



SLOVENSKI STANDARD SIST EN ISO 17523:2016

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Zdravstvena informatika - Zahteve za elektronske recepte (ISO 17523:2016)

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

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

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

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Ta slovenski standard je istoveten z: **EN ISO 17523:2016**

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ICS:

35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology
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EUROPEAN STANDARD

EN ISO 17523

NORME EUROPÉENNE

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

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

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

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

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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of an identical text or by endorsement, at the latest by December 2016, and conflicting national standards shall be withdrawn at the latest by December 2016.

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

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**Health informatics — Requirements
for electronic prescriptions**

*Informatique de santé — Exigences applicables aux prescriptions
électroniques*

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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).

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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*.

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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.

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