



NSAI
Standards

Irish Standard
I.S. EN 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)

I.S. EN ISO 11616:2012

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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)

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

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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of an identical text or by endorsement, at the latest by May 2013, and conflicting national standards shall be withdrawn at the latest by May 2013.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.

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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



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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.

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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*

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