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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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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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/

3.1.1
dispense, noun
series of events and activities that have the purpose of giving a medicinal product to a patient, whether or not as part of a planned treatment, or to be used in procedures such as anaesthesia or imaging, where the key activity is the act or effect of assigning a product to a patient

Note 1 to entry: Typically, a dispense is done at a community pharmacy when the product is provided to a patient, but also in care settings, where the product is either dispensed for a specific patient by a pharmacy, or picked for the patient from the ward stock, after being distributed by a pharmacy.

3.1.2
dispense event
time or event when a dispense is considered complete (which can vary across processes, jurisdictions, settings)

3.1.3
dispensing process
sequence of activities leading up to the dispense event, i.e. the activities done by the dispenser before the dispense is complete

3.1.4
dispense record
data set that identifies and describes the dispense activity/activities

Note 1 to entry: The above definitions enhance the definition of "dispensing" in ISO TS 17523 (where "dispensing" is the set of activities originating from a prescription until the actual delivery of the product to the patients). First, the present definition of dispense also includes the cases where a dispense is not a consequence of an existing prescription. Second, this definition of dispense also separates the actual dispense from the pharmaceutical review, validation or advice that is usually associated with the dispenser and many times done immediately prior to the dispense. Furthermore, actions upstream or downstream of this dispensing act are considered distribution and are not related to a specific patient, so they are not part of the definition of dispense. Example of upstream actions are bulk supply and inventory management. Examples of downstream actions are transport of a dispensed medication to the place of consumption, or shipment to the patient, etc.

3.1.5
dosage
intended or actual amount of medicinal product to be taken by the patient, including the dose form, route of administration as intended to be applied to be used in the patient's treatment

3.1.6
dispense record system
system of record of dispense
information system that collects the information about the dispense activity and provides the information contained in the dispense record

3.1.7
medicinal product
any substance or combination of substances that may be administered to human beings (or animals) for treating or preventing diseases, with the view of making a medical diagnosis or to restore, correct or modify physiological functions

3.1.8
encoding
<order> detailing a (medication) order from implicit or less specific information into more specific or detailed information

EXAMPLE 1 "1 tablet bid" can be encoded into detailed times: "one tablet at 8:00 and one tablet at 20:00".

EXAMPLE 2 "Paracetamol 500 mg" can be encoded into a specific medicinal product: "Sweetdream 500 mg tablets".

3.1.9
parapharmacy
non-pharmacy shop
place where medicinal products can be sold but not by a pharmacist or healthcare professional evaluating the impact of the medicinal product in the patient

Note 1 to entry: It is usually a retailer that sells health and hygiene products which do not require a prescription.

3.1.10
packaged medicinal product
medicinal product in a container being part of a package, representing the entirety of the unit that has been packaged for sale or supply

Note 1 to entry: Corresponds frequently to "secondary packaging".

[SOURCE: ISO 11615:2017, 3.1.55, modified — the note in ISO/TS 16791 has been added.]

3.1.11
prescription
set of data (values of attributes) that is produced as the output of a prescribing act, instruction or authorization for a patient to be administered a medicinal product

Note 1 to entry: It is beyond the scope of this document to define "prescription" — the definition provided here is functionally restricted to the minimum for the scope of this document.

[SOURCE: ISO 17523:2016, 3.7, modified — the definition has been revised and the original notes have been deleted.]

3.1.12
single dose
single item of medicine in an individual packaged component

Note 1 to entry: This could include a single medicine within a multi-dose blister pack, a syringe, a vial, or an ampoule.

EXAMPLE A single tablet of paracetamol 500 mg in a blister pack.

3.1.13
unit dose
particular dose of a medicinal product for a specific patient according to the patient-specific prescription

EXAMPLE Two tablets of paracetamol 500 mg packed together, if the prescription is for 1 000 mg of paracetamol.

3.1.14
supply
delivery and transport of (medicinal) products to a location, for dispensing or further distribution

3.1.15
subject of care
SoC
person that is expected to use the medicinal product

3.2 Symbols and abbreviated terms

ATC Anatomical Therapeutic Chemical – a classification system of active substances divided into different groups according to the organ or system on which they act and their therapeutic, pharmacological and chemical properties, defined and maintained by the WHO.

EHR Electronic Health Record

MPD Medicinal Product Dictionary
[SOURCE: ISO/TS 19256]

GInAS Global Ingredient Archival System

4 Dispense process and dispense event

4.1 General

This document presents a common specification that can be used to capture and exchange structured data in relation to the dispense of a medicinal product. This document serves to ensure the availability of the right information to generate a more complete medication profile of a subject of care within an electronic health record, as well as other clinical or operational purposes for which medication dispense information is relevant.

The requirements for a dispense record depend on the definition of

— the dispense event (i.e. when is the dispense record to be issued),

— the information available and the activities done by the dispenser in order to complete a dispense,

— the intended purpose of dispense information.

For this document, a generic definition of the above is important, so that this document applies globally.

4.2 Dispense record in diverse dispense processes

As illustrated by the examples in Annex D, the concept of dispensing can have diverse meanings across contexts (different national regulations and definitions, hospital vs. community settings). This is because dispensing entails a process, and this process varies across those contexts.

Basing a technical specification on one definition of a dispense process would require either

a) finding and globally agreeing upon one dispense process,

b) settling for one definition of dispense process in a given context (e.g. capturing community dispense for summary medication lists), or

c) analysing the different definitions and reach a common ground to which all the different dispense processes can relate.

This document favors option c) — a common base definition of dispense is used, which can be implemented and derived for concrete implementations. While this is more demanding and not implementable, it provides a reasonable level of abstraction for this document to be adopted globally.

Only this option allows, for example, that a dispense record issued within one context or region is still useful in a different context or region.

The base definition provided for dispense is “when a medication is assigned for a patient”. In practice, the dispense is considered complete when the dispensed product leaves the responsibility of the dispenser.

