



NSAI
Standards

Irish Standard
I.S. EN ISO 17523:2016

Health informatics - Requirements for electronic prescriptions (ISO 17523:2016)

© CEN 2016 No copying without NSAI permission except as permitted by copyright law.

I.S. EN ISO 17523:2016

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 17523:2016

Published:

2016-06-29

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

2016-07-17

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 17523:2016 is the adopted Irish version of the European Document EN ISO 17523:2016, Health informatics - Requirements for electronic prescriptions (ISO 17523:2016)

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

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 17523

NORME EUROPÉENNE

EUROPÄISCHE NORM

June 2016

ICS 35.240.80

English Version

Health informatics - Requirements for electronic prescriptions (ISO 17523:2016)

Informatique de santé - Exigences applicables aux prescriptions électroniques (ISO 17523:2016)

Medizinische Informatik - Anforderungen an elektronische Verschreibungen (ISO 17523:2016)

This European Standard was approved by CEN on 15 April 2016.

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, 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: Avenue Marnix 17, B-1000 Brussels

EN ISO 17523:2016 (E)

Contents	Page
European foreword.....	3

European foreword

This document (EN ISO 17523:2016) 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 December 2016, and conflicting national standards shall be withdrawn at the latest by December 2016.

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.

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, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 17523:2016 has been approved by CEN as EN ISO 17523:2016 without any modification.

This page is intentionally left blank

INTERNATIONAL STANDARD

**ISO
17523**

First edition
2016-06-01

Health informatics — Requirements for electronic prescriptions

*Informatique de santé — Exigences applicables aux prescriptions
électroniques*



Reference number
ISO 17523:2016(E)

© ISO 2016

ISO 17523:2016(E)



COPYRIGHT PROTECTED DOCUMENT

© ISO 2016, 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

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Conformance	3
4.1 Generic conformance.....	3
4.2 Data element conformance.....	4
5 General information	4
5.1 Structure of this International Standard.....	4
5.2 Usage of this International Standard.....	4
5.3 Use cases, actors, processes.....	4
5.4 Information objects.....	6
5.4.1 Prescription.....	6
5.4.2 Related information objects.....	6
6 Requirements for electronic prescriptions	6
6.1 Identification of the patient.....	6
6.2 Identity information of the prescribing healthcare professional.....	6
6.3 Identification of the prescribed medicinal product.....	7
6.4 Compliance to medicinal product dictionaries.....	7
6.5 Product use information.....	7
6.6 Authentication of the electronic prescription.....	7
6.7 Data elements.....	7
Annex A (normative) Data elements	8
Annex B (informative) Examples of elements and implementations of electronic prescription	14
Bibliography	18

ISO 17523:2016(E)

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 meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](#)

The committee responsible for this document is ISO/TC 215, *Health informatics*.

Introduction

Modern healthcare is rapidly advancing and relying on electronic communications. Many countries already have or are in the process of developing electronic systems to contain and distribute personal data regarding healthcare, among which is exchange of electronic prescriptions. Therefore, it becomes increasingly important to set up International Standards that in the end will facilitate safe and reliable dispensing and administration of the prescribed product to the patient. Also, since international travelling has become integrated into daily life, it is important that electronic communications regarding prescriptions can somehow be synchronized between prescribers and dispensers in different jurisdictions.

The most important question regarding electronic prescriptions is which information is required to accompany the electronic prescription in order to have exactly the intended medicine dispensed to the patient, including all relevant information with regard to its correct and safe use. This International Standard provides the basic set of information requirements to support electronic prescription.

While the organization of healthcare is national, the development and production of medicinal products on the other hand is truly international. The market authorization is strictly legislated in jurisdictional specific directives and laws. Part of this legislation regulates prescribing and dispensing of medicinal products. Information systems in healthcare must be designed so that end-users comply with this legislation (preferably without needing to pay too much attention). An International Standard on electronic prescriptions may support the implementation of (international) legislation on medicinal products in health informatics. For instance, the definition of the term “electronic prescription” has to comply with that of national legislations and multinational directives.

The prescription written on paper has a deeply rooted cultural history for both healthcare professionals and patients. Using an electronic prescription instead of paper is a change that must be guided to ensure society’s trust in healthcare professionals. Requirements for the processing of electronic prescriptions can fulfil this need. An example of use in practice of this specification is the following: a general practitioner prescribes a medicinal product for a patient with the aid of an information system and sends the electronic prescription to the local pharmacy where the patient picks up the medication a short while thereafter.

The benefit of an International Standard on the requirements of an electronic prescription is that it can serve as a starting point and reference for all kinds of records and messages related to electronic prescriptions, facilitating the communication between stakeholders and information systems.

The intended audience for this International Standard is made up of the developers of standards and information systems, so that in using their products, end-users (healthcare professionals) comply with legislation, regulations and expectations of society relating to the prescribing and dispensing of medicinal products. Specifically, this International Standard provides a basis for a common understanding of the data elements contained in an electronic prescription across legislations.

Health informatics — Requirements for electronic prescriptions

1 Scope

This International Standard specifies the requirements that apply to electronic prescriptions. It describes generic principles that are considered important for all electronic prescriptions.

The scope of this International Standard is constrained to the content of the electronic prescription itself, the digital document which is issued by a prescribing healthcare professional and received by a dispensing healthcare professional. The prescribed medicinal product is to be dispensed through an authorized healthcare professional with the aim of being administered to a human patient. Other messages, roles and scenarios (e.g. validation of a prescription, administration, medication charts, EHR of the patient, reimbursement of care and dispensed products) are out of scope of this International Standard, because they are more or less country or region specific, due to differences in culture and in legislation of healthcare. However, requirements and content of electronic prescriptions within the context of jurisdictions have a relationship with these scenarios. The way in which electronic prescriptions are made available or exchanged also fall outside the scope of this International Standard.

This International Standard is applicable to electronic prescriptions of medicinal products. Although other kinds of products (e.g. medical devices, wound care products) can be ordered by means of an electronic prescription, the requirements in this International Standard are aimed at medicinal products that have a market authorization and at pharmaceutical preparations which are compounded in a pharmacy. An electronic prescription is an information object that authorizes a healthcare professional to legally dispense a medicinal product.

This International Standard specifies a list of data elements that can be considered as essential for electronic prescriptions, depending on jurisdiction or clinical setting (primary healthcare, hospital, etc.).

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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 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*

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
-