



**NSAI**  
Standards

Irish Standard  
I.S. EN ISO 11616:2017

# Health informatics - Identification of medicinal products - Data elements and structures for the Unique Identification and Exchange of regulated Pharmaceutical Product Information (ISO 11616:2017)

© CEN 2017 No copying without NSAI permission except as permitted by copyright law.

## I.S. EN ISO 11616:2017

*Incorporating amendments/corrigenda/National Annexes issued since publication:*

The National Standards Authority of Ireland (NSAI) produces the following categories of formal documents:

I.S. xxx: Irish Standard — national specification based on the consensus of an expert panel and subject to public consultation.

S.R. xxx: Standard Recommendation — recommendation based on the consensus of an expert panel and subject to public consultation.

SWiFT xxx: A rapidly developed recommendatory document based on the consensus of the participants of an NSAI workshop.

*This document replaces/revises/consolidates the NSAI adoption of the document(s) indicated on the CEN/CENELEC cover/Foreword and the following National document(s):*

*NOTE: The date of any NSAI previous adoption may not match the date of its original CEN/CENELEC document.*

*This document is based on:*

EN ISO 11616:2017

*Published:*

2017-12-06

*This document was published  
under the authority of the NSAI  
and comes into effect on:*

2017-12-24

ICS number:

35.240.80

NOTE: If blank see CEN/CENELEC cover page

NSAI  
1 Swift Square,  
Northwood, Santry  
Dublin 9

T +353 1 807 3800  
F +353 1 807 3838  
E standards@nsai.ie  
W NSAI.ie

Sales:  
T +353 1 857 6730  
F +353 1 857 6729  
W standards.ie

Údarás um Chaighdeáin Náisiúnta na hÉireann

## National Foreword

I.S. EN ISO 11616:2017 is the adopted Irish version of the European Document EN ISO 11616:2017, Health informatics - Identification of medicinal products - Data elements and structures for the Unique Identification and Exchange of regulated Pharmaceutical Product Information (ISO 11616:2017)

This document does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

For relationships with other publications refer to the NSAI web store.

**Compliance with this document does not of itself confer immunity from legal obligations.**

*In line with international standards practice the decimal point is shown as a comma (,) throughout this document.*

This page is intentionally left blank

EUROPEAN STANDARD

**EN ISO 11616**

NORME EUROPÉENNE

EUROPÄISCHE NORM

December 2017

ICS 35.240.80

Supersedes EN ISO 11616:2012

English Version

**Health informatics - Identification of medicinal products -  
Data elements and structures for the Unique Identification  
and Exchange of regulated Pharmaceutical Product  
Information (ISO 11616:2017)**

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  
11616:2017)

Medizinische Informatik - Identifikation von  
Arzneimitteln - Datenelemente und -strukturen zur  
Identifikation und zum Austausch von  
pharmazeutischen Produktkennzeichen (ISO  
11616:2017)

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

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

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.

CEN members are the national standards bodies of 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 United Kingdom.



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

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

**EN ISO 11616:2017 (E)**

<b>Contents</b>	<b>Page</b>
<b>European foreword.....</b>	<b>3</b>

## **European foreword**

This document (EN ISO 11616:2017) 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 11616:2012.

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 11616:2017 has been approved by CEN as EN ISO 11616:2017 without any modification.

This page is intentionally left blank



# INTERNATIONAL STANDARD

**ISO  
11616**

Second edition  
2017-10

---

---

## **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 11616:2017(E)

© ISO 2017

**ISO 11616:2017(E)**



**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2017, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
Ch. de Blandonnet 8 • CP 401  
CH-1214 Vernier, Geneva, Switzerland  
Tel. +41 22 749 01 11  
Fax +41 22 749 09 47  
copyright@iso.org  
www.iso.org

# Contents

	Page
<b>Foreword</b> .....	<b>v</b>
<b>Introduction</b> .....	<b>vi</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms, definitions and abbreviated terms</b> .....	<b>2</b>
<b>4 Conformance terminology and context as it relates to the ISO IDMP standards and corresponding IDMP technical specifications</b> .....	<b>9</b>
<b>5 Requirements</b> .....	<b>9</b>
5.1 Elements required for the unique identification of pharmaceutical products.....	9
5.2 Exchange of pharmaceutical product information.....	10
<b>6 Description of the information modelling principles and practices</b> .....	<b>10</b>
6.1 General considerations.....	10
6.2 Conceptual overview diagrams.....	11
6.3 High-level diagrams.....	11
6.4 Detailed description diagrams.....	12
6.4.1 General.....	12
6.4.2 Relationships between classes.....	13
6.4.3 Attributes of classes.....	14
6.4.4 Generalised classes and patterns.....	14
6.4.5 Translation and language.....	14
<b>7 Identifying characteristics for the identification of pharmaceutical products</b> .....	<b>14</b>
7.1 Pharmaceutical product identification strata and levels.....	14
7.1.1 General.....	14
7.1.2 PhPID specified substance.....	15
7.1.3 Pharmaceutical product specified substance identification (PhPID SpSub).....	16
7.2 Cardinality.....	17
7.3 Representation of strength concentration.....	17
7.4 Pharmaceutical product identifier (PhPID).....	18
7.5 Pharmaceutical product substance stratum elements (PhPID_SUB_Lx).....	18
7.5.1 Construct of the pharmaceutical product substance stratum.....	18
7.5.2 Substance set.....	18
7.5.3 Administrable dose form.....	19
7.5.4 Unit of presentation.....	19
7.5.5 Medical device.....	19
7.6 Pharmaceutical product specified substance stratum elements (PhPID_SpSUB_Lx).....	19
7.6.1 Construct of the pharmaceutical product specified substance stratum.....	19
7.6.2 Specified substance set.....	20
7.6.3 Administrable dose form.....	20
7.6.4 Unit of presentation.....	20
7.6.5 Medical device.....	20
7.7 Identifying characteristics to express strength.....	20
7.7.1 Expressing strength.....	20
7.7.2 Attributes for representation of strength in PhPID stratum elements.....	21
7.7.3 Representation of strength for a patch.....	23
<b>8 Relationship between MPID/PCID and PhPID</b> .....	<b>23</b>
8.1 Concepts required for the unique identification of a Medicinal Product and the association with PhPIDs.....	23
8.2 Pharmaceutical product identification criteria.....	25
8.2.1 General considerations.....	25
8.2.2 Multiple products packaged as a kit and administered as separate Medicinal Products.....	25

**ISO 11616:2017(E)**

8.2.3	Multiple products packaged as a kit for reconstitution and administered as one Medicinal Product.....	26
8.2.4	Components of kits which are not packaged together (e.g. radiopharmaceutical kits).....	26
8.2.5	Different representations of strength in two or more regions for identical products.....	26
8.2.6	Representation of PhPID for a patch .....	27
<b>9</b>	<b>Relationship between IMPID/PCID and PhPID .....</b>	<b>27</b>
<b>10</b>	<b>Conceptual model .....</b>	<b>29</b>
	<b>Bibliography .....</b>	<b>30</b>

## Foreword

ISO (the International Organization for Standardisation) 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 organisations, 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 standardisation.

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](http://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](http://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](http://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 11616:2012), which has been technically revised.

## ISO 11616:2017(E)

### 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.

The purpose of this document is to present data elements, structures and their relationships in order to uniquely identify and exchange regulated pharmaceutical product information. This document 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);
- Package Component Identifier(s) (PCIDs);
- Investigational Medicinal Product Identifier(s) (IMPIDs);
- Investigational Package Component Identifier(s) (IPCIDs).

These standards and technical specifications for the identification of Medicinal Products 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. 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).

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





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

## 1 Scope

This document 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 document is essential to ensure that pharmaceutical product information is assembled in a structured format with transmission between a diverse set of stakeholders for both regulatory and clinical (e.g. e-prescribing, clinical decision support) purposes. This ensures interoperability and compatibility for both the sender and the recipient.

This document is not intended to be a scientific classification for pharmaceutical products. Rather, it is a formal association of particular data elements categorised in prescribed combinations and uniquely identified when levelling degrees of information are incomplete. This allows for Medicinal Products to be unequivocally identified on a global level.

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 document.

Medicinal products for veterinary use are out of scope 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 11615:2017, *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*

This is a free preview. Purchase the entire publication at the link below:

[Product Page](#)

- 
- Looking for additional Standards? Visit Intertek Inform Infostore
  - Learn about LexConnect, All Jurisdictions, Standards referenced in Australian legislation
-