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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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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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/

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.

4.3 Dispense record information purposes

The dispense information can be used for:

— transactional or workflow purposes, i.e. to enable subsequent processes after dispensing, such as administration, reimbursement, resupply, etc. or to update the prescription status and workflow. The dispense record can be a placeholder for information that is used by the different clinical actors when providing care;

— reporting or monitoring purposes, i.e. to add to the EHR and complement the patient's information, or to support traceability information, etc.;

— supporting or enriching the clinical decision processes, for example, provide information about prior dispenses when evaluating a new treatment or handling a follow-up dispense.

Any of these uses is optional. For example, there may not be an EHR to update, or there may not be a prescription to update.

For this reason, the dispense record and its content should not assume or assert one or another use, but rather support the diverse possible uses. Figure 1 presents an overview of some of these possible uses.

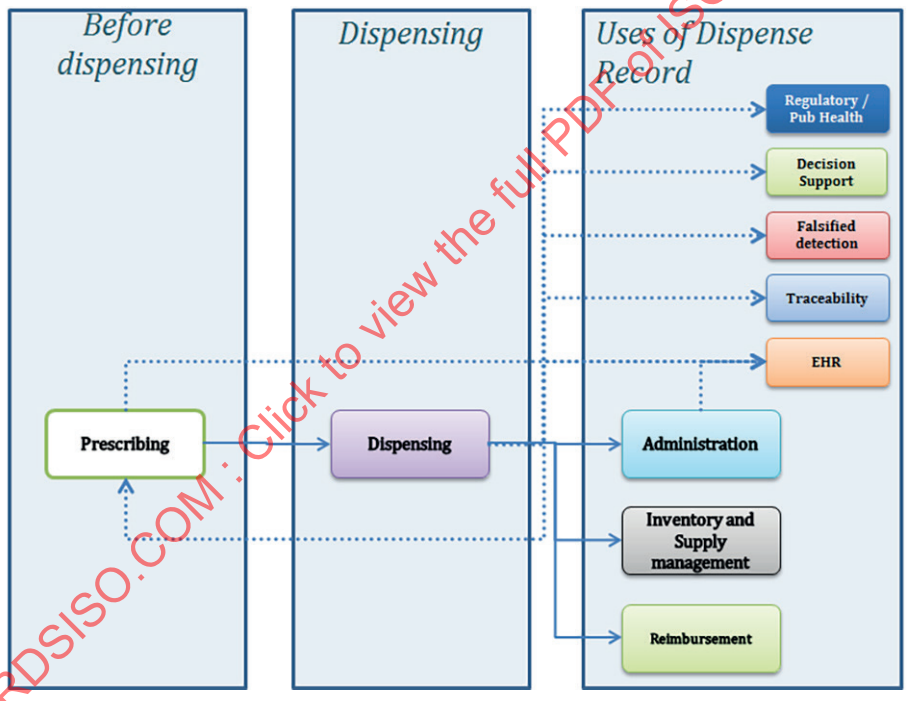

Figure 1 — Relation between dispense and adjacent processes

5 Requirements

5.1 General considerations

The requirements for the dispense record are derived from the scope and analysis in this document, and from the different scenarios covered by several references available. The bibliography mentions some references that encounter or address these requirements (use cases, technical implementations).

These requirements cover the logistical/inventory aspects of the dispense record as well as the clinical aspects. These are overlapping, and it is not convenient or feasible to separate them. For example, the lot number is usually logistically relevant, but also useful for pharmacovigilance or recalling products.

5.2 Issuance of the dispense record

5.2.1 General

There should be a dispense record every time that a medication is assigned to a patient, independently of any other preceding or subsequent activities. If the medication is dispensed for fulfilling a prescription, the dispense record shall be issued. If there is no prescription, the dispense record should be issued.

The dispense record shall be captured by the time the dispensing process is completed (see 3.1.2). Depending on the use cases (see Annexes A and B), the dispense information may be captured as soon as the medication is assigned to the patient or when other activities are completed.

In cases where a medication should be dispensed but is not (e.g. there is a decision not to dispense), the dispense record should also be issued.

5.2.2 Dispense record scenarios

The dispense record shall be issued for any of the following scenarios:

— dispensing in a healthcare institution (e.g. hospital) in response to a prescription;

— unplanned use of medication in an administration in an institution;

— dispensing in a community pharmacy from a prescription;

— dispensing in a community pharmacy without a prescription, if it is clear the patient that is intended to take the medication.

A dispense record should be issued in the following scenario:

— products, such as anaesthetics and radiology contrasts, that are not dispensed by a pharmacy, or that are used as an implicit part of a procedure are still considered relevant for the dispense record.

The dispense record can be issued in the following scenarios, but the constraints of these scenarios might not meet all the requirements described in these specifications (see Annex E for use case-specific constraints).

a) Use of medication products for a clinical trial

   — In this case, the product may not be revealed at the time of the dispense, but the dispense record may contain the product identification and this can be used for the patient record.

b) OTC sale or sale of medicinal products in a parapharmacy or similar (e.g. supermarket)

   — In this case, the dispense medication is given to a person but it is not usually possible to assert who is the patient that will take medication.

c) Use of medication samples for patients

   — In this case, the process of assigning the medication sample for a patient is varied and may or not be covered. It is, however, clinically relevant and may be included in systems of record.

5.2.3 Dispense record uniqueness

One dispense record entry shall be issued for each assignment of a medication to a patient, independently of the dispensing processes.

EXAMPLE In the case of hospital ward dispense, if the dispense process includes the pharmacist supplying the items to the ward, the nurse to retrieve the medicinal product for a patient, there is only one dispense process and as such one unique dispense record entry.

In case a medication is assigned to a patient and then individually repacked (e.g. an entire box is given to a patient and then the medication is repackaged), this is still one dispense and as such only one dispense record entry shall be issued. In this case, the dispense record is issued at first and then updated to inform of the later processes such as repackaging.

5.2.4 Dispense process unambiguity

The dispense record shall be clear about the context of the dispense, and unambiguous about what the dispensing process entails, and the event that triggers the record. The dispense record shall contain sufficient information for the interested parties to be informed about the activities in the dispensing process.

Rationale: While the dispensing process can vary and as such cannot be globally standardized, it is important to follow the local rules. When a medicinal product is dispensed, this may trigger processes like billing, administration, etc., and it is important to have an unambiguous record of what activities or events were part of that dispense. Besides enabling processes, the dispense record may also be useful for quality assurance.

EXAMPLE 1 In some countries, a hospital prescription must be validated by a pharmacist before dispensing, so the information about validation shall be explicit in the dispense record.

EXAMPLE 2 If a patient has some medication dispensed in a hospital setting, and some medication dispensed in the community. In a hospital, the dispense may not have required a check for falsification of the product, but in community it may have. Therefore, the dispense record includes the information (implicit or explicit) that in the first case there was no verification, but in the second case, that verification was made and was considered correct.

5.2.5 Dispense record unequivocal identification

Each dispense record entry shall include a unique identification that can sufficiently identify that dispense record entry.

The dispense record can be used to update the prescribing system about the act of dispensing, or it can be used in combination with other documents to contribute to the EHR. Each dispense entry has its own identity and needs to be uniquely identifiable for information lineage, and for proper updates.

EXAMPLE If there are two activities of dispensing the same product for the same patient (e.g. an automated dispenser and a pharmacist picking the medication and delivering it to the patient's cart), it is important to distinguish them if they are indeed different activities, or to combine them if they are just a duplicate of each other. In some cases, the unique dispense ID can be used to link the dispense to a prescription that will only be created later — in the case of an emergency dispense that will be subject of a prescription afterwards.

5.2.6 Dispense act date/time

The dispense record shall identify the date and time of the dispense.

Each dispense record entry shall contain only one date and time information.

In case the dispense entails different activities, and if it is deemed relevant to capture the time stamps for these activities, these time stamps should be associated with the data structure for those activities (see Annex F), and not superimposed on the dispense entry time stamp.

5.2.7 Dispense location — Institution/department

The dispense record should identify the location of the dispense.

Each dispense record should contain at least one identification of a location. In case the dispense entails different activities, the locations of several activities may be present, but the dispense record main location shall inform about the location where the most relevant activity has occurred. The most relevant activity may be defined differently across processes and legislations.

5.2.8 Confirmations, authorizations, or advice

For dispensing some medicinal products, or in some locations, there may be need for authorizations, confirmations issued, etc. For example, narcotics may need a special permit or form to be filled. It is sometimes legally imperative that the dispenser captures that authorization, to confirm that the dispense is legal. Sometimes, the authorization can be inferred from the simple existence of the dispense. If the medication is dispensed, then it is obvious that it has been authorized. These shall be part of the dispense record.

If the dispense activity entails any authorizations that are not captured elsewhere, because they are intrinsic to the dispense activity, these authorizations shall be captured in the dispense record.

In case the dispense entails different confirmation activities, all or part of these activities may be present in the dispense record.

5.2.9 Additional information to support the adequate and legal dispensing

The dispense record should contain the additional information that was used to support the adequate and legal dispensing — any checks (for example, capturing the identification and age of a person that receives a narcotic on behalf of the patient, or capturing the professional responsible for delivering that medicinal product). This information varies and it may be locally required to be in a dispense record.

5.2.10 Relevant findings elicited during the clinical review

If, during the dispense process, relevant clinical information is found (e.g. pregnancy status, contraindications), these should be captured in the dispense record. The actions undertaken for addressing these findings may be recorded in the dispense record. The implications of these actions on the dispense record (e.g. product not dispensed due to contraindication reported) may also be captured in the dispense record.

5.2.11 Decision not to dispense

During a dispense activity, there is the possibility that the medication is not dispensed.

The dispense record should still be issued when a dispense is planned but not effective. In such cases, the product information may be non-existing (since there is no dispensed product), but the dispense record should register a non-dispensing or null dispensing, as well as information around that non-dispense, for example, justification for that non-dispense or indication that prescription was not accepted.

5.3 Prescription-related

5.3.1 General

In many cases, the prescription is the trigger and authorization for the dispense. Prescriptions are issued electronically or on paper and produced as hard copies or submitted and consulted electronically. A dispense is a consequence of the prescription. The dispense record can be used to inform the prescribing system about the evolution in the process (informing that medication is dispensed). In some cases, there is no prescription information.

The following scenarios are considered.

a) Dispense is a consequence of an issued prescription. Different types of prescription can exist:

   — normal prescription by a GP or a specialist;

   — special prescription for specially regulated products (e.g. narcotics);

   — special type of authorizations by nurses, pharmacists, etc.

b) Dispensed product does not require a prescription.

c) Dispensed product normally requires a prescription but one is not available (yet).

This document does not intend to cover the details of the prescription itself, but to define one common dispense record structure that covers the common needs of all these cases.

Therefore, the following requirements apply.

5.3.2 Link to prescription

When a dispense is a consequence of an electronic prescription, a reference to that prescription shall be included in the dispense record.

This reference shall be unambiguous even in cross-jurisdiction contexts, i.e. the dispense record shall contain sufficient information (codes, coding systems, jurisdictions, or any other metadata) to avoid ambiguity about the prescription ID.

If the dispense record is a consequence of an electronic prescription, the dispense record may include the relevant prescription information (for example, prescribed product, professional, etc.) for purposes of checking, accessibility of information, or others.

NOTE In some cases, the dispense can be a consequence of a paper prescription, in which case the information can be available or not.

If the dispense record is a consequence of a prescription, the dispense record shall include the relevant prescription information. For example, if it is a paper prescription, it is important to capture the relevant prescription information so that there is a way to trace the information in the case of a substitution, approvals, or others.

5.3.3 Additional prescription linking data

The dispense record should contain all additional information for correctly updating the prescription-related processes.

Besides providing an unambiguous link to the prescription, the dispense record may also be used to confirm that the dispensation has been done in an adequate manner, including authorizations, verification steps, etc. for purposes of reimbursement or others. Examples are special authorization IDs, which are needed to conclude the prescription processing. These are needed to update the prescription status and should be retained in the dispense record.

5.3.4 Previous prescription changes/advice

If the dispense is issued in response to a prescription that has been changed, the dispense record should point to the latest known valid version of the prescription at the time of dispense. Alternatively, it can point to the information that is valid for dispense (e.g. the initial prescription and a set of subsequent changes or previous dispense). In any case, the dispense record shall unambiguously indicate which version of a prescription it has been acted upon.

5.3.5 Outcome of clinical review of the prescription

5.3.5.1 General

When dispensing, the dispenser may also provide a clinical review of the prescription.

This review may simply update the status of the prescription (e.g. “approved”), or it may update or change the prescription that is being dispensed.

Furthermore, when there is a change in treatment, this change can be impacting the present treatment (e.g. a substitution that is made just once to compensate for stock issues) or impacting future treatments (e.g. when a patient should take smaller tablets instead of the original prescription).

Besides the present dispensing action, any of these changes can be important for future use in the EHR (so that the EHR has up-to-date information about the treatment), or for reimbursement or any other purposes.

5.3.5.2 Review of treatment

When the dispenser provides a formal clinical review of the prescription, then the dispense record shall indicate that this review took place.

In case there is any status update from this review (e.g. "approved", "rejected", “changed”, etc.), then the dispense record shall also contain such information.

Where the review is not formally done, or where the outcome of such validation is implicit in the other dispense information, the dispense record does not have to explicitly contain such information.

EXAMPLE If there is an actual dispense, the approval or acceptance is implicit; in such cases, the dispense record can exclude an explicit indication about a clinical review and approval.

5.3.5.3 Changes to treatment

If the dispensing introduces changes to the treatment, these changes shall be captured implicitly or explicitly.

The most common case is substitution. For the scope of this document, it is considered that substitution exists when at least one characteristic of the dispensed product differs from the specified characteristics of the prescribed product.

EXAMPLE 1 If the strength or any other attribute is specified in the prescription and if that same attribute of the dispensed item is different, there is substitution.

EXAMPLE 2 If a prescription specifies a concrete medicinal product, and if a different medicinal product is dispensed (even if it is considered equivalent), there is a substitution.

EXAMPLE 3 If a prescription specifies a pharmaceutical product, but no medicinal product, and if the medicinal product dispensed contains the specified pharmaceutical product, there is no substitution, because all the specified attributes of the pharmaceutical product can still be observed in the medicinal product.

EXAMPLE 4 The change in dose form or the dosage.

If a change to the treatment (like a substitution) exists, the dispense record shall clearly indicate that there has been a change of the treatment.

This change shall be documented by capturing the outcome of the change, in a way that is always possible to clearly and unambiguously determine what is the final information. For example, “the actual dispensed strength is 500 mg”.

NOTE The changes can be captured as an addendum to the initial order, or as a complete new order that refers to the previous order but with the updated information. The requirement is about the information captured, so that it is always possible to clearly and unambiguously determine what were the changes. These changes and their reasons should be described in a controlled vocabulary, for semantic interoperability.

In case of substitution, the dispensed product shall be identified as required in 5.6.

Any other changes in the treatment should conform to the requirements in ISO 17523 for the identification of product or use controlled vocabularies.

Changes in dosage or dose forms shall be captured by capturing the changed dosage and the new dose form. The changed dose form shall conform to ISO 11239 as well as what is described in ISO 17523.

5.4 Dispenser identification

5.4.1 Dispensing professional

The dispense record shall identify the dispensing professional, i.e. the professional responsible for the dispensing. In case there are several participants performing a process under the responsibility of one professional, the responsible professional shall be identified. In case the dispensing process is split into several activities, e.g. in a hospital setting, one pharmacist reviews the medication and the other picks the medication items, and if this happens without an overall responsible dispenser, then the dispense record shall identify at least the professional that performs the latter activity, i.e. the one that picks the medication product.

In any of the cases where the dispensing process entails different activities from different professionals, the dispense record may identify each of the professionals, possibly by appending information of each activity.

5.4.2 Dispensing organization

The dispensing organization shall be identified in the dispense record.

In case there are several organizations or several structures of organizations involved, the dispense record shall contain the identification (single or multiple) that uniquely identifies the organization responsible for the dispensing professional and for the systems involved. This is the case, for example, where a dispensing organization has agreements with several other organizations, and for any specific purposes such as charging, both are required to be identified.

In case the dispensing process entails different activities in different organizations, the dispense record shall identify the organization that is ultimately responsible by the overall dispensing process.

In case the dispensing process entails different activities in different organizations, the dispense record may identify each of the organizations, possibly by appending information of each activity.

5.4.3 Automated and semi-automated dispensing systems

In case the medication is picked or distributed by an automated or semi-automated system (as far as these systems work with patient named packages), the dispensed record shall contain sufficient information to uniquely identify the system within the organization. This is important to ensure process traceability, e.g. to check any malfunctioning in such systems.

The dispense record is not the system of record for device management, so the system identification is only relevant to identify, and not fully describe, the equipment. For example, there is no need to consider software versions or maintenance status of the equipment, since it is expected that these are available from another system of record. The dispense record only retains the information that is sufficient to identify the system, which allows to retrieve any additional information.

5.5 Patient identification

5.5.1 General

The dispense record shall contain an unequivocal identification of the patient, including an unequivocal identification of the jurisdiction or context to which the patient identification pertains.

5.5.2 Patient identification verification

When the patient's identity is the subject of a verification or confirmation, like for example, when there is a mandatory verification of the identity for dispensing controlled medicinal products, the dispense record may contain the information about such verification.

5.6 Dispensed product

5.6.1 General

The information about the product actually dispensed is an essential part of the dispense record.

It is important to clarify the kind of product dispensed, for example, the medicinal product that has been dispensed like the brand name, or the medicinal product identifier. For example, the product dispensed is “Sweetdream 500 mg tablets, box of 30 tablets”.

It is also important to identify the physical instance of the product that has been dispensed, or provide relevant information relative to that physical instance. As an example, besides “Sweetdream 500 mg tablets. Box of 30”, it may be relevant to identify or further describe which of the actual boxes of Sweetdream are dispensed — indicating, for example, a lot number or expiry date.

The need to identify only the product kind or also the physical instance depends on the intended uses of the dispense record. For clinical processes (e.g. reconciliation, patient summaries, etc.), usually the kind of product is relevant. For pharmacovigilance and supply aspects, the actual physical item is important.

5.6.2 Dispensed product type

5.6.2.1 General

The dispense record shall contain an unambiguous identification of the product kind that is dispensed. The information in the dispense record shall be either an IDMP identifier (refer to ISO 11615 and ISO 11616) or sufficient information (attributes and identifiers) to identify the product. Annex D discusses the use of identifiers.

The dispense record shall contain the information to the most specific level that is available at the act of the dispensing. For example, if the dispenser uses a barcode which contains the package identifier, then the dispense record shall contain the package identification, and not only the pharmaceutical product identification.

Since a pharmaceutical product is not a dispensable item on its own (because it is a virtual product and is not available physically, but rather prepared and made available as a medicinal product), the dispense record shall contain additional information to identify the medicinal product ID or the packaged product dispensed.

5.6.2.2 Identification vs. description

The dispense record shall contain sufficient information to unambiguously identify the medicinal product. The dispense record is not responsible for describing all the details about the medicinal product. That would be the purpose of an MPD, which can be consulted if the dispense record contains unambiguous identification about the product.

5.6.2.3 Identification using IDMP identifiers or attributes

The identification of the product shall use either one of the IDMP identifiers or a set of IDMP attributes. These attributes shall be sufficient to unambiguously identify the product.

If the IDMP identifier is not sufficient to fully describe the dispensed item, the dispense record shall use a set of IDMP identifying attributes.

The dispense record shall use the information from a medicinal product dictionary (MPD), as defined in ISO 19256.

The dispense record shall not be used to describe the product characteristics. By containing sufficient information to identify a product, the dispense record enables that the product information is obtained from the MPD.

In case of compound products, the dispense record

— shall identify the active ingredient(s) in the compound medication,

— should identify all the ingredients, and

— should identify the dose form and strength of each of the components.

Annex D shows how the identification of products can be done using IDMP identifiers.

5.6.2.4 Identification using non-IDMP identifiers or attributes

Within a jurisdiction and context where IDMP is not (yet) implemented, the dispense record may identify the product using another identifier in the medicinal product dictionary (MPD). This implies that there is a possibility to convert such an identifier to the corresponding IDMP identifier or set of attributes. The identifiers in the MPD shall be traceable to global set of identifiers (see Annex D), preserving a similar level of granularity in the product identification.

In case non-IDMP identifiers or attributes are used, the dispense record shall contain information that is compatible with the available MPDs, which can later establish the correspondence between the pre-IDMP identifiers and the IDMP identifiers.

5.6.3 Dispensed physical item

5.6.3.1 General

Since the dispense record is expected to be useful for several purposes such as monitoring, traceability, etc., the dispense record should contain the available information about the physical product dispensed. This information may not be relevant for some of the clinical applications of the dispense record (e.g. patient summary) but are essential for other applications like traceability, pharmacovigilance and all supply matters.

5.6.3.2 Identification of actual product at the level it is known

When a regulated packaged product is dispensed, and there is a specific trade item ID, the dispense record shall contain the trade item ID. The trade item ID shall be traceable to an IDMP-compliant set of identifying attributes.

5.6.3.3 Expiry date (and time)

When the product has an expiry date (or an expired time, in case of short-life products such as reconstituted products), the expiry date or time shall be indicated in the dispense record.

In case of compound products, the dispense record

a) shall contain the expiry date for the compound product, if known or determined somehow, and

b) should contain the different expiry dates for each of the components.

5.6.3.4 Lot number (if available)

When the product has a lot number and it is captured, it should be indicated in the dispense record.

In cases of compound products, the dispense record should contain the lot number(s) for each of the component products that contain the active ingredient(s). The dispense record should contain the different lot numbers for each of the components.

5.6.3.5 Serial number (if available)

When the product has a serial number, it should be indicated in the dispense record.

In case of compound products, the dispense record should contain the serial number(s) for the active ingredient(s) and contain the different serial numbers for each of the components.

5.6.3.6 Observations about the dispensed physical item

The dispense record may contain any additional information about the dispensed physical item.

EXAMPLE If during the dispense the pharmacist checks the product to see if it is a suspect of falsification, or observes that the dispensed product's safety feature seems overt but is not well determined, or there is, if any, damage in the packaging, this can be mentioned in the dispense record.

5.7 Quantity

5.7.1 Dispensed product quantity

The dispense record shall contain the quantity dispensed. This quantity is the dispensed quantity and shall be identified as such, e.g. not to be confused with the quantity taken by the patient (which is not always the same).

The indication of quantity shall also include the unit in which that quantity is expressed.

5.7.2 Retrieved product quantity

The dispense record may contain the amount of product consumed from inventory if it differs from the actually delivered amount.

If the quantity of product delivered to the patient is different from the quantity retrieved from stock, this can represent wastage or be relevant for control of pharmaceutical activities.

In some cases, the amount of product retrieved is not the same as the amount of product delivered for the patient. For example, there are jurisdictions where a box of antibiotics contains 14 tablets, but the treatment is for 10 days, and in that case, the dispenser should only dispense the exact amount to the patient. So, 14 tablets are retrieved (and can be considered used or consumed) but the actual delivered amount is 10. It is important to capture the actual retrieved quantity, for example, to provide information about the dispense of antibiotics for auditing purposes. Another example is when half a tablet is needed, but to have this, a whole tablet has to be taken from stock. In this case, it may be important to inform that one complete tablet was retrieved (for inventory control purposes).

NOTE This requirement does not apply to the items retrieved from stock but then replaced in stock, e.g. when retrieving a bottle of 500 tablets from stock and taking only 30. In this case, only 30 tablets are actually taken from inventory.

5.8 Dispense repeat number

The dispense record shall contain the repeat number of the dispense, for example, if the dispense is a third refill of a prescription, this shall be captured in the dispense record.

5.9 Fulfilment notes

When the dispense contains fulfilment notes (e.g. "water is not added to facilitate transport"), these should be in the dispense record.

5.10 Patient instructions

5.10.1 General

When the dispenser indicates instructions to the patient (e.g. "add water"), these should be in the dispense record.

If these are already obtained from the prescription and the prescription is linked, these may be present. In any other case, they shall be present.

In other words, the instructions are mandatory if they are added during the dispense. Instructions that are copied from the dispense are optional if it is possible to retrieve the prescription and instructions.

5.10.2 Reimbursement

When specific information about reimbursement is important and available, this information may be in the dispense record. For example, there may be a dispensing fee, as shown in A.2.2, and this may be included.

5.10.3 Transport

When specific information about transport is important, this information may be in the dispense record. For example, this can be the transporter agent or transport conditions (e.g. to confirm the supply in controlled temperature conditions).

Annex A
(informative)

Examples of use cases (from NVN-ENV 13607)

NOTE 1 Due to translation, consistency of the vocabulary is not provided at this point of time.

NOTE 2 This story boards target on messages. They require adaptation the scope of this document, which is focussed on data elements (or information elements) to be stored [and used to populate messages, whatever they are (HL7 v 2.5 or CDA, etc.)]

A.1 Dispenser adds cautionary and advisory label

A.1.1 Story board

A general practitioner (GP) (healthcare person) (prescriber) has prescribed Sweetdream tablets 500 mg (prescribed medicinal product) 50 tablets (quantity of medicinal product), 1 tablet to be taken twice daily (dosage administration) for a patient.

Upon the clinical review of the prescription, the dispensing pharmacist dispenses the prescription items as requested and adds the appropriate cautionary and advisory label. Structured information for this purpose is provided by the MPD the pharmacist is using.

A.1.2 Data type and relationships

The following information (data types) is of relevance in this use case.

Date and time	Dispense record ID
Prescriber organization (healthcare provider) ID	Prescriber ID
Prescriber ID (general practitioner)	Prescription ID, subject of care ID
Prescription ID	Prescribed object (packaged medicinal product), quantity of medicinal product, dosage administration, instructions for use (cautionary and advisory label)
Prescribed object (packaged medicinal product)	MPD entry ID
Actual dispensed object	Reason for change towards the prescribed object
Dispensing organization (pharmacy) ID	Dispenser ID
Dispenser ID	Prescription ID, subject of care ID
Instructions for use	MPD entry

A.1.3 Graphical representation

See Annex C.

A.2 Dispense for subject of care with unknown identification (cost factor to be captured)

A.2.1 Story board

A hospital doctor (prescriber) issues a new prescription message containing two medicinal products identified by their proprietary names, strength and presentation form (prescribed medicinal product) for a new-born infant (subject of care), ready to be discharged from hospital.

The infant has not yet been allocated a healthcare identification number, therefore, the mother's identification, name, etc. (patient related party) is included on the new prescription message as the legal guardian.

The infant is entitled to public health service reimbursement (payment guarantor) for both products and reimbursement from an insurance company for one of the products, which is not fully reimbursed by public health service, covered by its mother's insurance agreement (service agreement type).

The pharmacist dispenses the prescription items. One item prescribed requires an antibiotic in liquid form, requiring the addition of a diluent and thus the payment of a special fee is due (dispensing fee indication).

A.2.2 Data type and relationships

Date and time	Dispense record ID
Prescriber organization (healthcare provider) ID	Prescriber ID
Prescriber ID (general practitioner)	Prescription ID " subject of care" (legal guardian) ID, subject of care information (e.g. age)
Prescription ID	Prescribed object (packaged medicinal product), quantity of medicinal product, dosage administration, instructions for use (cautionary and advisory label)
Prescribed object (packaged medicinal product)	MPD entry ID
Dispensed object	Reason for change towards the prescribed object – if different from prescribed object
Dispensing organization (pharmacy) ID	Dispenser ID Includes reference to country of origin
Dispenser ID	Prescription ID, " subject of care" (legal guardian) ID
Price information for reimbursement	Dispensing fee information for reimbursement
Instructions for use	MPD entry

A.3 Pharmacist adds information to physician's administration instructions

A.3.1 Story board

After examination of a male construction worker (subject of care) suffering from back pain, the GP (prescriber) initiates a new prescription message for direct transmission to the patient's nominated pharmacy (dispensing agent).

The patient arrives at the pharmacy, where the pharmacist has already received the new prescription message.

The pharmacist notes the medicinal product included in the message is Co-sweetdream (medicinal product name), a non-proprietary analgesic.

The quantity of medicinal product is 50 tablets.

In the prescription, the indicated dose for each administration is written to be “11 tablets”.

The pharmacist realizes there has been an inadvertent keying-in error by the GP and dispenses the prescription item labelling the medicine “One to be taken as required” (instructions for use).

The pharmacist additionally adds to the label the maximum daily dose of 8 tablets daily.

The pharmacist has noted the new prescription message includes patient supplementary information indicating his nationality is another, and so his language skills are considered.

The prescribed medication is handed to the patient when a carefully detailed verbal warning is given by the pharmacist not to exceed the stated dose.

The dispense record documents if the dispenser informed the prescriber, and the eventual response received that prescriber has been informed, and the response of the prescriber.

NOTE 1 Medication history can be made of a collection of dispense records or combined with patient statements, prescriptions, or other information.

NOTE 2 If a new prescription has to be issued, in replacement of the initial prescription, there is no dispense record for the first prescription. The dispense record is then linked to the second prescription.

A.3.2 Data type and relationships

Date and time	Dispense record ID
Prescriber organization (healthcare provider) ID	Prescriber ID Includes reference to country of origin
Prescriber ID (general practitioner)	Prescription ID, ”subject of care” (legal guardian) ID, subject of care information (e.g. age) *Includes reference to country of origin*
Prescription ID	Prescribed object (packaged medicinal product), quantity of medicinal product, dosage administration, instructions for use (cautionary and advisory label)
Prescribed object (packaged medicinal product)	MPD entry ID
Dispensed object	Reason for change towards the prescribed object
Dispensing organization (pharmacy) ID	Dispenser ID Includes reference to country of origin
Dispenser ID	Prescription ID, “subject of care” (legal guardian) ID
Price information for reimbursement	Dispensing fee information for reimbursement
Instructions for use	MPD entry
Follow-up notification to prescriber	Date
Supplementary information (could be used in communication to prescriber)	Information concerning the prescribing error or other information/request for correction
Correction notification received	Date

A.4 Dispensation of a substitution medicinal product

A.4.1 Story board

The GP (prescriber) issues a new prescription message containing 3 medicinal products. The products are identified by their generic names (pharmaceutical product names), the quantity to be supplied for

each, being a one-unit patient pack (medicinal product package). According to local reimbursement rules, one of the medicinal products may be substituted if a cheaper generic is available (substitution type), the others may not.

The pharmacist dispenses the prescription items.

On the completion of dispensing, the pharmacist substitutes a cheaper generic medicinal product. The substitution is documented in the dispense record, and the rationale for that substitution is captured (in this case: cheaper substitution medicinal product). The dispensation record documents if the prescriber has been informed about the substitution.

A.4.2 Data type and relationships

Date and time	Dispense record ID
Prescriber organization (healthcare provider) ID	Prescriber ID Includes reference to country of origin
Prescriber ID (general practitioner)	Prescription ID, "subject of care" (legal guardian) ID, subject of care information (e.g. age) *Includes reference to country of origin*
Prescription ID	Prescribed object (packaged medicinal product), quantity of medicinal product, dosage administration, instructions for use (cautionary and advisory label)
Prescribed object (packaged medicinal product)	Medicinal product dictionary entry ID
Actual dispensed object	Reason for change towards the prescribed object, medicinal product dictionary reference
Dispensing organization (pharmacy) ID	Dispenser ID Includes reference to country of origin
Dispenser ID	Prescription ID, "subject of care" (legal guardian) ID
Reason for change towards the prescribed object	Table of options: — generic equivalent; — cheaper alternative; — availability issues, — etc.
Price information for reimbursement	Dispensing fee information for reimbursement
Instructions for use	Medicinal product dictionary entry ID
Follow-up notification to prescriber	Date
Supplementary information (could be used in communication to prescriber)	Information concerning the prescribing error or other information/request for correction
Correction notification received	Date

A.5 Prescription requires conversion (encoding) in existing units and packaging

A.5.1 Story board

A specialist (healthcare person) in psychiatry (prescriber) issues a new prescription message for a human patient (subject of care).

The new prescription message contains 2 medicinal products, each characterized by medicinal product name, pharmaceutical strength and pharmaceutical dosage form.

The pharmacist (healthcare person) notes the quantity of the medicinal product is specified in the treatment regimen by the daily dose (quantity per time unit) and the number of days treatment (duration of treatment period).

This enables the pharmacist to calculate the quantity to dispense (quantity of medicinal product) and to identify the number of packaged medicinal product to be dispensed. Structured information for this purpose is provided by the medicinal product dictionary, which is integrated in the information system of the pharmacist.

The pharmacist dispenses the medicinal product, adding the instructions for use together with the appropriate cautionary/advisory labels. The information of the dispense event is recorded in the pharmacist information system.

The dispense record documents if the dispenser informed the prescriber, and the eventual response received that prescriber has been informed, and the response of the prescriber

A.5.2 Data type and relationships

The following information (data types) is of relevance in this use case.

Date and time	Dispense record ID	
Prescriber organization (healthcare provider) ID	Prescriber ID (medical specialist) Includes reference to country of origin	
Prescription ID	Subject of care ID Includes reference to country of origin	
Prescribed object (or INN, amount, daily dose, number of days), pharmaceutical dosage form, pharmaceutical strength	Prescribed object exists but is not available Treatment regimen by the daily dose, the number of days treatment is the rationale for defining the object to be dispensed	Prescribed object does not exist (abstract / virtual prescription) INN, amount, daily dose and number of days treatment is the rationale for defining the object to be dispensed.
Prescribed object (packaged medicinal product)	MPD entry ID	
Dispensed object	Instructions for use (cautionary and advisory label)	
Dispensing organization (pharmacy) ID	Dispenser ID Includes reference to country of origin	
Dispensation ID	Subject of care ID Includes reference to country of origin	
Instructions for use	MPD entry	
Prescriber informed	Response of prescriber	

A.6 Prescription with repeat dispensing

A.6.1 Story board

A general practitioner (healthcare person) (prescriber) issues a new prescription message for a patient (subject of care). The new prescription message contains 2 medicinal products to be repeated (repeat prescription instructions).

Two days later, the patient visits the pharmacy (dispensing agent) to collect the dispensed medicine.

A paper prescription form is generated to indicate that two medicinal products are to be repeated at subsequent times, transferring the repeat dispensing instructions for each prescription item from the new prescription message.

The pharmacist, in accordance with local legislation, signs the repeat prescription form generated, and hands it to the patient.

On completion of dispensing, the pharmacist hands the dispensed packaged medicinal product to the patient. A distinct dispense record is generated to capture each of the dispensation.

The information of the dispense event is recorded in the pharmacist information system.

The dispense record documents if the dispenser informed the prescriber, and the eventual response received that prescriber has been informed, and the response of the prescriber

A.6.2 Data type and relationships

NOTE SoC ID groups several prescriptions; each prescription groups one or several dispense records.

The following information (data types) is of relevance in this use case.

Date and time	Dispense record ID	
Prescriber organization (healthcare provider) ID	Prescriber ID (general practitioner) Includes reference to country of origin	
Prescription ID	Subject of care ID Includes reference to country of origin	
Prescription ID	Electronic prescription stored centrally Repeat prescriptions generated according the number of repetitions.	Prescription stored locally Repeat prescription generated at each dispensation.
Repeat prescription ID	Prescribed object (medicinal product), quantity of medicinal product, dosage administration, instructions for use (cautionary and advisory label)	
Prescribed object (packaged medicinal product)	MPD entry ID	
Dispensed object	Repeat prescription (paper form, signed)	
Dispensing organization (pharmacy) ID	Dispenser ID Includes reference to country of origin	
Dispensation ID	Subject of care ID Includes reference to country of origin	
Repeat dispensing instructions	MPD entry	
Prescriber informed	Response of prescriber	

Annex B
(informative)

Examples of use cases (other sources)

B.1 Dispense of controlled substance

B.1.1 Story board

A GP (prescriber) prescribes some narcotic for a subject of care.

The pharmacist reviews the prescription and proceeds to dispensing. The pharmacist dispenses the prescribed narcotic, and records that dispensation, including the control number of the prescription which allows linkage to the prescription.

In a later stage, the dispense record is queried to generate the regulatory information required to inform about dispensation of controlled substances.

B.1.2 Data type and relationships

Date and time	Dispense record ID
Prescriber organization (healthcare provider) ID	Prescriber ID Includes reference to country of origin
Prescriber ID (general practitioner)	Prescription ID, prescription control number, subject of care ID *Includes reference to country of origin*
Prescription ID	Prescribed object (packaged medicinal product), quantity of medicinal product, dosage administration, instructions for use (cautionary and advisory label)
Prescribed object (packaged medicinal product)	MPD entry ID
Actual dispensed object (optional information)	Reason for change towards the prescribed object
Dispensing organization (pharmacy) ID	Dispenser ID Includes reference to country of origin
Dispenser ID	Prescription ID, subject of care ID Includes reference to country of origin
Instructions for use	MPD entry ID

B.2 Verification of authenticity

B.2.1 Story board

A pharmacist (the dispenser) dispenses one medicinal product according to its prescription and one non-prescription medicinal product to the same subject of care.

When the pharmacist retrieves the medication, and before handing out to the SoC, the dispenser's system queries the national control database to verify uniqueness of the serial number on each medicinal product package. Result, with time stamp, is captured in the dispense record. If other packaging features (overt, respectively covert features to authenticate the packaging) should be checked for authenticity purpose, this is documented in the dispense record as well.

B.2.2 Data type and relationships

Date and time	Dispense record ID
Dispenser ID	Dispense record ID
Dispensing organization (pharmacy) ID	Dispenser ID Includes reference to country of origin
Dispense record ID	Prescription ID, SoCID (*Includes reference to country of origin)*, medicinal product ID
Packaged medicinal product ID	Status/outcome of the authenticity checking
Medicinal product ID entry in medicinal product dictionary	Ticking packaging integrity features

B.3 Supply of non-prescription product in a non-pharmacy shop

B.3.1 Story board

A customer selects on the shelf a box of 100 tablets of Ibuprofen 200 mg and presents this at the point of sale.

The shop IT system captures the supplied product and links this to customer's sales record. Product concerned by this process include medicinal products, food supplements, herbal medicine products, and others.

Customer's sales report can be used for statistical purposes on request of the regulatory bodies, according to the local legislation.

NOTE Sales record does not provide linkage to the subject of care, since the purchaser might not be the same individual as the patient.

B.3.2 Data type and relationships

Date and time	(dispense/store) organization ID
Product ID	Number of product

B.4 Dispense of an unlicensed medicinal product

B.4.1 Story board

A GP prescribes for a subject of care a medicinal product which is not marketed in the local jurisdiction. An alternative occurs as follows.

a) The pharmacist orders through a licensed distributor or an international pharmacy the prescribed medicinal product. When dispensing to the subject of care, specific information, including the delivery source, is captured in the dispense record. Details indicating that the medication is unlicensed in the jurisdiction and therefore administered under the direction of the clinician (prescriber) is documented.

b) The medication is unlicensed for the stated use but is licensed in the jurisdiction (off-label usage); the dispenser is informed about that situation (e.g. the prescriber did consult the dispenser).

The dispensing record clearly states that the medicinal product is being used for "off label" purposes if, for instance, the prescriber consulted the dispenser.

B.4.2 Data type and relationships

Date and time	Dispense record ID
Prescriber organization (healthcare provider) ID	Prescriber ID Includes reference to country of origin
Prescriber ID (generalpPractitioner)	Prescription ID, prescription control number, subject of care ID *Includes reference to country of origin*
Prescription ID	Prescribed object (packaged medicinal product), quantity of medicinal product, dosage administration, instructions for use (cautionary and advisory label)
Prescribed object (packaged medicinal product)	MPD entry ID
Order Date (out of stock item)	Date/time
Order ID:	Link/order number
Supplier:	Information could be held on ordering system
Estimated date of receipt:	Date/time
Dispensed object	MPD ID
Dispensing organization (pharmacy) ID	Dispenser ID Includes reference to country of origin
Dispenser ID	Prescription ID, subject of care ID Includes reference to country of origin
Instructions for use	MPD entry

B.5 Dispense of compound medicine

B.5.1 Story board

A physician prescribes a cytostatic medication for a subject of care.

The dispenser prepares the compounding according to the prescription. When dispensed, the medication is identified in such a way that the dispense record captures the dispense and the link to the compounding record, which in turn captures the prescription.

Rationale for the compounding is captured either in the prescription record or in the dispense record but not explicitly in the dispense record.

B.5.2 Data type and relationships

Date and time	Dispense record ID
Prescriber organization (healthcare provider) ID	Prescriber ID Includes reference to country of origin
Prescriber ID (general practitioner)	Prescription ID, subject of care ID Includes reference to country of origin
Prescription ID	Prescribed object, quantity of medicinal product, dosage administration, instructions for use (cautionary and advisory label)
Prescribed object	MPD entry ID
Dispensed objects	The items that were dispensed and consumed in order to be able to prepare the compound product, and that are ingredients of the compound product

Compounding system record ID	Reason for compounding?
Dispensing organization (pharmacy) ID	Dispenser ID Includes reference to country of origin
Dispenser ID	Prescription ID, subject of care ID Includes reference to country of origin
Instructions for use	MPD entry

B.6 Dispense in the hospital environment

B.6.1 Story board

A physician working in that hospital prescribes a medicinal product for a subject of care in the same hospital.

Situation 1: Dispensation is processed at the ward level. A nurse comes to the ward medication room (cupboard) and prepares the medications for the subject of care.

Situation 2: Dispensation is made for the subject of care at the pharmacy, where the medication(s) are prepared and placed in a container for the subject of care.

At a later stage, medication is administered to the subject of care according the prescription.

B.6.2 Data type and relationships

Date and time	Dispense record ID
Prescriber organization (healthcare provider) ID	Prescriber ID Includes reference to country of origin
Prescriber ID (general practitioner)	Prescription ID, subject of care ID Includes reference to country of origin
Prescription ID	Prescribed object, quantity of medicinal product, dosage administration, instructions for administration
Prescribed object	MPD entry ID
Option: information about reconstitution	Reference to MPD
Dispensing organization (ward/pharmacy) ID	Dispenser ID Includes reference to country of origin
Dispenser ID	Prescription ID, subject of care ID Includes reference to country of origin
Instructions for administration	MPD entry ID

B.7 Dispense prior to generation of prescription

B.7.1 Story board

A pharmacist dispenses a prescription medicinal product for a subject of care in an emergency situation. No prescription from medical doctor is available.

Situation 1: Medical doctor provides the prescription afterwards, which corresponds precisely to what had been dispensed.

Situation 2: Medical doctor provides a prescription afterwards which does not fully correspond to the dispensation.

B.7.2 Data type and relationships

Date and time	Dispense record ID
Prescriber organization (healthcare provider) ID	Prescriber ID Includes reference to country of origin
Prescriber ID (general practitioner)	Temporary prescription ID, subject of care ID Includes reference to country of origin
Temporary prescription ID	Prescribed object, quantity of medicinal product, dosage administration, instructions for administration Means on how the temporary prescription is expressed to the dispenser (phone, email, oral)
Final prescription ID	(virtual) Document which prescriber made available
Prescribed object	MPD entry ID
Actual dispensed medicinal product	Reference to MPD
Dispensing organization (ward/pharmacy) ID	Dispenser ID Includes reference to country of origin
Dispenser ID	Prescription ID, subject of care ID Includes reference to country of origin
Instructions for administration	MPD entry

B.8 Dispense of OTC medicine

B.8.1 Story board

A pharmacist in a retail pharmacy is consulted by a subject of care.

Pharmacist dispenses a non-prescription medicinal product to the subject of care.

(There is no reference to country of origin, since the dispensation is made on the same place as the virtual prescription.)

B.8.2 Data type and relationships

Date and time	Dispense Record ID
Prescriber organization (Pharmacy) ID	Prescriber ID (pharmacist)
Prescriber ID (pharmacist)	Prescription ID, subject of care ID Includes reference to country of origin
Prescription ID	Prescribed object, quantity of medicinal product, dosage administration, instructions for administration
Prescribed object	MPD entry ID
Dispensing organization (Pharmacy) ID [same as above]	Dispenser ID (pharmacist or assistant)
Dispenser ID (pharmacist or assistant)	Prescription ID, subject of care ID
Instructions for administration	MPD entry ID

B.9 Internet sale of prescription medicinal product

B.9.1 Story board

A subject of care consults some websites and finds a place to order a medicinal product subject to prescription.

Situation 1: Internet pharmacy requires an electronic prescription. Subject of care finds the recommended path to an "internet doctor" who issues the prescription without having seen the subject of care.

Situation 2: Internet pharmacy requires a prescription, which the subject of care has in hand. Subject of care scans the prescription and sends it to the practitioner.

At this point the dispensation follows the same rules as above.

B.9.2 Data type and relationships

Date and time	Dispense record ID
Prescriber organization (medicinal doctor organization) ID	Prescriber ID (medicinal doctor) Includes reference to country of origin
Prescriber ID (medicinal doctor)	Prescription ID, subject of care ID Includes reference to country of origin
Prescription ID	Prescribed object, quantity of medicinal product, dosage administration, instructions for administration
Prescribed object	MPD entry ID
Actual dispensed object	If different from prescribed object than justification for change
Dispensing organization (pharmacy) ID	Dispenser ID (pharmacist or assistant) Includes reference to country of origin
Dispenser ID (pharmacist or assistant)	Prescription ID, subject of care ID Includes reference to country of origin
Instructions for administration	MPD entry

Annex C
(informative)

Dispensing processes — Examples and variation

C.1 General

After research and discussions, it has been found that the concept of dispensing has different interpretations in different contexts.

— Different countries and jurisdictions can define “dispensing” differently.

— In community, the notion of dispense may sometimes differ from the institutional dispense.

This document does not standardize what are the precise activities related to the dispensing, but should identify the activities that may be present.

This approach to variability is demonstrated with a few common cases below.

In Figures C.1 to C.6, when colors are used, the color is an optional indication of some activity classification — yellow intends to convey more “clinical” activities, and purple is used for “delivery” activities. This is a visual aide in comparing the figures, and is less important than the sequence of activities itself.

C.2 Dispensing a prescribed medication in a community setting

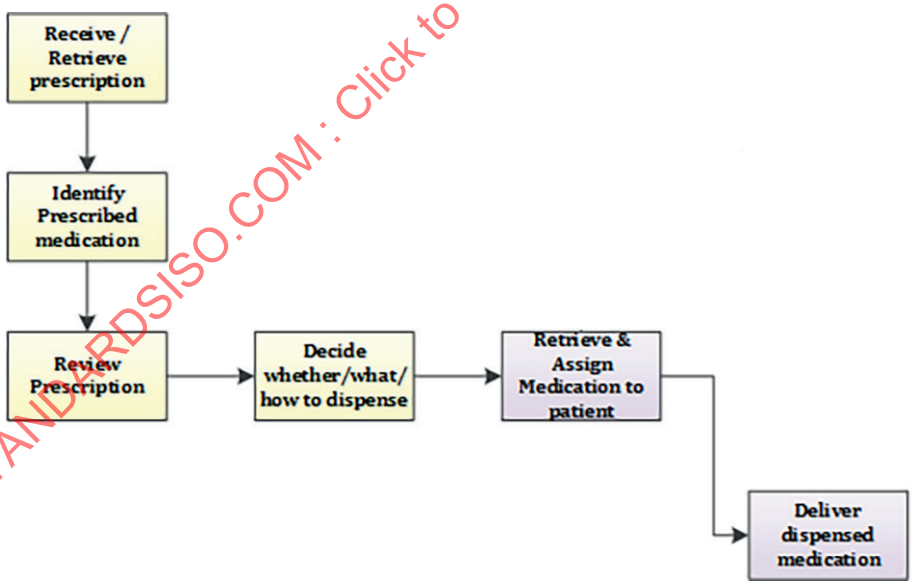

Figure C.1 — Community dispense of prescribed medication

In this common case, a person presents at the community pharmacy with a prescription for a relative. The pharmacist retrieves the prescription from that person, and after identifying what is the product prescribed, reviews it and decides that the medicinal product can be dispensed. The pharmacist then retrieves the medicinal product from stock and assigns it to the patient, delivering it to the person who is supposed to take it to the patient.

C.3 Dispensing a medication that has not been prescribed

Figure C.2 — Community Dispense without prescription

In this example case, the patient presents at the pharmacy with minor symptoms (headache) and asks the pharmacy for advice. The pharmacist listens to the patient and decides that the patient should be given a medicinal product — a non-prescription, over-the-counter medicinal product. After retrieving the medicinal product from stock, the pharmacist hands it to the patient. Depending on the legislation, there are many other situations where the patient asks for medication, e.g. when buying supplements or herbal medicinal products.

C.4 Dispensing a medicinal product in an institution in a hospital – pharmacy dispense

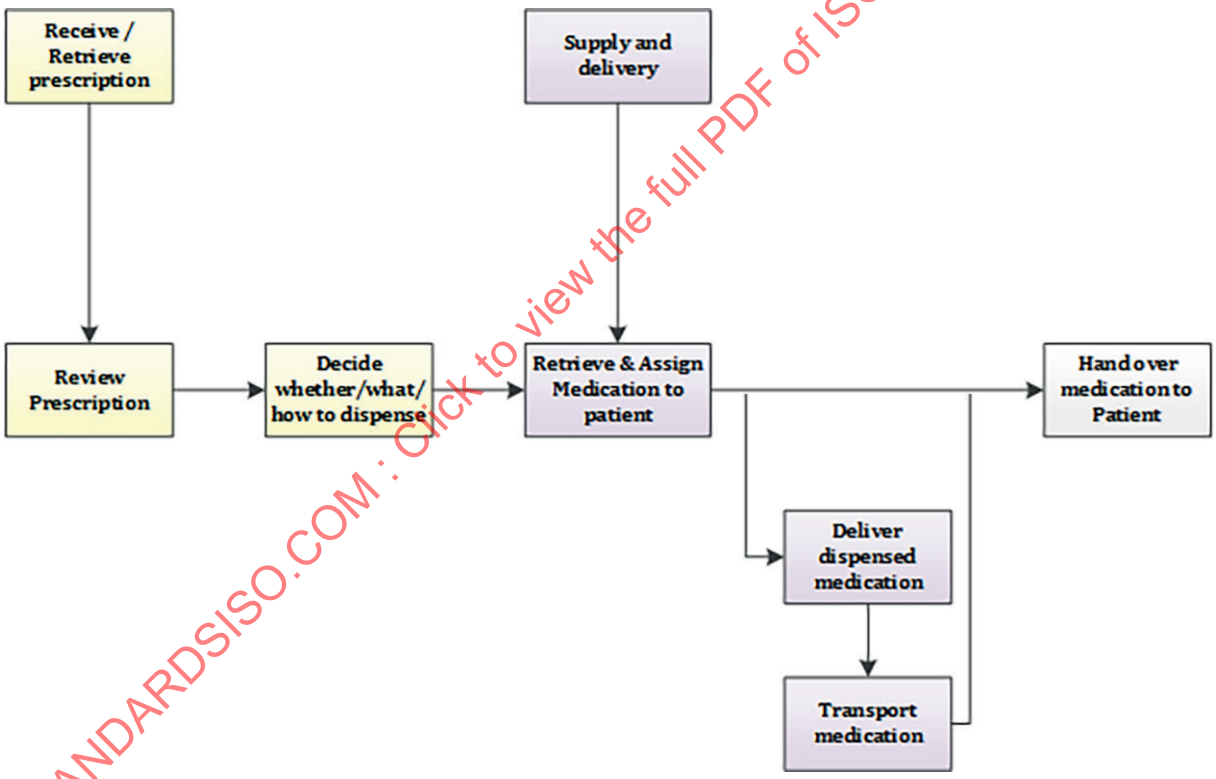

Figure C.3 — Hospital dispensing of a prescribed medicinal product

In this common case, a prescription is issued in the hospital system for the patient. The hospital pharmacist reviews the prescription and decides to dispense. In this case, the medication should first be ordered and supplied from a central location in the hospital, and then retrieved and assigned to the patient by an automated system. Then a pharmacist goes to the dispensing system and picks the medication, making it available for someone from the staff to transport it to the ward where it will be handed over to the patient.

C.5 Dispensing a medicinal product in an institution in a hospital — ward stock

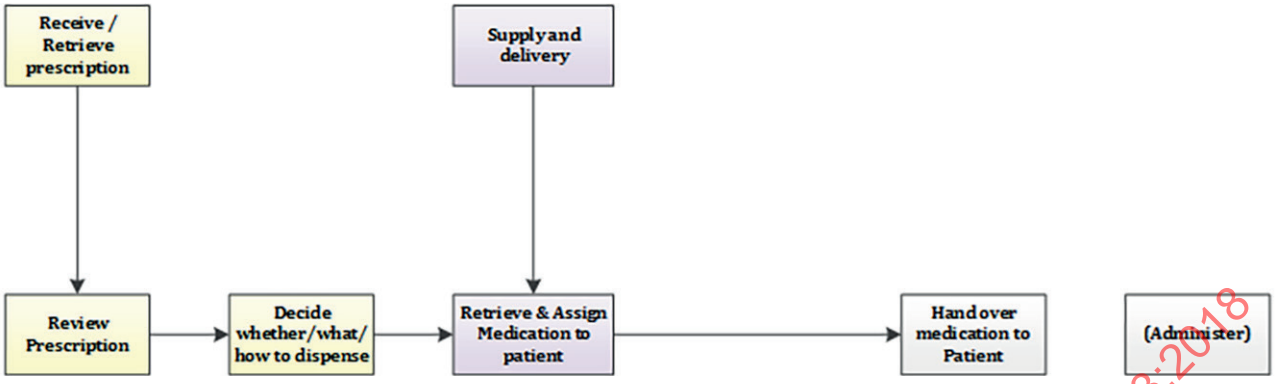

Figure C.4 — Hospital dispensing of a prescribed medicinal product

In this other very common case, a prescription is issued in the hospital system for the patient in the ward. The hospital pharmacist may or not have a "review" role. The pharmacist has the role of Supply and Delivery — distributing medication to the wards to ensure proper inventory levels. The nurse sees the prescription and eventually may be able/required to have a substitution (e.g. replace 1 × 1 000 mg tablet for 2 × 500 mg tablet). The nurse retrieves the medication product and hands it over to the patient (eventually proceeding to administering it, but administration is out of scope of this document).

C.6 Dispensing for home care

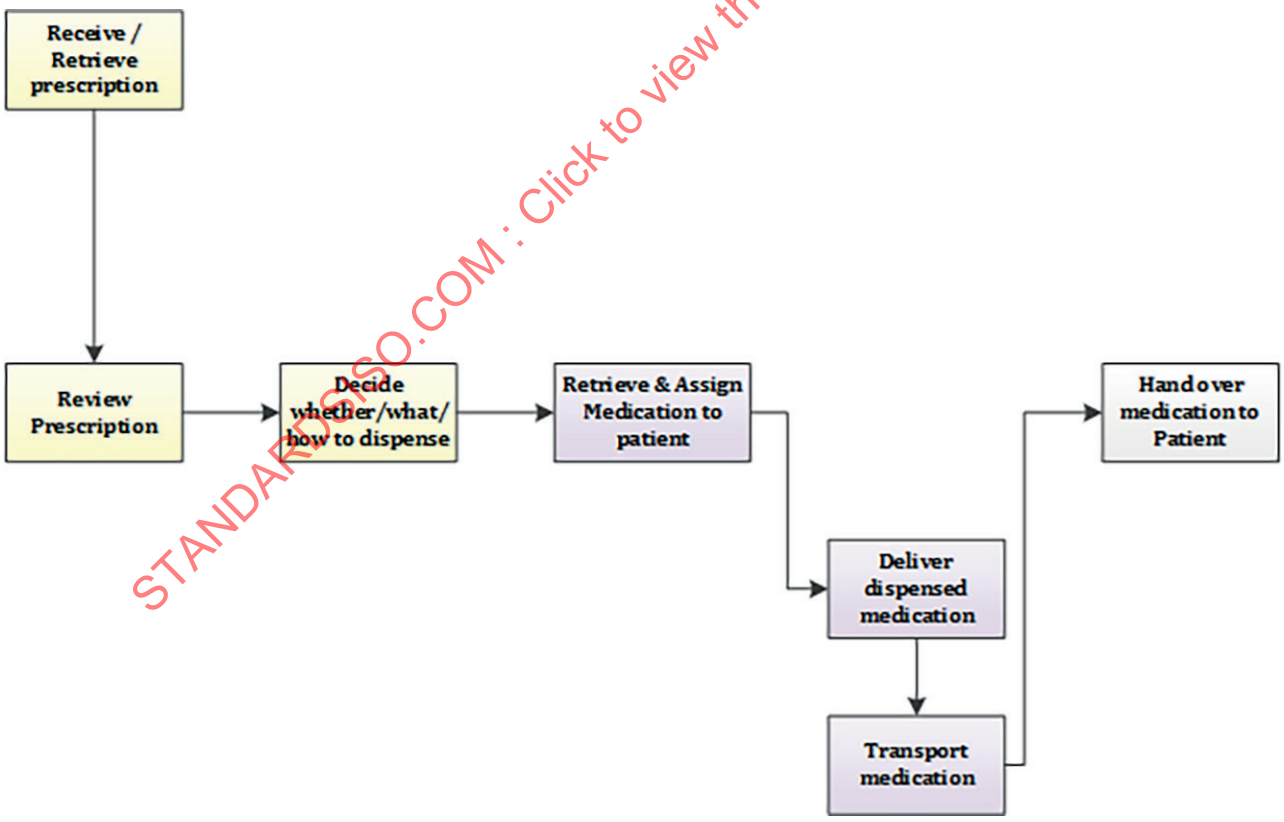

Figure C.5 — Dispensing for home nursing

This case presents another variation of the dispense process. It differs from hospital prescription and dispense mainly because there is a physical transport between the place of dispense and the point