 11615

— ISO/TS 20443;

— ISO 11616;

— ISO/TS 20451;

— ISO 11238;

— ISO/TS 19844;

— ISO 11239;

— ISO/TS 20440;

— ISO 11240.

These standards and technical specifications for the identification of Medicinal Products (IDMP) support the activities of medicines regulatory agencies worldwide by region. These include a variety of regulatory activities related to development, registration and life cycle management of Medicinal Products, as well as pharmacovigilance and risk management.

To meet the primary objectives of the regulation of medicines and pharmacovigilance, it is necessary to reliably exchange Medicinal Product information in a robust and consistent manner. The IDMP standards therefore support, at a minimum, the following interactions:

— regulatory medicines authority to regulatory medicines authority;

— pharmaceutical company to regulatory medicines authority;

— sponsor of a clinical trial to regulatory medicines authority;

— regulatory medicines authority to other stakeholders (as applicable);

— regulatory medicines authority to worldwide-maintained data sources.

The necessary messaging specifications are included as an integral part of the IDMP standards to secure the interactions above.

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

There are many terms in use to describe basic concepts in the regulatory, pharmaceutical and healthcare standards development domain for different purposes and in different contexts. The terms and definitions given in this document are to be applied for the concepts which are required to uniquely identify, characterise and exchange regulated Medicinal Products and associated information.

The terms and definitions adopted in this document are intended to facilitate the interpretation and application of legal and regulatory requirements.

This document has been developed in conjunction with the Common Product Model (CPM) and Structured Product Labelling (SPL) in HL7.

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 and with certainty identify Medicinal Products for human use;

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

In addition, reference to the use of other normative IDMP and messaging standards for Medicinal Product information is included in this document in order to support successful information exchange.

INTERNATIONAL STANDARD **ISO 11615:2017(E)**

Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information

1 Scope

This document establishes definitions and 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, the standards listed in the Introduction define, characterise and uniquely identify regulated Medicinal Products for human use during their entire life cycle, i.e. from development to authorisation, 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 use of other normative IDMP messaging standards is included, which are to be applied 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 639-1, *Codes for the representation of names of languages — Part 1: Alpha-2 code*

ISO 3166-1:2013, *Codes for the representation of names of countries and their subdivisions — Part 1: Country codes*

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 11616, *Health informatics — Identification of Medicinal Products — Data elements and structures for the unique identification and exchange of regulated pharmaceutical 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 guide for ISO 11615 data elements and structures for the unique identification and exchange of regulated Medicinal Product information*

ISO/TS 20451, *Health informatics — Identification of Medicinal Products — Implementation guide for ISO 11616 data elements and structures for the unique identification and exchange of regulated pharmaceutical product information*

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

HL7 Version 3 Standard, Structured Product Labelling

