

STN P	Zdravotnícka informatika Identifikácia liekov Implementácia dátových prvkov a štruktúr podľa ISO 11616 na jednoznačnú identifikáciu a výmenu informácií o regulovaných farmaceutických výrobkoch (ISO/TS 20451: 2026)	STN P CEN ISO/TS 20451 84 8133
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Health informatics - Identification of medicinal products - Implementation for ISO 11616 data elements and structures for the unique identification and exchange of regulated pharmaceutical product information (ISO/TS 20451:2026)

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. 07/26

Táto predbežná slovenská technická norma je určená na overenie. Prípadné pripomienky pošlite do mája 2028 Úradu pre normalizáciu, metrológiu a skúšobníctvo Slovenskej republiky.

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Supersedes CEN ISO/TS 20451:2018

English Version

**Health informatics - Identification of medicinal products -
Implementation for ISO 11616 data elements and
structures for the unique identification and exchange of
regulated pharmaceutical product information (ISO/TS
20451:2026)**

Informatique de santé - Identification des médicaments
- Implémentation des éléments de données et
structures ISO 11616 pour l'identification unique et
l'échange d'informations réglementées sur les produits
pharmaceutiques (ISO/TS 20451:2026)

Medizinische Informatik - Identifikation von
Arzneimitteln - Implementierungsleitfaden für ISO
11616 Datenelemente und Strukturen zur eindeutigen
Identifikation und zum Austausch von
vorgeschriebenen pharmazeutischen
Produktkennzeichen (ISO/TS 20451:2026)

This Technical Specification (CEN/TS) was approved by CEN on 26 April 2026 for provisional application.

The period of validity of this CEN/TS is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the CEN/TS can be converted into a European Standard.

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CEN ISO/TS 20451:2026 (E)

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European foreword

This document (CEN ISO/TS 20451:2026) 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.

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Endorsement notice

The text of ISO/TS 20451:2026 has been approved by CEN as CEN ISO/TS 20451:2026 without any modification.



Technical Specification

ISO/TS 20451

Health informatics — Identification of medicinal products — Implementation for ISO 11616 data elements and structures for the unique identification and exchange of regulated pharmaceutical product information

*Informatique de santé — Identification des médicaments —
Implémentation des éléments de données et structures ISO
11616 pour l'identification unique et l'échange d'informations
réglementées sur les produits pharmaceutiques*

**Second edition
2026-04**

ISO/TS 20451:2026(en)



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ISO/TS 20451:2026(en)**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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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/TS 20451:2017 [\[1\]](#)), which has been technically revised.

The main changes are as follows:

- alignment with the changes done in the first revision of ISO 11616 [\[2\]](#);
- addition of the concept for global PhPID (gPhPID).

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.

ISO/TS 20451:2026(en)**Introduction**

This document provides guidelines and requirements for implementing ISO 11616 [\[2\]](#), one of the five ISO standards on the identification of medicinal products (IDMP)¹⁾. The five ISO standards on IDMP and the corresponding four ISO Technical Specifications, when used together, provide the basis for exchanging data elements that will support the unique and unambiguous identification of medicinal products. The primary purpose of this document is to provide technical guidance to software implementers; short descriptions of business rationale are also included, where relevant, to provide context. Thus, this document focuses on business and technical considerations for implementation that will construct and parse well-formed, transmittable IDMP messages. Following transmission of required data elements, unique identifiers are to be produced in conformance with the standards to support applications where it is necessary to reliably identify and trace regulated biopharmaceutical products. However, this document does not include extensive information on creation or maintenance of identifier repositories. Reference is made to either regional guidance or implementation guides to support practical implementation within either a region or a jurisdiction. ISO/TR 14872 [\[7\]](#) describes the general core principles and proposed service delivery model for supporting implementation and ongoing maintenance of IDMP terminologies.

1) ISO 11615 [\[3\]](#), ISO 11616 [\[2\]](#), ISO 11238 [\[4\]](#), ISO 11239 [\[5\]](#), ISO 11240 [\[6\]](#).

Health informatics — Identification of medicinal products — Implementation for ISO 11616 data elements and structures for the unique identification and exchange of regulated pharmaceutical product information

1 Scope

This document provides requirements and recommendations related to the concepts required to associate pharmaceutical products or groups of pharmaceutical products with an appropriate set of PhPID(s) in accordance with ISO 11616 [2].

Pharmaceutical product identifiers and the related elements are intended to represent pharmaceutical products as defined within a medicinal product by a medicines regulatory authority. While the ISO standards on IDMP can be applied to off-label usage of medicinal products, such applications are currently outside of the scope of this document.

Reference to ISO 11238 [4], ISO 11239 [5], ISO 11240 [6], ISO 11615 [3], HL7 V3 messaging standards (HL7 Reference Information Model (RIM) [8], HL7 Common Product Model (CPM) [9] and HL7 V3 Structured Product Labelling (SPL) [10], and HL7 FHIR [11] can be applied for pharmaceutical product information in the context of this document.

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 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 unique identification and exchange of regulated pharmaceutical product information*

ISO/TS 19844, *Health informatics — Identification of medicinal products (IDMP) — Implementation guidelines for ISO 11238 for data elements and structures for the unique identification and exchange of regulated information on substances*

ISO/TS 20440, *Health informatics — Identification of medicinal products — Implementation guidelines for ISO 11239 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*

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ISO/TS 20443, *Health informatics — Identification of medicinal products — Implementation guidelines for ISO 11615 data elements and structures for the unique identification and exchange of regulated medicinal product information*

ISO 21090, *Health informatics — Harmonized data types for information interchange*

koniec náhľadu – text ďalej pokračuje v platenej verzii STN

2) <https://www.uml.org/>

3) <https://www.omg.org/about/omg-standards-introduction.htm>