SLOVENSKI STANDARD
kSIST-TS FprCEN ISO/TS 20443:2026

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Zdravstvena informatika - Identifikacija medicinskih izdelkov - Uporaba ISO 11615 podatkovnih elementov in struktur za enotno identifikacijo in izmenjavo predpisanih informacij o medicinskih izdelkih (ISO/DTS 20443:2026)

Health informatics - Identification of medicinal products - Implementation for ISO 11615 data elements and structures for the unique identification and exchange of regulated medicinal product information (ISO/DTS 20443:2026)

Medizinische Informatik - Identifikation von Arzneimitteln - Implementierungsleitfaden für ISO 11615 Datenelemente und Strukturen zur eindeutigen Identifikation und zum Austausch von vorgeschriebenen Arzneimittelinformationen (ISO/DTS 20443:2026)

Informatique de santé - Identification des médicaments - Lignes directrices pour limplémentation des éléments de données et structures ISO 11615 pour lidentification unique et léchange dinformations réglementées sur les médicaments (ISO/DTS 20443:2026)

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Technical Specification

ISO/DTS 20443

Health informatics — Identification of medicinal products — Implementation for ISO 11615 data elements and structures for the unique identification and exchange of regulated medicinal product information

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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).

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/TS 20443:2017) which has been technically revised.

The main changes are as follows:

— Extensive technical and structural revision of the standard, including more than 70 structural changes to improve clarity, consistency, and usability.

— Alignment with the latest developments of ISO 11615, including updates to the overall data model and related concepts.

— Major extension and refinement of the information model through the introduction of new attributes, associations, and classes, as well as refinement and reallocation of existing elements across pharmaceutical product, manufactured item, device, ingredient, substance, packaging, and regulatory domains.

— Redesign of the strength representation model, including the introduction of "Strength Type", "Strength", and "Reference Substance" constructs, revised substance-strength associations, and alternative linkage mechanisms consistent with ISO 11615, while preserving backward compatibility.

— Introduction of interoperability mappings and implementation artefacts, including a new informative Annex K defining mappings to HL7 FHIR, as well as inclusion of HL7 FHIR (XML/JSON) examples and updated HL7 SPL snippets.

— Strengthening of model constraints and data integrity through updates to cardinalities, mandatory elements, and classification structures (e.g. therapeutic indication, population grouping, product domain classification).

— Clarification and enhancement of existing requirements, including updates to cardinalities, classifications, and modelling constraints to ensure more precise and consistent interpretation.

— Addition of informative content, bibliographic references, and explanatory material to support implementation and understanding.

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 provides requirements and recommendations for implementing ISO 11615[1)]. It is one of the five ISO International Standards and four ISO Technical Specifications which together characterise the basis for the unique and unambiguous identification of medicinal products (IDMP). The ISO documents on IDMP are: ISO 11615, ISO/TS 20443 (this document), ISO 11616, ISO/TS 20451, ISO 11238, ISO/TS 19844, ISO 11239, ISO/TS 20440, and ISO 11240.

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 this information, unique identifiers are to be produced in conformance with the standards to support applications where it is important 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 regional guidance and implementation guides to support practical implementation within a given region or jurisdiction. ISO/TR 14872 describes core principles for supporting the development, implementation and ongoing maintenance of IDMP identifiers and terminologies.

The data elements and message specifications described in this document support, at a minimum, the following interactions within the following scope:

— regulatory medicines authority to regulatory medicines authority;

— pharmaceutical company to regulatory medicines authority;

— sponsor of a clinical trial to regulatory medicines authority;

— regulatory medicines authority to other stakeholders (as applicable);

— regulatory medicines authority to worldwide-maintained data sources.

Unique identifiers produced in conformance with this document are aimed at supporting applications where it is necessary to reliably identify and trace the use of medicinal products.

1) Third edition under preparation. Stage at the time of balloting: ISO/DIS 11615.

Health informatics — Identification of medicinal products — Implementation for ISO 11615 data elements and structures for the unique identification and exchange of regulated medicinal product information

IMPORTANT — The electronic file of this document contains colours which are considered to be useful for the correct understanding of the document. Users should therefore consider printing this document using a colour printer.

1 Scope

This document provides technical and business-oriented requirements and recommendations for implementing ISO 11615[2)] within systems that create, exchange, and process IDMP compliant medicinal product information. It focuses on the data elements, structures, and message specifications required to construct and interpret well-formed IDMP messages for regulatory and industry use. The scope covers interactions involving:

— regulatory authorities;

— pharmaceutical companies and marketing authorisation holders;

— clinical trial sponsors;

— other authorised stakeholders and global data sources.

This document applies to the exchange of medicinal product information needed to ensure unique, consistent, and traceable identification of medicinal products. Furthermore, to support successful information exchange, the use of the non-normative HL7®[3)] CPM (Common Product Model), the HL7® SPL (Structured Product Labeling), and HL7® FHIR®[4)] are described. References to the use of other relevant standards for medicinal product information are included in this document to support successful information exchange.

The document does not cover the governance, creation, or maintenance of identifier repositories, nor region specific regulatory procedures (e.g. marketing authorisation workflows), or internal business processes and system design for individual organizations, or training materials or domain-specific regulatory interpretations. Regional implementation guides can be consulted for jurisdiction-specific requirements.

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, *Code for individual languages and language groups*

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

ISO 8601-1, *Date and time — Representations for information interchange — Part 1: Basic rules*

2) Third edition under preparation. Stage at the time of balloting: ISO/DIS 11615:2026.

3) HL7 is the registered trademark of Health Level Seven International. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the product named.

4) FHIR is a trademark of HL7®. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the product named.

ISO 8601-2, *Date and time — Representations for information interchange — Part 2: Extensions*

ISO 12639, *Graphic technology — Prepress digital data exchange — Tag image file format for image technology (TIFF/IT)*

ISO/TS 19844:2018, *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 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 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*

ISO/TS 20451, *Health informatics — Identification of medicinal products — Implementation guidelines for ISO 11616 data elements and structures for the unique identification and exchange of regulated pharmaceutical product information*

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

ISO/HL7 27953-1:2011, *Health informatics — Individual case safety reports (ICSRs) in pharmacovigilance — Part 1: Framework for adverse event reporting*

ISO/HL7 27953-2, *Health informatics — Individual case safety reports (ICSRs) in pharmacovigilance — Part 2: Human pharmaceutical reporting requirements for ICSR*

3 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1 Abbreviations

ATC	anatomical therapeutic chemical
BAID	medicinal product batch identifier
BAID 1	medicinal product batch identifier (outer packaging)
BAID 2	medicinal product batch identifier (immediate packaging)
CDA	clinical document architecture
CEN	European Committee for Standardisation
CPM	common product model
EMA	European Medicines Agency, EU
FDA	Food and Drug Administration, US
FHIR®	Fast Healthcare Interoperability Resources
FLFS	fulfills relationship
GTIN®	Global Trade Identification Number; a trademark of GS1
GUID	globally unique identifier
HL7®	Health Level Seven
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICSR	individual case safety reporting
ID	identifier
IDMP	identification of medicinal product
IG	implementation guide
IMPID	investigational medicinal product identifier
IND	investigational new drug
INN	international nonproprietary name
ISO	International Organization for Standardisation
JSON	JavaScript object notation
LOINC	logical observation identifiers names and codes
MPID	medicinal product identifier
NCI	National Cancer Institute
NDA	new drug application
OID	object identifier
OMG	object modelling group

PCID	packaged medicinal product identifier
PCPC	personal care products council
PhPID	pharmaceutical product identifier
PSUR	periodic safety update report
RIM	reference information model
SDOs	standards development organizations
SME	small to medium enterprise
SmPC	summary of product characteristics
SPL	structured product labeling
Substance ID	substance identifier
UDI	unique device identification (code)
UML	unified modeling language
UUID	universally unique identifier
XML	extensible markup language

4 Message exchange

4.1 General

HL7® messaging standards have been widely implemented globally. The HL7® V3 architecture messaging standard deals with a static model of healthcare information as viewed within the scope of HL7® standards development activities. The HL7® FHIR® (Fast Healthcare Interoperability Resources) specification defines a set of capabilities for use across the healthcare process, about 157 modular components[5)] (called Resources) that can be assembled into working systems that support the wider healthcare domain. ISO recognises HL7® as an accredited partner organization for mutually issuing standards. The first mutually published standard was ISO/HL7 21731.

HL7® V3 was developed to address the complex requirements of health information technology. The HL7 Reference Information Model (RIM) is the cornerstone of V3 and the essential model from which all HL7 messages are derived. The RIM defines data content needed in a specific context and provides an explicit representation of the semantic and lexical connections that exist between the information carried in the elements of a message. V3 seeks to develop specifications that facilitate interoperability between systems. The HL7® model-driven methodology is used to develop consensus-based standards for healthcare system interoperability and information exchange. HL7® V3 messages are based on an XML encoding syntax.

FHIR® is a specification based on emerging industry approaches, but informed by years of lessons around requirements, successes and challenges gained through defining and implementing HL7® V2, HL7® v3 and the RIM, and CDA. FHIR® focuses to simplify implementations, it leverages existing logical and conceptual models to provide a consistent, easy to implement, and rigorous mechanism for exchanging data between healthcare applications. FHIR® has built-in mechanisms for traceability to the HL7® RIM and other important content models. This ensures alignment to HL7®'s previously defined patterns and best practices without requiring the implementer to have intimate knowledge of the RIM or any HL7® v3 derivations.

5) As per current FHIR® Release #5: https://hl7.org/fhir/

HL7® has confirmed that HL7® Version 3 is no longer actively developed[6] and almost all new HL7® projects have been building upon FHIR®. But some V3-based standards continue to be used in practice. For example, CDA (Clinical Document Architecture)[7] which is rooted in HL7® V3 models remains widely implemented in many national programs and regulatory workflows (e.g. clinical documents, discharge summaries, structured reports); the pharmacovigilance Individual Case Safety Report (ICSR) standards (ISO/HL7 27953-1 and ISO/HL7 27953-2) used for adverse event reporting are HL7® V3-based and continue to be officially reaffirmed and remain valid until at least December 2026 (as per ANSI/HL7 listings); the HL7® SPL (see Reference [8]) and HL7® CPM (see Reference [9]) are also HL7® V3-based standards used for regulatory use cases (including IDMP) in one of the ICH regions[7]. The framework described in ISO/HL7 27953-1 shall apply.

Although not all current HL7® projects are based on FHIR®, nearly all new development, innovation efforts, and strategic investments at HL7® now converge on FHIR®. This includes emerging interoperability initiatives, accelerator programs, implementation guides, new tooling such as FHIR® Foundry, and federal interoperability strategies, all of which overwhelmingly prioritize FHIR®.

The ISO standards on IDMP were designed to specify the necessary data elements and associated standards to be used for unique identifiers. These were developed as an integral part of the IDMP consensus requirements and are consistent with the HL7® Common Product Model (CPM) and the HL7® FHIR® specification. The IDMP data elements represent a subset of those in the CPM and FHIR®. The use of HL7® messaging standards will facilitate the integration of IDMP into the broader healthcare community, improve interoperability through standardized resource-based data exchange, support FAIR data principles[8], reduce integration costs and complexity, and provide a future-proof foundation for advanced analytics and decision support.

4.2 Message exchange format

In the context of this document, the message exchange formats to be utilised as informative reference in transactions are the HL7® SPL (Structured Product Labeling) and HL7® FHIR®. The HL7® SPL is a standard message exchange format based on Clinical Document Architecture (CDA) and the HL7® Reference Information Model (RIM). FHIR® and SPL instances (code snippets) and FHIR® mappings (see Annex K) are provided in this document to illustrate the representation of an IDMP concept within the HL7® SPL message exchange format and within HL7® FHIR® specification. Technical conformance criteria for messages will not be addressed in this document and shall be left to regional guidance and implementations per their respective requirements. A reference to the most up to date HL7® CPM, HL7 SPL, and HL7® FHIR® reference as a resource for IDMP implementation is accessible on the HL7® portal[9],[10].

4.3 Controlled vocabularies

A controlled vocabulary is a standardised, predefined set of terms used to describe, categorize and retrieve information in a consistent and unambiguous way. It ensures that everyone uses the same authorised terms to refer to the same concepts, improving search accuracy and reducing confusion. Controlled vocabularies:

— ensure terminology consistency in how concepts are named and described (e.g. “oral tablet” is always coded the same way);

— eliminate ambiguity by ensuring each term refers to only one concept (e.g. regulators and applicants use the same semantics through medicines’ life cycle);

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6) The withdrawal and retirement of V3-based specifications signify the cessation of all maintenance activities, including the discontinuation of tooling and editorial support, and formally denote that the specification has reached a mature state and will no longer be subject to further enhancement.

7) US FDA.

8) The FAIR data principles are a set of internationally recognized guidelines designed to ensure that data can be Findable, Accessible, Interoperable, and Reusable (Reference [10]).

9) https://www.hl7.org/

10) https://hl7.org/fhir/