ICS 35.240.80 SLOVENSKÁ TECHNICKÁ NORMA December 2016

STN	**Zdravotnícka informatika. Požiadavky na elektronické recepty (ISO 17523: 2016).**	**STN EN ISO 17523** 84 8126

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 11/16

Obsahuje: EN ISO 17523:2016, ISO 17523:2016

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 17523

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

Ref. No. EN ISO 17523:2016 E

Contents

Page

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.

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)

COPYRIGHT PROTECTED DOCUMENT

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

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.

INTERNATIONAL STANDARD **ISO 17523:2016(E)**

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*

ISO 17090-1, *Health informatics — Public key infrastructure — Part 1: Overview of digital certificate services*

ISO/TS 16791, *Health informatics — Requirements for international machine-readable coding of medicinal product package identifiers*

ISO/TS 22220, *Health informatics — Identification of subjects of health care*

ISO/TS 27527, *Health informatics — Provider identification*