SLOVENSKI STANDARD
SIST-TS CEN ISO/TS 19293:2018

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Zdravstvena informatika - Zahteve za zapise o izdaji zdravila (ISO/TS 19293:2018)

Health Informatics - Requirements for a record of the dispense of a medicinal product (ISO/TS 19293:2018)

Medizinische Informatik - Anforderungen an die Akte zur Abgaben eines Arzneimittels (ISO/TS 19293:2018)

Informatique de santé - Exigences relatives à un enregistrement de la délivrance d'un médicament (ISO/TS 19293:2018)

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English Version

Health Informatics - Requirements for a record of the dispense of a medicinal product (ISO/TS 19293:2018)

Informatique de santé - Exigences relatives à un enregistrement de la délivrance d'un médicament (ISO/TS 19293:2018)

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This Technical Specification (CEN/TS) was approved by CEN on 19 February 2018 for provisional application.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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European foreword

This document (CEN ISO/TS 19293:2018) 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 19293:2018 has been approved by CEN as CEN ISO/TS 19293:2018 without any modification.

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Health informatics — Requirements for a record of a dispense of a medicinal product

Informatique de santé — Exigences relatives à un enregistrement de la délivrance d'un médicament

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Foreword

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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 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 the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 215, *Health informatics*.

Introduction

The record of dispensed medicinal product(s) plays an important role in the patient safety domain. When a medicinal product has been prescribed, it then has to be dispensed before being administered to the subject of care. The dispensed product may correspond exactly to what was prescribed, but it may equally be different for various reasons, such as substitution, unavailability of medicinal product in the prescribed dosage or route of administration, etc.

There are further situations, when medicinal products are dispensed or supplied without any prescription. This should also be captured since a non-prescribed medicinal product may have interactions or other influences with prescribed medicinal products.

When creating a list of a patient's medication history, prescriptions can provide valuable information, but the dispensation is sometimes considered a better indicator of the medication taken by a patient than a prescription, i.e. although neither is information about compliance or administration, the dispense record is many times considered a more reliable indicator of actual medication use than a prescription (even if it also not an unequivocal indication of administration). Therefore, there is a need to capture the dispensation, as the dispensation either completes the logical chain from prescription to administration, or provides information for later prescriptions or dispensation, for instance, if interactions can be anticipated and avoided.

The dispense record should provide information in such a way that it is accurate and reusable; for example, statistics and other information can be collected across the dispensers for public health purposes, or for regulatory needs (e.g. controlled substances control).

Additionally, the dispense record is a traceability element. For clinical purposes, it supports recording the process from prescribing to administration. For supply chain, it allows reconstruction of the supply chain, for example, in the contexts of recalls or supply chain integrity.

This document defines the information that may be contained in a dispense record, and the applicability and constraints of such information. It defines a set of conditions that should be verified on detailed interoperability implementations.

This document also defines requirements for when the dispense record should be issued in the cases where it is needed. This is not required as a specific moment in a process — which would depend on a variety of processes and factors — but by providing a common set of activities that are included in a dispense.

This document addresses the requirements which are to be fulfilled by the systems that record medicinal product dispensation. It is based on use cases which are chosen from the daily life within the same jurisdiction, and when the prescription and dispensation have occurred in different jurisdictions. This document relies on the assumption that prescription and dispensation are supported by medicinal product dictionaries that ensure interoperability.

One key aspect in this document is that the notion of dispense can vary according to context (hospital versus community), jurisdiction, and other factors. The uses of the dispense record can also vary. These variations can have a strong impact on the definition of dispense.

For example, the process of dispensing a medication varies considerably between hospital and community settings, and even inside a hospital. Another example is if the dispense record is used mostly for operational concerns (reimbursement), the relevant dispense information is obtained when the medication is retrieved for that patient. But if the dispense record is supposed to support clinical systems, it may be better to capture information until the medication is delivered to the patient or handed to a next of kin and thus presumed to be delivered to the patient. It is important that the medication dispense record contains sufficient information to support these different and variable uses.

Another example of process variability is how a dispense record can be a consequence of an electronic prescription. However, in some cases, there are dispenses without a prescription. The scope of this document considers dispensing with or without the existence of a prescription.

There is an increasing number of scenarios for electronic capture of dispensing information and an increasing need to exchange this information in electronic health information systems, in particular, for purposes of clinical care, decision support, claiming and reimbursement, research, statistics, regulation, as well as for product integrity.

This document is, thus, not about the processes but the information content. This document does not impose any activity to be part of the dispense process, but informs what information may be captured from each activity.

Other uses for this information are identified, not for exhaustively listing them — which would be limiting and impractical — but to ensure that the scope of this document covers the expected scenarios and uses.

In this way, the information in a dispense record can be correctly recorded and used in any of the contexts of dispense, ensuring the global applicability of this document.

Health informatics — Requirements for a record of a dispense of a medicinal product

1 Scope

This document specifies requirements for a record of a dispense of a medicinal product.

It is intended to be adopted by detailed, implementable specifications, such as interoperability standards, system specifications, and regulatory programs.

This document applies to information systems in which a dispense of a medicinal product is registered, and the systems that consume such information. These systems are usually in pharmacies or other healthcare institutions. This document does not necessarily apply to non-pharmacy shops or other non-clinical systems (e.g. supermarket cashiers).

The scope of this document includes the activities relating to the dispensing of a medicinal product and the information content for the capture of structured information produced in those events.

These activities include any actual dispense, cancellation or other outcome that may have occurred at the time of planned or actual dispense. In other words, the dispense record also contains information that medication was expected to be dispensed but was not dispensed.

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 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 17523, *Health informatics — Requirements for electronic prescriptions*

ISO/TS 19256, *Health informatics — Requirements for medicinal product dictionary systems for health care*

3 Terms, definitions and abbreviated terms

3.1 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological 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/