ICS 35.240.80 SLOVENSKÁ TECHNICKÁ NORMA September 2023

STN	**Zdravotnícka informatika Identifikácia liekov Dátové prvky a štruktúry pre jednoznačnú identifikáciu a výmenu regulovaných informácií o farmaceutických dávkovacích formách, jednotkách, možnostiach podania a balenia (ISO 11239: 2023)**	**STN EN ISO 11239** 84 8111

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 11239:2023)

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. 08/23

Obsahuje: EN ISO 11239:2023, ISO 11239:2023

Oznámením tejto normy sa ruší
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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11239

June 2023

ICS 35.240.80

Supersedes EN ISO 11239:2012

English Version

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 11239:2023)

Informatique de santé - Identification des médicaments - Éléments de données et structures pour l'identification unique et l'échange d'informations réglementées sur les formes pharmaceutiques, les unités de présentation, les voies d'administration et les emballages (ISO 11239:2023)

Medizinische Informatik - Identifikation von Arzneimitteln - Datenelemente und -strukturen zur Identifikation von pharmazeutischen Darreichungsformen, pharmazeutischen Konventionseinheiten, Anwendungsarten und Verpackungen (ISO 11239:2023)

This European Standard was approved by CEN on 9 May 2023.

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

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

Ref. No. EN ISO 11239:2023 E

Contents

Page

European foreword

This document (EN ISO 11239:2023) 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 2023, and conflicting national standards shall be withdrawn at the latest by December 2023.

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 11239:2012.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 11239:2023 has been approved by CEN as EN ISO 11239:2023 without any modification.

INTERNATIONAL STANDARD

ISO 11239

Second edition
2023-06

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

Informatique de santé — Identification des médicaments — Éléments de données et structures pour l'identification unique et l'échange d'informations réglementées sur les formes pharmaceutiques, les unités de présentation, les voies d'administration et les emballages

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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 document 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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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For an explanation of 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 215, *Health informatics,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 251, *Health informatics,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 11239:2012), which has been technically revised.

The main changes are as follows:

— it is now specified that pharmaceutical dose form attributes can in some cases be used directly in order to describe features of a medicinal product, rather than just serving as internal attributes to classify the pharmaceutical dose form.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document was developed in response to a worldwide demand for internationally harmonized specifications for medicinal products. It is one of a group of five International Standards, which together provide the basis for the unique identification of medicinal products; the four other International Standards are ISO 11615, ISO 11616, ISO 11238 and ISO 11240.

These International Standards on the identification of medicinal products (IDMP) can be used in the activities of medicines regulatory agencies worldwide. 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.

The International Standards on IDMP therefore can be used in the following interactions (this is not an exhaustive list):

— regulator to regulator;

— pharmaceutical company to regulator;

— sponsor of clinical trial to regulator;

— regulator to other stakeholders;

— regulator to worldwide-maintained data sources.

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

Unique identifiers produced in conformance with the International Standards on IDMP are aimed at supporting applications where it is needed 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.

In the context of identification of pharmaceutical dose forms, units of presentation, routes of administration and packaging, this document 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 document.

The high-level concepts described 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:

a) terms and codes;

b) translations;

c) versioning;

d) mapping.

INTERNATIONAL STANDARD ISO 11239:2023(E)

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

1 Scope

This document specifies:

— the data elements, structures and relationships between the data elements required for the exchange of information, which uniquely and with certainty identify pharmaceutical dose forms, units of presentation, routes of administration and packaging items (containers, closures and administration devices) related to medicinal products;

— a mechanism for the association of translations of a single concept into different languages, which is an integral part of the information exchange;

— a mechanism for the versioning of the concepts in order to track their evolution;

— rules to help regional authorities to map existing regional terms to the terms created using this document, in a harmonized and meaningful way.

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 639-1, *Codes for the representation of names of languages — Part 1: Alpha-2 code*

ISO 3166-1, *Codes for the representation of names of countries and their subdivisions — Part 1: Country code*