SLOVENSKI STANDARD
oSIST prEN ISO 11239:2010

01-november-2010

Zdravstvena informatika - Identifikacija medicinskih izdelkov - Elementi in zgradba podatkov za enotno identifikacijo in izmenjavo predpisanih informacij na obrazcih o farmacevtskih odmerkih, predstavitvenih enot in administrativnih poti (ISO/DIS 11239:2010)

Health informatics - Identification of medicinal products - Data elements and structures for unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation and routes of administration (ISO/DIS 11239:2010)

Medizinische Informatik - Identifikation von Arzneimitteln - Struktur und kontrollierte Vokabularien für pharmazeutische Dosierungsformen, zusammengesetzten Einheiten in Arzneiformen und Anwendungsarten (ISO/DIS 11239:2010)

Informatique de santé - Identification des produits médicaux - Éléments de données et structures pour l'identification unique et l'échange d'informations réglementées concernant les formes des doses pharmaceutiques, les unités de présentation et les voies d'administration (ISO/DIS 11239:2010)

Ta slovenski standard je istoveten z: prEN ISO 11239

ICS:

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

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EUROPEAN STANDARD

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Health informatics - Identification of medicinal products - Data elements and structures for unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation and routes of administration (ISO/DIS 11239:2010)

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This draft European Standard is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 251.

If this draft becomes a European Standard, 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.

This draft European Standard was established by CEN 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 Management Centre has the same status as the official versions.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents

Page

Foreword

This document (prEN ISO 11239:2010) 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 document is currently submitted to the parallel Enquiry.

Endorsement notice

The text of ISO/DIS 11239:2010 has been approved by CEN as a prEN ISO 11239:2010 without any modification.

DRAFT INTERNATIONAL STANDARD ISO/DIS 11239

ISO/TC **215** | Secretariat: **ANSI**

Voting begins on: **2010-09-23** | Voting terminates on: **2011-02-23**

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

Health informatics — Identification of medicinal products — Data elements and structures for unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation and routes of administration

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ICS 35.240.80

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

In accordance with the provisions of Council Resolution 15/1993 this document is circulated in the English language only.

Conformément aux dispositions de la Résolution du Conseil 15/1993, ce document est distribué en version anglaise seulement.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

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.

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.

ISO 11239 was prepared by Technical Committee ISO/TC 215, *Health informatics*, and by Technical Committee CEN/TC 251, *Health informatics* and in collaboration and with the co-operation of the Clinical Data Interchange Standards Consortium (CDISC), Health Level Seven (HL7) and the International Health Terminology Standards Development Organisation (IHTSDO).

0 Introduction

0.1 General introduction

This standard was developed in response to a worldwide demand for internationally harmonised specifications for medicinal products. It is one of a group of five standards which together uniquely identify medicinal products. The group of standards comprise:

- ISO/DIS 11238 Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on substances

- ISO/DIS 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/DIS 11240 Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of units of measurement

- ISO/DIS 11615 Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information

- ISO/DIS 11616 Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information

The 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 exchange medicinal product information in a robust and reliable manner. The IDMP standards therefore support the following interactions:

— regulator to regulator e.g. European Medicines Agency to the US Food and Drug Administration (FDA) or vice versa;

— pharmaceutical company to regulator, e.g. Pharma Company A to Health Canada;

— sponsor of clinical trial to regulator, e.g. University X to Austrian Medicines Agency;

— regulator to other stakeholders, e.g. UK Medicines Health Regulatory Agency (MHRA) to National Health Service (NHS);

— interaction of regulator with worldwide-maintained data sources, e.g. Japanese Pharmaceutical and Medical Device Agency (PMDA) and the assignment of a new substance identifier.

The necessary messaging specifications are included as an integral part of the IDMP standards to secure the interactions above.

Unique identifiers produced in conformance with the IDMP standards are aimed to support 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

described in this standard shall 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 standard are intended to facilitate the interpretation and application of legal and regulatory requirements but they shall be without prejudice to any legally binding document. In case of doubt or potential conflict, the terms and definitions contained in legally binding documents shall prevail.

0.2 Context of identification of pharmaceutical dose form, unit of presentation, routes of administration and packaging

This standard describes the essential elements for the specification, translation and versioning of the specified controlled terms. Also described are recommendations concerning the mapping of terms that are already used by stakeholders to the concepts arising from the implementation of this standard.

The high level concepts defined consist of: Pharmaceutical dose form; Unit of presentation; Route of administration; Packaging.

The supporting, more mechanical, components are described separately from the high level clinical concepts. The supporting concepts consist of: Terms and codes; Translations; Versioning; Mapping.

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.

