SLOVENSKI STANDARD
SIST EN ISO 11616:2013

01-februar-2013

Zdravstvena informatika - Identifikacija medicinskih izdelkov - Elementi in zgradba podatkov za enotno identifikacijo in izmenjavo predpisanih informacij o farmacevtskih izdelkih (ISO 11616:2012)

Health informatics - Identification of medicinal products - Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information (ISO 11616:2012)

Medizinische Informatik - Identifikation von Arzneimitteln - Datenelemente und -strukturen zur Identifikation und zum Austausch von pharmazeutischen produktkennzeichen (ISO 11616:2012)

Informatique de santé - Identification des médicaments - Éléments de données et structures pour l'identification unique et l'échange d'informations réglementées sur les produits pharmaceutiques (ISO 11616:2012)

Ta slovenski standard je istoveten z: EN ISO 11616:2012

ICS:

11.020	Medicinske vede in zdravstvenovarstveni pripomočki na splošno	Medical sciences and health care facilities in general
35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology

SIST EN ISO 11616:2013 en

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11616

November 2012

ICS 35.240.80

English Version

Health informatics - Identification of medicinal products - Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information (ISO 11616:2012)

Informatique de santé - Identification des médicaments - Éléments de données et structures pour l'identification unique et l'échange d'informations réglementées sur les produits pharmaceutiques (ISO 11616:2012)

Medizinische Informatik - Identifikation von Arzneimitteln - Datenelemente und -strukturen zur Identifikation und zum Austausch von pharmazeutischen Produktkennzeichen (ISO 11616:2012)

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

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Foreword

This document (EN ISO 11616:2012) 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 May 2013, and conflicting national standards shall be withdrawn at the latest by May 2013.

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Endorsement notice

The text of ISO 11616:2012 has been approved by CEN as a EN ISO 11616:2012 without any modification.

INTERNATIONAL STANDARD

ISO 11616

First edition
2012-11-01

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

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

Reference number
ISO 11616:2012(E)

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Published in Switzerland

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 11616 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

Introduction

This International Standard was developed in response to a worldwide demand for internationally harmonized specifications for medicinal products. It is one of five standards which together provide the basis for the unique identification of medicinal products. The group of standards comprises:

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 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.*

The purpose of this International Standard is to present data elements, structures and their relationships in order to uniquely identify and exchange regulated pharmaceutical product information. This International Standard provides an accurate and consistent mechanism to fully represent the relationship of Pharmaceutical Product Identifier(s) (PhPID) with the following:

— Medicinal Product Identifier(s) (MPIDs);

— Investigational Medicinal Product Identifier(s) (IMPIDs).

These standards for the identification of Medicinal Products (IDMP) support the activities of medicines regulatory agencies worldwide by jurisdiction. 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 reliable manner. The IDMP standards therefore support 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.

Unique identifiers produced in conformance with the IDMP standards are intended to support applications where it is necessary to reliably identify and trace the use of medicinal and pharmaceutical products.

Messaging specifications are included as an integral part of the IDMP standards. This is critical to describing and protecting the integrity of the interactions listed above for the submission of regulated medicinal product information in the context of unique product identification and acknowledgement of receipt (which includes the validation of transmitted information).

There are many terms in use to describe basic concepts in the regulatory and pharmaceutical standards development domain for different purposes and in different contexts. The terms and definitions described in this International Standard are to be applied for the concepts required to uniquely identify, characterize and exchange regulated medicinal products and associated information.

The terms and definitions adopted in this International Standard are intended to facilitate the interpretation and application of legal and regulatory requirements but they are without prejudice to any legally binding document. In case of doubt or potential conflict, the terms and definitions contained in legally binding documents prevail.

This International Standard has been developed in conjunction with the Common Product Model in HL7. It is anticipated that implementation will use HL7 V3 messaging to transmit information between stakeholders.

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

1 Scope

This International Standard is intended to provide specific levels of information relevant to the identification of a medicinal product or group of medicinal products. It defines the data elements, structures and relationships between data elements that are required for the exchange of regulated information, in order to uniquely identify pharmaceutical products. This identification is to be applied throughout the product lifecycle to support pharmacovigilance, regulatory and other activities worldwide. In addition, this International Standard is essential to ensuring that pharmaceutical product information is assembled in a structured format with transmission between a diverse set of stakeholders. This ensures interoperability and compatibility for both the sender and the recipient.

This International Standard is not intended to be a scientific classification for pharmaceutical products. Rather, it is a formal association of particular data elements categorized in prescribed combinations and uniquely identified when levelling degrees of information are incomplete. This allows for medicinal products to be unequivocally identified.

References to other normative IDMP and messaging standards for pharmaceutical product information are included in Clause 2, to be applied in the context of this International Standard.

Medicinal products for veterinary use are out of scope of this International Standard.

2 Normative references

The following referenced documents are indispensable for the application 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 11615, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information*

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*

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, definitions and abbreviations

3.1 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1.1
administrable dose form
pharmaceutical dose form as administered to the patient, after any necessary transformation of the packaged pharmaceutical dose form has been carried out

EXAMPLES Solution for injection, tablet for oral use, hard-capsule powder for inhalation.

3.1.2
adverse drug reaction
noxious and unintended response associated with the use of a drug in humans

NOTE 1 This can be post-approval (an adverse event that occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of diseases or for modification of physiological function) or pre-approval (an adverse event that occurs at any dose and where a causal relationship is at least a reasonable possibility).

NOTE 2 FDA 21 CFR 310.305 defines an adverse drug experience to include any adverse event, "whether or not considered to be drug-related." CDISC recognizes that current usage incorporates the concept of causality.

NOTE 3 Adapted from WHO Technical Report 498(1972); ICH E2A.

3.1.3
clinical trial
research investigation involving human subjects that is designed to answer specific questions about the safety and efficacy of a biomedical intervention (drug, treatment, device) or new ways of using a known drug, treatment, or device

[ICH E6 Glossary, Directive 2001/20/EC:2002, Version: 1-2009/04/19]

3.1.4
clinical trial registration number
registration number (identifier for tracking purposes) for a clinical trial as assigned by the Regulatory Medicines Authority

3.1.5
code value
result of applying a coding scheme to an element within a coded set

NOTE Adapted from ISO/IEC 2382-4:1999.

3.1.6
coding scheme
collection of rules that maps the elements of one set onto the elements of a second set

NOTE 1 The coding scheme applied in this International Standard refers to the following standards:

— ISO 11615, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information*;

— 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*.

NOTE 2 Adapted from ISO/IEC 2382-4:1999.

3.1.7
controlled vocabulary
finite set of values that represent the only allowed values for a data item

NOTE These values may be codes, text, or numeric.

[CDISC Clinical Research Glossary V8.0, 2009]

3.1.8
TermID
controlled vocabulary term identifier
concept identifier intended to be used as the preferred unique identifier for that concept in that code system and which is published by the author of a code system

NOTE 1 The TermID remains constant over time, independent of the particular version of the knowledge resource.

NOTE 2 Adapted from HL7 Core Principles.

3.1.9
designation
symbolic representation of a concept

NOTE Adapted from ISO 1087-1:2000.

3.1.10
dose form
pharmaceutical dose form
physical manifestation of a product that contains the active ingredient(s) and/or inactive ingredient(s) that are intended to be delivered to the patient

NOTE Pharmaceutical dose form may refer to the administered dose form or the packaged dose form, depending on the product it is describing.

3.1.11
globally unique identifier
identifier that is different from any other such identifier in any domain namespace

3.1.12
healthcare professional
person entrusted with the direct or indirect provision of defined healthcare services to a subject of care or a population of subjects of care

EXAMPLES Qualified medical practitioner, pharmacist, nurse, social worker, radiographer, medical secretary or clerk.

[ENV 1613:1995]

3.1.13
identifier
description that is sufficient to differentiate objects in a given environment

[ENV 12610]

NOTE In the context of this International Standard, this is a list of identifying characteristics that together unambiguously identify a medicinal product, pharmaceutical product, substance, detailed substance description, excipient, route of administration, dose form and any other element that requires to be uniquely identified.

3.1.14
investigational code
sponsor code
code assigned by a regulatory authority to a sponsor's investigational new drug application prior to the initiation of a clinical trial