Irish Standard
I.S. EN ISO 11615:2012

Health informatics - Identification of medicinal products - Data elements and structures for the unique identification and exchange of regulated medicinal product information (ISO 11615:2012)

I.S. EN ISO 11615:2012

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EUROPEAN STANDARD

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English Version

Health informatics - Identification of medicinal products - Data elements and structures for the unique identification and exchange of regulated medicinal product information (ISO 11615:2012)

Informatique de santé - Identification des médicaments - Éléments de données et structures pour l'identification unique et l'échange d'informations réglementées sur les médicaments (ISO 11615:2012)

Medizinische Informatik - Identifikation von Arzneimitteln - Datenelemente und -strukturen zur Identifikation von Arzneimitteln für den Austausch von behördlich genehmigten Arzneimittelinformationen (ISO 11615:2012)

This European Standard was approved by CEN on 24 May 2012.

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

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Foreword

This document (EN ISO 11615:2012) 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of an identical text or by endorsement, at the latest by May 2013, and conflicting national standards shall be withdrawn at the latest by May 2013.

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

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Endorsement notice

The text of ISO 11615:2012 has been approved by CEN as a EN ISO 11615:2012 without any modification.

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I.S. EN ISO 11615:2012

INTERNATIONAL STANDARD

ISO 11615

First edition
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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 réglementées sur les médicaments

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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 International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 11615 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*.

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 consistent manner. The IDMP standards therefore support, at a minimum, the following interactions:

— regulator to regulator;

— pharmaceutical company to regulator;

— sponsor of clinical trial to regulator;

— regulator to other stakeholder;

— regulator 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 International Standard are to be applied for the concepts which are 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.

In the context of exchange of regulatory information, the purpose of this International Standard 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 International Standard in order to support successful related information exchange.

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

1 Scope

This International Standard 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, characterize and uniquely identify regulated Medicinal Products for human use during their entire life cycle, i.e. from development to authorization, post-marketing and renewal or withdrawal from the market, where applicable.

Furthermore, to support successful information exchange in relation to the unique identification and characterization of Medicinal Products, the use of other normative IDMP messaging standards is included, which are to be applied in the context 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 639-2, *Codes for the representation of names of languages — Part 2: Alpha-3 code*

ISO 3166-1, *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 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*

ISO 21090, *Health informatics — Harmonized data types for information interchange*

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

3 Terms, definitions and abbreviations

3.1 Terms and definitions

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